Supporting information

Safer Controlled Drug Use - Preventing Harms From Fentanyl and Buprenorphine Transdermal Patches

Patient safety incident reports with Controlled Drug (CD) transdermal patches
Large numbers of patient safety incidents involving fentanyl and buprenorphine transdermal patches have been reported to the National Reporting and Learning System (NRLS).

There were a total of 5,139 patient safety incidents reported between the July 2009 and July 2012. Of these, 734 incidents reported actual harm.

Incident report examples

Overdose, wrong strength
Patient brought into Accident and Emergency after being found collapsed in nursing home with Glasgow Coma Scale 3 (Suspected CVA). Also attended [place] 3-4 weeks ago with respiratory arrest. Responded instantly to naloxone. Obviously no CVA symptoms. Contacted nursing home and discovered patient being treated with Fentanyl patches (75 micrograms). Patient very elderly and lower than average body weight due to bilateral above knee amputation. Medication too strong for patient. Patient later stated that she often felt unwell when patches applied and nursing home confirmed periods of drowsiness. (Severe Harm).

Overdose, use of multiple patches
Several fentanyl patches were found on a patient, when only one at a time should have been applied. Overdose inducing decreased level of consciousness. This required ICU admission for naloxone infusion and monitoring for 12 hours. (Severe)

Overdose, use of multiple opiates
Transdermal fentanyl patch applied to patient for acute pain at 2145 hrs. Continued to receive oral morphine at 1800 hrs observations recorded respiratory rate 5 per minute. Doctor called; naloxone prescribed and given at 1830 hrs (100 microgram) respiratory rate increased to 24 per minute. Continued to have respiratory rate between 4-8 until 0800 hrs [date + 1 day]. Required further 5 doses naloxone. (Severe Harm)

Overdose, opiate naïve patient
Patient previously opiate - naive prescribed a fentanyl patch for back pain whilst on CCU. 18 hours later after transfer unconscious and low respiratory secondary to opiate toxicity. Three days of ventilation was required for clearance of the medication. She did initially receive naloxone but with no improvement. (Severe Harm).

Overdose, dose conversion error

Patient's palliative care commenced with fentanyl patch [date]. Continuing gradual deterioration [date + 3 days] so fentanyl converted to s/c diamorphine [GP1] via syringe driver. District nurses visited that afternoon to set it up. [date + 4 days] GP2 called late afternoon - patient passed peacefully away. Death certificate left for GP2 to complete [date + 5 days]. Copy of notes and death certificate faxed to medical examiner's office. GP2 then received call asking why opiate dose increased so much from patch to s/c driver. Rang GP1 at home who realised they had made a mistake in using the BNF conversion tables (given approximately 3 times previous patch dose). (Death)

Underdose

Patient has a long history of pain in the back radiating down her left leg to the knee and also pain in the neck radiating down left arm into her hand and fingers . She has had recent fall and was admitted to hospital with rib fracture and some bruising and pain in her chest and ribs . Prior to her fall and admission , patient was using a Fentanyl 25 microgram / hour patch , and taking codeine 60mg qds with Oramorph 10mg prn for her chronic pain . Patient was initially admitted to Ward. The fentanyl patch was reduced to 12micrograms / hour and codeine phosphate discontinued.. There is no documented rationale for this reduction. She was subsequently referred to the Chronic Pain Team due to increasing pain , and the fact that her Oramorph requirements had increased. (Moderate Harm)

Omitted and delayed dose(s)

Second agency Bank Nurse did not administer regular controlled drug to the patient. The drug was prescribed on the drug chart correctly by Doctor. As a result, the patient was in a lot of pain and distressed for couple of days because the staff were unaware that she did not have it. (Moderate Harm)

Omitted doses – withdrawal symptoms

Administration of Butrans [buprenorphine] patch had been overlooked by care home staff 5 days earlier and patient had become distressed and agitated. Diazepam had been prescribed to relieve the agitation after which the omission of the medication was discovered and patient suspected to be displaying symptoms of withdrawal. (Moderate Harm)

International recognition of risks with 'CD' patches

The International Medication Safety Network undertook an analysis of fentanyl patch incidents reported in Canada, Ireland, UK and USA in 2009.[4]

The Analysis identified four major themes:

- too much medication or administered too soon
- too little medication or administered too late

- patient didn't need or should not have received the medication
- other

Six potential areas for improvement:

- health care practitioners' lack of awareness of critical information regarding transdermal fentanyl
- patient education
- complexity of transdermal fentanyl administration
- communication of patch information
- product design
- use of transdermal fentanyl not identified or recognized through interfaces of care

A summary of research and NHS communications describing these risks and recommended safer practice is included below.

