

Safeguarding Users of Opioid Patches by Standardising Patient/Caregiver Counselling

September 2016

(August 2018 - Minor update to include information on co-sleeping)

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Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group



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BACKGROUND

The aim of the counselling checklist is to assist healthcare professionals, working in community pharmacies, primary care and secondary care, in the essential counselling of patients on the safe and effective use of opioid patches. The inclusion of a checklist for patients/carers to refer to following counselling will also encourage the safe use of opioid patches.

Fentanyl patches are strong opioid analgesics indicated for chronic intractable pain. Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that transdermal fentanyl patches are contraindicated in opioid naive patients in the UK¹. Buprenorphine patches are strong opioids indicated for moderate to severe chronic cancer pain and moderate to severe pain unresponsive to non-opioid analgesics². Fentanyl is a Schedule 2 Controlled Drug and buprenorphine is a Schedule 3 Controlled Drug³.

In 2008, the National Patient Safety Agency published a Rapid Response Report, alerting all healthcare professionals to the risks of patients receiving unsafe doses of opioid medicines⁴. In 2014, the Medicines and Healthcare products Regulatory Agency (MHRA) highlighted the risk of inadvertent exposure to fentanyl patches⁵, emphasising the need for providing information to patients and caregivers regarding the safe handling of patches. The MHRA had also previously issued a drug safety update in September 2008, detailing serious and fatal overdose from dosing errors, accidental exposure and inappropriate use⁶. In December 2015, Welsh Government issued a [Patient Safety Notice regarding the risk of harm from the inappropriate use and disposal of fentanyl patches](#)⁷. In September 2020, the MHRA published two drug safety updates: 'Fentanyl patches for non-cancer pain: do not use in opioid-naive patients' and 'Opioids: risk of dependence and addiction'^{1,8}.

It is important that patients who are prescribed opioid patches are appropriately counselled on the safe use, storage and disposal of their medicine, so as to reduce the risk of overdose from dosing errors, accidental exposure and inappropriate use⁹. Patients should also be counselled on the risk of dependence and addiction with long-term use and on the signs and symptoms of opioid overdose¹.

On the advice of the CHM, the patient information leaflet (PIL) for fentanyl patches has been updated with harmonised headline information regarding their safe use (Available here: <https://www.medicines.org.uk/emc/product/2072/pil>). The MHRA recommend directing both new and current users of fentanyl patches to the updated PIL¹. The MHRA also highlight the importance of reporting suspected adverse drug reactions, including dependence, accidental exposure, or overdose via the Yellow Card scheme¹.

If appropriate, it is beneficial for a patient's carer to be involved in any counselling, especially as symptoms experienced in the event of overdose may prevent a patient from seeking help. In community pharmacies, ascertain who is collecting the medication and make a record of it. Patients and carers should be told to keep the manufacturer's PIL for reference^{1,10}. It is important that information regarding safe use and side effects is reiterated when patients collect their prescriptions, even for those using opioid patches long-term. Consider documenting that the checklist has been discussed with the patient/carers (e.g. by using a Read Code). The Patient Medication Record (PMR) or a Medicines Use Review (MUR) form can also be used to document counselling given.

Information on the initiation of treatment with transdermal opioids can be found in various resources, including the Summary of Product Characteristics (SPC), British National Formulary (BNF), and Monthly Index of Medical Specialities (MIMS). Opioids should be withdrawn gradually unless there are signs and symptoms of opioid toxicity^{1,2,6}.

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Opioid patches may affect the patient's ability to drive and operate machinery; patients should not drive until they know how the medicine affects them. For further advice, see [Department for Transport guidance for healthcare professionals on drug driving](#).

Various medicines can interact with opioids and potentiate the associated risks of their use (consult the BNF or SPC for full details)²; a careful drug history in a patient unfamiliar to you is therefore essential, even if it means contacting the prescriber. This is particularly important for patients new to opioid patches. It is good practice to record any over the counter (OTC) items supplied to the patient and check these for interactions with opioid patches. It is important to establish whether there are any concurrent co-morbidities, and opioid patches should be used with extra caution in special populations (consult the BNF or SPC for full details).

If you have any concerns/suspicious regarding a particular patient and patch abuse potential, please contact the prescriber or your local substance misuse specialist team.

OPIOID PATCH SAFETY: COUNSELLING CHECKLIST *

- If the patient is calling back, please attach a counselling required note.
- Appropriate health professional to issue prescriptions (e.g. assistant technical officers or students are **not** to issue these prescriptions without supervision).

