CHAPTER FIVE

Arrangements for Dealing with Controlled Drugs in General Practitioners' Surgeries

Introduction

5.1 In Chapters Three and Four, I mentioned some of the requirements imposed upon general practitioners (GPs) by the Misuse of Drugs Act 1971 (MDA 1971), the Misuse of Drugs Regulations (MDR) 1973–2001 and the Misuse of Drugs (Safe Custody) Regulations 1973 (the Safe Custody Regulations). I shall describe them in a little more detail in this Chapter. They are set out in tabular form at Appendix C to this Report.

Legislation

5.2 Regulation 5 of the Safe Custody Regulations requires a GP who keeps stocks of certain controlled drugs (otherwise than in a locked safe, cabinet or room which is so constructed as to prevent unauthorised access to the drugs) to store them in a locked receptacle, which can be opened only by the GP or someone acting on his/her authority. The regulation applies to all controlled drugs in Schedule 2 to the MDR 2001 (except quinalbarbitone) and to a small number in Schedule 3. The receptacle is usually the 'doctor's bag'.

5.3 Regulation 19 of the MDR 2001 requires GPs who keep a stock of Schedule 2 drugs to maintain a controlled drugs register (CDR) detailing the particulars of every such drug obtained and supplied by him/her. A separate CDR or a separate part of it has to be used for each controlled drug. The form of the CDR is illustrated in Schedule 6 to the Regulations. However, this Schedule shows only a blank table with a series of unidentified columns. Regulation 20 requires that the class of drugs to which the entries on a given page relate shall be specified at the top of that page. Every entry must be made on the day of the supply or, if that is not reasonably practicable, on the following day. Corrections must be indelible and made by a note in the margin or as a footnote. Cancellations, obliterations and alterations are not allowed. The CDR is not to be used for any purpose other than the purpose of the Regulations.

5.4 Under regulation 27 of the MDR 2001, GPs who keep a stock of Schedule 2 drugs may not destroy or cause to be destroyed any such controlled drugs except in the presence of, and in accordance with any directions given by, a person authorised by the Home Secretary to witness such destruction. The date of destruction, the quantity destroyed and the signature of the witness should all be recorded in the CDR. Those authorised include police constables, Home Office Drugs Inspectorate inspectors and Royal Pharmaceutical Society of Great Britain (RPSGB) inspectors. This provision applies to 'out of date' and contaminated drugs but not to 'patient returns', which, by virtue of regulation 6, can be destroyed without formality.

5.5 The practical arrangements made by practitioners in order to comply with these requirements vary from one practice to another. To an extent, this is understandable and reflects the existence of a wide variety of practice styles. However, this variability

is partly attributable to a lack of knowledge and understanding of the requirements on the part of many GPs and to the absence of any mechanism for inspecting or approving the arrangements made at GPs' surgeries. As will become clear from the rest of this Chapter, ignorance of and failure to comply with the requirements is widespread among GPs. Arrangements are often informal, and staff and doctors sharing premises may not be aware of the arrangements made by individual colleagues.

The Arrangements in the Practices where Shipman Worked

5.6 Shortly after his arrival at the Abraham Ormerod Medical Centre in Todmorden in 1974, Shipman took over responsibility for the ordering of controlled drugs for the practice. The doctors in the practice shared the use of a controlled drugs cabinet and only one CDR was kept. Shipman was responsible for recording in the CDR any Schedule 2 controlled drug obtained by the practice, and each doctor was responsible for making an entry in the 'drugs supplied' section when s/he removed a quantity of drug from the cabinet for supply or administration to a patient. Shortly after his arrival, Shipman began to order large quantities of pethidine and to divert them for his own use. Initially, he made entries in the 'drugs obtained' section of the CDR but made no entries in the 'drugs supplied' section. In July 1975, after suspicion had been aroused by the quantities of pethidine purchased for the practice, the police and a Home Office drugs inspector visited the practice. Shipman and his partners were advised of their obligation to complete both sides of the register. Thereafter, Shipman continued to order supplies of pethidine on requisition and to divert them for his own use, but ceased making any entries at all in the CDR. In September 1975, Shipman's actions came to light. He was dismissed from the practice and he was prosecuted.

5.7 After he left Todmorden, Shipman never again kept a CDR and never officially used a **'locked receptacle'** for controlled drugs. Provided he was not holding any stock of Schedule 2 drugs or the relevant Schedule 3 drugs, there was no requirement for him to do so. When being interviewed by members of the Donneybrook practice, Hyde, prior to his appointment to the practice in October 1977, Shipman said that he did not intend to keep controlled drugs but would use Fortral (which was not then a controlled drug) for pain relief. In fact, he usually did have a secret stock of diamorphine. It is not clear where this was kept. It seems likely that he usually kept his supplies in a bag or box in his motor vehicle. He probably also kept some in a secret place in his consulting room. After his arrest, some diamorphine was found at his home. But, when anyone asked him whether he kept controlled drugs – as a regional medical officer (RMO) and a medical adviser employed by the Family Health Services Authority (FHSA) did – he told them that he did not. Had a search taken place (which it did not until he was under suspicion of murder) and had any controlled drugs been found, he would no doubt, at least after 1985 (when the relevant provisions were introduced), have claimed that they were patient returns, which he was entitled to receive for the purpose of destruction without keeping any record.

