CHAPTER EIGHT

Controlled Drugs in the Community

Introduction

8.1 In the preceding Chapters, I have examined the Regulations governing the prescribing and dispensing of controlled drugs. When controlled drugs are dispensed at a community pharmacy, the person who collects them is not normally required to provide his/her name or address and, consequently, no record is made of such information. Once a controlled drug has been dispensed and any necessary entries made in the controlled drugs register (CDR) (or, in some cases, in the private prescriptions book), there is no legal requirement to keep any further record of any kind. In most cases, therefore, any possible audit trail ceases at the time of dispensing. There is an exception to this general rule in that there are record keeping and custody requirements in relation to controlled drugs prescribed to patients living in a care home. I shall refer to them again later in this Chapter.

8.2 Apart from cases in which a patient is living in a care home, there are two types of situation in which a record is commonly made in relation to a controlled drug after dispensing. In these cases, the records are made, not in order to comply with a legal duty, but as a matter of good practice or to comply with advice or instructions given by an employer or a professional association. First, a district nurse will keep a record, on a patient drug record card (PDRC), of controlled drugs administered through syringe drivers by him/her to a patient in accordance with the instructions given by a doctor on the prescription, and will also make a record of any controlled drug that s/he destroys after a patient's death. He or she will do so to comply with his/her professional duty and, probably also, with the instructions of his/her employer. Second, a general practitioner (GP) or pharmacist might make a record of the destruction of controlled drugs returned to him/her for the purpose of destruction. Pharmacists are advised to do so by the Royal Pharmaceutical Society of Great Britain. Many doctors and pharmacists ask a colleague to witness the destruction of controlled drugs. However, there is no legal obligation to do so; the drugs can be destroyed without any formality.

8.3 The position of a district nurse is to be contrasted with that of a community midwife who keeps a supply of controlled drugs for administration to patients during childbirth. Regulation 21 of the Misuse of Drugs Regulations 2001 imposes specific record keeping requirements on midwives. They have to keep a book for recording the details of any Schedule 2 drugs obtained; the details include the date, the name and address of the supplier and the amount and form of the drug obtained. On administering such a drug to a patient, the midwife must enter, as soon as practicable, the name and address of the patient, the amount administered and the form in which the drug was administered.

The Administration of Controlled Drugs by District Nurses

8.4 For many years, district nurses have administered controlled drugs to patients suffering severe pain in the course of a terminal illness. Until recent years, it was common for a patient to take an oral preparation, containing an opioid analgesic, sometimes known as

the Brompton mixture or Brompton cocktail. If this became insufficient, a doctor or district nurse would give periodic injections of diamorphine. Nowadays, methods of pain control are much improved. Initially, the pain will be controlled by the ingestion of a slow release tablet containing morphine sulphate, or by the application of a fentanyl patch, which allows the gradual absorption of fentanyl, an opioid analgesic. District nurses are not usually involved in the patient's daily care at this stage. However, when these measures become insufficient, and the patient needs stronger analgesia, the most usual solution is the provision of a syringe driver. A syringe driver is a portable battery-operated pump. Over a 24 hour period, it ensures the gradual release of diamorphine, administered in combination with an anti-sickness drug. Usually, by this stage, the patient will require general nursing care; the district nurse will set up the syringe driver and will refill the syringe each day, in accordance with the doctor's instructions as to dosage.

8.5 The introduction of syringe drivers has enabled terminally ill patients who choose to be nursed at home, rather than in a hospital or a hospice, to remain at home in far greater comfort than previously. The syringe driver avoids the soreness associated with repeated injections and achieves a steady flow of analgesia. According to Mr Ian Hargreaves, retired Regional Director of the Royal College of Nursing (RCN), adequate pain control was often not achieved prior to the introduction of syringe drivers. In his view, it is impossible to overstate their value. In Tameside, the first syringe drivers were purchased in 1993. The evidence before the Inquiry suggests that their use is increasing.

8.6 It is often necessary for a patient with terminal cancer to be given quite large amounts of diamorphine through a syringe driver. Not only will the pain worsen, but the patient will become habituated to the drug and increasing amounts will be required to provide adequate relief. Large quantities are prescribed and are usually collected by a relative or carer and kept at the patient's home. Sometimes, particularly if a patient is being cared for by an elderly person, it may be difficult for the carer to go to a pharmacy. In such circumstances, GPs and district nurses will sometimes collect medication from the pharmacy as an act of kindness.

