Inappropriate fentaNYL patch prescriptions at discharge for opioid-naïve, elderly patients

We recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fentaNYL patches for elderly patients. In most cases, the pharmacists reviewing the patients’ orders determined that the fentaNYL patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. In several cases, the fentaNYL patches had been prescribed because of a documented allergy to another analgesic, such as codeine. However, further investigation showed that the “allergy” was a minor intolerance to the analgesic, usually gastrointestinal, such as mild nausea or constipation. The more common underlying cause of prescribing fentaNYL patches inappropriately appears to be a knowledge deficit about the dangers of prescribing this potent opioid analgesic to opioid-naïve patients. Several of these events began in a hospital, with opioid-naïve patients receiving prescriptions for fentaNYL patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. ISMP has written about this well-known problem for decades. Since it is STILL an ongoing problem, it is time to revisit this issue.

Background

In 1990, DURAGESIC (fentaNYL transdermal system) was approved by the US Food and Drug Administration (FDA). Years later, generic fentaNYL patches became available. As early as 2005, FDA published a public health advisory and information for healthcare professionals regarding the appropriate and safe use of the fentaNYL transdermal system, noting that serious, life-threatening, or fatal respiratory depression may occur.1 FDA followed up with another advisory in 2007, stressing that transdermal fentaNYL is only indicated for use in patients who are opioid-tolerant with documented chronic, moderate-to-severe pain.2

Today, the official prescribing information recommends use of fentaNYL patches only in opioid-tolerant patients for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. According to the prescribing information, patients considered opioid-tolerant are those taking, for 1 week or longer, at least:

- 60 mg of oral morphine per day
- 60 mg of oral HYDROcodone per day
- 30 mg of oral OXYCODONE per day
- 25 mg of oral OXYMORphone per day
- 8 mg of oral HYDROMorphone per day
- 25 mcg of transdermal fentaNYL per hour
- An equianalgesic dose of another opioid

In addition, in 2012, FDA approved an extended-release (ER) and long-acting (LA) opioid analgesic Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of prescribing ER and LA opioids, including fentaNYL patches, outweigh the risks.3 In 2018, that REMS was modified to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to all prescription opioid analgesics.4 The REMS strongly encourages specific training about the risks and safe use of opioids for all healthcare providers involved in

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the management of patients with acute or chronic pain. FDA believes that, with training, the proper analgesic will be selected for the patient and used with appropriate clinical oversight and monitoring. The agency has even created a blueprint to specify the content of an opioid educational program for healthcare providers. However, there is no mandatory federal requirement for REMS-compliant education about opioids, including fentaNYL patches, as a precondition to prescribing, as FDA concluded that monitoring compliance would be unduly burdensome.

Inappropriate prescribing of fentaNYL patches

The LTC pharmacy that reported the rise in inappropriate prescribing of fentaNYL patches provided numerous examples, three of which originated in hospitals and are described below. Again, most of these events demonstrated the prescribers’ lack of knowledge about avoiding this analgesic in opioid-naïve patients and/or an inaccurate classification of a drug intolerance as an allergy. Prescribing a fentaNYL patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose. Additionally, with the elderly population, there are a number of risk factors, including age-related comorbidities, polypharmacy, and drug-drug interactions, that can further contribute to an unintentional overdose if opioids are inappropriately prescribed.

Event 1

An 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge from the ED, the resident was prescribed a transdermal fentaNYL patch, 25 mcg/hour, every 72 hours. When the resident returned to the LTC facility, a consultant pharmacist reviewed the medication orders. Looking at the resident’s medication history, the pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fentaNYL patch. The ED physician reported that the resident had received “3 small IV push doses” of fentaNYL in the ED, mistakenly believing this to mean the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fentaNYL patch because the resident had a documented allergy to codeine. Thus, the ED physician mistakenly believed the fentaNYL patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and stomach upset while taking HYDROcodone and acetaminophen (VICODIN) when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident’s analgesic to oral oxycodone 5 mg as needed every 4 to 6 hours.

