

Fentanyl Patch Linked to Another Death in Canada

Incidents associated with fentanyl patches have previously been described by both the Institute for Safe Medication Practices Canada (ISMP Canada) and its US counterpart (ISMP). In August 2006, ISMP Canada highlighted the deaths of two Canadian adolescents, reviewed the voluntary reports that had been received to date, and made recommendations for preventing similar incidents.¹ ISMP (US) recently reported that fentanyl patches continue to be inappropriately prescribed, dispensed, and administered to opioid-naïve patients with acute pain.² Advisories and warnings about the use of fentanyl patches have been issued by Health Canada^{3,4,5} the US Food and Drug Administration,⁶ and manufacturers⁷. In addition, according to a recent news report, the Office of the Chief Coroner for Ontario is reviewing several deaths involving fentanyl patches.⁸ Use of transdermal fentanyl can be an effective option for the treatment of chronic pain; however, its use also continues to pose problems for health care providers and their patients.

The following case was recently reported to ISMP Canada and is shared to provide an additional alert:

An adult patient with a history of chronic obstructive pulmonary disease (COPD) presented to an emergency department for management of severe back and leg pain. The patient had been receiving acetaminophen with codeine on an as-needed basis (to a maximum of 480 mg codeine per day) and had received a prescription for oral hydromorphone 2-4 mg every four hours as needed the day before from the family physician. In the emergency department, the patient was treated with intravenous ketorolac with effect, and a fentanyl patch was applied. The patient was also instructed to continue taking the previously prescribed pain medications as needed. Three days later, the patient was experiencing severe pain and returned to the family physician, who increased the fentanyl patch dose from 75 mcg/hour to 125 mcg/hour. The prescription for the new patch also included instructions for the patient to continue taking the oral hydromorphone as needed for pain. The patient returned to see the family physician the next day, reporting that the pain had improved. That evening, the patient appeared confused. The following morning, the patient was found unresponsive. Although emergency services were called, resuscitation measures were unsuccessful and the patient died.

ISMP Canada did not receive all the necessary information required for an in-depth root cause analysis⁹ but the following factors were identified as *possibly* contributing to this sentinel event:

- significant increase of opioid dose within a short time frame;
- complexity of titrating fentanyl patch doses;
- lack of awareness on the part of the patient and family members about the potential side effects of opioid use that would require immediate medical attention; and
- the presence of underlying COPD.

Recommendations

In addition to the recommendations made in a previous bulletin on this topic,¹ the following measures are recommended to reduce the risk of medication incidents associated with fentanyl patch therapy.

1. Prescribing and Administration of Fentanyl Patches

- Ensure that the complete medical history and full medication history are available to verify that all criteria for initiating and continuing fentanyl patch therapy are met.
- Consider the value of adjunctive treatment (e.g., a nonsteroidal anti-inflammatory agent) to decrease the opioid dose requirement.
- Ensure the patient is sufficiently opioid-tolerant for the fentanyl patch dose prescribed (e.g., for a 25 mcg/hour fentanyl patch, patients should be receiving the equivalent of at least 60 mg oral morphine per day, and have been taking the opioid around-the-clock for an extended period of time.¹⁰ Refer to the product monograph for additional information).
- Ensure that the patient and family members understand how the product is to be used, are aware of the signs and symptoms of opioid overdose and know to remove the patch and seek immediate medical attention should signs of overdose occur. (The Duragesic[®] monograph identifies a number of key issues to be reviewed with patients and provides a consumer information sheet.¹⁰)
- When possible, ask family members who are with the patient at various times of the day and night if the patient is unknowingly experiencing any dangerous side effects.

2. Dispensing of Fentanyl Patches

- Ensure that each patient's medication profile is reviewed in full by a pharmacist whenever a new prescription or dose change for fentanyl patch therapy is received.
- Consider implementing computerized alerts in pharmacy information systems for scenarios that may require extra attention (e.g., dosage increase of a fentanyl patch that is greater than 25 mcg/hour or a dose increase prescribed in less than 6 days).
- For outpatients, provide and review written information with the patient (and family) whenever a new fentanyl patch dose is dispensed to ensure that information (e.g., signs and symptoms of overdose) is not overlooked.

3. Manufacturers of Fentanyl Patches

- The following considerations for product monographs for the fentanyl patch are recommended:
 - ◆ Include information that will assist practitioners to assess opioid tolerance. Such information is currently lacking in the product monographs for all brands of fentanyl patches.

- ◆ Include in the product monograph a checklist or algorithm for initiation and titration of the fentanyl patch.

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Enhanced Labelling of Neuromuscular Blocking Agents Makes a Difference

“Ideal features” for packaging and labelling of neuromuscular blocking agents were discussed during a collaborative meeting convened by ISMP Canada in 2006.[†] Since then, several manufacturers of these agents have incorporated some or all of the recommended features. ISMP Canada has received a report in which packaging features for a neuromuscular blocking agent helped to prevent a mix-up from reaching the patient:

A nurse inadvertently selected a vial of the neuromuscular blocking agent succinylcholine (QUELICIN[®], manufactured by Hospira) instead of the intended vial of heparin. As she was walking back to the patient’s bedside, she noticed white lettering on the red cap that read “WARNING: PARALYZING AGENT”. This prompted her to realize that she had selected the wrong vial. Incorrect administration and serious patient harm were thus averted.

ISMP Canada commends the manufacturers who have implemented the ideal features in their packaging and labelling of neuromuscular blockers and encourages all manufacturers to do so.[†]



Figure 1: Succinylcholine vials with a red cap, red ferrule with the words: “WARNING: PARALYZING AGENT”.

[†]Neuromuscular blocking agent labelling and packaging initiative [Internet]. ISMP Can Safe Bull. 2006 [cited 2007 Oct 1];6(2):2. Available from: <http://www.ismp-canada.org/download/ISMPCSB2006-02PotassiumPhosphates.pdf>

Manufacturer Removes Logo to Enhance Medication Safety

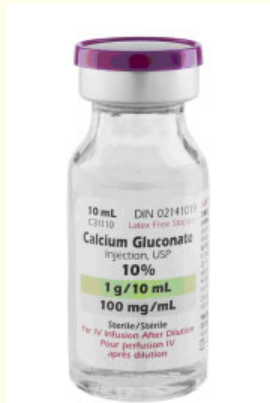


Figure 2: New PPC label for calcium gluconate vial. Note: manufacturer’s logo has been removed to enhance prominence of critical information.

Pharmaceutical Partners of Canada (PPC) recently revised the labelling of its 10 mL format of calcium gluconate. Specifically, the PPC logo has been removed from the label in an effort to make the critical information (drug name and dose) more prominent. ISMP Canada commends PPC for this action.

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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.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System