CONTROLLED DRUGS NEWSLETTER

NHS ENGLAND SOUTH (SOUTH WEST)

April 2018

STAY ONE STEP AHEAD – LEARN FROM THEMES IN REPORTED INCIDENTS

In this newsletter we are sharing some of the learning from themes in the incidents that are reported to us. Incidents involving the dispensing and supply of methadone oral solution are reported to us more frequently than any other, and as a result this newsletter has a focus on substance misuse prescribing and dispensing, and related issues

‘Hand out’ (supply) errors in pharmacies

The supply of medication to the wrong patient continues to be a commonly reported error.

Many incidents that have been reported to us involved the supply of methadone to the wrong patient. These had all occurred because proper checks of the dispensed medicine, the prescription, and the identity of the patient were not carried out. Even if a patient is known to you, it is still important to adhere to your hand out SOPs. These will normally instruct you to check the patient’s name, postcode and/or date of birth every time before administering or handing out medicines. These checks should be made with reference to the prescription form, with a re-check of the labels of the dispensed medicines for the name and quantity before hand out. When supplying medication to treat substance misuse, it is also good practice to ask the patient what dose or quantity they are expecting as an additional check.
If the wrong patient’s medication is handed out, there could be serious consequences for both the patient and pharmacist.
Local Police CD Liaison Officers have advised that if someone else’s methadone is administered or supplied to a patient resulting in an overdose and the prescribing team is not available or able to locate the patient for assessment, then the police should be involved to check the welfare of the patient.

HAND OUT ERROR EXAMPLE

Steve comes in for his regular daily supervised instalment of 50ml of methadone solution.

The pharmacist recognises Steve – she sees him every day. She retrieves his prescription and then takes a pre-packed bottle of methadone solution from the CD cabinet, hands it to Steve and supervises the consumption of this dose.

Steve leaves the pharmacy and the pharmacist then notices that the bottle in her hand is not for Steve. It is for Shaun, and it contained 80ml.

There is significant potential for Steve to suffer serious harm. The pharmacist tries to contact Steve to advise him to seek medical attention. She documents this, and informs the prescriber. The police are called and they visit Steve to check his welfare.

Number of instalments on FP10MDA prescription forms

We have received incident reports that have involved supplies being made to substance misuse patients that had not been prescribed. This was because supplies were inadvertently made against prescriptions which were no longer valid.

Pharmacy staff are advised to scrutinise instalment prescriptions immediately upon receipt:

- Is the prescription written legally?
- Check the daily dose, and total quantity prescribed
- How many days treatment are prescribed?
- On which date should the first instalment be supplied?
- On which date should the last instalment be supplied?
- Which formulation has been prescribed (Sugar Free?)
- Is supervised consumption requested?

If the first dose is due on a day that your pharmacy will be closed, then contact the prescriber as soon as possible to request a replacement prescription that starts on Tuesday - Thursday. If it is necessary that it starts on a Monday or Friday, suggest that two prescriptions could be issued. For example: one prescription for supply up to and including Tuesday and one prescription for supply starting on Wednesday. Subsequent prescriptions can then start on the Wednesday.

First, do no harm - the ‘three day rule’ with daily opioid maintenance doses

There have been a number of incidents reported to us in which pharmacists supplied methadone to patients that missed doses for 3 days or more. The risk of harm from opioid overdose here is significant - giving nothing is safer. If 3 days’ doses have been missed then contact the prescriber immediately. Don’t wait until the patient comes back - you will then have a plan for if and when they do. It is important not to supply until the prescriber has been contacted as they may need to assess the patient before deciding whether to continue with the current prescription, or replace it with a different dose. Please ensure that all staff are aware of this, and if a prescription is suspended or cancelled that there are systems in place at the pharmacy to communicate this to all staff. This rule equally applies for weekend collections when it may not be possible to contact the prescriber until the Monday.

INSTALMENT ERROR EXAMPLE

Pharmacy staff have been supplying Jane with her regular daily supervised instalment of 60ml of methadone 1mg/ml oral solution.

They issue 14 daily doses as usual from a blue FP10MDA that was sent to the pharmacy.

No new prescription arrives so the pharmacy staff contact the prescriber who says Jane did not attend her appointment last week when they were going to review her dose. They will not issue another prescription until they see her, and are under the impression that she has had no methadone for the last week.

The last FP10MDA form was for 7 days’ supply only but pharmacy staff assumed it was for 14 days.

‘THREE DAY RULE’ EXAMPLE

Dave has missed three daily doses of his methadone but pharmacy staff haven’t notified the prescriber. Dave attends on the fourth day (Saturday) and asks for his dose.

