CONTROLLED DRUGS NEWSLETTER

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

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A GUIDE TO DESTRUCTION

Some recent correspondence suggests that a recap on good destruction practice may be helpful.

Patient returned medication

Medication which is no longer required should be returned to a pharmacy (or dispensing practice) for destruction. Their NHS contract requires pharmacies to receive these and NHS England funds a collection service. They need not be returned to the place of issue – any pharmacy can take them. Some pharmacies may refuse to accept sharps (including prefilled syringes) because they have no means of forwarding them.

Patient returned controlled drugs can be destroyed by pharmacies and dispensing practices using their own staff in accordance with their SOPs. There is no need to ask for an authorised witness. Other GP practices should signpost patients wishing to return medicines to their nearest pharmacy.

If a practice or pharmacy wants to dispose of its own **surplus stock**, the destruction must be witnessed by an authorised witness. Some multiple pharmacies have a special arrangement, but most witnesses work for CCGs. Bridget authorises them as Accountable Officer by agreement with their CCG. However, please note that the person sent is a *witness* – they do not perform the destruction themselves, but observe it being done by local staff. We have had examples of witnesses being expected to conduct the destruction. That is not their role and they have no authority to do that. The Misuse of Drugs Regulations 2001 provide that:

27. (1) No person who is required by any provision of … these Regulations to keep records with respect to a drug specified in Schedule 1, 2, 3 or 4 shall destroy such a drug or cause such a drug to be destroyed except in the presence of and in accordance with any directions given by a person authorised (whether personally or as a member of a class) for the purposes of this paragraph by the Secretary of State …

The power to authorise witnesses was delegated to Accountable Officers in 2007 but the regulation only allows destruction in their presence, not destruction by them.

The witnesses work within the SOPs of the premises where they are observing destruction; this is logical, because safe destruction is a duty of the healthcare practice, so it has to be their policy which is followed. The identity of the person doing the actual destruction is for the practice or pharmacy to determine, but it should be someone authorised to make register entries.

T28 exemption

Denaturing of a controlled drug is necessary because it is unlikely that a waste carrier would be authorised to possess a controlled drug. If they are prepared to receive them, the controlled drug would need to be segregated and identified. We have had cases of healthcare professionals placing controlled drugs in their waste without denaturing or notice to their carrier, but this is an offence and the penalties for doing so can be severe.

Unwanted or out of date controlled drugs must first be denatured so that they cannot be recovered, retrieved or re-used. Denaturing via a controlled drugs kit will render them harmless and unfit for use until they are totally destroyed via incineration. However, the process of denaturing is a waste handling process that would normally require a licence. In order to promote easier destruction with the minimum of bureaucracy the Environment Agency has introduced the T28 exemption, which allows destruction by healthcare professionals without a licence provided certain conditions are met.

First, the exemption relates to a specific address, so if you operate from two addresses you need an exemption for each. This is described as "the place of production" – that is, the place at which the drug became waste, which it did when you decided you did not need it any longer. For this reason T28 does not apply to patient returns, because in those cases the place of production is the patient's home. However, the Environment Agency has accepted that there is an over-riding public interest in having patient-returned drugs promptly destroyed and will agree to destruction following RPS guidelines – see https://www.gov.uk/government/publications/denaturing-of-controlled-drugs.

Second, you can store up to one cubic metre of this waste for up to six months. These limits must not be exceeded.

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. Please be careful to tick T28 as the exemption you want. The other options may be fascinating but having a T27 exemption to denature sheep dip or a T29 to treat non-hazardous pesticide washings before disposing of them to land will not be much help to a practice. Not having a valid and correct exemption exposes the practice to risk of prosecution.

A pharmacy has queried whether it is necessary to book an authorised witness to oversee the destruction of expired stock temazepam. Although this is not a legal requirement for schedule 3 controlled drugs, authorised witnesses are happy to oversee this denaturing alongside any expired schedule 2 CDs that a pharmacy may have. All expired temazepam must be denatured prior to collection by a waste carrier. If a pharmacist chooses not to ask for an authorised witness to oversee this denaturing then it is good practice for another member of staff to witness it instead.

Stock from doctors' bags

The Environment Agency will accept that stock in doctors' bags can be treated as waste produced in the practice and it can therefore be returned to a central point for denaturing. When this happens, register entries should be made to enable an audit trail to be followed and to ensure that stock balances are correct in each place. The destruction does not have to be conducted by any particular partner so long as the staff member present is authorised to make register entries.

