CONTROLLED DRUGS NEWSLETTER

SHARING GOOD PRACTICE IN DEVON, CORNWALL AND THE ISLES OF SCILLY

Volume 2 / Issue 2

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SIGNIFICANT EVENTS AND THEIR AFTERMATH

In an average quarter about 150 incidents of varying degrees of concern are reported to the AO team. We customarily ask those reporting incidents what steps have been taken to prevent a recurrence, and it is not uncommon to receive responses telling us that the necessary staff have been reminded of proper procedures or have undergone some retraining.

It is therefore disquieting when the same providers make the same mistake repeatedly. Lately we have had a number of cases of substantially similar errors; for example, a repeated failure to apply fentanyl patches on the due date or failure to record personal administration of controlled drugs from practice stock.

An important part of any learning process is to check that the measures taken have been effective. We expect that remedial actions taken as a result of significant events will be audited to verify that the action has made a difference. **If a provider subsequently repeats the incident we give notice now that we will not accept the same assurances.** This implies that any response may need an implementation or action plan, whose complexity will depend on the scope of the service. A single-site GP practice may be able to implement change via a practice meeting, whereas a multi-site provider may need to outline a more extensive communications plan.

We have no wish to increase bureaucracy, but it is clear that, at present, the assurances we receive from some providers cannot be relied upon. A more structured approach to verifying improvement should help to provide those assurances.

TRAMADOL

Tramadol is now a schedule 3 controlled drug. This means that it cannot be prescribed electronically (at present) or via repeat dispensing schemes, nor can emergency supplies be made by pharmacies. It is exempt from safe storage requirements.

PRACTITIONER SELF-ASSESSMENTS

Before a person is issued with Controlled Drugs requisition forms (CDFs) or Private Controlled Drugs prescription forms (PCDs) we customarily require satisfactory completion of a self-assessment. The Area Team has been in place for over a year now and we are beginning to come to the point at which those self-assessments may need revisiting.

However, a system in which self-assessment is triggered by the need for more stationery is not sufficiently systematic. In our view, review of the self-assessment would be better conducted as a scheduled part of a practice's annual programme of clinical governance. We would expect practices to be able to forward their most recent review on request, and for that review to be reasonably current – which we interpret as meaning that each practitioner using controlled drugs has reviewed their self-assessment within the past 18 months.

Our self-assessment form is available on request.

CONTROLLED DRUGS IN SYRINGE DRIVERS

Despite raising this subject many times we continue to experience problems leading to serious patient inconvenience and potential harm. **Every prescription for schedule 2 or 3 controlled drugs must bear a dose including a quantity. It cannot refer to another document for dosage details.**

Thus "as directed" or "as per syringe driver chart" are not legal doses and those prescriptions cannot be dispensed. This is not a technical error that can be corrected by a telephone call to the pharmacy. Those prescriptions must be replaced, which means that there is inevitable delay to treatment, particularly out of hours.

"One as directed" is a legitimate dose, though poor practice since it does not allow the dispenser to verify the safety of the amount prescribed. The dose cannot be implied either; we have had prescribers saying that "Diamorphine 10mg ampoules x 10, use every four hours" implies that the dose is 10mg, or they would have prescribed other strengths. However, the strength and the dose are not necessarily linked and there is nothing there to tell the patient or carer how many ampoules to use.

DISPOSAL OF CONTAINERS

There is no specified method of dealing with the disposal of part doses such as the unused part of an ampoule or the contents of a syringe driver at the end of treatment. In one sense this is understandable, because it is difficult to frame one rule that could apply in all circumstances. For example, if we said that a part used vial must always be destroyed, that would prevent the use of multidose vials.

There have been extensive discussions with the Environment Agency and others over the years, but it is clear that the advice given is not always consistent and it is usually specific to the circumstances of an enquiry and therefore cannot be shared elsewhere. We are returning to the issue on a national basis to see if we can get some clarity for providers from discussions between EA, CQC and NHS England. However, it is likely that those discussions will not produce firm rules, but are more likely to define principles which providers will have to reflect in their own Standard Operating Procedures.