The dose should not be supplied. Tell the patient that the procedure is not to supply doses as there is a potential for overdose and harm if you decide to make a supply.

Document your actions. A decision to supply may harm the patient. You will not be criticised for withholding the supply if you cannot contact the prescriber

Spillages of liquid Controlled Drug stock

When a liquid medication containing a CD is spilt we have to balance the need for accuracy in management of controlled drugs with the health and safety implications of having a dangerous liquid on the bench or the floor. In our view, the health and safety requirements mean that the spillage must be promptly cleared up but we would expect the following to be considered:

- The fact that there has been a spillage should be shared with a colleague who should, so far as possible, confirm the identity of the spillage.
- The spillage should be mopped up. Any paper towels, tissues or absorbent used should be placed in a CD destruction container. It is not necessary to retain these for *our* inspection but please do follow your own SOP should this advice differ
- It will not always be possible to calculate the exact amount of the spillage, but the best estimate should be made.
- Conduct a stock check of the item and make an entry in the register giving the current verified stock. You should distinguish between measured and estimated spillages.

As with any other CD incident, report this to the Accountable Officer via www.cdreporting.co.uk

SPILLAGE EXAMPLE A

John measures 50ml of methadone oral solution in a glass measure but then knocks it onto the bench. The spillage is therefore known to be 50ml and can be noted precisely in the register.

SPILLAGE EXAMPLE B

James knocks a stock bottle of methadone oral solution onto the floor. According to the register, it should have contained 400ml. When it is righted and measured, it is found to contain 280ml. If the 400ml figure has not been checked recently, it may not be correct. All we know is that there is now 280ml, so the entry in the register notes that there was a spillage estimated at 120ml and the balance is noted as 280ml.

Timely reporting of fraudulent/forged prescriptions

Please ensure that the reporting of fraudulent prescriptions is timely. We recently had an incident in which a fraudulent prescription was presented to a pharmacy on a Monday afternoon where it was correctly spotted as being fraudulent, not dispensed and retained by the pharmacist. This incident was not reported to the Accountable Officer until the following Friday afternoon. It came to light that this patient had other post-dated prescription forms in their possession that could have been presented in the interim period.

When we receive notification that lost or stolen prescription forms are in circulation we alert pharmacies in the locality by e-mail. If you believe that you are not on our circulation list for these (because you have never received any), please contact alerts.scwcsu@nhs.net and inform them of your location and work e-mail address.
Please also ensure that you know how to access your pharmacy's NHSnet e-mail address.

FORGERY EXAMPLE

We had a spate of forged prescriptions in the Torbay area in 2017 following the theft of a number of forms from a GP practice.

The theft was not reported, but the presentation of fraudulent prescriptions was reported by pharmacy staff and the sharing of this information prevented many forged prescriptions that were subsequently presented from being dispensed. The matter is now in the hands of the police.

Calculating balance discrepancies for liquid stock

The measures that we use for dispensing have allowable limits of error. These vary from 0.5% for a 100ml measuring cylinder (so when we read 100ml that is actually 99.5-100.5ml) to 1.0% on a 10ml measuring cylinder (so when we read 10ml that is actually 9.9-10.1ml).

Manufacturers of liquid medicines always fill their bottles with a small overage, and so you will encounter discrepancies no matter how careful you are. 'Natural overage' is typically of the order of 10-15ml in a 500ml bottle.

We accept that many SOPs require a report to be made to the Accountable Officer for any balance discrepancy and we are always happy to receive them. This article describes how we will deal with those discrepancies.

Whenever you report a balance error for a liquid, we need to know two facts:

1. The size and direction ('underage/overage') of the discrepancy
2. The total amount dispensed since the last correct balance check
   We do not need to know the amount you have in stock, because that is not part of the calculation.

Note that if you have a shortage (underage) in one form of methadone and an excess (overage) in the other, then this could suggest a selection error whilst dispensing.

Divide the discrepancy by the total amount dispensed since the last correct balance check. If the result is an underage of less than 0.01 (1%), then you can go ahead and correct the balance in your CD register. We would not require you to report this, though if your SOP says that you should, we're happy to receive it. Ordinarily, we would take no further action, and we would not regard this as an error.

If the result of this sum is an underage of more than 0.01 (1%) or an overage of more than 0.03 (3%) we will expect further investigation depending on the result you get and the size of measures you have had to use to measure the doses required.

- Most original packs of liquid preparations have some degree of manufacturer's overage – e.g. 15ml (3%) in a 500ml bottle.

DISCREPANCY EXAMPLE A

Adrian has found that his methadone balance is 15ml less than expected.