8.7 After the drug has been brought to the house, the district nurse will enter the amount into the receipt column of the PDRC. The dosage, as authorised by the doctor, is entered on the card and signed by the doctor. Any alteration to the dosage is recorded by the doctor during a visit. This provides the nurse's authority to administer the drug. The nurse will keep a continuous record of drugs received and administered, including a running balance of stocks held at the house.

The District Nurses in Tameside

8.8 Mrs Diane Nuttall, Directorate Manager of the Community Care Directorate of the Tameside and Glossop Primary Care Trust (T&G PCT), successor body to Tameside and Glossop Community and Priority Services NHS Trust (T&G CPST), described the district nursing service as it is provided in Tameside. About 120 persons are employed; some are qualified district nurses, some are registered nurses and some are care assistants. They operate from 14 bases in the Tameside area with teams of between five and seven nurses working from each base. They provide a service seven days a week. The general role of

district nurses is to ensure that patients of their allocated GP obtain all necessary nursing assessments and nursing care. This, of course, includes palliative care for terminally ill patients living at home.

8.9 In 1995, Shipman joined a fundholding consortium of small general practices, known as the Tameside Consortium, which negotiated an arrangement whereby district nurses based at a clinic in Dukinfield were allocated to serve the patients of members of the Consortium. From April 1995, Shipman's patients were attended by Mrs Marion Gilchrist, who became the 'named nurse' for his practice. Mrs Gilchrist had qualified as a registered general nurse in 1974, and had begun working for the T&G CPST in 1990 as a relief district nursing sister. She worked as a district nurse until her promotion to district team leader in 1998 and became a senior district nurse in September 2001. When Mrs Gilchrist was on holiday or otherwise unavailable, other nurses would cover for her and visit her patients.

8.10 Mrs Gilchrist gave oral evidence to the Inquiry. Understandably, this was a distressing experience for her, given the close working relationship she had once enjoyed with Shipman. Mrs Gilchrist used to meet Shipman weekly to discuss those patients of his whom she was responsible for nursing. She held him in high regard. According to her, he seemed to know all his patients and their extended families. She had the impression that he really cared about them. She felt that he was an 'old-fashioned' GP, which she clearly intended as a compliment. She said that he treated her as a fellow professional and listened to her ideas and suggestions. He made her feel a valued member of the team. From 1995, Mrs Gilchrist was responsible for setting up and replenishing syringe drivers for Shipman's patients. She said that Shipman seemed to be more interested than other doctors in the care of his terminally ill patients. He visited them more frequently and was more willing than other doctors to prescribe diamorphine.

Shipman's Diversion of Diamorphine Prescribed for Use in Syringe Drivers

8.11 As I have explained in Chapter One, Shipman sometimes collected drugs from a pharmacy, ostensibly out of kindness to the patient's family, but in fact to give himself an opportunity to steal some or all of the patient's drugs. He well knew that, if he prescribed the drug, presented the prescription for dispensing and then delivered the drug, no one would notice if he delivered an amount smaller than he had prescribed. He did this on several occasions. For example, on 3rd July 1997, Shipman prescribed 2300mg diamorphine for Mrs Maureen Jackson; he delivered only 1500mg to her house. Mrs Gilchrist entered the amount of 1500mg on the 'receipt' side of the PDRC; she had no means of knowing that a larger amount had been prescribed and dispensed.

8.12 On other occasions, Shipman attended at a patient's house soon after the patient had died and took possession of the unused stock of diamorphine, saying that he would destroy it. For example, he did this in the case of Mr Raymond Jones in 1993, and in the case of Mr James Arrandale in 1995. Sometimes, he would make a note on the PDRC, to the effect that he had taken the drug for destruction. Provided that the deceased's family consented, as they did, he appeared to be acting lawfully. It never occurred to Mrs Gilchrist that Shipman might be doing wrong. In fact, he was acting unlawfully, because the law allowed

him to take the drug for destruction, not to keep it for himself. However, his intentions remained secret and his failure to destroy the drug was not detected.

