JUST IN CASE BAGS AND CARE HOMES

A question that we have been asked illustrates a misconception that we need to put right. We try very hard here to distinguish between legal requirements and advice on good practice. We are not in a position to tell anyone to ignore legal requirements, so where normal practice and the law clash, practice has to change.

In this particular case, we understand that some care homes have been in the habit of receiving just in case bags for their residents and only recording the receipt of any controlled drugs inside them when the JIC bag is needed. The justification given to us is that the bag is sealed and not meant to be opened.

However, if you are required to keep a stock register – which will usually be the case for care homes providing nursing services – you are also required to enter controlled drugs entering the premises, for which purpose the JIC bag needs to be opened. It can, of course, be resealed afterwards. Even if you are not required to keep a register, common sense dictates that the contents of the bag should be checked as any discrepancy needs to be discovered at the time of receipt, and not some time later.

If the whole bag can fit in the controlled drugs cabinet, then this can be done. If not then the controlled drugs can be removed and stored in the cupboard with the other medicines being stored elsewhere. If the seal is in some way tamper-evident, then the bag does not need to be opened and resealed at each stock check.

The continuing need for a just in case bag should be reassessed at intervals to prevent the accumulation of unused controlled drugs.

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We can no longer receive or send faxes.
The Faculty of Pain Medicine has published its Opioids Aware resource pack for patients and healthcare professionals. It can be found at https://www.fpm.ac.uk/faculty-of-pain-medicine/opioids-aware and looks extremely useful to us.

One key message is to include all opioids in dose assessments, and not just those which are fully controlled drugs. Regular readers will know that this is an issue that we have covered before. In one of their tables the authors give relative potencies for codeine (100mg codeine = 10mg morphine), dihydrocodeine (100mg dihydrocodeine = 10mg morphine) and tramadol (100mg tramadol = 15mg morphine).

An example will illustrate the importance of this. A patient had prescriptions as follows:

1. Co-codamol 30/500 capsules 2 qds (100)
2. Tramadol 50mg capsules 2 qds (100)
3. Morphine sulfate solution 10mg/5ml 5ml prn (500ml)

The prescriber was comforted by the thought that he had avoided giving the patient any opiates, by which he meant that no schedule 2 CDs were in use. However, since the patient collected a bottle of Oramorph® every time she picked up the capsules, she was effectively using 500ml in 12.5 days, or 40ml a day. As a result the total morphine equivalent of this regimen was 164mg:

240mg codeine = 24mg morphine
400mg tramadol = 60mg morphine
40ml Oramorph® = 80mg morphine

This is not an inconsiderable quantity of opioid.

Prescribers may want to review their liquid morphine prescribing with some simple checks.

For each patient:

1. Search records for Oramorph® or morphine sulfate oral solution.
2. Check that the morphine has not been inappropriately added to their repeat list
3. Calculate the amount of morphine that they appear to be taking each day based on the amount prescribed and the intervals between scripts. Remember that 1ml = 2mg.
4. If the calculation at (3) appears high, consider whether their other analgesia is optimal.

CONTROLLED DRUGS REQUISITIONS

With effect from 30th November, the use of the CDF requisition form to obtain stock controlled drugs became mandatory rather than advised. This does not apply to purchases from wholesalers or for stock obtained for hospices and some private hospitals. This is no longer a paper form but a downloadable form which can be found at http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/6-1387-Form_FP10CDF_v5_final.pdf

We must also remind suppliers of the need to have wholesaler licences where such supplies are made. This requirement is not of our making and we are not empowered to waive it.
EPS REPEATABLE PRESCRIPTIONS AND DIAZEPAM

It is legally possible to issue repeatable prescriptions for diazepam. However, two considerations need to be noted.

First, most indications for diazepam are for short-term use only. The question of whether a repeat prescription is appropriate therefore needs to be considered.

Second, electronic prescriptions are issued bearing the date of the original prescription and with a validity date which is fixed at the first issue. Since prescriptions for controlled drugs are only valid for 28 days this places a limitation. On single FP10s it is possible to specify a date for each dispensing which may be in the future and becomes the date from which the 28 days are calculated, but all the prescriptions in a repeatable batch bear the same instructions so this option is not available to prescribers.

GOING ON HOLIDAY?

If you customarily keep your controlled drugs in a locked bag in the boot of your car, where are you going to keep them while it is in an airport car park?