For example, nobody suggests that pharmacies should throw out conical glass measures that have been used to measure methadone after each use, which means that they will have to be rinsed, and the rinsings will necessarily enter the water system. However, the amounts involved from such a cylinder are minute and if they are well diluted public risk should be minimal. By analogy, the rinsing of bottles that have held methadone should be permissible and those bottles could then be disposed of by recycling in the usual way. We are aware of providers who have been regarding every rinsed bottle as clinical waste, which substantially increases the volumes of those collections. This is precisely the kind of issue we are trying to clarify nationally.

Obviously where the container holds more than residual trace amounts of controlled drug the contents would have to be denatured before disposal in the usual way.

Another question we are sometimes asked is how the denaturing or disposal of a syringe driver's contents can be recorded given that the exact amount remaining cannot easily be determined. Our answer is that the syringe driver chart should record what happened to the remainder, albeit as an unspecified amount such as "Remaining contents of syringe driver denatured by nurse A and nurse B".

RISK ASSESSMENTS OF SAFE STORAGE

Readers may recall that in newsletter 5 we made reference to a Safeguarding report issued in Derbyshire following consumption by a child of methadone prescribed for their parent. We have had a similar incident in our area following an adult consuming methadone intended for another person, and the Office of the Chief Coroner has another incident involving a client having used methadone prescribed to cover a holiday period in a binge.

While these incidents happen to relate to methadone, the coroners have not restricted themselves to that drug but have invited us to emphasise to prescribers the need to assess the risk to service users and others of allowing them to have quantities of controlled drugs in the home. This assessment could potentially include the need for supervised consumption, a structured briefing for service users on safe use of their medication, and consideration of managing holiday prescriptions (for example, where a client is on Monday/Wednesday/Friday pickup over Easter, moving the pickup days to Thursday/Saturday/Tuesday may be safer than giving a week's supply on the Wednesday). Let us be clear that there is no suggestion that Sunday take-home doses present any special hazard.

We hope shortly to have advice for patients on safe storage of medicines, asking them to Find a Safe Place and reminding them to consider visitors as well as residents. For example, elderly patients may not have children in their houses but may have visiting grandchildren.

SAFER PRESCRIBING OF FENTANYL

A coroner in London has published a Report to Prevent Future Deaths which has application outside her own area.

Mrs R had been bedbound for several years and her health was deteriorating. She developed a bedsore for which she was prescribed morphine sulfate oral solution 5mg twice daily. Nine days before her death another GP switched her to fentanyl, prescribing 100mcg/hour patches in error as a result of misunderstanding the conversion factor for morphine to fentanyl. Patches were applied twice before the mistake was realised, but Mrs R died five days later of bilateral pneumonia, Alzheimer's disease and fentanyl toxicity. While fentanyl was not the immediate cause of death, the pathologist gave evidence that it was likely to have caused respiratory depression increasing the risk of pneumonia.

The coroner has expressed her concern that there is no mandatory training in the prescribing of opiates and has asked RCGP to make proposals to rectify this deficiency. We do not yet have the College's response.

In the interim, we take this opportunity to collect some messages about fentanyl for consideration.

- Titration of dosage using fentanyl is extremely difficult. Patients' needs should be determined using short-acting opiates with conversion once stable if necessary.
- Conversions should be calculated using existing published and validated charts. If possible, the calculation should be checked by another person.
- There will be a need for a dose of oral opiate given at the same time as the first patch is applied because there is a time delay before therapeutic levels of fentanyl are reached.
- Whatever recording system is used by carers, it should ensure that others can see quickly when the patch was last applied, where it was applied, and when it is due to be changed.
- The need for continued fentanyl at the present dose should be re-evaluated at intervals.

It goes without saying that the treatment used should be selected to suit the needs of the patient rather than the convenience of the carers.

MORPHINE SULFATE OVERDOSE

A further Coroner's Report relates to a care home resident admitted to hospital having become unresponsive and showing signs of morphine overdose. Her prescription was for Oramorph 10mg/5ml, 5ml when required to a maximum of 20ml daily. At no time was she actually given the full 20ml. Despite this, she exhibited pinpoint pupils and toxicology showed morphine overdose.

The coroner has written to NICE, and a section of his letter appears below:

> My concern relates to how it is that a person who is prescribed morphine and who has less than the amount prescribed for them, can nevertheless suffer an overdose. I write to enquire whether attention needs to be given to the maximum dose that can be recommended and whether it is, or should be, subject to factors such as body weight, any co morbidities and any other factors and whether attention should be directed towards the possible buildup of morphine in the body for those involved in long-term therapy.

