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# Overdose a risk of transdermal patch in diverse settings

## Problems occur even with discarded patch

RECENT CANADIAN STUDIES[1-5] HAVE INDICATED THAT A SIGNIFICANT number of adverse events occurring in Canadian health care facilities involve medications. High-alert medications are defined by the Institute for Safe Medication Practices (ISMP) as medications "that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these medications, the consequences of an error are clearly more devastating to patients." [6] Children are more likely than adults to experience harm from medication errors, therefore extra safeguards should be in place when dispensing high-alert medications, especially opioids, to this age group.

Fentanyl is one such high-alert medication, and as of September 2005, ISMP Canada has received 112 error reports related to fentanyl and 60 error reports associated with fentanyl patches, used for pain control. Through analysis of its database of medication safety issues in long-term care, ISMP Canada has identified recurrent problems with the use of fentanyl patches, particularly neglecting to remove the current patch before applying the next one, as a high priority for intervention. As a result, ISMP Canada will focus on fentanyl patches as part of its initiative in long-term care this year.

Medication errors associated with transdermal fentanyl or fentanyl patches, some causing death, have been reported from both institutional and community settings in Canada and the United States. As a result of the deaths, the US Food and Drug Administration (FDA) has issued a general advisory regarding fentanyl patches (www.fda.gov/cder/drug/advisory/fentanyl.htm), and Health Canada has issued new safety warnings for this formulation both to the public (www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/duragesic_pa-ap_e.html) and to health care professionals (www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/duragesic_hpc-cps_e.html).

The US Institute for Safe Medication Practices (ISMP) published information about fentanyl patches in two of its recent *Medication Safety Alert Community/Ambulatory Care Edition.*[7-8] The first of these articles[7] reported that the FDA is investigating a number of deaths due to overdose via fentanyl transdermal patches. As an example, the article described a 77-year-old

## ISMP Canada

The Institute for Safe Medication Practices Canada (ISMP Canada) is committed to the safety of the medication system and has been working with government agencies at both the national and provincial levels and with health care institutions and professional associations to improve patient safety. Pharmacists, who work on the front line with patients in the community, have an important role in supporting and promoting medication safety as part of this effort.

ISMP Canada is a national, independent non-profit agency that was established to collect and analyze medication error reports and to develop recommendations, educational materials, and tools for the enhancement of patient safety. This patient safety organization, which has the vision and passion needed to promote medication safety, is staffed by a team of pharmacists, nurses, and physicians, as well as human factors engineering consultants.

ISMP Canada is a key partner, with Health Canada and the Canadian Institute for Health Information, in the Canadian Medication Incident Reporting and Prevention System (CMIRPS), which will be officially launched in early 2006. ISMP Canada is also engaged in a number of provincial medication safety initiatives, including the medication safety support services of the Ontario Ministry of Health and Long-Term Care, the Health Quality Council of Alberta, and the British Columbia Patient Safety Task Force. Although its initial safety efforts were focused on acute care settings, ISMP Canada is also dedicated to improving medication safety in other health care sectors, such as community pharmacy, long-term care facilities, and emergency medical services in the community.

Information on medication safety issues pertinent to community practitioners will be shared in this new *CPJ* column. By sharing information about medication errors, near misses, and other medication safety concerns, ISMP Canada hopes to prompt pharmacists to critically analyze their products, processes, and environments in an effort to avoid similar errors in their own practices. In this spirit, safety issues related to the use of transdermal fentanyl are described in this issue.

woman who was found dead after administration of a patch combined with application of heat to the site. The article also mentioned the deaths of two Canadian adolescents, both opioid-naïve patients, who went into respiratory depression.[9] In one of these cases, a 15-year-old girl with chronic headaches died after the first patch of Duragesic 25 was applied. In the other case, a 14-year-old boy with throat pain due to mononucleosis was found in respiratory arrest 14 hours after the first patch of Duragesic 25 was applied.

