Guidelines on the use of Transdermal (TD) Fentanyl in a primary care setting in cancer and non-cancer pain

Introduction

These guidelines are designed to advise prescribers of the place of fentanyl patches in prescribing and to support their safe use. Strong opioids are well established in the management of cancer pain but evidence demonstrating sustained analgesic efficacy in chronic non-malignant pain in the long term is lacking. Prescribing of fentanyl patches has potential safety and cost implications. See NHS Sheffield Fentanyl Patient Information Leaflet.

Indications

- Sheffield’s first choice strong opioid is oral morphine (for slow release use Zomorph® capsules). Fentanyl patches are an alternative (not necessarily better) method of drug administration.
- There is little evidence that opioids are helpful in long term non-cancer pain – see Faculty Of Pain Medicine Opioids Aware: A resource for patients and healthcare professionals and Prescribing in Chronic Non-Malignant Pain in Adults
- Fentanyl patches should be reserved for patients with stable opioid sensitive pain AND when either:
  - Oral route is unacceptable e.g. dysphagia, poor compliance OR
  - Renal failure (fentanyl is less likely to cause toxicity in renal failure than morphine) OR
  - Oral morphine cannot be tolerated (note: most side effects can be predicted and treated e.g. constipation with laxatives).
- Fentanyl patches are more expensive than oral morphine at equivalent doses.
  ***Fentanyl patches are NOT suitable for unstable pain due to delay in achieving stable blood levels***

MHRA safety issues

- Fentanyl is a potent opioid.
- Because of a risk of significant respiratory depression fentanyl should not be used in patients who are opioid naïve.
- Reports have been received of unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source. Temperature increase e.g. fever, heat pad or hot bath may increase the delivery rate of drug from the patch causing toxicity and shortening duration of action. Fatalities have occurred as a result.
  ***provide clear information to patients and care givers regarding risk of accidental patch transfer and ingestion of patches, and need for appropriate disposal of patches. Children are at particular risk. Do not let children hear you call the patches stickers***

General prescribing points

- The TD route has a SLOW onset and offset of both action and side effects. Do NOT use for acute and / or unstable pain or when a quick dose titration is required.
- For continuity, prescribe by brand.
- Sheffield Formulary choice is the matrix patch Mezolar®
- Fentanyl patches are just as likely to cause side effects such as nausea and vomiting, but may reduce incidence of constipation (generally when converting from oral morphine to fentanyl patches half the laxative and re-titr ate).4
- Opioids should be withdrawn if there is no significant improvement in pain and/or functional ability after a suitable trial e.g. 4 weeks.
- After removal of the patch a reservoir of active drug remains in the skin which can cause difficulties when switching to alternative analgesics.
- See Drugs and driving: the law
  ***Do NOT go above TD Fentanyl 25mcg / hour for Chronic Non-Malignant pain without specialist advice, local advice from Pain Clinic***

Approximate dose conversion table (150:1) for adult patients requiring opioid rotation (for patients on a stable well tolerated opioid regimen manufacturers recommend a conversion of 100:1)

<table>
<thead>
<tr>
<th>Fentanyl TD (3 day patch)</th>
<th>Oral morphine (24 hour dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 mcg / hour</td>
<td>45mg</td>
</tr>
<tr>
<td>25 mcg / hour</td>
<td>90mg</td>
</tr>
<tr>
<td>37.5 mcg / hour</td>
<td>120mg</td>
</tr>
<tr>
<td>50 mcg /hour</td>
<td>150mg</td>
</tr>
<tr>
<td>75 mcg /hour</td>
<td>240mg</td>
</tr>
</tbody>
</table>

Produced by: Medicines Management Team, NHS Sheffield CCG, April 2018 (review date: April 2021)
Determining initial dosage