Obviously you would only leave them there as an oversight, but the question has arisen whether a doctor can take them into his or her practice rather than keeping them in their empty house.

Our pragmatic view is that we would rather they were in a secure place than an unattended building. So long as there is no risk of their being mistaken for practice stock, we see no objection to their being stored in a practice’s CD cabinet. However, they cannot become part of the practice stock, and should not be entered into the practice register. Instead we suggest that they are placed in a sealed bag clearly labelled with the name of their owner.

NICE GUIDANCE ON THE USE OF CONTROLLED DRUGS

NICE has published guidance on the safe use and management of controlled drugs which can be viewed at https://www.nice.org.uk/guidance/ng46. A number of people from the South West have been involved in this.

ORIGINAL PACKS

There seems to be a persistent issue when original packs are dispensed by mistake when one month’s supply has been ordered. For example, the prescription may call for 56 doses of a drug which comes in packs of 60, or for 28 from a pack of 30. Please take extra care when dispensing these quantities.

TEAM CHANGES

You may notice a couple of changes in our contact details. Sam Hazell left us to produce a new little Hazell, and Vicky Bawn has joined us in her place. Graham

PART SUPPLIES

One of the differences between community and hospital practice was drawn out in the preparation of the new NICE guidelines on Controlled Drugs (see item elsewhere!)

In community practice, any owing portion will be dispensed up to 28 days later. It transpires that in many hospitals there will be only one supply, and the ward order is simply endorsed with the amount given. This has occasionally led to failures of care when the ward staff have thought that the controlled drugs would automatically follow later and supplies have run out.

The NICE guidelines stress that there should be a consistent practice and that the recipients should know what that is.

SUBMITTING YOUR PRIVATE PRESCRIPTIONS TO NHSBSA

Download the submission form at http://www.nhsbsa.nhs.uk/2473.aspx (or use the QR code below) - click on “Submission document for submitting controlled drugs through a private account.”

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. You can report at http://www.nrls.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/ or via QR below.
Brack’s secondment from NHS Kernow CCG came to an end at the start of March but he remains attached to us on a sessional basis. The most efficient way of contacting him by phone is via Vicky.

**EMERGENCY SUPPLY OF BUPRENORPHINE**

A service user presented at their usual pharmacy with several prescriptions for buprenorphine. One Saturday a locum noticed that the dates were not continuous. For some reason the weekend’s doses were missing, and the next prescription did not start until Monday. The locum tried to obtain a replacement prescription but was unsuccessful, and ultimately decided to issue an emergency supply of buprenorphine rather than interrupt the person’s treatment.

Whilst this is understandable it was plainly illegal because emergency supplies are not permitted for schedule 2 and 3 controlled drugs, except phenobarbital. It was unfortunate that the prescriptions were not checked more carefully on issue and on receipt, when the mistake could have been rectified which would have avoided putting a colleague in a very difficult position.

This is not an unusual problem with buprenorphine. Another difficulty we see arises when a patient is being titrated upwards. For example:

- Buprenorphine – 2mg on Friday, 4mg on Saturday, 8mg on Sunday and thereafter

But what happens if the patient doesn’t turn up on Friday? The only legal option is to give 4mg on Saturday but that is not what the prescriber wants, nor is it necessarily safe. One alternative might be to prescribe:

- Buprenorphine – 2mg on the first day, 4mg on the second day, 8mg thereafter for 12 days.

**LEGISLATIVE CHANGES**

On 7 January 2015, sodium oxybate (Xyrem®) was rescheduled as a Schedule 2 Controlled Drug (CD POM). It was previously a Schedule 4 Part 1 CD. This drug is licensed for the treatment of narcolepsy with cataplexy in adult patients. Sodium oxybate is now subject to the full prescription writing, requisition, destruction and safe custody requirements of all schedule 2 CDs.

The Psychoactive Substances Act 2016 came into force on 26th May 2016. This has been well advertised. Since it is concerned with non-medical uses it is unlikely to be of day to day concern to the NHS, but the CD Locality Intelligence Networks will receive reports from the police forces about local incidents in this area.

**CQC PUBLICATIONS**

CQC has reorganised its controlled drugs sub-committees, and the vigilance sub-group has released its first newsletter. Copies can be seen at [https://www.cqc.org.uk/sites/default/files/20151124_controlled_drugs_national_group_vigilance_v1_no1.pdf](https://www.cqc.org.uk/sites/default/files/20151124_controlled_drugs_national_group_vigilance_v1_no1.pdf).