Event 2

An 85-year-old hospitalized patient with persistent pain from a recent fall was discharged with orders for HYDROmorphine 1 mg by mouth every 4 hours as needed for pain, which he had received during his 3-day hospitalization. Before the patient was transferred to a LTC facility, the physician also prescribed a 50 mcg/hour fentaNYL patch to be applied at discharge for pain management. When reviewing the transfer orders, a LTC pharmacist noticed that the patient did not have a history of taking opioids prior to his 3-day hospitalization and was concerned about the fentaNYL patch that had been applied prior to transfer, particularly in combination with the prescribed HYDROmorphine. The pharmacist contacted the LTC physician, who initially did not want to discontinue the fentaNYL patch since it had been recommended by the hospital physician. The pharmacist was persistent and convinced the LTC physician that the fentaNYL patch was unsafe in the elderly, opioid-naïve patient. The patch was removed and discarded.

Event 3

A 65-year-old patient with back pain had been taking HYDROcodone with acetaminophen 5 mg/325 mg once or twice daily for the past week. When he was hospitalized for continued on page 3 — Inappropriate fentaNYL patches

SAFETY briefs

Letting the docs dispense. A recent editorial in The Wall Street Journal roused some concerns when the authors suggested that, “instead of forcing patients to stand in line at a drugstore to fill their prescriptions, it would be easier and cheaper if these patients could get their meds directly from the doctors prescribing them” (www.ismp.org/ext/506). The editorial provided commentary about a lawsuit by 3 doctors in Montana who are seeking the freedom to dispense “non-controlled medications directly to their patients at cost,” which is currently banned in their state. The editorial said the ban was less about protecting patients and more about protecting a middleman from competition. continued on page 3 — SAFETY briefs
Recommendations

ISMP is concerned about these and other reports of inappropriate prescribing of fentaNYL patches for opioid-naive patients. FentaNYL patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. This is so critical to safety that, in 2018, ISMP called for the elimination of prescribing fentaNYL patches for opioid-naive patients and/or patients with acute pain in their Targeted Medication Safety Best Practices for Hospitals (www.ismp.org/node/160). In 2020, this Best Practice was incorporated into a new Best Practice (#15) to verify and document the patient’s opioid status and type of pain before prescribing and dispensing ER or LA opioids.

The most recent stream of reports, some of which are described above, are closely associated with a knowledge deficit about pain management and proper prescribing of fentaNYL patches. These examples and others help substantiate the fact that reliance on product labeling and practitioner education alone will not do enough to solve this life-threatening problem. Yes, prescribers should be educated about safe fentaNYL patch prescribing, and their competency should be verified as a prerequisite to prescribing this potent opioid. However, education alone is a weak safety strategy (www.ismp.org/node/18343), and there will always be some who are unaware of the great risks they take when prescribing fentaNYL patches to opioid-naive patients to treat acute pain. Thus, system safeguards must be established for this high-alert medication to avoid the risk of harm.

The examples of inappropriate prescribing of fentaNYL patches described above occurred upon transfer to a LTC facility. Thus, our typical recommendations alone to improve proper inpatient prescribing (e.g., automatic interchange, pharmacy interventions with prescribers), safe storage only in clinical locations where chronic pain is primarily treated, and mandatory discharge and ambulatory patient education, may not be enough to reduce the risk of inappropriate prescriptions upon transfer. While all of these instances of inappropriate prescribing were thankfully detected by LTC pharmacists after patients had been transferred to a LTC facility, thus preventing serious patient harm, additional strategies before these transitions in care should be implemented in the hospital.

For example, when entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria, including in the ED. Also consider creating a daily list of discharge prescriptions and transfer orders for fentaNYL patches generated from the order entry system, and requiring a hospital pharmacist to review the orders and prescriptions to verify that the patient is opioid-tolerant and has chronic pain.

