Fentanyl Transdermal Patches
More Protection Needed for Patients and Their Families

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**PROBLEM:** The Institute for Safe Medication Practices (ISMP) has received several reports of deaths that occurred after accidental exposure to adhesive fentanyl skin patches.

**Report No. 1:** A nurse practitioner’s 77-year-old family member died after a fentanyl patch was incorrectly prescribed and subsequently misused. A week before the death, the family member had been given a prescription for hydrocodone and acetaminophen (Vicodin, Abbott) at a dose of 5 mg/500 mg four times daily for sciatica. She took about four doses each day for a week but was still in pain.

The patient’s primary care physician called the pharmacy and prescribed a fentanyl 50-mcg per hour patch (e.g., Duragesic, PriCara) to be applied every 48 to 72 hours. A friend picked up the prescription. She was given a box of five patches, but the pharmacist did not provide educational materials or instructions for use of the patch. Not understanding how the patch worked, the friend helped the patient place a patch on her buttock, the site of her pain. When the patient went to bed, she placed a heating pad on her lower back and found her dead in bed. Only three fentanyl patches were left in the box.

After not hearing from the patient for two days, friends went to her apartment and found her dead in bed. Only three fentanyl patches were left in the box.

It is suspected that the patient had applied a second patch without removing the first patch. According to the nurse practitioner, the pharmacist did not question the prescription about the initiation of fentanyl therapy or about the strength of the prescription and did not provide counseling when the prescription was picked up. The physician had prescribed fentanyl over the telephone without examining the patient and without advising her about the drug and its potential adverse effects. The patient had not been warned to avoid applying heat over the patch, which increases the rate of drug absorption.

**Report No. 2:** A grieving mother reported that her child had died after exposure to a fentanyl transdermal patch. The mother, who had chronic pain from Crohn’s disease, reported that her four-year-old son either had used a discarded patch retrieved from the trash or had opened a wrapper from a box of stored patches and applied a patch to his body. His mother found him dead on the floor near an overturned wastebasket that held torn wrappers and disposed patches. It is not known how long the patch had been in place.

**Report No. 3:** A child was accidentally exposed to a fentanyl patch that had fallen off the skin of a family member. No serious injury occurred.

**Report No. 4:** A boy removed a patch while his grandmother was sleeping and applied it to himself. Fortunately, again, in this case, the child was not seriously injured.

In addition to these scenarios, a review of error reports in both the ISMP Medication Errors Reporting Program and the Pennsylvania Patient Safety Reporting System revealed numerous cases of hospitalized patients who were wearing more than one transdermal patch. This can happen if nurses do not have a good system in place to remind them to remove patches before they administer the next dose. It is also unfortunate that patches from various manufacturers can be clear or translucent, thereby rendering them difficult to see after they are applied. Although the drug name may be printed on the patch, this does not always increase visibility. Poor visibility of the patch may also hinder the ability of emergency services personnel to properly assess and treat an individual who has overdosed and needs a narcotic antagonist. Patches can also fall off during use.

Several problems contributed to these serious errors and fatalities in the four reports listed. In the first case, the elderly woman was not an appropriate candidate for a fentanyl patch. The product’s label states that this patch is intended only for patients who are already tolerant to opioid therapy of comparable strength; this patient was not. Non-tolerant patients may develop respiratory depression, potentially leading to death. Instead, fentanyl patches should be used to manage persistent, moderate-to-severe chronic pain that necessitates continuous, around-the-clock opioid administration for an extended period of time and to manage pain that cannot be controlled by non-steroidal analgesics, opioid combination products, or immediate-release opioids.

Transdermal fentanyl should be used only in patients who require a total daily dose of other opioids at least equivalent to a 25-mcg-per-hour fentanyl patch. Patients who are considered opioid-tolerant are those who have been taking at least 60 mg of morphine daily for a week or longer, at least 30 mg of oral oxycodone daily (e.g., OxyContin, Percocet), or at least 8 mg of oral hydromorphone daily (e.g., Palladone, Dilaudid) or an equianalgesic dose of another opioid.

An FDA advisory, as well as the product labeling, specifically mentions the need to dispose of used patches by folding the sticky sides together and flushing the patch down the toilet. However, patient education alone does not always prevent serious accidents. In the case of the child who died after placing a patch on his body, the mother had been informed about proper disposal. Yet she decided to throw used patches in the trash because she was concerned that she might clog the toilet or that the drug’s chemicals might have a negative effect upon the environment, as she had recently read.

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SAFETY PRACTICE RECOMMENDATIONS: Here are some suggestions to help prevent accidental patch exposure:

- Fentanyl patches for use at home should include a risk-management program that calls for disposal of patches in biohazard containers that cannot be opened.
- Drug manufacturers and pharmacists should be required to package and dispense patches in child-resistant packages. Children enjoy applying stickers, bandages, tattoos, and the like on themselves, a motivating factor that the mother believed might have played a role in her son’s death. Some children might also mimic adults after seeing them apply a patch.
- In the hospital, the drug entry on the medication administration record (MAR) should be accompanied by a second entry by which nurses can document the location and time of application and removal of the patches. At home, a dosing calendar can serve the same purpose to note the site and time of patch application and removal. An auxiliary label can be applied to the patch to prompt documenting the application date and time.
- For increased visibility, notes should not be written directly on the patch. Caution should be used with pens: ink might leak through the “skin” of the patch into the drug reservoir, and a ball-point pen could accidentally puncture the patch.

The reports described in this column were received through the ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP Web site (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAILSAFE or via e-mail at ismpinfo@ismp.org.