The second article published by ISMP[9] described unintentional harm to children associated with fentanyl. Children may be attracted to the product, wishing to mimic their parents or mistakenly associating this product with an adhesive bandage or a children's sticker. For example, a four-year-old boy was found dead near an overturned trashcan that held torn pouches and discarded patches; the boy had a fentanyl patch on one leg. Accidental exposure to a caregiver (e.g., sitting on a patch that has been removed) has been reported to cause serious harm as well.

The important lesson to be learned from these experiences is that pharmacists should provide adequate education about this drug to their patients, so as to prevent harm to patients, their families, caregivers, and even pets. Patients must be educated about the effects of and hazards associated with this drug and must be instructed on proper storage (locked securely) and disposal (fold the patch with the sticky side in, and flush down the toilet immediately on removal from the skin). Patients who are concerned about the toilet becoming plugged should be given a biohazard container that cannot be opened; alternatively, they can be given a small bottle with a child-resistant cap (intended for oral liquids) for disposal of used patches. Patients should be told about signs of overdose (e.g., trouble breathing, sleepiness, inability to think, talk, or walk normally, feeling faint, dizzy, or confused) and should be instructed to seek medical attention immediately if such signs occur.[10] Patients should also be taught about correct use of the drug and the need to avoid direct external heat sources, alcohol, and other medications that affect brain functions, such as sleeping pills, muscle relaxants, and antihistamines, any of which can increase the potential for serious adverse events.[10] Pharmacists should ensure that they are thoroughly knowledgeable about the pharmacokinetics and approved use of fentanyl transdermal patches.

ISMP Canada would appreciate learning of errors and near misses in community practice to ensure that our safety initiatives are appropriately directed. Sharing information about medication incidents is one way that each of you can contribute to making the system safer for our patients. ■

### Safe use of fentanyl

- Educate the patient about potential hazards in its use, storage, and disposal.
- Alert the patient and his or her caregivers to the possibility of accidental exposure and instruct them to check regularly to ensure that the patch is adhering properly. If needed, first aid tape may be used along the edges of the patch.
- Ensure that appropriate patient selection criteria are used, that appropriate starting dose and dose adjustment recommendations are applied, that contraindications are taken into consideration, and that safe administration procedures are followed.

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To improve medication-related processes, it is important that we hear about your medication errors and near misses. Report medication incidents to www.ismp-canada.org or 1-866-544-7672. Any pharmacist interested in receiving ISMP safety bulletins, please contact kwichman@ismp-canada.org to be added to our mailing list.

### References

**1.** Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170(11):1678-86.

**2.** Forster AJ, Clark HD, Menard A, et al. Adverse events among medical patients after discharge from hospital. *CMAJ* 2004;170(3):345-9.

**3.** Forster AJ, Asmis TR, Clark HD, et al. Ottawa Hospital Patient Safety Study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital. *CMAJ* 2004;170(8):1235-40.

**4.** Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med* 2005;165:424-9.

**5.** Gurwitz JH, Field TS, Judge J, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med* 2005;118(3):251-8.

**6.** ISMP's list of high-alert medications. Huntingdon Valley (PA): Institute for Safe Medication Practices; 2005. Available: www.ismp.org/Tools/highalertmedications.pdf (accessed Sept. 16, 2005).

**7.** Little patches…big problems. New safety warnings about fentanyl patches — Part 1. *ISMP Medication Safety Alert Community/Ambulatory Edition* 2005;4(8):1-3.

**8.** Little patches…big problems. New safety warnings about fentanyl patches — Part 2. *ISMP Medication Safety Alert Community/Ambulatory Edition* 2005;4(9):1-3.

**9.** Transdermal fentanyl (Duragesic): respiratory arrest in adolescents. *Can Adverse React Newsl* 2004;14(4). Available: www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v14n4_e.html (accessed Sept. 26, 2005).

**10.** Health Canada. Public Advisory. Duragesic (fentanyl transdermal system) Safety Information. Available: www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/duragesic_pa-ap_e.html (accessed Sept. 26, 2005).