A Serious Threat to Patient Safety: The Unintended Misuse of FentaNYL Patches

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FentaNYL transdermal patches (Duragesic and other generic brands) are a mainstay in the treatment of chronic pain, yet the US health care community and patients alike continue to face challenges regarding the safe use of this product. Despite numerous warnings from drug manufacturers, patient safety groups, and even the Food and Drug Administration (FDA), the Institute for Safe Medication Practices (ISMP) continues to receive serious event reports about FentaNYL patches to its national medication error reporting program.[1–5] Unfortunately, a significant number of reports of FentaNYL patch misuse have resulted in patient harm and even death. Tragically, on further investigation, most of these events were found to be preventable. Such events are described herein.

Case I

An elderly woman who had been treated with over-the-counter pain relievers for her sciatica was prescribed 20 mg of an oral opioid derivative daily for pain management. Still in pain after 4 doses, she consulted her physician by telephone, who prescribed FentaNYL patches, 50 mcg/hour, to be applied every 48 to 72 hours. This 48-hour dosing interval for a non–opioid-dependent patient, though inappropriate, was not questioned by the pharmacy provider. After applying the patch to the area of most discomfort, the woman positioned herself in bed with a heating pad and tried to sleep. She was found dead 2 days later by a friend.[5]

On further review, it was determined that the dosing of this potent narcotic patch was inappropriate for an opioid-naive, elderly patient. According to the labeling guidelines, FentaNYL patches are reserved for use in "opioid-tolerant" individuals who have not been well controlled on other oral options and never as a means to treat acute pain.[5–7] (Opioid tolerance is often defined as taking the equivalent of 60 mg of oral morphine per day, 30 mg of oxycodone daily, or 8 mg of oral hydromorphone per day for a full week or longer.[5–7]) In addition, in this case the patient was never warned about the dangers of using a heating pad or similar device along with the patch: exposure to direct heat sources (eg, heating pads, hot tubs, or saunas) while one is using a FentaNYL patch can cause a sudden and possibly catastrophic increase in the absorption of the drug.[1,7,8]

Case II

A 2-year-old boy named Blake (Figure) died after accidental exposure to a used FentaNYL patch. Two days after a visit to his great grandmother in a long-term care facility, young Blake was found unresponsive at home and could not be resuscitated. The medical examiner found what appeared to be a "small piece of tape" in the child's mouth, which was later confirmed to be a used FentaNYL patch. The medical examiner determined that Blake had died from a lethal dose of FentaNYL that was absorbed through his oral mucosa. In the follow-up investigation of the event, detectives and the state health department learned of Blake's visit to the long-term care facility, and during a subsequent visit themselves to the facility, they found that used medication patches such as FentaNYL were often not properly disposed of. The investigators found medication-containing patches remaining in trashcans, stuck on bedside tables, stuck to bed rails, and in other unsecured locations. The theory regarding

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*ISMP is a nonprofit organization that works closely with health care practitioners, consumers, hospitals, regulatory agencies, and professional organizations to educate caregivers about preventing medication errors. ISMP is the premier international resource on safe medication practices in health care institutions. If you would like to report medication errors to help others, E-mail us at: ismpinfo@ismp.org or call (800)FAIL-SAF(e). This Medication Error Reporting Program keeps information confidential and secure. We will include only the level of detail that the reporter wishes in our publications.

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FIGURE

Two-year-old Blake died after inadvertently ingesting a fentaNYL patch. Photo reprinted with permission.

Blake's death is that while visiting his great grandmother, he may have run over a patch with his Tonka truck wheels and later removed the patch from the wheel of the truck and stuck it in his mouth.[3,9]

Discussion

It is important for health care providers and patients alike to understand that used FentaNYL patches are known to contain a significant amount of active drug, even after 72 hours of use. For example, a 50-mcg/hour Duragesic-brand patch contains 5,000 mcg of FentaNYL. At an absorption rate of 50 mcg/hour, an application lasting 3 days will result in the presence of roughly 28% of the active drug at the time of removal.[5–7,10] Other studies with generic FentaNYL patches have shown upwards of 30% to 50% of the drug remaining after a 3-day use period.[11] For this very reason, proper disposal of used FentaNYL patches is critical to avoid inadvertent exposure to an unsuspecting individual or to discourage individuals who may be seeking to intentionally misuse the drug for recreational use from gaining access.