Patient details

For completion by the clinical checker

		Yes	No	Comment
A	Has the patient received this treatment before? <i>Check that not opioid naïve.</i>			
B	Has the dose changed?			
C	Is the brand of opioid patch the same as previously used?			
D	Double-check for drug interactions when new items are prescribed			
E	Has the patient been given information on breakthrough pain relief?			
F	Presence of PIL within the packaging			

Counselling checklist: For completion by the counsellor

Check the patient knows:		Yes	No	Already aware
a	How many patches to apply and how often			
b	To choose the patch application site carefully and to not apply to the same site twice in a row (see PIL)			
c	To not apply the patch to broken, irritated or irradiated skin. Ensure skin is non-hairy and dry before application. If necessary, cut hair with scissors; do not shave the area before applying a patch			
d	Never to cut the patch			
e	The process for applying the patch (refer to PIL): <ul style="list-style-type: none"> • Remove old patch and carefully fold it over so sticky sides are stuck together. Put back in its original pouch and safely dispose of it out of sight/reach/discovery of children/animals • Apply new patch (avoid touching sticky sides) • Press patch firmly in place for 30–60 seconds and wash hands afterwards 			
f	That it may be helpful to use a calendar to record day of application			
g	That the patch may not start or stop working straight away			
h	If the patch falls off, start another patch. Do not re-use patch. If the edge of the patch starts to peel, use suitable tape (e.g. white surgical tape, transparent adhesive film dressing) to secure the patch			
i	To keep patches out of sight/reach/discovery of children and animals and to seek immediate medical attention if patch is swallowed, or it is applied to the skin of anyone other than the patient. Patches are not plasters! Incidents have involved children mimicking what they have seen others do. <i>Deaths</i> have occurred where children have removed patches from co-sleeping adults. Wearing an item of clothing over the patch when sharing a bed with children or a partner is recommended. <i>Deaths</i> have also occurred where children have swallowed discarded/'fallen-off' patches			
j	The effect of heat on patch. Avoid exposure of patches to heat including via hot water (e.g. hot baths, hot showers, hot water bottles, heat pads or heat blankets). Avoid hot tubs and saunas. Keep the patch area out of excessive sun. Store patches away from heat sources. Seek urgent medical advice if feverish. <i>The body can absorb too much medicine if patch is exposed to excessive heat</i>			
k	Signs and symptoms of too much medicine and what to do. Seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected. For example, if trouble breathing, or shallow/very slow breathing; extreme sleepiness or sedation; inability to think/walk/talk normally; feeling faint, confused or more dizzy than usual			
l	That opioid patches may cause drowsiness and affect ability to drive/operate machinery. Do not drive/operate machinery if affected. Alcohol may potentiate these effects			
m	That long-term use of opioids in non-cancer pain (>3 months) carries an increased risk of dependence and addiction, even at therapeutic doses.			
n	To use a regular community pharmacy and seek their advice when buying OTC/herbal products (e.g. <i>antifungals for thrush, antihistamines</i>)			
o	To bring medicines/current medicines list to clinic/hospital/attend out-of-hours services/dentist/A&E/for scans, X-rays or any hospital procedures. <i>Medicine-containing patches cannot be worn during an MRI scan</i>			
Discussed with:		Counselled by:		Date:
		Information to patient/carer <input type="checkbox"/>		
		Documented (e.g. on PMR/MUR) <input type="checkbox"/>		

* These resources have been updated to capture the MHRA drug safety updates published in September 2020: 'Fentanyl patches for non-cancer pain: do not use in opioid-naïve patients' and 'Opioids: risk of dependence and addiction'.

Safeguarding Users of Opioid Patches by Standardising Patient/Caregiver Counselling

The *Opioid Patch Information to Keep Patients Safe*, on the following page (in English and Welsh), should be given to patients to serve as a reminder of the safety issues discussed with the healthcare professional regarding the use and storage of their opioid patch. It should therefore be given to the patient after the healthcare professional has completed the *Opioid Patch Safety: Counselling Checklist* (see previous page).

OPIOID PATCH INFORMATION TO KEEP PATIENTS SAFE

You may find this information helpful if you are a patient who uses opioid patches (e.g. fentanyl patches/buprenorphine patches), or you care for someone who uses opioid patches. You should read the patient information leaflet in the packaging along with this information. Use the patch exactly as directed by your doctor, nurse or pharmacist.