8.13 On one occasion, in 1998, Mrs Gilchrist had occasion to question Shipman about the amount of diamorphine in stock at the home of a patient, Mr John Henshall, who was suffering from cancer and had a syringe driver. On Monday, 6th July 1998, Mrs Gilchrist found that there was a difference between the stock balance, in which Shipman had made the last entry, and the actual stock. There was a deficit of five 10mg ampoules. Mrs Gilchrist asked Shipman about this. At first, he suggested that the PDRC was correct and sought to explain why this was so. Mrs Gilchrist could not understand his explanation and began to feel foolish. However, she asked him specifically about the five 10mg ampoules and he then said that he had given them to a colleague from whom he had previously borrowed a similar quantity of the drug. Mrs Gilchrist accepted this explanation. She thought Shipman's practice in this respect was poor, but she did not for a moment think that Shipman had stolen the drug, as I am sure he had. Nor did she think seriously about reporting him. In that respect, she behaved differently towards a doctor from the way in which she would have behaved to a nursing colleague. She told the Inquiry that, had a nursing colleague 'borrowed' and 'repaid' a controlled drug, she would have made a report to her employers. Following Shipman's arrest, Mrs Gilchrist's failure to report Shipman's unorthodox practice to her employers was 'noted' on her personnel records. This was a minor form of disciplinary action. She was advised that she had failed to comply with her employer's policy that all such irregularities should be reported. I have no doubt that this policy is correct and that it is important that all irregularities should be reported. However, in the context of Mrs Gilchrist's working relationship with Shipman, I find it wholly understandable that she did not report him to her employer. By this time, Shipman had already killed his last victim.

Attempts to Improve the System of Control in Tameside

8.14 Shipman exploited to the full the lack of any regulation of controlled drugs after dispensing. Since his activities came to light, those with responsibility for the district nursing service in Tameside have sought to devise ways of improving their procedures in the hope of deterring or detecting any possible repetition of Shipman's conduct.

Conveying Controlled Drugs to a Patient's Home

8.15 As I have said, it is usual for drugs for use in a syringe driver to be collected from a community pharmacy by a relative or carer of the patient. However, this is not always possible. Some pharmacies offer a delivery service, but not all. On occasions, the healthcare professionals caring for the patient may perceive a need to collect the drugs from the pharmacy. Mrs Gilchrist explained that such a need arises most often in the case of elderly couples, without friends or family able to assist, where the spouse of the patient is unable to drive.

8.16 Mr Hargreaves told the Inquiry that most primary care trusts (PCTs) have a policy that district nurses should not collect medicines of any description for their patients; the prohibition applies particularly to controlled drugs. The T&G CPST had such a policy

during the 1990s. However, it appears that, from time to time, the district nurses 'bent the rules' in cases where they felt that it was necessary, for the welfare of patients, for them to collect medication. Recently, the policy has been formally relaxed, as the result of pressure from the district nurses. The policy now recognises that, in exceptional circumstances, it will be acceptable for a nurse to collect controlled drugs, provided that prior notice is given by the district nurse to a senior staff member. The present policy is that:

> **'... where there is an urgent need for medication and every avenue for delivery and collection has been explored to no avail, a Registered Nurse may contact his/her manager or senior nurse on duty and may subsequently carry medication from the community pharmacy directly to the patient's home'**.

8.17 I can see no objection to this practice, provided it remains the exception rather than the rule. It seems to me that the safeguard imposed by the Tameside policy is a sensible one. It protects the district nurse from possible criticism and permits the employing trust to supervise its employees. However, in my view, a more important general safeguard would be a requirement that the pharmacist should record in the CDR the name of any healthcare professional who collects Schedule 2 controlled drugs on behalf of a patient.

The Patient Drug Record Card

8.18 I have already explained that the PDRC contains the doctor's authority for the district nurses to administer the drug prescribed. The primary purpose of the PDRC, which has equivalents in hospital practice, is clinical. It exists to ensure that a proper record of drug administration is maintained. It is not primarily intended to provide a record of the movement of drugs for audit purposes. Nor is its purpose the recording of the disposal or destruction of a controlled drug, although it is sometimes used to that end.

8.19 The version of the PDRC in use in Tameside during Shipman's time contained spaces for recording the identities of the patient, the GP and the district nurse. It also contained a number of columns and rows for the recording of the nature and amount of drug obtained and the amount administered. It required the administering nurse to sign each entry and to record the stock balance following each administration. GPs would not usually administer the drug. The only entries that a GP would usually make related to the dosage as initially directed and as subsequently revised. The PDRC contained no space specifically designated for the recording of this information.