Unfortunately, Blake is not the first child to die after accidental exposure to FentaNYL patches. Young children are particularly at risk because of their natural curiosity and method of mobility, which provides them with opportunities to find lost patches on the ground or stuck to furniture or to remove them from trashcans. More than 5 years ago, ISMP received a report of a 4-year-old child who was found dead near an overturned trashcan that contained used FentaNYL patches belonging to his mother. The mother, who had Crohn's disease, reported that her son had applied one of the used patches to his leg before his death.[8] In other cases serious harm to children and even infants has resulted from inadvertent exposure to FentaNYL patches that have fallen off of a family member.[9] According to the FDA, since 1997, there have been 26 cases of accidental pediatric exposure, including 10 deaths and 12 hospitalizations. "Sixteen events involved children 2 years of age and younger."[2] Although most of these events occur at home, these events can occur in health care facilities (hospitals, rehabilitation centers, and long-term care locations) where families with young children may visit.[2,9]

Although emergency department nurses may not be as familiar with the actual administration of FentaNYL patches, they commonly have exposure to this drug patch and the patients who use them. Thus emergency nurses armed with knowledge of the dangers of this product can have significant impact on its safe use. During triage or initial assessment, emergency nurses must inquire about the use of any type of medication patch, because patients/families often do not think of them as medications. This may be a perfect time to have a quick conversation about the dangers of these medications and the importance of safe handling. Opportunities for impact also exist to identify a possible unintended overdose of FentaNYL during a thorough physical assessment and identification of multiple simultaneous FentaNYL patch applications. ISMP and the Pennsylvania Patient Safety Authority Reporting System commonly receive such reports.[1,3,5,7,8,10] Very often, it is the emergency nurse who discovers the cause of an elderly person's somnolence or deteriorating ability to function by early assessment and recognition of multiple patches adhered to the individual.[3,7]

Emergency nurses also have the unique opportunity for supporting targeted discharge education for patients/families to discuss safe handling of FentaNYL patches at home. Discharge instructions should include removing the first patch before a second is applied; avoiding the use of heating pads, hot showers, or other heat sources that could inappropriately affect the absorption of the drug; proper handling of FentaNYL patches with special care around young children and pets; and signs and symptoms of FentaNYL overdose.

One of the most important points of discussion before discharge of any patient receiving FentaNYL patches is how to properly dispose of the patch to avoid inadvertent exposure by others.[2,9,12] Despite concerns from environmental groups, recent guidance from the FDA requires the disposal of FentaNYL patches by folding them in half to eliminate exposure and flushing them down the toilet. Although the FDA does acknowledge environmental concerns, they believe that "the risk associated with accidental exposure to this strong narcotic medicine outweighs the potential risks associated with disposal by

flushing."[2] Placing used patches in trashcans or even sharps containers in health care facilities is also discouraged because there have been reported cases of individuals with drug-seeking behaviors who will reach into a sharps container to retrieve an old drug patch. Drug seekers have been known to remove the remaining FentaNYL from the patch in multiple ways or will even directly chew on the patch to obtain the opioid effect.[3,5]

ISMP has long promoted the idea of sharing safety-related resources with patients. Example safety monographs for staff to use with patients who are discharged from the emergency department with a FentaNYL patch can be obtained for free from ISMP through the following link: http://www.ismp.org/docs/fentanyl-brochure.pdf.[12]

Emergency nurses play an important role in public health by sharing their knowledge of high-alert medications with patients. Using their unique access to patients as a mechanism for education and awareness, emergency nurses can be a vital link toward the reduction of serious and even fatal events with FentaNYL patches. Let's do it for Blake, and all others who have been inadvertently harmed.

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