This patch is designed to provide you with better overall background pain relief. If you still experience pain throughout the day, you can take fast-acting painkillers exactly as advised by your doctor, nurse or pharmacist. Contact your doctor, nurse or pharmacist if you have any queries or would like more information.



What do I need to know about opioid patches?

Using and disposing of your opioid patch safely

- Make sure you know how many patches to apply and how often you should apply them.
- Make sure you know the correct place on your body to apply the patch. When you change to your next patch, you should take the old one off and then apply the new patch to a different area of skin on your body.
- Where possible, you should use the same make of patch each time. If you notice that your patch looks different from those that you are used to using, ask your pharmacist for advice.
- **Do not apply patch to broken or irritated skin.** Do not use the patch on skin that has undergone radiation therapy. Use the patch on non-hairy and dry skin. Cut any hair in the area with scissors. Do not shave the area before applying a patch as this may irritate the skin.
- **Never cut the patch.**
- Make sure you **follow the correct process for applying the patch:**
 - **Remove the old patch** and **carefully fold it over** so the sticky sides are stuck together. Put it back in its original pouch.
 - **Make sure you safely dispose of patches out of the reach/discovery of children/animals.** This may be in a bin with household rubbish.
 - Apply new patch (avoid touching sticky sides).
 - Press the patch firmly in place for 30–60 seconds.
 - Wash hands afterwards.
- It may be helpful to use a calendar to record the day you put the patch on.
- The patch may not start or stop working straight away. You may need to take additional fast-acting painkillers when starting the patch, as advised by your doctor, nurse or pharmacist.
- If the patch falls off, start another patch. Do not re-use patch. If the edge of the patch starts to peel, use suitable skin-friendly tape (e.g. white surgical tape) to secure the patch.



Keeping yourself and others safe

- **Keep out of sight/reach/discovery of children and animals. Seek immediate medical attention if patch is swallowed, or it is applied to the skin of anyone other than yourself.** Patches are not plasters! Incidents have involved children mimicking what they have seen others do. **Deaths** have occurred where children have removed patches from co-sleeping adults. Wearing an item of clothing over the patch when sharing a bed with children or a partner is recommended. **Deaths** have also occurred where children have swallowed discarded/'fallen-off' patches. 
- **Seek medical attention straight away if the patch is swallowed** by yourself or others. If the patch sticks to the skin of anyone other than you, remove it and seek medical attention straight away.
- **Avoid placing heat sources against/near the patch**, e.g. hot water bottles, heat pads or heat blankets. Avoid hot tubs and saunas. Caution with long hot baths. Keep the patch area out of excessive sun. Store patches away from heat sources. **The body can absorb too much medicine if the patch gets too hot.** 

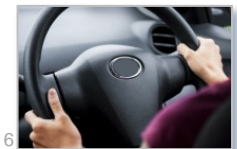
Signs and symptoms of too much medicine and what to do

- **Seek medical attention immediately if:**
 - feverish;
 - trouble breathing, or shallow/very slow breathing;
 - extreme sleepiness or sedation;
 - inability to think/walk/talk normally;
 - feeling faint, confused or more dizzy than usual.



Increased sleepiness and driving or operating machinery

- Opioid patches may make you **sleepy** and **affect your ability to drive/operate machinery.**
- **Do not drive/operate machinery if affected.**
- Drinking alcohol whilst using opioid patches can also make you more sleepy.



Taking other medicines and using medical services

- Use a regular community pharmacy and seek their advice when buying over the counter medicines/herbal products.
- Bring your medicines or a list of your current medicines with you if you come to clinic/hospital/attend out-of-hours services/dentist/A&E/for scans, X-rays or any hospital procedures. Opioid patches cannot be worn during an MRI scan.

Further information

- Fentanyl information leaflet for patients and caregivers (Medicines and Healthcare products Regulatory Agency), available at: <https://assets.publishing.service.gov.uk/media/54730808e5274a1301000046/con437440.pdf>
- Fentanyl patch patient information leaflet, and Opioids and driving patient information leaflet (Velindre Cancer Centre), available at: www.velindrecc.wales.nhs.uk/palliative-care-1
- Drugs and driving: the law (Department for Transport), available at: www.gov.uk/drug-driving-law
- Opioids in Palliative Care – Patient Information Manual (AWMSG), available at: <https://awmsg.nhs.wales/medicines-appraisals-and-guidance/medicines-optimisation/patient-information-leaflets/>