References

1. National Patient Safety Agency. NPSA terms and definitions for grading patient safety incidents. Seven Steps to Patient Safety. 2004:100. http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=59971&type=full&servicetype=Attachment (accessed 17/1/2013)
2. National Patient Safety Agency. Reducing harm from omitted and delayed medicines in hospital 2010(Feb) http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66720 (accessed 17/1/2013)
3. National Patient Safety Agency. Reducing dosing error with opioid medicines. 2008 (July) http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888
4. International Network Safe Medication Practice Centres. Medication incidents related to the use of fentanyl transdermal systems: An international aggregate analysis 2009;(Oct) http://www.intmedsafe.net/ArticleFiles/FentanylPatchesReport.pdf (accessed 6/2/2013)

Key resources

- British National Formulary 65ed 2013(Mar-Sept). Prescribing in palliative care, Opioid analgesics section 4.7.2: 21,268,273www.bnf.org. Note page 21, table 24 hour oral morphine to 72 hour fentanyl patches
- East & South East England Specialist Pharmacy Service. Implementing NPSA requirements and NICE Guidance: Opioids. 2013 http://www.nelm.nhs.uk/en/Communities/NeLM/SPS-E-and-SE-England/Meds-use-and-safety/Patient-safety/Learning-safety-solutions/Opioids/Implementing-NPSA-Requirements-and-NICE-Guidance-Opioids-Vs3/ (accessed 31/1/2013)
- Twycross R. Wilcock A (eds). Palliative Care Formulary 4th ed. 2012 (Sept) http://www.palliativedrugs.com/press-news/january/pdf-version-of-pcf4-now-available.html(accessed 17/1/2013)
- The patient safety first www site is open to all NHS healthcare practitioners. Resources will be posted there as they become available. The site includes a dedicated forum for discussion http://www.patientsafetyfirst.nhs.uk (accessed 17/1/2013)

- British National Formulary 64ed 2012(Sept). Prescribing in palliative care, Opioid analgesics section 4.7.2: 21,268,273www.bnf.org
- The Medicines and Healthcare products Regulatory Agency (MHRA). Fentanyl patches: serious and fatal overdose from dosing errors, accidental exposure, and inappropriate use. Drug Safety Update 2008;2(2):2-3. http://www.mhra.gov.uk/home/groups/pl-p/documents/publication/con025632.pdf (accessed 6/2/2013)

Practice guidance from NHS organisations on the safe use of CD transdermal patches

- NHS Sheffield. Guidelines on the use of opioid transdermal patches in a primary care setting. 2011;(April). http://www.sheffield.nhs.uk/professionals/resources/formulary/transdermalpatchesguidelines.pdf (accessed 6/2/2013)
- MTRAC (Midlands Therapeutics Review and Advisory Committee). Fentanyl transdermal patches for chronic intractable non-cancer pain 2012 http://www.keele.ac.uk/media/keeleuniversity/fachealth/fachealthsop/mtrac/documents/summary/Fentanyl%20TD%20SUM%206.pdf (accessed 6/2/2013)
- NHS Buckinghamshire and Oxfordshire Cluster. Good Practice Guidance 5: Use of fentanyl patches in Care Homes 2011;(May) http://www.oxfordshirepct.nhs.uk/professional-resources/care-homes/documents/GoodPracticeGuidance5-UseoffentanylpatchesinCareHomes_002.pdf
- Northern and Yorkshire Regional Drug and Therapeutics Centre. Safer Medication Use. (no 8). Using strong opioids safely. 2010 http://www.nyrdtc.nhs.uk/docs/smu/RDTC_SMU_08_Strong_Opioids.pdf (accessed 6/2/2013).
- NHS Leeds. Patches. http://www.leeds.nhs.uk/About-us/Information%20for%20Professionals/Medicines%20Management/patches.htm (accessed 6/2/2013)
- NHS Plymouth. Opioid-analgesics. http://www.plymouthformulary.nhs.uk/472-Opioid-analgesics/ (accessed 6/2/2013)
- NHS Cornwall & Isles of Scilly. Formulary advice. Fentanyl patches. (URL to follow)

Articles

- Grissinger M. Inappropriate prescribing of fentanyl patches is still causing alarming safety problems. Medication Errors 2010:35(12):653-4
- Butts M, Jatoi A. A systematic compilation of reports published on opioid-related problems. J Opioid Manage 2011;7(1):35-45.