

CHA Medication Safety Committee High Alert Medication Guideline - FentaNYL Transdermal Patch

April 2011



Despite warnings from the [FDA](#), manufacturers, and various patient safety agencies, transdermal fentaNYL patches continue to be prescribed inappropriately to treat patients with acute pain and patients who are not opioid tolerant. [ISMP](#) issued a Medication Safety Alert in June 2007, which may be found at <http://www.ismp.org/Newsletters/acutecare/articles/20070628.asp>.

This guideline document is intended to summarize safe use practices to reduce the preventable harm to patients in the hospital setting.

FentaNYL patches are only for patients who are **opioid-tolerant** for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time AND cannot be managed by other means.

The patches are **NOT** to be used to treat sudden, occasional or mild pain, or pain after surgery.

Opioid tolerance may be identified in individuals who have been taking opioids for a week or longer. Opioid tolerant is defined as taking oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day.

Medication Use Step	Actions to Consider to Increase Medication Safety
General	<ul style="list-style-type: none"> ➤ Define and educate staff on opiate tolerance <p>Opioid tolerance may be identified in individuals who have been taking opioids for a week or longer. Opioid tolerant is defined as taking oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day.</p> <ul style="list-style-type: none"> ➤ Consider eliminating storage in Emergency rooms, PACU, Operating rooms, short day surgery, which are considered problem-prone areas for fentaNYL use
Pharmacy Purchasing, Storage and Product Labeling	<ul style="list-style-type: none"> ➤ Ensure manufacturer provides clear identification of patch contents once it is removed from the packaging. Be sure your product clearly identifies the ingredient fentaNYL and strength. ➤ Secure utilizing ADC controlled substance cabinets in different lockers. ➤ If ADC is not available segregate your strengths in your locked storage system. ➤ Storage bins should utilize TALLman lettering fentaNYL

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<p>Unit Storage of Medications (includes automated dispensing cabinets- ADC such as Pyxis MedStation)</p>	<p>Hospitals with ADC configuration:</p> <p>With 24/7 pharmacy coverage</p> <ul style="list-style-type: none"> ➤ <u>Never place on an override medication list.</u> ➤ Consider bar code verification upon refill or a pharmacist check post load/refill. ➤ Stock in a single access pocket and not in a communal (matrix) pocket. ➤ Load only in ADC cabinets that are profiled and releases medication only after the pharmacist order verification has occurred. ➤ In non profiled areas, have pharmacy send stock patient specific once pharmacist order validation has occurred. <p>Without 24/7 pharmacy coverage</p> <ul style="list-style-type: none"> ➤ Stock with caution* in all areas that are not profiled ➤ *Caution = limited quantities & strengths available, additional safeguards such as 2 independent practitioners (double check) ➤ Utilize Pop-up alerts for opiate tolerance assessment (example below) in all stocked cabinets <ul style="list-style-type: none"> Question: Review of patient opiate history confirms opiate tolerance? YES - proceed with removal NO - contact prescriber for alternative medications <p>Hospitals without ADC-configuration:</p> <ul style="list-style-type: none"> ➤ Require second verification as to medication appropriateness ➤ Promote patient-specific pharmacy dispensing of doses on demand ➤ Segregate strengths in separate locations ➤ Label doses with warning against cutting patches
<p>Prescribing</p>	<ul style="list-style-type: none"> ➤ FentaNYL patches should ONLY be prescribed to manage persistent, moderate-to-severe chronic pain that requires continuous, around-the-clock opiate administration for an extended period of time, particularly when the pain cannot be managed by other means such as non-steroidal analgesics, opiate combination products, or immediate-release opiates. ➤ Consider use of a pre-formatted order form that requires the prescriber to identify appropriate indications for use prior to pharmacist dispense. ➤ Consider requiring the prescriber to document in the medical record that the patient meets criteria for using the patch. Ideally this documentation would list previous drug dosing history. ➤ Provide guidance on appropriate starting dose and opioid dosing equivalence ➤ Consider prescriber limitations for use (specific trained prescribers or maximum dosing of 25 mcg/hr patch for general practitioners) ➤ Consider pharmacist-driven protocol for use of fentaNYL patch ➤ Dosage modifications should not be made prior to 72 hours after initiation of therapy, and not prior to 6 days after dose changes. (per package insert)