Since his last balance check he has dispensed 1800ml. The number we want is therefore 15 /1800, which is 0.0083. This is less than 0.01, so Adrian can just adjust the balance in his register himself. If his SOP requires it, he can inform us, but we do not require it.

DISCREPANCY EXAMPLE B

Barbara has an underage of 3ml and has used 50ml since the last correct check.

This is more than 0.03 but the volume she has used is very small and therefore the allowable error on the measures she has is larger. We would ask her to correct the balance in her register, noting that she has reported it to us and that we have agreed to the correction.

DISCREPANCY EXAMPLE C

Charles has discovered an error of 150ml and has used 2500ml since his last correct check. This is 6%. This is the same figure as Barbara's but because Charles' dispensed volume is higher we would expect a smaller proportion of error than for Barbara. We would ask Charles to correct his register as above, but we may ask for additional information to explain the discrepancy.

Investigating balance discrepancies for liquid stock

The most common reasons for discrepancies are:

- Overage in delivered containers
- Measurement inaccuracies
- Arithmetic errors
- Stock received but not entered in the register
- Stock supplied but not entered in the register
- Obsolete stock not included in calculations
- Pre-packed stock not included in calculations
- Spillage
- Wrong product selection (e.g. methadone oral solution DTF supplied but an entry made in the CD register for methadone sugar free oral solution)

Consider each of these in your investigation into any balance discrepancy.

The importance and value of regular balance checks

It is much easier to investigate balance discrepancies if regular balance checks are taking place as the tasks that are required to investigate the discrepancy are far less onerous.

An incident was reported to us in 2017 in which a pharmacist manager identified that he had more Zomorph 10mg MR capsules and less Zomorph 100mg MR capsules in stock than the register indicated.

The pharmacist realised that it was possible that a dispensing error with potentially fatal consequences had occurred. He then contacted all patients for whom register entries for supplies of Zomorph 10mg MR capsules had been made since the date of the last balance check to confirm with them what they had received.

All patients said that they had received the correct medication, but the pharmacist was naturally still concerned and decided to then visit the address of each patient to ask to see their medication. One of the patients had indeed received Zomorph 100mg MR capsules in error, but luckily had not yet taken any.

DISCREPANCY EXAMPLE D

Debbie notices that the balance of methadone oral solution in her controlled drugs cabinet is 1845ml, but her register says 1750ml and she is concerned that the overage is 95ml which is over 5% of the balance in the controlled drugs cabinet.

She has checked that sugar-free methadone has not been dispensed instead. When investigating she realises that the balance hasn't been checked for three weeks and in that time she has dispensed ten full bottles of 500ml.

Rather than calculating against the balance in the cabinet, 95ml is 1.9% of the 5000ml dispensed over the previous three weeks.

This would be a reasonable quantity as overage where the natural overage is usually 10 to 15ml for each full bottle.

Debbie realises that she should check her balances more frequently, and amends her balance accordingly with a footnote to explain the build-up.

Whenever a balance adjustment is made in the register there must be an accompanying explanation.

How to report controlled drugs incidents

The NHS England online controlled drugs website www.cdreporting.co.uk has been successfully up and running in the South West for several months now. All incidents relating to Controlled Drugs should now be reported to us via this website.

This system will ensure that we have a complete record of all the information that we need and enable us to share the learning. The system will also e-mail you a copy of the information that you have provided for your own records.
You do need to set up an account before you use the website but it is easy to register on the site.
If you require advice please do contact us by telephone or e-mail.

What a good incident report looks like

- Report the incident promptly - has anyone been harmed?
- State the facts - what happened? Be open and honest.
- Have you explained what has happened to any patients involved and apologised if appropriate?
- Tell us why you think it happened.
- Tell us what you have done to try to prevent it from happening again.
- What have you learnt as a result by reflecting on what happened? Have you shared this with your team?
- How will you check that the change in your practice is working?

Our priority is to ensure that the incident is investigated fully and that a recurrence of the incident is less likely as a result of the learning that has taken place, which we aim to share

How to request an authorised witness for a controlled drugs destruction

Remember you do not need a witness authorised by NHS England to destroy patient returned CDs or CDs in schedule 3 or 4 (part 1)

Ensure that your pharmacy has a 'T28 exemption' from the Environment Agency so that you can legally denature medicines on the premises. You can register this for free on the EA website. You need this to denature any controlled drugs, regardless of schedule, and whether stock or returns.

Ensure you always have denaturing kits in stock.

For stock schedule 2 CDs you do need an NHS England authorised witness. If you do not have one you can request this via www.cdreporting.co.uk

We are happy to arrange witnesses for excess and obsolete in-date stock as well as for out-of-date stock

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REPORT A CONTROLLED DRUGS INCIDENT

Online at:
www.cdreporting.co.uk

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