While we cannot be certain, it seems unlikely that the lady could have progressed to unresponsiveness without signs of opiate overdose having been exhibited earlier. It is hard to avoid the conclusion that doses were still being administered when care home staff should have been able to see signs of opiate overdose.

The case also reminds us that relatively small doses of Oramorph can be hazardous. We have remarked before here that some practices may not realise that their systems allow frequent repeat prescribing of Oramorph because it is not a schedule 2 controlled drug. In this case, it is likely that dehydration contributed to the high blood level of opiate detected. This suggests that where an elderly patient is receiving opiates over a long period the prescriber will need to assure themselves that adequate hydration is being achieved.

BEFORE REQUESTING A WITNESS FOR CD DESTRUCTION...

Please note that we cannot arrange a witness until we have evidence that you have a valid T28 exemption in force and that you have access to appropriate denaturing containers. Please also note that the witness is not attending to perform the destruction, but to observe your staff doing so in accordance with your Standard Operating Procedures.

A T28 exemption is free of charge and lasts for three years. You can apply via https://www.gov.uk/waste-exemptions-treating-waste#t28-sort-and-denature-controlled-drugs-for-disposal. Not having a valid and correct exemption exposes the practice to risk of prosecution.

SUBMITTING YOUR PRIVATE PRESCRIPTIONS TO NHSBSA

Download the submission form at **http://www.nhsbsa.nhs.uk/2473.aspx** - click on "Submission document for submitting controlled drugs through a private account."

CD requisition forms

These are provided by NHS SBS following approval by the AO Team. Dispensers are required to forward completed CDFs to the NHS Business Services Authority who inform us of those received.

There appears to be a mismatch between numbers issued and used. Sometimes we are asked to supply further CDFs to practices that should have some in hand. The likeliest reason is that dispensers have not yet forwarded the CDFs, but we cannot easily check this unless we know where the CDF was sent. It is therefore helpful if those who use CDFs can note where each CDF was dispensed as part of the secure stationery monitoring system in the practice.

Dentists' Private CD Codes

Each of the old PCTs had a separate code and each dentist within its area who applied for a private CD code was allocated the local PCT code.

The Area Team now has a specific code to replace these which is 611433 (the old NHS Devon code). Prescriptions dispensed with the former PCT codes will only be attributed to this Area Team until the end of January 2015 and any dentist wishing to continue to prescribe privately will require stationery with the 611433 code before then.

If you are holding pink FP10PCD private prescription forms, please check the preprinted code. If it is 611433 you can continue to use them. If not, please apply to us for replacements. Please don't delay!

STOCK SEGREGATION

There seems to be some confusion about the correct way to store out of date stock and patient returned controlled drugs. Obviously it is important to segregate these within the CD cabinet in order to avoid using them on patients, but because the record keeping and destruction requirements are different, it is convenient to segregate these from each other too.

	Expired stock	Patient returns
Record-keeping	Expired stock is still part of your stock and should be included in your stock totals until it is destroyed. However, to show clearly what part of the stock is available for use, you may wish to show the out of date stock separately, e.g.if you have 15 diamorphine 10mg ampoules of which 3 are out of date you could show the stock as 12(+3 ood) or 15 inc 3 ood.	Patient returns are NOT part of your stock and should not be entered in your registers. However, you should have a separate patient returns book for controlled drugs.
Storage	Store in CD cabinet segregated from usable stock.	Store in CD cabinet segregated from usable stock.
Destruction	An authorised witness is required. Destroy in their presence in accordance with your own SOPs.	No witness is required – destroy in accordance with your own SOPs.

WHOLESALER AND HOME OFFICE LICENCES

There continues to be some confusion about the regulations relating to provision of drugs by wholesale dealing. Broadly, the Medicines and Healthcare products Regulatory Agency regards any transaction which is not for a specified patient as a wholesale transaction. In the context of controlled drugs, that means that any supply on a CDF requisition is a wholesale transaction – but we must emphasise that what follows applies to all drugs, not just controlled drugs.