At the same time the Patient Safety sub-group also issued a newsletter: [https://www.cqc.org.uk/sites/default/files/20151120_controlled_drugs_national_group_patient_safety_newsletter_v1_%20no1.pdf](https://www.cqc.org.uk/sites/default/files/20151120_controlled_drugs_national_group_patient_safety_newsletter_v1_%20no1.pdf)

Our team has played a major part in CQC’s work and intends to continue to do so.
OXYCODONE CONFUSION

It is settled guidance that oxycodone modified release products should be prescribed by brand name to ensure consistency and reduce the risk of confusion. Unfortunately it has become clear that some prescribers are not clear which products are modified release and which are immediate release.

Modified release brands include OxyContin, Reltebon, Longtec, Oxylan and Oxeltra.

Immediate release forms include OxyNorm, Lynlor and Shortec.

SYRINGE DRIVER PRESCRIPTIONS

Every issue of this newsletter has contained a reminder that “as directed” or “as on syringe driver sheet” are not legal directions and prevent patients receiving the immediate care they need. Despite this, every month we receive reports of prescriptions that could not be dispensed because the dosage instructions were expressed in this way.

Please ensure that all relevant staff know that the dose must appear on the face of an FP10 – and cannot be referred to any other document – and that there must be a quantity stated. Pharmacists have no discretion on this matter – they must refuse your prescription. Rectifying these mistakes is a significant additional workload for out of hours services which could be avoided.

THE THREE DAY RULE

On grounds of safety, once a substance misuse client has missed three days’ supply they cannot be dispensed to until they have been reassessed. However, there has been some inconsistency in how this is handled which requires addressing.

Typically prescriptions have borne a phrase such as “If three days are missed do not supply.” In some areas the normal practice has been to place such a prescription on hold, but reactivate it if asked to do so by the addiction services team. On a strict reading of the law, this was incorrect. If a prescription is in the form “If A happens, do B”, then once that condition is reached the prescription cannot be reactivated.

Accordingly, we are talking to services with a view to agreeing an alternative wording which is likely to tell the dispenser that if three days have been missed, no supply should be made until the patient has been assessed and a further instruction given to the pharmacist. This allows for the possibility that the instruction will be to make a supply and continue to do so until the end of the current prescription.

If the dose needs to be changed an alternative prescription will be provided.

However, there are also responsibilities lying on pharmacists in these circumstances.

1. The fact that three days have been missed should be communicated by the pharmacist to the prescriber or prescribing service. This should be done by some immediate method such as telephone.
2. The fact that a prescription is on hold should be made clear to other relevant staff in the pharmacy by some agreed means – perhaps a note attached to the prescription – together with a clear indication of when that happened. This should prevent a prescription being restarted in error by another pharmacist.
3. If the prescription is recommenced the name of the person authorising the resumption, if not the original prescriber, should be noted in case of further query.

It is neither possible nor desirable to be prescriptive about how this is done, given the very different systems in use in pharmacies, but it is important that some robust system exists to prevent accidental dispensing of a prescription to a patient in whom it may no longer be safe.
PREScriBER GUIDANCE FOR COMMONLY MISUSED DRUGS

Prescribers need to be especially mindful of their responsibility for outcomes when prescribing medications that carry a recognised risk of misuse and/or dependence. It is advisable to be aware of these as medico-legal exposure will be increased where such risks are well-known. The type of associated risks include dose escalation beyond recommended levels, consequences of intoxication, overdose, acute or chronic adverse effects, and diversion of medication to black markets, other vulnerable adults and children.

Commonly misused medications in the UK with potential for diversion and/or dependence are:

- Benzodiazepines: e.g. diazepam, clonazepam, lorazepam, temazepam
- Z-drugs: e.g. zopiclone, zolpidem
- Opioids: codeine, tramadol, dihydrocodeine, oxycodone, Oramorph®
- Pregabalin, gabapentin
- Amitriptyline, mirtazapine
- In addition, risks also exist with over the counter medication, particularly in combinations, such as Nurofen plus®

Factors which further increase prescribing risks include:

- Personal/family history of problematic alcohol/substance misuse
- History of difficult life events such as childhood trauma or abuse
- Severe mental health disorders including personality disorders
- History of pain issues
- Time spent in secure environments or Local Authority Care systems