Fentanyl Patch Fatalities: We ALL Have a Role in Prevention!

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The Institute for Safe Medication Practices (ISMP) learned about another child who died after gaining access to a transdermal fentanyl patch. This time it was a 15-month-old boy who had been cuddling with his mother, sleeping on her chest as they both took a nap. The boy’s mother had been wearing a fentanyl patch on her chest to treat pain associated with multiple sclerosis. When the mother awoke, she found her son unresponsive. The child was rushed by ambulance to the hospital. Resuscitation efforts continued in a pediatric emergency department without success. The child’s mother noticed that the patch on her chest was missing. The baby apparently ingested the patch, although the patch was never found. During intubation, vomitus was visualized in the baby’s esophagus and trachea, indicating aspiration, and perhaps the patch was overlooked in the vomitus. A medical examiner confirmed the child’s access to the patch, revealing physical findings of pulmonary congestion and edema, and toxicology findings of acute fentanyl intoxication.

Repeated Tragic Events

Sadly, this is a recurring story in health care—one that has been told over and over again without substantial acknowledgement and action by individual practitioners, health care organizations and systems, community pharmacies, public policy agencies, pharmaceutical companies, professional organizations, and advocacy groups. The prior events are just as heartbreaking as the latest event. A 2-year-old boy died after ingesting a used fentanyl patch that stuck to the wheels of his toy truck while playing in his grandmother’s room at a long-term-care facility.1 A 1-year-old girl swallowed a 25-mcg/hour fentanyl patch that had been lying on the floor, and she was found dead just two hours after her parents tucked her into bed and kissed her good night.2 Other fatalities have occurred with confused elderly adults, opioid-abusing teens, and adults who have chewed and/or ingested fentanyl patches.3

Absorption of Ingested Fentanyl Patches

Transdermal fentanyl is designed to release the drug in a slow, steady manner over 72 hours. But uncontrolled quantities of the drug may be rapidly absorbed via the buccal route if the patch is ingested, often with disastrous results.4 The rate of drug absorption and severity of toxicity is dependent on the amount of time the fentanyl patch is in direct contact with the oral mucosa and whether the patch is chewed or sucked on or swallowed intact. A patch chewed or sucked on will release large quantities of drug rapidly. Chewing is particularly dangerous because it disrupts the patch integrity and releases a full dose in a much shorter period than an intact patch.5 Also, fentanyl is absorbed more rapidly through buccal mucosa4 and has more than a 30-fold increase in absorption when compared to transdermal absorption.5 Swallowing an intact patch results in less rapid drug release, but systemic absorption is still significant.4-5

Given that each patch holds a relatively large dose of fentanyl and that about half of the total drug amount remains in a patch after three days of use,6 chewing or sucking on a patch—even a used one—can result in a large overdose. Faust et al. provide the following example: A 50-mcg/hour patch the authors tested held nearly 8,400 mcg of fentanyl (the actual amount varies depending on the design of the patch). If the patch in this example and its entire contents were ingested intact, about 1,680 mcg would enter the systemic circulation. If the entire contents of the patch were removed (by chewing, for example) and absorbed buccally, the dose entering the circulation would be about three times higher (about 5,000 mcg) than swallowing the patch intact.5

Other Fentanyl Patch Tragedies

Children have also been victims of fatal fentanyl overdoses after they applied a patch intended for an adult to their skin. A 4-year-old child died after finding a used fentanyl patch in a trash can and placing it on his body like a Band-Aid.6 An uninformed mother placed a fentanyl patch, which had been prescribed to her after a car accident, on her 6-year-old daughter’s neck when the young child complained of neck pain before going to bed; the child was found dead the next morning. The Food and Drug Administration (FDA) evaluated 26 cases of pediatric accidental exposures to fentanyl patches reported during a 15-year period.7 Of these, 10 resulted in death and 12 in hospitalization. Sixteen of the 26 cases occurred in children 2 years of age or younger. The mobility and curiosity of young children provide ample opportunity to find fallen patches, improperly discarded patches, or improperly stored patches.