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<p>Pharmacist Order Entry Process</p>	<ul style="list-style-type: none"> ➤ Have references and tools for pharmacist assessment of appropriateness. ➤ Establish requirements for minimum pharmacist review with the goal of identifying the potential for adverse consequences. To include pharmacist assessment of: <ul style="list-style-type: none"> ○ Appropriate indication (severe chronic pain) ○ Opiate-tolerance. Opioid tolerant defined as taking oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day ○ Appropriate starting dose based on dosing history and indication ○ Potential drug interactions ○ Validation of home dosing - last refill information ○ Change in patch strength – pharmacist to ensure that strength is not changed prior to 3 days after initiation or 6 days after dose increase. ➤ Consider Black Box Warning (BBW) pop-up warning to remind pharmacist of appropriate indications and to require documentation of pharmacist intervention through computer order entry.
<p>Pharmacy Dispensing</p>	<ul style="list-style-type: none"> ➤ Require pharmacist review for dispensing of all fentaNYL patches (remote review, on site review). ➤ When a prospective pharmacist review is not conducted, a retrospective review to occur on all patients to assess for appropriateness of use
<p>Nursing Administration</p>	<ul style="list-style-type: none"> ➤ Never cut the patch ➤ Caregiver should use gloves when handling the patch and wash hands immediately after handling the patch (for placement or disposal) ➤ Apply patch to non-irritated skin such as chest, back, flank or upper arm. Do not shave skin; hair at application site may be clipped ➤ Add MAR warning note that includes monitoring parameters and appropriate administration technique ➤ Avoid external heating sources (heating blankets, hot baths). Monitor patients for core body temperature above 102, as heat may result in increased release of drug from transdermal system, leading to potential toxicity. ➤ Monitor all patients for toxicity (alertness, respiratory drive, vital signs) ➤ Verify patch placement upon admission and transfer. ➤ Consider additional documentation requirements for: <ul style="list-style-type: none"> ○ Documentation of patch placement ○ Daily check for presence of a patch ○ Removal of old patch BEFORE placement of a new patch
<p>Monitoring</p>	<ul style="list-style-type: none"> ➤ Implement a monitoring policy that includes assessment of alertness, respiratory and cardiovascular systems throughout use of patch, with special emphasis on the initial 24 hours after patch placement or after dose increases. ➤ Conduct periodic audits to monitor if healthcare staff are following policies and monitoring parameters at all steps in the med use process.

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<p>Other Considerations</p>	<ul style="list-style-type: none"> ➤ Disposal: Do NOT flush patches. Dispose in <u>secured</u> pharmaceutical waste container per appropriate medical waste management regulations. ➤ Implement hospital policy to identify appropriate actions for patients who undergo MRI, with detailed in place policy identifying who is responsible for identifying the presence of a patch with metal backing, who can remove it, how it is replaced after procedure and where this process is documented. ➤ Define opiate tolerance and dose equivalence. Consider use of reference card for opiate equivalencies ➤ Develop policy on escalation of medication orders (when pharmacist and prescriber do not agree) if the patient does not meet dosing criteria, or if initial dosing exceeds recommended criteria ➤ Define emergencies - determine when appropriate for patch to be utilized in patients treated in non-profiled areas ➤ Develop competencies for all clinical staff involved with process ➤ Consider adding naloxone to order sets or have emergency guidelines for when naloxone is appropriate ➤ Consider the potential for suicidal tendency of a patient when prescribing fentaNYL patch for ambulatory care use ➤ Consider discharge planning responsibilities to ensure the patients will not suffer adverse health consequences upon discharge and that those who are given fentaNYL patch upon discharge are given discharge teaching and instructions related to the medication. ➤ Ensure patients upon discharge understand how properly and securely dispose of used patches so children can't find them
<p>References</p>	<ul style="list-style-type: none"> ➤ Institute for Safe Medication Practices (ISMP) ➤ Food and Drug Administration (FDA) ➤ fentanNYL patch manufacturer package insert ➤ Black Box Warning ➤ FDA Safety Alert
<p>Definitions</p>	<ul style="list-style-type: none"> ➤ <i>ADC</i>- Automated Dispensing Cabinets ➤ <i>Profiled ADC</i>- an automated dispensing cabinet that requires a pharmacist to review and approve a medication <u>before</u> they are available for selection and administration by clinical staff, unless the medication is available on an override medication list ➤ <i>Override medication</i>- a pre-approved list of medications that may be removed from a specific patient care area ADC for selection and administration without a prospective pharmacist review ➤ <i>MAR</i>= medication administration record