A small number of practices do not hold any central stock and therefore have no central registers. In those circumstances the witness needs to have the doctor's register with the stock whose destruction is being witnessed. A destruction request will therefore mean that we check a) you have a valid T28 in place b) a staff member will conduct the destruction and c) the necessary registers will be present.

SYRINGE DRIVERS AND BREAKTHROUGH DOSES

There have been continued problems with these around the country, with some evidence that risks are not being handled well.

First, we reiterate that a prescription for controlled drugs to be used in a syringe driver must bear a dose. “As directed on syringe driver sheet” is not an acceptable dose. We realise that it is not possible to predict changes in dosage reliably and it is therefore likely that sometimes the dose will change after a supply of CD has been received.

It is poor practice for pharmacies to re-label medicines that they have already dispensed. In the case of controlled drugs, it may also create misleading entries in an electronic stock register. Nevertheless, pharmacists have reported being asked by carers to re-label medicines to reflect a change in dose. This should not be necessary because the administration directions on a syringe driver sheet, if timed and dated, should provide clear instructions on the current dosage to be given.

We have discussed this with CQC and have agreed some principles. At the moment of dispensing, the medicine label, the medicines administration record (MAR) and the syringe driver record chart (SDC) should agree. If they do not, then clarification must be sought and a record made as to how they were brought into agreement. Thereafter, the administration charts, which are the responsibility of the care service, should contain the latest directions for use. A care service meets its duty if it annotates the medicine label (when necessary) to note that this is not the current dose. It should be possible to trace the record of dosage changes by means of professional visit records or patient notes.

Sometimes prescribers are concerned that writing as required doses may lead to excessive use. However, not doing so may impede good patient care and leave patients in pain. In some circumstances it may be appropriate to specify a breakthrough dose but limit either the frequency (“not more often than two-hourly”) or the number (“no more than three doses in all”) of breakthrough doses.

MORPHINE SULFATE ORAL SOLUTION

In the last issue we discussed the monitoring of the prescribing of Morphine Sulfate solution for patients receiving regular opiates. Please note that Morphine Sulfate is only classified as a Schedule 5 controlled drug and therefore may not be automatically subject to the normal flagging procedures that a surgery may have to highlight the prescribing of Schedule 2 controlled drugs such as morphine tablets and diamorphine ampoules. It is recommended that each practice also has a system in place so that they are able to monitor the prescribing of Morphine Sulfate solution to ensure that it continues to be appropriate for each patient.

FP10PCDs AND FP10CDFs

Please note that although we authorise the supply of these, NHS England does not keep the forms and therefore cannot influence how quickly they arrive. Once we have the information we need, we issue an authority to NHS Shared Business Services which actually makes the supply.

Those requesting these forms are required to complete a declaration. This is not a mere formality, and we have to be assured that the necessary Standard Operating Procedures are in place and are being used consistently before we can authorise a supply. In some cases we may have evidence that although SOPs are in place, they are not being followed and insufficient corrective work is being undertaken – see next item!

PREDISPENSING OF METHADONE

It is unfortunately the case that we are seeing increasing numbers of cases where a predispensed supply of methadone has been given to the wrong person, or on the wrong day, or in the wrong amount. We understand that some pharmacists feel that they need to prepare doses in advance in order to reduce delays in dispensing, but if it is to be done, then the

pharmacy must have rigorous SOPs in place to manage the risks that this introduces. It is not our place to lay down how this must be done, but there are some sensible pointers that we can offer based upon the reports that we see.

How many days in advance?
If you are going to prepare doses in advance, you need to have sufficient storage space to keep each person's doses separate. Remember also that this methadone still forms part of your stock and should be included in stocktakes. Whether you dispense a day or a week in advance, the same time should be adopted for all your patients – dispensing for different lengths of time for different people is likely to lead to confusion.

Stock segregation
The prepacked stock should not be mingled with bulk stock. This reduces the risk that a prescription will be dispensed from someone's prepackaged stock. For example, for a patient who received 100ml daily collected on Wednesday and Saturday, a pharmacy prepared bottles of 400ml and 300ml, but then used the 400ml bottle to dispense 30ml for another service user.

Labelling
The label should clearly identify the patient, the amount and the date of supply. If that is not the date of preparation then both should appear.

Containers
Follow the guidance in your local Service Level Agreement – there are differences between Cornwall and Devon. It is good practice to tell a client on supervised consumption how much they are being given. Your SOP should state clearly what is to be done with the bottle after use. Some pharmacies refill the same bottles although it is probably uneconomic to wash, dry and relabel the same bottle.

