Expected Practice: Fentanyl Transdermal Patch Standard Procedures

August 2014 – UPDATE

PURPOSE

- To promote a standard procedure to ensure the safe and proper use of fentanyl transdermal patch
- To reduce preventable harm from improper use of the fentanyl transdermal patch
- To identify a complete procedure addressing the multifactorial components of safe prescribing, dispensing, and administration of the fentanyl transdermal patch.

OVERVIEW

Fentanyl transdermal patches have been associated with a number of serious adverse events and deaths nationwide. Safety warnings have been addressed regarding its proper prescribing and usage. Clinicians should only prescribe the fentanyl transdermal patch for a **chronic pain** indication. Numerous safety warnings address the proper prescribing, handling, usage, and monitoring of the fentanyl transdermal patch. The fentanyl transdermal patch carries multiple FDA Boxed Warnings, including the risk of serious, life-threatening, or fatal respiratory depression, even when used as recommended.

INDICATIONS:

1. Fentanyl patches are indicated for the management of persistent, chronic pain severe enough to require continuous opioid administration for an extended period of time (weeks or longer) in opioid tolerant patients 2 years of age and older
   AND
2. Cannot be managed by other means, such as non-steroidal analgesics, opioid combination products, or immediate-release opioids because they are either ineffective, not tolerated, or would be otherwise inadequate to provide sufficient pain management.

CONTRAINDICATIONS

1. Patients who are **NON-**opioid tolerant
   - Patients are considered to be opioid tolerant if they have been using, for a minimum of seven days, at least 60 mg of oral morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid
2. Management of post-operative pain, including use after out-patient or day surgeries
3. Management of acute or intermittent pain, or in patients who require opioid analgesia for a short period of time
4. Management of mild pain
5. In patients with significant respiratory compromise, especially if adequate monitoring and resuscitative equipment are not readily available.
6. Patients who have acute or severe bronchial asthma
7. Patients with suspected or known paralytic ileus
8. In patients with known hypersensitivity to fentanyl or any components of the transdermal system.

EXPECTATIONS

There are general principles to follow when prescribing fentanyl transdermal patch for chronic pain. When

Original Date Approval: 7/11
Revised: 4/13, 8/14

initiating or modifying treatment regimen, the following actions are expected:

- Converting from other opioids to the fentanyl transdermal patch requires calculating the equianalgesic dose prior to initiation
- Calculate the previous 24 hour opioid analgesic requirement for the opioid-tolerant patient.
- Convert this amount to the equianalgesic dose for initial dose of fentanyl transdermal patch (Table 1)
- Discontinue the previous opioid and initiate patient on fentanyl transdermal patch treatment using the recommended dose and titrate patients upward, no more frequently than 72 hours (3 days) after the initial dose and no more frequently than every 144 hours (6 days) thereafter.
- Although the recommended conversion starting dose may be up to 50% lower than what the patient needs, this dose is recommended to **minimize potential overdosing with the initial patch.**

Considerations for the use of Table 1:

- This is **NOT** a table of equianalgesic doses.
- The conversion doses in this table are **ONLY** for the conversion **from** one of the listed oral or parenteral opioid analgesics **to** the fentanyl transdermal patch.
- Tables 1 **cannot** be used to convert **from** the fentanyl transdermal patch **to** another opioid.
  Doing so will result in an overestimation of the dose of the new opioid and may result in fatal overdose.

Table 1: Converting patients on other oral or parenteral opioids to fentanyl transdermal system (DO NOT use this table to convert fentanyl patch dose to other therapies)

Current Analgesics	Daily Dosage (mg per day)			
Codeine-Oral	150-447			
Hydromorphone-Oral	8-17	17.1-28	28.1-39	39.1-51
Hydromorphone-IV	1.5-3.4	3.5-5.6	5.7-7.9	8-10
Meperidine-IM	75-165	166-278	279-390	391-503
Methadone-Oral	20-44	45-74	75-104	105-134
Morphine-Oral	60-134	135-224	225-314	315-404
Morphine-IV/IM	10-22	23-37	38-52	53-67
Oxycodone-Oral	30-67	67.5-112	112.5-157	157.5-202
Hydrocodone-Oral	60-134	135-224	225-314	315-404
	↓	↓	↓	↓
Recommended Fentanyl Transdermal Dose	**25 mcg/h**	**50 mcg/h**	**75 mcg/h**	**100 mcg/h**

Adapted from Duragesic® Package Insert; April 2014 (rev.)