GWYBODAETH AM GLYTIAU OPIOID ER MWYN CADW CLEIFION YN DDIOGEL

Efallai y bydd y wybodaeth hon yn ddefnyddiol i chi os ydych yn glaf sy'n defnyddio clytiaau opioid (e.e. clytiaau fentanyl/clytiaau buprenorphine), neu eich bod yn gofalu am rywun sy'n defnyddio clytiaau opioid. Dylech ddarllen y daflen gwybodaeth i gleifion sydd yn y pecyn ynghyd â'r wybodaeth hon. Defnyddiwch y clwtyn yn union fel y cyfarwyddwyd gan eich meddyg, nyrs neu fferyllydd.

Bwrriedir i'r clwtyn roi gwell lleddfiad poen cefndir cyffredinol i chi. Os ydych chi'n dal i gael poen drwy gydol y dydd, gallwch gymryd cyffur lladd poen sy'n gweithio'n gyflym yn union fel y cynghorwyd gan eich meddyg, nyrs neu fferyllydd. Cysylltwch â'ch meddyg, nyrs neu fferyllydd os oes gennych unrhyw gwestiynau neu os hoffech gael rhagor o wybodaeth.


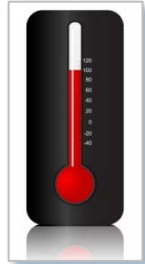
Beth sydd angen i mi wybod am glytiaau opioid?

Defnyddio a gwaredu eich clwtyn opioid yn ddiogel


- Gwnewch yn siŵr eich bod yn gwybod sawl clwtyn i'w ddefnyddio a pha mor aml y dylech eu defnyddio.
- Gwnewch yn siŵr eich bod yn gwybod lle yn union ar eich corff i osod y clwtyn. Pan fyddwch yn newid i'ch clwtyn nesaf, dylech dynnu'r hen un i ffwrdd ac yna rhoi clwtyn newydd ar ran gwahanol o groen ar eich corff.
- Pan fo hynny'n bosibl, dylech ddefnyddio clwtyn o'r un gwneuthuriad bob tro. Os ydych chi'n sylwi bod eich clwtyn yn edrych yn wahanol i'r rheini yr ydych yn arfer eu defnyddio, gofynnwch i'ch fferyllydd am gyngor.
- **Peidiwch â rhoi clwtyn ar groen sydd wedi torri neu sy'n llidus.** Peidiwch â defnyddio clwtyn ar groen sydd wedi derbyn therapi ymbelydredd. Defnyddiwch y clwtyn ar groen heb flew a sych. Torrwch unrhyw flew yn yr ardal gyda siswrn. Peidiwch ag eillio'r ardal cyn gosod clwtyn gan y gallai hyn lidio'r croen.
- **Peidiwch byth â thorri'r clwtyn.**
- Gwnewch yn siŵr eich bod yn **dilyn y broses gywir ar gyfer gosod y clwtyn:**
 - **Tynnwch yr hen glwtyn a phlygwch ef yn ei hanner** fel bod yr ochrau gludiog yn sownd i'w gilydd. Rhowch ef yn ôl yn y cwdyn gwreiddiol.
 - **Gwnewch yn siŵr eich bod yn gwaredu clytiaau allan o gyrraedd/darganfyddiad plant/anifeiliaid.** Gallai hyn fod mewn bin gyda sbwriel y cartref.
 - Gosodwch glwtyn newydd (osgowch gyffwrdd â'r ochrau gludiog).
 - Gwasgwch y clwtyn yn gadarn yn ei le am 30-60 eiliad.
 - Yna golchwch eich dwylo.
- Efallai y byddai'n ddefnyddiol i ddefnyddio calendr er mwyn cofnodi'r diwrnod y gwnaethoch osod y clwtyn.
- Efallai na fydd y clwtyn yn dechrau neu'n stopio gweithio ar unwaith. Efallai y bydd angen i chi gymryd cyffur lladd poen sy'n gweithio'n gyflym yn ychwanegol pan fyddwch yn dechrau ar y clwtyn, fel y cynghorir gan eich meddyg, nyrs neu fferyllydd.
- Os bydd y clwtyn yn syrthio i ffwrdd, dechreuwch un arall. Peidiwch ag ail-ddefnyddio clwtyn. Os yw ymyl clwtyn yn dechrau plicio, defnyddiwch dâp sy'n addas ar gyfer y croen (e.e. tâp llawfeddygol gwyn) i osod y clwtyn yn sownd.