Opioid-naïve adults have also fared poorly when prescribed fentanyl patches inappropriately for acute pain or when instructions for use were not provided and understood. For example, an otherwise healthy opioid-naïve 47-year-old man died one day after discharge from a hospital where he was given a prescription for fentanyl patches for postoperative pain following spinal surgery.8 A 77-year-old woman was found dead at home with multiple fentanyl patches on her body and a heating pad over one of the patches.9

Impetus for Change

Can you imagine the grief of the parents who found their lifeless children, or the family members who lost their loved ones to this preventable event? Health care

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professionals typically exhibit profound empathy for those who suffer such a loss, but not all may feel personally responsible to prevent these events. What if you were the physician who prescribed a fentanyl patch that led to a fatal event, or a community pharmacist who dispensed the patch involved in a fatal outcome, or the nurse who discharged a patient from the hospital with a prescription for a fentanyl patch that ultimately resulted in such a tragedy? Must it take personal involvement in an actual event for all individuals to feel the weight of these fatal errors and incite preventative action?  

Preventing Fentanyl Patch Tragedies

The prescribing physician and the discharging nurse cannot just rely on each other or a hospital/community pharmacist to verify the appropriateness of fentanyl patches and doses or to educate patients about important risks and proper use. The hospital/community pharmacist cannot simply assume that the drug and dose is appropriate or that the patient has been educated. All health care providers must individually instruct patients and caregivers about proper use and risks. Professional associations that support physicians, pharmacists, and nurses cannot remain silent on this important issue. Safety organizations, including ISMP, need to step up efforts to make fentanyl patch safety among the highest priorities. Pharmaceutical companies can no longer sidestep improved label warnings, fail to provide secure disposal containers for patches, or ignore further exploration of steps to prevent misuse and errors, such as making the patch wholly unpalatable. Professional licensing agencies and accrediting organizations need to set standards regarding patient education that specifically address the risks associated with fentanyl patches.  

The FDA issued a Drug Safety Communication in 2013 requiring manufacturers to change the color of fentanyl patches and to clearly label each patch with the drug name and strength so they can be more easily seen on the patient’s body or if the patch falls off. More can be done, however. The FDA needs to expand its risk evaluation and mitigation strategies (REMS) for long-acting opioids to include required patient education by prescribers, pharmacists, and nurses, and the agency needs proper legislative authority to require prescriber education or perhaps a special restricted distribution program for the drug. This time around, we hope organized groups that represent pharmacy chains, pharmacy boards, and pharmacy practice will support expansion of the REMS to include pharmacists in consumer education for long-acting opioids, including fentanyl patches.

Focused Education

Patients who are using a fentanyl patch or their caregivers need to know about proper use, storage, and disposal, and other risks, particularly when using the patches around children. To assist, ISMP has developed a free patient education checklist and consumer leaflet for use during consumer education that can then be given to the patient for reference. The checklist/leaflet includes, among other important information, 10 key safety tips for consumers using fentanyl patches. The FDA also requires a medication guide to be given to patients, and the agency has developed a safe use initiative around proper disposal of the patches. It’s one thing to tell people to read these materials and hope that they do; it’s quite another to accept personal responsibility for providing this education to patients face to face.

No patient should ever be allowed to walk out of a doctor’s office, hospital, clinic, or pharmacy without face-to-face instructions on the use of fentanyl patches and related safety concerns, as well as verification of consumer understanding. Everyone must take responsibility and never assume someone else will act. The change necessary to improve patient safety will always depend on individuals who, never satisfied with being a bystander, are drawn into the lifesaving work of keeping patients safe from harm. Widespread adoption of required consumer education will also be more effective if influential groups work together and if external forces provide the necessary pressure via regulations, standards, public policy, or incentives.

REFERENCES


