

Shipman Inquiry: views on tightening of Controlled Drug regulations sought

A paper published this week by the Shipman Inquiry sets out topics for discussion around the use and monitoring of Controlled Drugs in the community. Clare Bellingham reports

THE way in which Controlled Drugs (CDs) are handled will change. Little doubt exists that the outcome of the Shipman Inquiry will result in substantial revision of the existing arrangements. What is not known is what these modifications will be.

The publication this week of a paper setting out topics for consideration by the next stage of the Shipman Inquiry gives some insight into the inquiry's thought process. This next part of the inquiry — stage three — is perhaps the most relevant to pharmacists since it tackles issues around CDs (see Panel overleaf).

Safeguards in place in the current system failed when it came to Shipman. He was able to obtain large quantities of CDs for his own purposes (in the words of the report). Some of the patients he obtained diamorphine for were dead, some had no need for the drug, and to others he gave only part of their supply that he had collected from the pharmacy. After a patient's death, he would collect any remaining supplies of CDs from their home and retain it for his own purposes.

So it is little surprise that the inquiry notes: "Evidence heard by the inquiry suggests that the existing arrangements for the handling of CDs require overhaul." It adds: "Where CDs are concerned, it is unwise to rely on a system that depends wholly on trusting those who have access to them. Everyone's actions should be subject to some degree of supervision, inspection or audit."

This week's discussion paper — called "The use and monitoring of Controlled Drugs in the community" — sets out questions in the following areas: prescribing of CDs, security and record keeping, inspec-

tion and monitoring, collection and delivery of CDs, and administration, return and destruction of CDs.

Stephen Lutener, head of professional conduct at the Royal Pharmaceutical Society, comments: "The Society has co-operated fully with the Shipman Inquiry, and has already produced a large volume of evidence." He adds that the Society will be responding to this week's consultation document and has been invited to participate in seminars to be held next year (see Panel below).

PROFESSIONAL RESTRICTIONS

Should the number of pharmacies that handle CDs be limited? This is one suggestion made in the document. If the number is limited then "inspection would be simplified and it would be easier to arrange for the destruction of out-of-date or returned drugs". Other potential benefits include making arrangements for delivery and supervised consumption easier.

So the paper asks: "Should all pharmacies continue to be allowed and required to dispense CDs? Or should this be confined to specialist pharmacies?" Further clarification is needed over the need for an out-of-hours service, a delivery service and supervised consumption.

Doctors could face similar restrictions. Although the inquiry does not advocate prohibiting the prescribing of diamorphine, it suggests that some limit could be placed on who can prescribe CDs. For example, doctors might have to be licensed to be able to prescribe a CD or perhaps only a patient's own general practitioner could prescribe a CD for them. However, the inquiry will not "suggest any changes to the more limited freedom to prescribe for addiction".

The inquiry also questions dispensing doctors' right to both prescribe and dispense CDs and asks if a policy shift to encourage more community pharmacies in rural areas would reduce the need for doctors to provide dispensing services.

Prescriptions for CDs might also be changed. The Home Office is currently carrying out a consultation about whether computer-generated prescriptions and electronic registers for CDs should be allowed (see *PJ*, 31 May, p739). Yet the inquiry has a number of questions about prescriptions for CDs, including whether computer-generated prescriptions should be permitted or encouraged. Furthermore, it wonders if CD prescriptions should be transmitted electronically.

The inquiry suggests the following potential requirements for CD prescriptions:

- The time, as well as date, to be recorded on the prescription
- The professional registration number and profession of the prescriber to be indicated on the prescription
- A limit on the period covered by the prescription
- A limit to the amount of a particular CD that can be prescribed on one occasion
- Reducing the time a prescription is valid for (currently 13 weeks), perhaps to seven or 14 days
- An indication of the medical condition for which the CD is prescribed

Other considerations include relaxing the rules on making alterations to handwritten prescriptions (although with alternative safeguards) and writing private prescriptions for CDs on the same forms as NHS prescriptions.

A COMPLETE AUDIT TRAIL

The paper highlights a lack of a "satisfactory audit trail" of CDs from manufacturer to patient. The weakness is between the pharmacy and patient. It is not the pharmacist's fault: there is no requirement to record who collects a CD from the pharmacy. But perhaps this is something that might improve the security of the current system. So the paper asks:

- Should the pharmacist be required to record and obtain some proof of the identity of the person collecting CDs and evidence that he or she is authorised to do so? What level of identification is appropriate?
- What identification should be required of a doctor requesting drugs on requisition or emergency supply?

One of the reasons Shipman was able to obtain large quantities of CDs is that he collected supplies from the pharmacy, on the pretence that it was on behalf of a patient when he was actually retaining them for his own purposes. Should doctors be prohibited from collecting patients' supplies or are new safeguards needed instead? One suggestion is for senior colleagues to be aware of the professional's intention to collect a CD on behalf of a patient.

A possible way to improve the audit trail would be to introduce bar coding of all CDs. The Prescription Pricing Authority and NHS Information Authority are currently working on increasing the use of coding and these developments could be used for CDs.

