Inappropriate Prescribing of Fentanyl Patches Is Still Causing Alarming Safety Problems

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**Problem:** Despite warnings from the FDA, drug manufacturers, and patient safety agencies, fentanyl transdermal patches continue to be prescribed inappropriately to treat acute pain in opioid-naive patients, sometimes in large doses or in combination with oral or intravenous (IV) opioids. Some of these prescribing errors have occurred in hospitals; other mistakes have originated in physicians’ offices or ambulatory surgery centers, where well-meaning but misinformed primary care physicians or surgeons have prescribed the drug for opioid-naive patients with contraindications such as acute postoperative pain.

Unfortunately, pharmacists have often filled fentanyl prescriptions without questioning whether the dose was correct, and nurses have applied the patches to patients without recognizing various possible prescribing errors. The Institute for Safe Medication Practices (ISMP) has been troubled by the steady stream of reports of adverse events associated with the patches, including fatalities, resulting from inappropriate prescribing, dispensing, and administration.

As noted last year in one of my columns in *P&T*,1 Ortho-McNeil/Janssen, the maker of Duragesic, issued a “Dear Health Professional” letter to bring attention to new boxed warnings in the product label related to improper prescribing.2 The FDA also issued a Public Health Advisory to alert health care providers that deaths and overdoses had occurred in patients using both the brand-name product Duragesic and the generic product.3 Despite these warnings and label changes,4,5 some practitioners still seem unaware of the proper prescribing guidelines for this potent narcotic. Following are two scenarios involving improper prescribing.

**Case 1.** A patient who had been given a morphine infusion immediately after surgery was discharged the next day. A nurse applied a prescribed fentanyl patch, at a dose of 75 mcg/hour, to the patient’s skin before discharge and gave the patient three patches to take home. The patient also received a prescription for oxycodone (OxyContin, Purdue Pharma), as needed, every four to six hours. Unfortunately, the patient died within 12 hours of discharge.

The coroner attributed the patient’s death to application of the patch. Not only was this patient opioid-naive and his pain not chronic; he was also being treated for sleep apnea and bronchopneumonia at the time of the surgery. Existing respiratory compromise is another contraindication to fentanyl administration.

**Case 2.** An elderly patient was admitted to the hospital after application of a fentanyl transdermal patch at a dose of 100 mcg/hour. A family member had called the clinic where the patient had been receiving periodic epidural injections for back pain. The relative asked a nurse to arrange for an ambulance to transport the patient to the next visit. Because this represented a change in the patient’s status, the nurse questioned the family and learned that a fentanyl patch had been prescribed and that the patient had continued taking two tablets of oxycodone 5 mg/acetaminophen 325 mg (Percocet 5/325, Endo) three or four times per day.

After calling the patient’s pharmacist to confirm his prescribed medications, the nurse advised the patient’s relatives to remove the patch immediately and to take the patient to the emergency department. The patient was admitted to the step-down unit. During the call to the patient’s family, the nurse also confirmed that the patient and family had not been counseled when they picked up the prescription and that they were not aware of the drug’s potency. Fortunately, this patient did not experience any permanent adverse consequences.

**Safe Practice Recommendations:** These scenarios reflect a knowledge deficit about the proper prescribing of fentanyl patches. Relying on product labeling and instructing health care practitioners alone does not do enough to solve this life-threatening problem. Some clinicians will always remain unaware of the great risks they take when they prescribe fentanyl patches to treat acute pain in opioid-naive patients. To help avoid the risk of patient harm from this high-alert medication, clinicians and prescribers might benefit from establishing the following procedures:

1. **Creating prescribing guidelines.** Specific prescribing and dispensing guidelines for fentanyl patches that are congruent with the product labeling should be developed and referenced by prescribers or pharmacists during computerized prescriber order entry (CPOE) of the medication in both inpatient and outpatient settings. Fentanyl patches should be used only by patients who are opioid-tolerant and who have chronic pain that has not been well controlled with shorter-acting analgesics. Prescribers should also include equianalgesic conversion tables in the guidelines to help in switching patients to an appropriate fentanyl transdermal dose based on pre-existing opioid doses that the patient has been taking.

2. **Determining the indication.** The pharmacist should determine the drug’s indication and should ensure that the patient is opioid-tolerant and has been having chronic pain before the patch is prescribed. In inpatient settings, this information may come from the admission data set or nursing staff. In outpatient settings such as community pharmacies,
the information must come from the patient’s profile; the prescriber; or, ideally, the patient or family when the prescription is dropped off. If necessary, the information can be obtained when the pharmacist is providing counseling. If an opioid-naive patient is given a new prescription or if the patch is intended to treat short-term, intermittent, or post-operative pain, the pharmacist should call the prescriber to question the order. The pharmacist should verify the indication and should document any conversations with the prescriber regarding the patient and the medication in a consistent place.

3. **Setting dosing limits.** The patch should always be prescribed at the lowest dose needed for pain relief. Inpatient and outpatient pharmacy computer systems, as well as CPOE systems, should be designed to flash an alert on the screen, and to create a hard stop if more than 25 mcg/hour has been prescribed as a first-time dose. For patients who are admitted to the hospital and who have been using fentanyl patches at home, the dose should be verified during medication reconciliation, and the verified drug list should be sent to the pharmacy.

4. **Assessing the concomitant use of opioids.** To reduce the risk of a drug overdose, prescribers should take into consideration any other opioids that have been ordered for the patient when they are evaluating the appropriateness of the patient’s dose.

5. **Limiting prescribing privileges.** In inpatient settings, it might be prudent to restrict the prescribing of fentanyl patches to certain categories of prescribers who are already educated about the drug and who have privileges to prescribe it. Alternatively, orders for patches in doses higher than 25 mcg/hour could be limited to certain prescribers, or an organization could require a review by a pain-management specialist within a certain time period.

6. **Mandatory patient education.** Patients, as well as their caregivers, should be shown how to use the patch safely. In both inpatient and outpatient settings, this education should be mandatory and scripted for pharmacists and nurses in order to promote consistent discussions about the drug’s indications; potency; dose; safety precautions; and application, removal, and disposal, as well as signs of toxicity. The patient and family, for instance, should be advised to avoid heating pads or hot tubs and to remove the old patch before they apply a new patch. In outpatient settings, pharmacists should use this counseling opportunity to verify that the patient is opioid-tolerant and is being treated for ongoing chronic pain. The pharmacist should document all patient education.

7. **Recognizing an overdose.** Health care practitioners who prescribe fentanyl patches, as well as nurses, patients, and caregivers who place the patches on the skin, should know the signs of a fentanyl overdose—respiratory distress; shallow breathing; tiredness; extreme sleepiness, or sedation; an inability to think, talk, or walk normally; and feeling faint, dizzy, or confused. If any one of these signs occurs, patients or their caregivers should seek medical attention immediately.

**REFERENCES**


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.