New CD regulations will not obstruct “another Shipman” who intends to kill

In this article, Cathal Gallagher argues that the Shipman Inquiry has failed to close the loopholes in the regulation of Controlled Drugs used by Shipman. Inherent in the work of doctors is a level of trust, he says, and it is still possible for GPs to divert CDs for nefarious purposes.

It is now over 18 months since the fourth report of the Shipman Inquiry, examining the regulation of Controlled Drugs in the community, was published. It sought to address how, over the course of 20 years, Shipman acquired the large quantities of diamorphine that he used to kill over 200 patients. Despite the regulatory controls in place, Shipman’s diversion of diamorphine went undetected. When it eventually came to light, it was not because his unlawful acquisition of the drug had been detected, but because he had come under suspicion of murdering Kathleen Grundy. The report made apparent that the regulatory framework governing the use of CDs had not operated as it should. The purpose of regulation, according to the report, is to ensure accountability for the use of CDs, so as to avoid their diversion to improper use, and to detect such diversion if it occurs.

Regulation had, obviously, failed in this case. The terms of reference of the inquiry required Dame Janet Smith to “examine the actions of those involved in the operation of these arrangements and to recommend changes that would lead to the better protection of patients in future”.1 Now that legislators have had a chance to digest the contents of, and act upon, the recommendations of the Shipman Inquiry, it is timely to discuss, with particular reference to the fourth report, the key changes recommended and the extent to which the recommendations have passed into current law on CDs. Furthermore, an analysis of how effective the changes will be in achieving the principal objective of the inquiry — to protect patients in the future from “another Shipman” — is now warranted.

To gauge accurately the effectiveness of the Shipman Inquiry, it will be necessary to identify the key recommendations of the inquiry, and assess whether each of these recommendations complies with the principal objective of the inquiry, namely, “to establish what changes to current systems should be made in order to safeguard patients [from a recurrence of these events] in the future”.2 If the recommendations are not consistent with the primary remit of the inquiry, it will be useful to identify any other mischiefs that they correct, and whether these provide any benefit for patients or health care professionals. To establish if a change of the regulations relating to CDs will help prevent “another Shipman”, a good starting point is to examine the illegal activities, most specifically those relating to the diversion of CDs, carried out by the original offender.

Shipman’s methods of obtaining CDs

Shipman obtained his supplies of pethidine and diamorphine from community pharmacies. It was not possible for the inquiry to find out exactly how he obtained his supplies of CDs during the late 1970s and the 1980s, because the relevant pharmacy records and prescription forms from that period have long

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since been destroyed. Records from the 1990s, however, were still available at the time of the inquiry, giving an insight into Shipman's methods. After a cancer patient had died, he would, if he had the chance, take any unused drugs for himself, telling whoever was present that he was doing so for the purpose of destroying them. To any observer this behaviour would seem legal, consistent with the (current) Misuse of Drugs Regulations 2001, as well as those in force at the time. On at least one occasion in the 1990s, he prescribed a large quantity of diamorphine for a patient who died on the same day; he collected the drugs and kept them for himself. None of these methods of obtaining was likely to lead to detection, because the patients were genuinely suffering from cancer and the prescriptions were all properly made out. Each dispensing would be recorded in the CD Register at the pharmacy. Although the quantity of the drug prescribed was often large, this would be quite plausible in the case of a patient in the final stages of terminal illness.

However, between February and August 1993, Shipman wrote 14 prescriptions for a single 30mg ampoule of diamorphine. The prescriptions were in the names of 13 different patients. This gave the CD Register of the pharmacy that dispensed these drugs a most unusual appearance, one that perhaps should have given the pharmacist, who dispensed all but one of these single ampoules, cause for alarm. Drilling down into the attention of the Greater Manchester Police.

Although Dame Janet found it to be reasonable for the pharmacist to assume that the doctor would give the patient an appropriate dose, and that she might be reasonably satisfied that the patient would not come to harm, the pharmacist still had a duty to prevent the supply of unnecessary and excessive quantities of medicines.

Areas where change needed identified
An analysis of Shipman's activities directed attention to five major areas of the CD regulations that warranted changes. These areas were:

- Handwriting requirements for controlled drug prescriptions
- CD registers for GPs and pharmacies
- Post-dispensing regulation of CDs
- Supervision of CD administration
- Restrictions of prescribing rights

Here, each of these areas will be discussed in turn, as will some of the more notable areas of omission, including the possession of CDs for the purpose of destruction.

Handwritten prescriptions: At the time of publication of the report, all prescriptions for CDs other than those specified in Schedules 4 or 5, were required to be handwritten, in accordance with the Misuse of Drugs Regulations 2001. The main disadvantage of handwritten prescriptions was identified by the inquiry as the higher incidence of errors that occur than when they are generated by computer. To remedy this, it was suggested that the printing of prescribing information onto the prescription form and subsequent writing of it again in the space between the lines, should be adopted more widely, not as a legal requirement but as a matter of good practice. The inquiry found that the introduction of computer-generated prescriptions for all CDs would bring significant advantages by reducing errors and facilitating monitoring. Following the inquiry, the Regulations were amended to allow full details on prescriptions for Schedule 2 and 3 CDs, apart from the signature, to be generated by computer. The recommendation regarding inclusion of both handwritten and printed information was not carried through into law, nor indeed to the General Medical Council’s good practice regulations which in have not been updated since May 2001, despite the ease with which this could have been effected.