Handover procedures
The same SOP should be used for handing the medicines to the patient as for any other drugs. It seems to be the case that other medicines are likely to be handed over by the counter staff whereas pharmacists may prefer to hand out controlled drugs themselves. This means that the SOP is being used for the riskiest medicines by the person who is probably least familiar with operating it. If the pharmacist handing over the dose did not dispense it, they need to be able to check that it has been properly prepared. **The incidents that we are seeing suggest that names and addresses are not being properly checked before allowing the client to consume.**

Register entries
A register entry will be required as soon as possible after dispensing, but because the pharmacies which pre-prepare doses are doing so because they are busy, they are also likely to face difficulty in making prompt register entries. It is not unknown for a client who was already collected to re-present later and if a register entry has not been made it may be unclear that they have already had a supply. Whatever system is used, it should be immediately clear to a pharmacist what supplies have been made, even if the register has not yet been completed. This might mean entering the name and volume in the register and returning later to complete the entry, for example.

Making time
When we receive error reports of this kind, pharmacists frequently remark that they made the mistake because there was a queue and they felt under pressure, or because they have inadequate dispensing support staff. We can sympathise with both of these, but we are bound to point out that a court would probably discount both. It has consistently been the view of judges that it is a hallmark of professionals that they take the time necessary to do their job properly, whatever pressure is applied. If a pharmacist feels that he or she is being asked to complete too much work with the resources available, it is their duty to make that point to their line manager and, if this does not produce improvement, to us at NHS England.

NEXT CD LIN MEETING

Our next CD Locality Intelligence Network meeting is a joint meeting of all three LINs on 4th June at the China Fleet Country Club, Saltash.

SUBMITTING YOUR PRIVATE PRESCRIPTIONS TO NHSBSA

You can download the submission form by going to **http://www.nhsbsa.nhs.uk/2473.aspx** and then clicking on "Submission document for submitting controlled drugs through a private account."

SUGARED v SUGAR-FREE METHADONE

One of the commonest sources of error recently has been the dispensing of the wrong type of methadone to clients. This is often associated with dispensing in advance of the client's arrival and then handing out the wrong bottle. Pharmacies where this is common practice should have procedures in place to guard against this risk.

PEOPLE HAVE BEEN RETRAINED, LESSONS HAVE BEEN LEARNED…

Those of us who have had small children may have noticed that in their minds saying sorry does not necessarily include any commitment not to do the same thing again. Following incidents it is not uncommon to receive reports in which we are told that training has been given and lessons have been learned. If, despite this, similar incidents recur, we are entitled to assume that the issues are not being addressed effectively.

We have lately seen two patterns of repeated mistakes. One is the pre-dispensing of methadone mentioned earlier; the other is a failure to change fentanyl patches on the correct day (or at all) within care services. In our view, when an error has arisen and an action plan is produced, the effectiveness of the steps taken in preventing a recurrence should be automatically audited without waiting for another incident. An assurance that lessons have been learned will not be adequate if it does not include a plan to check that this is actually true.

CO-OPERATION WITH THE ENQUIRIES OF OTHERS

All healthcare professionals have a duty of co-operation to secure safe use of controlled drugs. Our attention has been drawn to a request from the Accountable Officer of a hospital trust to pharmacies in the Plymouth area to check their dispensing records for specified lost prescriptions. A very small number of pharmacies responded. In these circumstances we would expect a response, even if it is a nil return. A failure to respond to a reasonable request from an Accountable Officer may call into question an organisation's competence self-assessment.

Reporting to others

We do not routinely forward reports to other agencies that may need to be informed. Where patient safety may have been compromised there is still an obligation to report the incident to the National Reporting and Learning Service promptly. You can do this at http://www.nrls.nhs.uk/report-a-patient-safety-incident/. Comparison of local data suggests that many reports made to us are not also made to NRLS.

Please note also that when a patient receives another person's medicine, there may have been a breach of confidentiality requiring reporting.

Substance misuse – 3 day rule

If a client misses 3 days' supply of their prescribed medication (NOT 3 pickups) it is normal practice to notify the prescriber and not to dispense again to that client until they have been reassessed. This is not a punishment for the client, but an essential safety measure designed to reduce the risk of dispensing to a person whose tolerance of their medication has been reduced. It is good practice to note that the prescription is on hold pending a reply to prevent accidental dispensing.

If the prescription specifies that a supply must not be made if 3 days have been missed, it cannot be reactivated once that has happened, and a new prescription will be required.