- Initial dose should be based on the patient’s current opioid use.
- As a ‘rule of thumb’ the total daily dose should not be increased in steps greater than 50% of the previous total daily dose.
- To convert from an oral opioid to fentanyl; the regular opioid needs to be continued for the first 12 hours after the patch is applied. e.g.
  - 4 hourly medication: apply patch and continue with next three doses of regular analgesia, then discontinue
  - 12 hourly medication: apply patch with last dose of slow-release opioid, then discontinue

***Dose conversion charts only provide approximate dose equivalence. Monitor for breakthrough pain and signs of toxicity***

Patch application

- Fentanyl patches are changed every 3 days. Always remove the old patch before applying a new one.
- If there is a decrease in analgesic efficacy between 48 and 72 hours, seek specialist advice.
- Apply patches to dry, cool, non-irritated and hairless skin on a flat surface of the torso or upper arm (apply to upper back on children making it difficult to remove). Do not apply to the same place twice in a row. Any hair should be clipped not shaved and if the area needs to be cleansed prior to applying patch only use water. Inspect patches prior to use. Do not use any cut or damaged patches (a damaged reservoir patch can lead to leaking and overdose).
- Make sure the patch will be covered by loose clothing and not stuck under a tight or elasticated band
- Avoid touching adhesive side of the patch. Press the patch lightly in place with palm of the hand for approximately 30 seconds, making sure the contact is complete, especially around the edges.
- Any additional fixing is off licence. If the patch falls off after following manufacturer’s directions contact Palliative Care or Medicines Management Team for advice.
- After taking a patch off, immediately fold it firmly in half so the sticky side sticks to itself. Place the used patch in the empty fentanyl sachet and dispose as instructed.
- Keep used patches out of sight and reach of children - used patches still contain fentanyl which may harm children and may even be fatal. Do not let children hear you call the patches stickers.
- Always wash hands with clean water.

Breakthrough analgesia

- After the first patch application serum fentanyl concentrations increase gradually, generally levelling off between 12 and 24 hours; therefore pain control may be erratic initially
- Consider prescribing ‘when required oral morphine for breakthrough pain’; calculate 1/6th of the equivalent 24 hour dose of morphine
- Short acting fentanyl preparations are only licensed in cancer pain and should be specialist initiation only. They are not usually recommended for breakthrough pain

***Do not prescribe breakthrough analgesia in non-cancer pain, refer to pain clinic***

Discontinuing fentanyl patches

- After removal of a fentanyl patch a reservoir of fentanyl within the subcutaneous tissue will continue to provide clinically significant levels of fentanyl for several hours after the patch has been removed.
- It may take 20 hours or more for the fentanyl serum concentrations to decrease 50%. In general, the discontinuation of opioid analgesia should be gradual in order to prevent withdrawal symptoms

Converting to oral SR morphine or oxycodone preparations

- If discontinuation of fentanyl patches is necessary, replacement with other opioids should be gradual.
- Sheffield PCF3 advises: Remove the patch
  - Calculate equivalent 24 hour opioid dose, give half this dose in first 24 hours increasing to full equivalent oral opioid dose after 24 hours
  - Administer as ‘TWICE DAILY’ SR preparation with access to breakthrough analgesia PRN (1/6th of full equivalent 24 hour dose)

***If fentanyl is changed to another opioid monitor patient for signs of breakthrough pain and opioid toxicity for 24-48 hours***

See Sheffield Palliative Care Formulary, 4th Edition

References:
1. MHRA Drug Safety Update 2008 2/2 Fentanyl patches: serious and fatal overdose from dosing errors, accidental exposure, and inappropriate use
2. Drug Safety Update. Transdermal fentanyl patches: reminder of potential for life threatening harm from accidental exposure, particularly in children. 2.7.2014
3. Sheffield Palliative Care Formulary. 4th Edition
4. PCF online www.palliativedrugs.com accessed Jan 2018

See also: Care Quality Commission. Safer Controlled Drug Use – Preventing harms From Fentanyl and Buprenorphine Transdermal Patches. NHSE.

For individual Drug Data Sheet see: https://www.medicines.org.uk/emc

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