Section 10(7) of the Medicines Act 1968 gave pharmacies an exemption from the need to hold a wholesale dealer's authorisation in most circumstances. That part of the Act was repealed in 2012, so pharmacies are no longer exempt. MHRA has set out the position in an explanatory note (http://www.mhra.gov.uk/home/groups/comms-ic/documents/regulatorynews/con394660.pdf) which says:

> MHRA takes the view that the supply of medicines by community and hospital pharmacies to other healthcare professionals in the UK who need to hold small quantities of medicines for treatment of or onward supply to their patients represents an important and appropriate part of the professional practice of both community and hospital pharmacy. Also community and hospital pharmacies may need to obtain small quantities of a medicine from other pharmacies to meet a patient's individual needs. Both these activities are considered by MHRA to fall within the definition of provision of healthcare services. In such circumstances, provided the transaction meets all of the following criteria MHRA will not deem such transactions as commercial dealing and pharmacies will not be required to hold a WDA(H):
>
> - it takes place on an occasional basis
> - the quantity of medicines supplied is small
> - the supply is made on a not for profit basis
> - the supply is not for onward wholesale distribution.
>
> Conversely, pharmacies who wish to engage in commercial trading in medicines are entitled to do so only if they hold a WDA(H) and comply with all the relevant requirements. As the authority responsible for enforcement MHRA will take appropriate

> action to enforce the requirement of the legislation and will require any commercial trade in medicines to be undertaken only by holders of a WDA(H).

It follows from this note that pharmacies that regularly supply others, or which do so at a profit, will be required to hold a Wholesale Distribution Authorisation (Human). However, since there is a substantial cost involved in such an application (£1803 or £902 where an application for a wholesale dealer's licence "relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the sale of authorised medicinal products carried on at that pharmacy" – see http://www.legislation.gov.uk/uksi/2013/532/pdfs/uksi_20130532_en.pdf , plus £303 or £181 for an inspection) it is very likely that most pharmacies will not have sufficient business to warrant obtaining such a licence, though WDA(H)s can cover more than one site if they have the same owners. It is therefore likely that doctors and others will have difficulty finding a supplier for small quantities of stock in future.

We have made this point in correspondence with NHS England and CQC. While there is some sympathy for the difficulties that will be faced, they point out that they are not the enforcement authorities. However, if there is evidence that patient care is being impeded by this restriction, they would be very happy to receive details so that they can use this information in discussions with MHRA.

A pharmacy does not normally require a Home Office licence to supply controlled drugs. However, the Home Office says: The majority of retail pharmacies will continue to benefit from the Home Office licensing 'exemption'. However, where a pharmacy requires a wholesale dealer's licence from the Medicines and Healthcare products Regulatory Agency (MHRA) for its activities, it would also require a Home Office Controlled Drug domestic licence. (See https://www.gov.uk/controlled-drugs-licences-fees-and-returns). Since MHRA has widened the need for wholesale dealer's licences, it follows that some pharmacies may now require Home Office licences.

DISPOSAL OF FENTANYL PATCHES

An MHRA notice (http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON437720) advises that "People using fentanyl skin ('transdermal') patches and their carers should check that the patches are stuck on securely and are disposed of safely," and gives specific advice which needs to be passed on to patients:

> It is extremely important when applying a fentanyl skin patch that people check that they are stuck on securely. A patch may cause serious harm if it accidentally sticks to somebody else's skin or is swallowed.
>
> The used patch should be folded in half so that the adhesive side sticks firmly to itself. It should then be safely thrown away in a secure bin so that it is not picked up by young children. If a patch is transferred to another person, remove it and get medical help immediately. If a patch is swallowed, get medical help immediately.
>
> People who use fentanyl patches should be careful to keep them out of the reach and sight of children and dispose of them carefully.
>
> If you have suffered any side-effects which you suspect may have been a result of using these products, or know anyone who has, please report it to us via our Yellow Card Scheme www.mhra.gov.uk/yellowcard.

NEXT CDLIN MEETINGS

North & East Devon	7 October	Middlemoor Police Station, Exeter
South & West Devon	21 October	Peninsula House, Saltash
Cornwall	15 October	Venue to be confirmed

NATIONAL REPORTING AND LEARNING SYSTEM (NRLS)

Please note that reporting incidents to us does not obviate the need or meet the duty to report to NRLS. We do not forward your reports.