FENTANYL PATCH PROTOCOL

The contents of this clinical practice guideline are to be used as a guide. Healthcare professionals should use sound clinical judgment and individualize patient care. This CPG is not meant to be a replacement for training, experience, CME or studying the latest literature and drug information.

All fentanyl patch orders must be reviewed by the entering pharmacist for the following criteria. Only patients who meet the following criteria may receive fentanyl patches. There are no exceptions.

Inclusion criteria (initiating fentanyl patch use):

- History of persistent, moderate to severe CHRONIC pain.
- Patient requires CONTINUOUS, AROUND-THE-CLOCK opioid administration for an extended period of time.
- Pain cannot be managed by other means, such as non-steroidal analgesics, opioid combination products, or immediate release products.
- Patient is <u>OPIOID TOLERANT</u>. This means that the patient has been receiving 60 mg morphine, 30 mg oral oxycodone, or 8 mg oral hydromorphone <u>daily</u> or equianalgesic opioid dose for <u>ONE WEEK OR LONGER</u>.

Exclusion Criteria (fentanyl patch use is contraindicated):

- Non-opioid tolerant patients.
- Acute pain management requiring short-term opioids.
- Post-operative pain management including outpatient or day surgeries, mild pain management and intermittent or as needed pain management.
- In patients with significant respiratory depression and patients who have acute or severe bronchial asthma.
- Patients who are under 2 years of age.

There is a risk of serious or life-threatening hypoventilation even in opioid-tolerant patients during initial application period since peak fentanyl levels occur between 24-72 hours of treatment. Fatal overdose with the 1st dose can occur due to overestimation of conversion from another opioid. Monitor and treat patients with serious adverse events including overdose for more than 24 hours since the half life of transdermal fentanyl is 17 hours.

Monitoring:

- Respiratory and cardiovascular status; blood pressure, heart rate.
- Signs of misuse or addiction.
- Monitor for 24 hours after application of first patch.

How to use:

- Apply to clean, dry, unbroken skin. Hairy areas should be trimmed (not shaved).
 Calculate dose of fentanyl patch to be given based daily dosage of previous opioid using the below table.
- Requires 24 hours to reach full therapeutic effect, therefore only use for pain that is stable.

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- Never cut or trim the patch.
- Change patch every 72 hours. Each patch should be applied to a different skin site after removal of the previous transdermal patch. Old patches should be folded in half (so that the adhesive side adheres to itself) and discarded in the pharmaceutical waste receptacle with nurse double check documentation.
- Avoid exposing the patch to direct external heat sources such as heating pads, electric blankets, saunas, and hot tubs. Contact physician if patient develops a high fever due to the potential of temperature-dependent increase in fentanyl release.
- The recommended initial dose of fentanyl is based upon the below chart and is quite conservative. Fifty percent of patients are likely to require a dose increase. The dose of fentanyl may be increased after 3 days based on the daily dose of supplemental opioid analgesics required (see box below). After a dosage is increased, a further dosage increase should not be made sooner than 6 days after the latest increase. In other words patients should wear the higher dose through 2 applications, as it may take this long for the patient to reach equilibrium on the new dose.
- To discontinue fentanyl, remove patch and titrate dose of a new analgesic based on the patient's report of pain. Seventeen hours or more are required for a 50% decrease in serum fentanyl concentrations. Opioid withdrawal symptoms (nausea, vomiting, diarrhea, anxiety, shivering) are possible so a gradual downward titration is advised.

Please use the following guideline to calculate a fentanyl patch dose increase:

Fentanyl dosage increase guideline is based on the daily dose of supplementary oral morphine:

45mg/24 hours oral morphine = 12.5mcg/h increase in fentanyl patch dose.

For patients on opioids other than *oral* morphine, please use the following chart to calculate the equianalgesic daily dose of supplementary *oral* morphine:

Drug	Equianalgesic dose		
	Oral	IV/SQ/IM	
Morphine	60 (30) mg	10 mg	
Hydromorphone	7.5 mg	1.5 mg	
Meperidine	NA	75 mg	
Methadone	20mg	10 mg	
Oxycodone	30 mg	15 mg	
Oxymorphone	10 mg (PR)	1 mg	
Codeine	200 mg	130 mg	

For example, if patient has received 7 mg of IV morphine over 24hrs and currently has a 50mcg/hr patch applied, the 7 mg of IV morphine would equate to 42mg of *oral* morphine. The 42mg additional morphine does not meet the criteria of 45mg within 24hours to increase the fentanyl patch by 12.5mcg/hr. Therefore a change would not be warranted.

^{*} The conversion ratio of 10 mg parenteral morphine = 30 mg oral morphine is based on clinical experience in patients with chronic pain. The conversion of 10 mg parenteral morphine = 60 mg oral morphine is based on a potency study in acute pain. Reference Ashburn and Lipman (1993) Management of pain in the cancer patient. Anesth Analg 76:402-416.

^{**} All IM and po doses in this chart are considered equivalent to 10 mg of IM morphine in analgesic effect. This is based on studies in which an IM dose of each drug listed was compared with morphine to establish relative potency. Oral doses are those recommended when changing from a parenteral to an oral route. Reference: Foley, K.M. (1985) The treatment of cancer pain. NEJM 313(2):84-95

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Please use the following chart to determine whether or not the prescribed fentanyl dose is appropriate for your patient.

Fentanyl Dose Conversion guidelines					
Current analgesic	Daily Dosage (mg/d)				
Oral morphine	60-134	135-224	225-314	315-404	
IM/IV morphine*	10 to 22	23-37	38-52	53-67	
Oral oxycodone	30-67	67.5-112	112.5-157	157.5-202	
IM/IV oxycodone	15-33	33.1-56	56.1-78	78.1-101	
Oral codeine	150-447	448-747	748-1047	1048-1347	
Oral hydromorphone	8 to 17	17.1-28	28.1-39	39.1-51	
IV hydromorphone	1.5-3.4	3.5-5.6	5.7-7.9	8 to 10	
IM meperidine	75-165	166-278	279-390	391-503	
Oral methadone	20-44	45-74	75-104	105-134	
IM methadone	10 to 22	23-37	38-52	53-67	
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Recommended fentanyl/Duragesic dose	25 mcg/h	50 mcg/h	75 mcg/h	100 mcg/h	

^{*} Based on a morphine PO:IV ratio of 6:1

References:

Duragesic (Fentanyl Transdermal System) Full Prescribing information, Janssen Pharmaceutica Products, L.P., 2003 Fentanyl. www.lexi-comp.com (Accessed July 25th 2011)

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