Better use of computer technology could also improve the audit trail. An electronic CD register could make record keep-

How to respond

Comments are invited on the topics outlined in "The use and monitoring of Controlled Drugs in the community", published this week by the Shipman Inquiry. The document is available on the inquiry's website at www.the-shipman-inquiry.org.uk and the closing date for comments is Friday 26 September.

Responses will be posted on the inquiry's website and will be used to inform discussion at the seminars to be held in January in Manchester.

Written responses and the seminar discussions will be considered by Dame Janet Smith, the chairman of the inquiry, in making her final recommendations for change.

ing easier for pharmacists. Other possible advantages include being able to integrate information sent by or shared with wholesalers or manufacturers. If prescriptions were also in an electronic form then details could be directly transferred to the CD register from the prescription. Such technological improvements in communication could allow pharmacists to transfer information back to the prescriber about when a CD had been dispensed. An electronic CD register also opens the door to making remote inspections of registers possible, and the paper asks whether this is a good idea.

The inquiry also highlights wider access to patient records and invites comments on how integration of records via NHSnet could improve the prescribing and dispensing of CDs, including whether the system should allow pharmacists access to the patient's CD history.

Possible modifications to the CD register are also suggested. Perhaps it should contain a running balance, record the identity of the person collecting the medicine, record the professional registration number of the prescriber, and identify the pharmacist responsible for dispensing the drug. Another possible change is the time for which CD registers have to be retained and the document asks for suggestions as to what period would be appropriate.

COLLECTION OF CDs

At the moment, no requirement exists to give patients, or their representatives collecting a CD on their behalf, specific guidance about the storage and disposal of the drug. Some pharmacists give information but not all. "Should an explanatory leaflet be handed out with each CD prescription, explaining the key issues relating to CDs and emphasising the need for safe storage and disposal," the paper asks. Furthermore, it wonders whether pharmacists should be under a professional duty to explain to the person collecting the supply about the potential for abuse and the need to keep the CDs safe. Should the person collecting the items have to:

- Sign the prescription or the pharmacist's records to acknowledge receipt of the drug?
- State that he or she will not pass the CDs on to a third party and that the drugs are for the patient's consumption only?
- Acknowledge his or her duty to keep the drugs safe?

Under the current system, no record is kept of what happens to a CD after it leaves the pharmacy. Is it time for all CDs to be dispensed with some sort of documentation? "In the case of CDs which are to be administered by a health professional, should a continuing record be kept of the transfer, administration and disposal of CDs once they have been dispensed by the pharmacist," the document asks. Such a card could be completed by the relevant professional when they administer a dose of the drug. Whether or not information from the card should be added to patient's records or on a central register on the NHSnet needs to be debated.

This type of card system could allow an audit trail to track the CD to an end point: either when all the supply has been used and the card is completed, or when any unused supplies are returned to the pharmacy.

Which brings the subject round to disposal of waste. When a CD is dispensed it becomes the property of the patient (or the patient's estate after death) and there are no requirements on patients to dispose of CDs in a particular way. Some people do return unused CDs to pharmacies but at present the destruction of patient-returned medicines does not need to be witnessed.

The paper asks what arrangements are needed to enable unwanted CDs to be returned to safe custody. Should primary care trusts (PCTs) be required to take possession of CDs following a patient's death?

It also asks what is the best way to approach the destruction of CDs. "Who should be authorised to witness such destruction?" And "is it desirable or practicable that there should be a uniform method of denaturing and disposal and what should this be?" In addition, the paper questions whether the current distinction between out-of-date and patient-returned CDs should be maintained.

There is also a question around double checking of administration or destruction of CDs and whether it should be a requirement for either process to be witnessed by two health professionals.

INSPECTIONS

Community pharmacies are inspected regularly: both CD registers and security of drug storage are assessed. Meanwhile routine inspection of doctors' practices is not undertaken and many doctors have never had an inspection of their CD cabinet.

So for pharmacies, the paper asks whether the current arrangements should continue or whether alternatives are needed. Should police officers carry out inspections in the future or should this be transferred to other people? And if so,

which organisation should be responsible for these inspections? The paper also asks if there should be routine inspection of doctors' surgeries and, if so, by whom. It suggests PCT medical or pharmaceutical officers, Royal Pharmaceutical Society inspectors or Home Office inspectors as possibilities.

Issues also surround the purpose of an inspection visit. Who should examine CD registers to look for patterns of irresponsible or concerning prescribing? And how should information gained from pharmacy inspections be combined with information about a prescriber? Should the inspecting authority have access to a doctor's history of prescribing CDs?

CHANGE

Many questions have been asked by the Shipman Inquiry and more will be raised in the subsequent debate. This gives some idea of just how much change pharmacists should expect. The detail of the changes will not be known until next year but it is clear that the impact will be felt by all community pharmacists.

The Shipman Inquiry

The Shipman Inquiry is divided into two phases. The first phase examined how many patients Shipman killed and how he did it. The second phase looks at wider issues:

- Stage one: Police investigation
- Stage two: Death and cremation certification
- Stage three: Controlled Drugs
- Stage four: Monitoring and disciplinary systems and complaints

Oral evidence on Controlled Drugs has been heard by the inquiry and seminars will follow in January 2004.