

ISMP Medication Safety Alert: Fentanyl Patch with Opioid-Naive Patients

Background:

- Duragesic (fentaNYL transdermal system) is an opioid analgesic first approved in 1990.
- Per current prescribing information, transdermal fentaNYL is only indicated to treat patients who are identified as opioid-tolerant and have documented chronic, moderate-to-severe pain.
- For a patient to be considered opioid-tolerant they must have taken the following medication(s) for at least 1 week or longer:
 - 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 HYDROmorphine per day
 - 25 mcg of transdermal fentaNYL per hour
 - An equianalgesic dose of another opioid
- The FDA approved a REMS (Risk Evaluation and Mitigation Strategy) program that included fentaNYL to ensure providers weighed the risks versus the benefits and to decrease the risk of abuse, misuse, addiction, or overdose due to all opioid analgesics.
- Transdermal fentaNYL can lead to life-threatening or fatal respiratory depression, especially in elderly opioid-naive patients.
- Many reports of inappropriate prescribing of fentaNYL transdermal patches stem from two main issues:
 - Inadequate understanding of the difference between opioid-naive and opioid-tolerant.
 - Inadequate understanding of the difference between a true allergy (ex. anaphylaxis) and an intolerance (ex. stomach upset).

Case Scenario:

1. 88 year-old patient was admitted with multiple rib fractures from a LTC facility. In the ED, patient received 3 small IV push doses of fentaNYL. Patient was discharged back to LTC with fentaNYL patch (25 mcg/hour every 72 hours) because of documentation of allergy to codeine. Patient stated that while taking hydrocodone-acetaminophen (VICODIN) he experienced mild nausea.

Recommendations:

- Improving documentation
 - Verify and document the patient's opioid status and type of pain BEFORE prescribing
 - When allergies are collected ensure they are distinguished between TRUE and INTOLERANCE.
- Establishing system safeguards
 - Interactive alerts requiring confirmation that patient is opioid-tolerant
 - Hard stops if patient does not meet criteria
- Increasing the pharmacist's role
 - Requiring a hospital pharmacist to review the orders and prescriptions to verify that the patient is opioid-tolerant and has chronic pain