8.20 In the light of the lessons learned since the discovery of Shipman's crimes, a revised version of the PDRC has been introduced in Tameside. One face of the card is intended exclusively for completion by the GP and specifically provides for entries covering the dosage, frequency and route of administration of the drug prescribed. The other face, for use by the district nurse, is in the same format as the old card. The new PDRC is plainly an improvement. However, there is still no system by which anyone can check that the amount of the drug dispensed by the pharmacy is the same as the amount entered on the PDRC. A doctor could still perpetrate the deception employed by Shipman in, for example, the case of Mrs Jackson. Mrs Nuttall told the Inquiry that the district nurses in

Tameside would welcome a document issued by the dispensing pharmacist that recorded what had been dispensed so that they could be sure that each entry on the acquisition side of the card reflected what had left the pharmacy.

8.21 At the moment, following the patient's death or following cessation of district nurse involvement, PDRCs are archived by the T&G PCT. They are not 'married up' with the GP or pharmacy records. Nor, until recently, was there any audit or review of their contents. Mrs Nuttall explained that samples of PDRCs are now reviewed for legibility and accuracy and 'benchmarked' against records provided by other trusts. She said that an audit of every PDRC would be feasible and that it might well be worth giving consideration to reviewing every PDRC.

8.22 Mr Hargreaves, on behalf of the RCN, made the suggestion that a new drug administration record card could be opened by the dispensing pharmacist and could accompany every supply of the drug to the patient's home. That arrangement would deter anyone from removing part of the consignment. Administrations of the drug would then be entered onto the card until either the drug was exhausted or the patient died. If there were unused drugs after death, the destruction of the excess would have to be entered on the card and witnessed by another healthcare professional. Used cards could be reviewed by an officer of the PCT and, if all was found to be in order, could be 'married up' with the patient's medical records. In this way, the cards could provide a complete audit trail for the drugs, and the patient's medical records would be complete in this important respect.

8.23 Under this system, it would not be permissible for a doctor to remove controlled drugs from the patient's house; they would have to be destroyed in the presence of another healthcare professional and the destruction recorded. Even if the rule permitting a doctor to take drugs away with him/her for destruction were to be retained, a record that s/he had done so would be useful. A review of comments written by Shipman on the PDRCs kept for some of his patients would have given rise to concern. For example, the mutually inconsistent entries that he made on the PDRC of Mr Keith Harrison, saying **'All Drugs Destroyed'** and **'returned to Chemist for destruction'**, might have been queried.

8.24 I shall consider the RCN's suggestion further in Chapter Fourteen. It may provide a useful additional safeguard, at least in connection with injectable drugs such as diamorphine, which are usually administered by a doctor or district nurse. I do not think it would be practicable in the case of other controlled drugs that are usually administered by the patient or a carer.

The Administration of Controlled Drugs by a Single District Nurse

8.25 When considering Shipman's methods of diverting controlled drugs, the Inquiry also heard evidence that other healthcare professionals, such as nurses, are sometimes found to have committed offences of a similar kind. Some nurses fear accusations of misconduct of this type and feel vulnerable to possible criticism, even when behaving with complete integrity. In Tameside, the district nurses have suffered a deep sense of shock on learning that a doctor whom they trusted implicitly should have been so profoundly dishonest. It is entirely understandable that they should feel the need for additional procedures that will enable them to demonstrate that they have behaved properly.

8.26 The policy in hospitals used to be that, in the interests of patient safety, two nurses should be present at the administration of all drugs. The policy now applies only to controlled drugs, and the justification is no longer patient safety but the prevention of diversion. There has never been such a general rule in the district nursing service. In Tameside, such a policy has recently been introduced for both the administration and destruction of controlled drugs. I was told that the district nurses feel more secure operating in this way. I can understand why, given the particular sensitivities in Tameside, it has been thought appropriate to introduce such a requirement there. In most areas, however, there is no such policy.

8.27 Mrs Nuttall said that the adoption of this policy had had no adverse impact on human resources. The nurses planned their visits so that they could work in pairs when necessary. However, one of the district nurses, Mrs Barbara Sunderland, said that they would rarely otherwise work in pairs, and I cannot see how the imposition of such a restriction could fail to have significant resource implications. Certainly, the weight of opinion of those who contributed to the Inquiry's seminars was that it would have such implications. Given the shortage of nurses at the present time, it would seem to me that such a policy could be justified only if it had advantages for patient safety (for example, by reducing medication error), as well as providing a safeguard against diversion. Mr Hargreaves said that there was no evidence that attendance by two nurses did reduce medication error. It had been found that there was no significant increase in medication error when the policy in hospitals was abolished for drugs other than controlled drugs. While that might appear surprising, I can see that, when a nurse is routinely required to check a colleague's performance of a procedure, which will almost always be correctly carried out, s/he might well cease to give the process the attention required to provide a real check. Also, I can see how a nurse who knows that his/her procedures will always be checked might be less careful than one whose work is not routinely checked.