Although the introduction of computer-generated prescriptions for CDs, integrated with computerised systems of record-keeping for producers, wholesalers and pharmacists, may provide a more tangible audit trail, this is achieved only by virtue of the secure storage potential of computer-generated data. There has been no amendment to the Regulations that compels any party to retain the prescription, or any record of it, beyond the periods that have already been in place. This omission, and its possible remedy, is discussed below under “CD registers for pharmacies”.

CD registers for pharmacies: Post-Shipman, the definition of a CD register has been amended to make it permissible to maintain a computerised CD register provided that every computerised entry can be attributed to an author and is capable of being audited. In effect, this means that it must not be possible to alter entries at a later date, and that a log of all data entered is kept and can be recalled. Above any other single factor, it was the absence of control after dispensing that enabled Shipman to obtain diamorphine illicitly and to avoid notice. Shipman was able to divert supplies of diamorphine to his own use by presenting a prescription he had issued, collecting the drugs and removing part of the consignment before delivering it to the patient’s home. Additionally, diamorphine that he obtained for the purpose of destruction was also diverted. The inquiry found that it would be beneficial to formalise the arrangements for the destruction of all Schedule 2 CDs at the home of a deceased patient. It was suggested that this could be achieved by the issuing of a post-dispensing record card (PDR C) with each CD, on which administration and destruction could be recorded.

The inquiry failed to dismiss the PDR C system as toothless in its goal of preventing “another Shipman”, despite the fact it “would not detect a doctor who issued a prescription for a CD, presented it at a different pharmacy from the one usually used by the patient’s family, collected the drugs and kept the whole consignment for [himself]” — mirroring almost exactly Shipman’s own activities.

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PDR C system has, at the time of writing, not been addressed by any amendments to existing CD R egulations, nor has it been included in any professional guidance produced by either the GMC or the Royal Pharmaceutical Society.

Not considered in the inquiry’s examination was the introduction of a register for recording the receipt of CDs for the purpose of destruction, or at least the inclusion of CDs obtained in this way in the protocols laid out in the M isuse of Drugs R egulations 2001. Although it would be wholly impractical for GPs who are not routinely in possession of a stock of Schedule 2 drugs to maintain a CD register, more stringent protocols for circumstances when they come into possession of CDs for the purpose of destruction should be applied. Although by no means a complete solution, the application of R egulation 27(3), which at present does not apply to CDs obtained in this manner, would make it most difficult for someone like Shipman to divert CDs obtained in the presence of a colleague. Additionally, such a measure could be easily applied by a simple revocation of R egulation 27(6) of the 2001 amendment to the Act. There can be no doubt that, in the right circumstances, measures such as those outlined above could prevent the diversion of CDs from their intended destination. However, in instances where a GP or district nurse is working without the supervision of a colleague, these measures could quite easily be subverted, as could the suggested PDR C protocols. A record in a PDR C does not necessarily correspond to the administration of a drug, but rather to its alleged administration.

Double checking of CD administration

The inquiry heard evidence that, since the discovery of Shipman’s crimes, a rule has been introduced in Tameside whereby CDs are administered by two health care professionals rather than one. This is the only sure-fire way to prevent diversion of CDs and their inappropriate administration to patients. However, it would be wholly impractical to apply such a system to doctors visiting patients out of hours, and would result in terminally and chronically ill patients being left in pain. On this point, the inquiry found that the adverse resource implications of double checking would far outweigh any possible advantage in reducing the risk of diversion of the drugs. This highlights the inherent weakness in the inquiry’s findings, namely, that there is a level of trust inherent in the work of health care professionals, not least doctors. They are imparted, through education and experience, with a level of knowledge of disease and the human condition that is almost always addicts, often trying to obtain supplies of CDs from more than one prescriber. As such, their professional activities cannot be policed by the omnipus commuter, since he does not have sufficient knowledge of how these activities should be properly carried out. Although the GMC and the N HS do police the professional conduct of doctors on a macroscopic scale, the only body who can regulate their day-to-day practices are, perhaps unfortunately, themselves as individuals. As the opening of two new medical schools since 2002 and the introduction of graduate-entry medical degrees at existing schools demonstrates, there is a chronic shortage of doctors practicing in the U.K. The introduction of an additional policing role would only serve to further stretch the (already strained) system.

Restriction of prescribing rights

At present, every registered medical practitioner is entitled to prescribe prescription only drugs, including CDs, unless he is subject to some specific restriction. The inquiry noted that some doctors, such as those employed in, or even retired from, a purely administrative post, prescribe CDs on an occasional basis although they have no list of patients. It concluded that doctors should be entitled to prescribe or administer CDs only if they need to do so for the purposes of the “actual clinical practice” in which they are engaged.