In addition, distinguishing between true allergies and drug intolerances is critical to the proper selection of analgesics. When allergy information is collected, include prompts to obtain and document in a standardized manner the reaction type (e.g., side effect, intolerance, toxicity, immune response) and description (e.g., rash, pruritus, swelling, etc.).

What cannot easily be dismissed are the potential safety issues with physician dispensing, such as bypassing safety alerts issued during order entry with clinical decision support; labeling and packaging issues; the potential for conflict of interest where a profit motive may exist (rare, and not the case in the Montana lawsuit); and availability of third-party reimbursement. From a patient safety standpoint, ISMP cannot support physician dispensing at this time since the process has not been well-thought out, does not incorporate critical safety measures to protect against medication errors, and there is no regulatory oversight.

Nymalize oral syringes to be adapted for ENFit. As mentioned in our May 21, 2020 newsletter, Arbor Pharmaceuticals has made changes to NYMALIZE (mODipine) oral solution, including a change in concentration from 3 mg to 6 mg per mL, availability only in a prefilled oral syringe, and discontinuation of unit dose cups and a 473 mL (pint) bottle. Providing the medication solely in prefilled oral syringes led to concerns from hospitals that have converted to ENFit tubing, which is not compatible with oral syringes.

ISMP discussed the situation with Arbor and the US Food and Drug Administration (FDA). We learned last week that the company is working on both short- and long-term solutions for hospitals that use ENFit. Arbor said the company is in the process of transitioning to a prefilled oral syringe.
Update on Omnicell variable character search feature

As we have seen repeatedly, problems can occur with automated dispensing cabinet (ADC) drug name searches when just 2 or 3 characters are typed to select medications via override or from a non-profiled cabinet. This problem was illustrated most recently in our May 14, 2020, issue (www.ismp.org/node/17746) when a patient received verapamil instead of VERSED (a former brand of midazolam). A nurse used the cabinet override feature to select and access the drug “Versed” by entering the first few letters of the drug name. However, she accidentally selected and removed a vial of verapamil (5 mg/2 mL) from the ADC, which was available via override. Verapamil was then administered to the patient by IV push. The incident was strikingly similar to an earlier tragic error in which a patient died after receiving vecuronium instead of Versed after entering just “V-E” in the drug name search field (www.ismp.org/node/1326).

Searching drug names using just 1, 2, or 3 letters can lead to these situations, which is why we have recommended using at least 5 letters when searching for a drug in electronic systems. In the 2019 article cited above, we called upon ADC vendors to consider software changes to allow a configurable option for the required number of letters to narrow the choices, ideally to one drug or drug category. So far, we only know of Omnicell having such a feature (in the Omnicell XT ADCs), although BD/Pyxis has promised enhancements soon as well.

We recently learned a little more about how the Omnicell function works. The character search configuration is at the cabinet level and not at the individual drug item level. There is a series of tabs for clinicians to select the category of medication being removed, such as “Scheduled Meds,” “Active Med Orders,” “PRN Only,” and “Stocked Meds.” “Stocked Meds” is where the override function resides. If nurses access a medication via override, the cabinet can be set to address safety so that at least 5 letter characters must be entered to select a drug (Figure 1). The search functionality under “Scheduled Meds,” “Active Med Orders,” and “PRN Only” was not changed, so these do not require a 5-character search. Only medication searches for drugs obtained via override (“Stocked Meds”) require a 5-character search. Requiring a 5-character search for scheduled, active, and PRN medications may cause frustration and may not be required, as only medications prescribed and verified for the patient will appear during these drug name searches. We hope those who have Omnicell XT ADCs will make sure this important feature is set to require a 5-character search for drugs obtained via override.

Figure 1. With Omnicell XT ADCs, stocked items obtained via override require the entry of at least 5 characters during searches.

Reference