8.28 Finally, Mr Hargreaves explained that, in areas of dispersed population, it might be extremely difficult to achieve the implementation of such a policy. I can readily see that it might be wasteful of resources if two nurses had to travel long distances together, when the only purpose of the journey for one of them was to witness the work of the other.

Storage and Security

8.29 The exacting storage and security requirements that apply to controlled drugs in pharmacies are immediately relaxed when controlled drugs are released into the community. At first sight, this seems surprising and even alarming. I heard evidence that controlled drugs such as diamorphine are often kept on a table or in a cupboard in the room where the patient is being nursed. It may be said that this does not matter greatly because the quantities taken into the patient's home are much smaller than those stored in a pharmacy. I appreciate that a locked cabinet will not always be available in a patient's home although it might be worth considering the feasibility of providing one on loan to any patient for whom a syringe driver is supplied. I do accept that strict rules for the custody of controlled drugs in a patient's home would not be practicable or enforceable.

8.30 That said, it does appear to me that more could be done to educate patients and their relatives about the need to keep controlled drugs as securely as possible. I am sure that

most pharmacists advise patients or their relatives to keep such drugs out of the reach of children. However, I was concerned to hear that pharmacists do not usually explain that the drugs are vulnerable to misuse. Their justification is that they fear that patients might be worried by the responsibility they are taking on and might not use the drugs. I find this attitude rather condescending. I think that most patients and their families are capable of understanding that a drug which is appropriate to their particular needs might be a temptation or a danger to others, and that it should be looked after accordingly. I think that there is a need for greater frankness with patients and for a heightened awareness of the potential of such drugs for diversion.

The Destruction of Controlled Drugs after Death

The Legal Position

8.31 An unexpected issue arose in the course of the Inquiry's consideration of the various procedures adopted to dispose of unused controlled drugs following the death of the patient for whom they were prescribed. It concerned the right of a district nurse or doctor to remove drugs from a patient's home following the death. By virtue of the provisions of section 52 and section 58 of the Medicines Act 1968, the dispensing of pharmacy medicines and prescription only medicines (including controlled drugs) by a community pharmacist is regarded as a retail sale of the drug, even though the patient might not have paid for the drug, or even paid a contribution by way of prescription charge. The legal effect of the transaction is that the drug becomes the property of the patient. There are, of course, limitations on what the patient can do with a controlled drug; for example, s/he might commit a criminal offence if s/he supplied it to someone other than to a doctor or pharmacist for the purpose of destruction. However, if the patient dies, ownership of drugs passes to his/her estate. In the immediate post-death period, that will mean that the drugs become the property of the executor or the personal representative of the deceased. There are limitations also on what that person can lawfully do with the drugs; in practice, s/he can only give them to a doctor or pharmacist for destruction. If, however, that person leaves them in the deceased's house, it is doubtful whether s/he is committing any offence. He or she is, however, creating a risk that the drugs will find their way into the wrong hands.

8.32 In Tameside, the district nurses usually offer to destroy any excess diamorphine as this can easily be done within the home. The legality of this procedure is uncertain, as nurses (unlike doctors and pharmacists) do not have a statutory right to receive controlled drugs for the purpose of destruction. However, it is not unlawful for a district nurse (or indeed anyone) to destroy a controlled drug on behalf of the person legally entitled to its possession. The district nurses in Tameside find that the families of deceased patients are content for them to destroy excess drugs and I am sure that many wish this service to be performed on their behalf. Perhaps the niceties of the legal position do not greatly matter, as the executor or personal representative would not be able to make use of the drugs and it is plainly in the public interest that the drugs be destroyed as soon as possible. However, the district nurses cannot lawfully insist on destroying any excess controlled drugs, or on taking them away for destruction by a pharmacist, in the face of objection from the family. Mrs Kay Roberts, Lead Pharmacist for the Royal College of General Practitioners National

Drug Misuse Training Programme and pharmacist member of the Advisory Council on the Misuse of Drugs, explained how, in one case in Glasgow, difficulties were encountered by a district nurse where the offspring of a deceased patient were drug abusers.