In 1999, a recommendation made in the Crown R eview to extend prescribing powers to supplementary prescribers was published. This suggested that once a doctor or dentist had diagnosed a patient’s condition, a clinical management plan could be set up in agreement with the patient, which would enable responsibility for that patient’s care to be passed to another health professional, namely, a nurse practitioner or pharmacist. On 4 April 2003, amendments made by the D epartment of H ealth to the Prescription Only Medicines (Human Use) O rder 1997 allowed supplementary prescribers to come into force for medicines other than CDs. Furthermore, the amendments made by the M isuse of Drugs (A mendment) R egulations 2005 enabled supplementary prescribers to administer, supply and give directions for the administration of certain CDs under, and in accordance with, the terms of a clinical management plan, and enable other persons to administer certain CDs in accordance with the directions of such a supplementary prescriber.

Notwithstanding that any restriction in prescribing rights flies in the face of health care policy, which is geared towards increasing the number of health care professionals who can legally prescribe, Shipman himself was involved in “actual clinical practice”, and would not, if he were still practising today, be subject to any such restrictions.

Dame Janet recognised that some patients, almost always addicts, often try to obtain supplies of CDs from more than one prescriber concurrently, a practice known among health care professionals as “double scripting”. She further recognised that the nomination of one GP to be responsible for the care of a patient receiving CDs would assist in the prevention and detection of “double scripting”. However, her recommendations in this matter do not relate to the principal objective of the inquiry, which was to protect patients from “another Shipman”. Again, the point that Shipman was a practising GP, and that his victims were patients on his list, is ignored by the report.

Planned legislation

New arrangements for supplying CDs were introduced on 1 April 2006. Although, initially, they were unenforceable due to a lack of statutory backing, pharmacists were expected to adopt the new system by the R oyal Pharmaceutical Society. The M isuse of Drugs (A mendment) N o 2) R egulations came into force on 7 July 2006 (with the exception of regulations concerning the new format for CD registers, which will become a legal requirement in January 2007), giving pharmacists a legal incentive to work harder with little gain in public safety. A new N HS pre-
Prescription Pricing Authority on a monthly to forward copies of all dispensed CD pre-
when combined with plans for pharmacists will strengthen the CD audit trail, especially
trust. Undoubtedly, these new regulations amorphine from seemingly legitimate
Shipman obtained most of his stock of di-
Health has, again, failed to recognise that obtain illicit drugs in this manner will cer-
more difficult for CD prescriptions to be CD registers.
A note of this fact must be recorded in their
Schedule 2 CDs. If they do not, as discretion of identification from anyone collecting
CDs will be expected to request some form
forms, on which all non-NHS prescriptions was de-
CDs, began to be phased in from early April
completed. Additionally, new private prescription as circulated stocks of old forms were de-
the patient or the patient's representative, whether evidence of identity was requested
person who collected the drug was (legally) in possession into the register whether the person who collected the drug was the patient, the patient's representative or a health care professional acting on behalf of the patient and (i) if the
whether different drugs or strengths of drugs comprised within the class of drugs to which
regarding the use of a separate section within a register or separate part of a register in respect of different drugs or strengths of drugs comprised within the class of drugs to which that register or separate part relates.

The Misuse of Drugs (Amendment) Regulations 2005 (Reg 27[3]): Nothing in paragraph (1) or (3) shall apply to the destruction of a drug which has been supplied to a practitioner or pharmacist for that purpose in pursuance of regulation 6(2) or (3).

The Misuse of Drugs Regulations 2001 (Reg 21[3]): Nothing in paragraph (1) or (3) shall be preserved for a period of two years from the date on which the last entry therein is made.

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The Misuse of Drugs (Amendment) Regulations 2005 (Reg 27[1]): Nothing in paragraph (1) or (3) shall apply to the destruction of a drug which has been supplied to a practitioner or pharmacist for that purpose in pursuance of regulation 6(2) or (3).

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18. Ibid. Chapter 14, Section 251.
19. Ibid. Chapter 14, Section 234.
20. Misuse of Drugs Regulations 2001 (Reg 21[3]): Nothing in paragraph (1) or (3) shall apply to the destruction of a drug which has been supplied to a practitioner or pharmacist for that purpose in pursuance of regulation 6(2) or (3).
22. Ibid., Chapter 14, Section 236.
23. McGuire v. Western Morning News [1903] 2 KB 100.
25. Ibid. Chapter 14, Section 14.
28. The Misuse of Drugs (Amendment) Regulations 2005 (Reg 2[6]).
29. The Misuse of Drugs (Amendment) Regulations 2005 (Reg 27[1]).
32. Ibid. Chapter 14, Section 36.
33. Currently, such prescriptions are valid for 12 weeks after the date specified in the prescription — The Misuse of Drugs Regulations 2001 (Reg 16).