Each facility will govern the safe and appropriate use of Fentanyl Transdermal Patches through their respective Medication Safety and Pharmacy & Therapeutics Committees. The Medication Safety Committee will be responsible for trending and tracking the use of Fentanyl Transdermal Patches and report all results, events, and related adverse drug events to the Pharmacy & Therapeutics Committee. The Pharmacy & Therapeutics Committee shall be responsible for any new formulary updates as deemed necessary and will assist in the quality assurance of Fentanyl Transdermal Patch usage.
Each DHS site is expected to review the attached expectations (Attachment A) and take appropriate actions to improve medication safety in the identified risk areas. Significant among these expectations include the following:

1. Fentanyl Transdermal Patches will only be stocked in areas with profiled automated dispensing cabinets and inaccessible via override.
2. Utilize a preformatted order form, which identifies appropriate indications for use and assessment of opioid history.
3. Prior to using fentanyl transdermal patches, prescribers, pharmacists and nurses will have received

training in the safe use of fentanyl transdermal patches.

4. Pharmacists should maintain competency when evaluating and dispensing Fentanyl Transdermal Patches.
5. Nursing will document application of each new patch placement and removal of previous patches. Nursing will also ensure that the patch is intact and adherent.
6. Implement policy for monitoring patients for initial 24 hours after each new patch placement or changes in regimen. Monitoring parameters should include, but are not limited to, respiratory rate, temperature, heart rate and lethargy.

The Expected Practice of Fentanyl Transdermal Patch: Standard Procedures shall be reviewed annually and updated as deemed necessary by the DHS Medication Safety Committee.

Original Date Approval: 7/11
Revised: 4/13, 8/14

Attachment A: 2014 Guidelines for the Safe Handling of Fentanyl Transdermal Patch

Los Angeles County Department of Health Services

Storage and Labeling	Unit Storage (ADC Configuration)	Prescriber Order Requirements	Pharmacist Order Entry Process	Dispensing	Nursing Administration	Monitoring	Patient Education	Other Considerations
Secure via automated dispensing cabinet (ADC)	Inaccessible via override	Utilize preformatted order form, which identifies appropriate indications for use and assessment of opioid history	Provide references and tools for pharmacist assessment of patch appropriateness	Pharmacist requirement and documentation for appropriate use prior to initiating therapy	Do not use patch if broken or damaged. Never allow a patch to be cut	Implement policy for monitoring patients for initial 24 hours after new patch placement or changes in regimen	Avoid external direct heating adjacent to the patch. If patient experiences temperature >102°F, contact physician ASAP	Define opiate tolerance and dose equivalence, see Table 1
Segregate by different strengths	Stock in pharmacy and areas that have profiled automated dispensing cabinet	Provide guidance on appropriate starting dose and opioid dosing equivalence	Pharmacist review of medication order must include identification for potential adverse drug consequences		Nurse documentation requirements: • New patch placement • Application site • Daily check ensuring patch is intact and adherent • Removal of patch • Patient's Pain Score	Conduct periodic audits to ensure practitioners are adhering to policy and procedures	Apply patch to hairless, non-irritated and non-irradiated skin Rotate application sites on different flat surfaces, such as chest, back, flank, or upper arms	Implement policies and procedures identifying appropriate actions to prevent burning in patients undergoing a MRI
Labeled storage bins should utilize tallman lettering **"fentaNYL"**	Stock in single access pocket and not in "communal pockets"	Restrict to authorized prescribers or Pain Service	Assure change in patch strength is not prior to 72 hours for initial therapy or six days thereafter		Avoid external heating sources. Monitor patients for core body temperature>102°F. Notify prescriber if patient develops a fever.	Provide retrospective review and audit on all patients for appropriate use	Do not use a patch if it is broken or damaged. Never cut a transdermal patch	Ensure policies and procedures address dose escalation when prescribing does not meet pre-defined criteria
	Pop-up alerts for opiate tolerance assessment	Dose modifications should not be ordered prior to 72 hours (3 days) after initiation of therapy and not prior to six days thereafter	Provide BBW pop-up warning to remind pharmacist of appropriate indication and require documentation of pharmacist intervention(s)		Monitor all patients who experience ADRs for a minimum of 24 hours post event due to long half-life		After use, dispose patch by folding sticky sides together and disposing properly in a secure location	Develop competencies for all clinical staff who prescribe, dispense, handle and administer patch Assess and monitor those patients with drug abuse potential and suicidal tendencies
			Add MAR warning note which includes monitoring parameters and appropriate administration		Site of administration should be rotated after removal of previous patch. Patches should be placed on different flat and hairless surfaces, such as the chest, back, flank, or upper arms		Read medication guide prior to use Keep out of reach of children and pets	Define policies and procedures to ensure patients receive patch promptly in non-profiled areas

Original Date Approval: 7/11; Revised: 4/13, 8/14