8.33 The present legal situation is anomalous and unsatisfactory. This problem does not arise where drugs are provided to a patient in hospital because, in that situation, the drugs never become the property of the patient. I would urge that consideration be given to changing the law to avoid this potential difficulty. I will address the question in greater detail in Chapter Fourteen.

Practical Problems Connected with Disposal

8.34 It is clear that the informal arrangements relating to the destruction of unused controlled drugs are open to abuse by dishonest doctors, pharmacists or nurses. However, other, quite separate practical problems arise in connection with the disposal of controlled drugs. The Inquiry learned that doctors and pharmacists who are completely honest experience problems arising from the safe and secure disposal of such drugs. They would welcome an improved system, not necessarily imposing rules and regulations, but providing a method of safely discharging the responsibility that is put upon them when they receive 'patient returns'. District nurses are not under any legal responsibility to dispose of returned drugs but find themselves having to deal with the problem. The Department of Health acknowledges these problems and is considering whether to impose on PCTs a duty to establish a scheme for the secure collection and disposal of controlled drugs.

8.35 Following the death of a patient who has been nursed at home and who has used a syringe driver, the patient's GP is often called out to confirm that death has occurred and to certify its cause. That was the occasion that Shipman would exploit in order to take drugs away if, as was often the case, a district nurse was not present. As a general rule, doctors do not remove excess drugs unless specifically asked to do so by a member of the patient's family. More usually, the drugs will be dealt with by the district nurse who will attend, probably within 24 hours of the death, to dismantle and remove the syringe driver and possibly other items of equipment lent to the family for the patient's use. The district nurse will often deal with the excess drugs as part of his/her professional responsibility towards the patient.

8.36 District nurses do not always perform this service. The Association for Nurse Prescribing produced to the Inquiry the policy of one PCT that directs district nurses to advise patients' families to return unused controlled drugs to the dispensing pharmacy. Some NHS trusts advise district nurses not to accept drugs for return to the pharmacy in order to avoid accusations of diversion and to reduce the risk of attack.

8.37 In Tameside, district nurses are permitted to destroy controlled drugs at a patient's home and, according to Mrs Nuttall, this is what they prefer to do. This avoids the risk that the drugs might be stolen while being taken to a pharmacy for destruction.

8.38 The most common method of destruction of diamorphine within a patient's home is for the ampoules to be broken open and the contents flushed down a sink or lavatory. The powder

is very soluble. There are no legal restrictions on putting drugs into waste water or sewage systems from domestic premises. However, such a process is probably not ideal from an environmental point of view. Some nurses put the ampoules into a tamper-proof container for surgical waste, which is then taken for incineration, and this is probably preferable.

8.39 The practice in Tameside is for the destruction to take place at the patient's home in the presence of a witness, with a signed record being made on the PDRC. Until recently, there was no requirement that the witness should be a nurse or other healthcare professional and, in practice, it was often a relation of the deceased. Now, however, the T&G PCT requires that any destruction of controlled drugs by a district nurse should be witnessed by a second registered nurse, who should sign a record of the destruction. The initiative for this change came from the district nurses, who felt that the person who acted as a witness to the destruction should be a person who fully understood the process and its purpose. Family members might be very distressed and quite unable to exercise an effective check on what was happening. A doctor or nurse, intending to divert drugs for his/her own purposes, could easily 'pull the wool over the eyes' of a family member, either by sleight of hand or by the misleading use of language. In any event, according to Mrs Nuttall, families do not always wish to be involved in witnessing the process and I do not think that they should be required to do so. Mrs Nuttall said that, in the past, destruction was sometimes witnessed by a neighbour who had a key and had let the district nurse into the house. Not only would a neighbour be unable to confirm in an informed way what the doctor or nurse had actually done by way of destruction, s/he would have no authority to sanction the destruction.

8.40 I have already mentioned that there is no special place on the PDRC for the recording of the details of destruction. Even the most recent guidance in Tameside specifies only that a record of destruction be made and signed by a second nurse; it does not specify what the record should comprise. According to Mrs Nuttall, the nurses know that they must state exactly what has been destroyed but they would be complying with the strict wording of the current policy if they were simply to record, as Shipman sometimes did, 'all remaining drugs destroyed' or something similar. In Chapter Fourteen, I shall consider whether there should be a requirement that a formal, detailed record be made of the destruction of leftover drugs.