Cadw eich hun ac eraill yn ddiogel

- **Cadwch glytiau allan o olwg/cyrraedd/darganfyddiad plant ac anifeiliaid. Ceisiwch sylw meddygol ar unwaith os llyncir clwtyn, neu os rhoddir ar groen unrhyw un heblaw chi.** Nid plasteri yw clytiau! Cafwyd digwyddiadau lle gwelwyd plant yn dynwared yr hyn y maent wedi gweld eraill yn ei wneud. Bu **marwolaethau** pan fo plant wedi tynnu clytiau oddi ar oedolyn sy'n cysgu gyda nhw. Argymhellir gwisgo dilledyn dros y clwtyn pan fyddwch yn rhannu gwely gyda phlant neu bartner. Bu **marwolaethau** hefyd pan fod plant wedi llyncu clytiau sydd wedi'u taflu neudisgyn i ffwrdd o'r croen. 
- **Ceisiwch gyngor meddygol ar unwaith os caiff y clwtyn ei lyncu** gennych chi neu unrhyw un arall. Os bydd y clwtyn yn glynu ar gorff unrhyw un heblaw chi, tynnwch y clwtyn i ffwrdd a cheisiwch gyngor meddygol ar unwaith.
- **Osgowch roi ffynonellau gwres yn erbyn/yn agos i'r clwtyn**, e.e. poteli dŵr poeth, padiau gwres neu flancedi gwres. Osgowch dybiau poeth a sawnau. Byddwch yn ofalus os cewch fath poeth hir. Cadwch ardal y clwtyn allan o haul eithafol. Storiwch glytiau oddi wrth ffynonellau gwres. **Gall y corff amsugno gormod o feddyginiaeth os yw'r clwtyn yn mynd yn rhy boeth.** 

Arwyddion a symptomau gormod o feddyginiaeth a beth i'w wneud

- **Ceisiwch sylw meddygol ar unwaith os ceir profiad o unrhyw rai o'r canlynol:**
 - twymyn;
 - anhawster anadlu, neu anadlu bas/araf iawn;
 - cysgadrwydd neu lonyddiad eithafol;
 - methu â meddwl/cerdded/siarad yn arferol;
 - teimlo'n wanlyd, dryslyd neu'n fwy penysgafn nag arfer.

Cysgadrwydd cynyddol a gyrru neu weithio peiriannau

- Gall clytiau opioid eich gwneud yn **gysglyd** ac **effeithio** ar eich gallu i yrru/gweithio peiriannau.
- **Peidiwch â gyrru/gweithio peiriannau os effeithir arnoch.**
- Gall yfed alcohol pan fyddwch yn gwisgo clytiau opioid hefyd eich gwneud yn fwy cysglyd. 

Cymryd meddyginiaethau eraill a defnyddio gwasanaethau meddygol

- Defnyddiwch fferyllfa gymunedol reolaidd a cheisiwch eu cyngor wrth brynu meddyginiaethau/cynnyrch llysieuol dros y cownter.
- Dewch â'ch meddyginiaethau neu restr o'ch meddyginiaethau presennol gyda chi os ydych yn dod i'r clinig/ysbyty/mynychu gwasanaethau tu allan i oriau/deintydd/damweiniau ac achosion brys/ar gyfer sganiau, pelydr-X neu unrhyw weithdrefnau ysbyty. **Ni ellir gwisgo clytiau opioid yn ystod sgan MRI.**

Gwybodaeth bellach

- Taflen wybodaeth fentanyl ar gyfer cleifion a rhodddwyr gofal (Asiantaeth Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd), ar gael yn: <https://assets.publishing.service.gov.uk/media/54730808e5274a1301000046/con437440.pdf>
- Taflen gwybodaeth i gleifion clwtyn fentanyl, a thaflen gwybodaeth i gleifion opioidau a gyrru (Canolfan Cancer Felindre), ar gael yn: www.velindrecc.wales.nhs.uk/palliative-care-1
- Cyffuriau a gyrru: y gyfraith (Yr Adran Drafnidiaeth), ar gael yn: www.gov.uk/drug-driving-law
- Opioidau mewn Gofal Lliniarol – Llawlyfr Gwybodaeth i Gleifion (AWMSG), ar gael yn: <https://awmsg.nhs.wales/medicines-appraisals-and-guidance/medicines-optimisation/patient-information-leaflets/>

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