8.41 I have already discussed the resource implications of the requirement that two nurses be present at the administration of diamorphine in a patient's home. Similar consequences would follow the requirement that two nurses attend to witness destruction although, of course, administration takes place daily, whereas destruction would normally occur only once in the case of each patient.

Care Homes

8.42 At the beginning of this Chapter, I mentioned that there are special requirements in respect of the keeping of controlled drugs for patients who live in care homes. The Inquiry has not considered these requirements in any detail, as there was no evidence of poor practice in the homes occupied by Shipman's patients. The Care Standards Act 2000 and associated Regulations (which became operational in April 2002) require the person in

charge of registered care homes to **'make arrangements for the recording, handling, safekeeping, safe administration and disposal of medicines received into the care home'**. The Act also confers on the Secretary of State for Health the power to produce statements of national minimum standards which are to be taken into account by the regulatory authorities when exercising their powers under the Act.

8.43 Statements of minimum standards have now been published. Among other things, these state that care homes must comply with the requirements of the Misuse of Drugs Act 1971. Certain homes providing nursing care have to comply with the Misuse of Drugs (Safe Custody) Regulations 1973. In addition, the administration of a controlled drug by a member of staff must be witnessed by another member of staff. A CDR must be kept recording the receipt, administration and disposal of controlled drugs. Responsibility for ensuring compliance has now passed from the National Care Standards Commission (NCSC) to the Commission for Social Care Inspection (CSCI), which is required to carry out at least two statutory inspections annually.

8.44 Before 2002, it appears that some local authorities and primary care organisations laid down guidelines on good practice in connection with the keeping of medication in care homes. I have seen one such set of guidelines promulgated by Tameside Metropolitan Borough Council and the Tameside Family Health Services Authority in 1995. These guidelines were eminently sensible. They included a requirement that the receipt, administration and return of controlled drugs should be recorded in a CDR. Although these guidelines did not have the force of law, the local authority had the power to inspect care homes and was able to enforce compliance through its power to grant or withhold a licence to keep the home.

8.45 I received evidence from Mr Mark Shockledge, Director of Care Services at the Laurel Bank Residential Care Home, where a number of Shipman's patients lived. He told the Inquiry that the home complied with the guidelines to which I have referred and now complies with the applicable standards. He explained that all drugs prescribed by residents' GPs are dispensed at a designated pharmacy. All controlled drugs prescribed for residents are kept in a cabinet, to which only team leaders have access. On receipt of the controlled drug, details are entered in a bound book known as the Controlled Drugs Record of Administration, which has pages similar in layout to the Tameside PDRC. Each page is specific to a particular resident. Mr Shockledge said that, at the time when he made his statement, there were twice-yearly inspections of the premises by the NCSC, which monitored compliance with procedures at the home and had the power to issue compliance notices. Also, the pharmacist from the home's designated pharmacy regularly monitored the home's compliance with its procedures. It appears to me that these arrangements should keep the risk of diversion to a minimum. Similar arrangements apply at the Hyde Nursing Home. The Inquiry considered several deaths that took place there and at the Laurel Bank Residential Care Home. There is nothing to suggest that the procedures in operation there were in any way unsatisfactory.

8.46 In February 2004, a letter was received by the Inquiry, from a NCSC inspector, expressing concern about the potential for diversion of controlled drugs that exists in children's homes, residential homes, younger adult placements, boarding schools and secure units.

It is beyond the scope of the Inquiry to examine compliance with standards in such establishments. The CSCI has also recently raised certain concerns, which I readily understand, connected to issues of storage and disposal of controlled drugs in the premises that they visit. Again, however, these concerns do not fall within my remit.

8.47 For the sake of completeness I mention that, if a care home wishes to keep a stock of controlled drugs (as opposed to drugs prescribed for an individual patient), the manager must obtain a licence from the Home Office.

Conclusion

8.48 In this Chapter, I have highlighted the almost complete absence of any regulation of controlled drugs once they have left the pharmacy. Shipman took advantage of the informality of the current arrangements. So, no doubt, do other dishonest doctors and healthcare professionals. In my view, it is necessary that there should be some improvement in the methods of tracking controlled drugs from the pharmacy until the point where they are consumed or destroyed. I shall discuss the means by which this might be achieved in Chapter Fourteen.