5.8 In Phase One of the Inquiry, 11 GPs, who had at various times been at the Donneybrook practice, provided details of their personal arrangements for holding the relevant Schedule 2 and Schedule 3 controlled drugs. Most kept their own stock in their doctor's

bags and maintained their own CDRs. One of them, Dr Ian Napier, used to have his record of drug acquisitions in the CDR witnessed by a pharmacist. Two said that they did not keep a stock of controlled drugs; they could use non-controlled drugs for emergency pain relief and wished to avoid the risk of theft inherent in carrying a controlled drug.

5.9 Staff at the Donneybrook practice were not aware that any controlled drugs were kept on the premises. Mrs Vivien Langfield, the practice manager, said that, for security reasons, drugs were not usually kept on the premises. Drugs returned by, or on behalf of, patients were stored in a cupboard in reception prior to being sent for use in the Third World.

5.10 The staff at the Market Street Surgery, to which Shipman moved in 1992, were unaware of the arrangements Shipman made as regards controlled drugs. They were unaware too of the statutory requirements which would have applied if he were to have kept a stock of controlled drugs. Mrs Carol Chapman, who started working as a receptionist for Shipman in 1992, recalled that she twice saw a 'drugs bag', which Shipman kept in his motor vehicle. She said that she did not know whether diamorphine was regularly kept on the premises but she recalled that, on one occasion, probably Saturday, 27th December 1997, when she was suffering from acute back pain, Shipman gave her an injection of diamorphine at the surgery. He did not leave his room to obtain the drug, so it was clear to her that it must have been kept there. Neither Mrs Chapman nor the other staff to whom she mentioned the episode expressed surprise that Shipman should have been able to give her such an injection. They are not to be criticised for that. They had had no training in the requirements relating to controlled drugs.

The Position Today

5.11 At the present time, many GPs do not keep controlled drugs either in their bags or at their surgeries. They are, therefore, under no obligation to keep a CDR. There are a number of reasons why doctors do not keep controlled drugs. Many doctors practising in urban areas are fearful that carrying controlled drugs would make them a target for theft or robbery. Doctors in such areas would, in any event, have ready access to a pharmacy. It appears that doctors in rural areas are more likely to carry a supply of controlled drugs. However, many doctors find that there is no need to carry controlled drugs, as non-controlled alternatives are available. The Royal College of General Practitioners (RCGP) provides advice to doctors about the contents of an emergency bag. Some form of analgesia is required but this need not be in the form of a controlled drug. The British Medical Association pointed out to the Inquiry that changes in the arrangements for the provision of out of hours services and the increased provision of care by paramedics in the ambulance service may also account for a reduction in the number of GPs carrying controlled drugs.

5.12 In those practices where doctors do keep a stock of controlled drugs, the methods of record keeping and stockholding vary. In some cases, a central cupboard and CDR are kept; in others, the doctors make their own personal arrangements.

Lack of Inspection

5.13 Until 1991, RMOs visited GPs' premises periodically. The purpose of the visit was mainly pastoral; advice could be given on any matter of concern. The RMO would inspect the GP's arrangements for keeping controlled drugs and the CDR and give advice, if necessary. If a GP failed to heed advice given by the RMO about such matters as the excessive prescribing of any drugs, s/he might be referred to the local medical committee (LMC). However, it appears that this occurred only very infrequently and that, when it did occur, the focus was on discouraging unnecessarily costly prescribing, rather than on preventing diversion of controlled drugs.

5.14 In 1991, the task of inspecting GPs' premises passed to the NHS body with responsibility for the local provision of primary care services. Initially, this was the FHSA; it is now the primary care trust (PCT). Medical advisers were appointed by the FHSAs and a system of annual surgery visits was developed. However, it appears that these visits did not focus on the arrangements for keeping controlled drugs. As a result, most practices have not had their arrangements inspected for many years.

Lack of Compliance and Understanding

5.15 The effect of this lack of inspection and support has been clearly demonstrated in the report of a survey completed in January 2002 by Professor Richard Baker, Director of the Clinical Governance Research and Development Unit, University of Leicester, and colleagues, entitled 'Reducing Leakage of Prescribed Drugs'[1]. The study was commissioned by the Leicester, Leicestershire and Rutland Drug Action Team and was undertaken to assess the risk in Leicestershire and Rutland of leakage of prescribed controlled drugs. Leakage was defined as the use of controlled drugs for purposes other than those for which they were prescribed. It was recognised that shortcomings in the systems of control and in their day-to-day application could increase the risk of leakage.

5.16 The study had two phases. Initially, a number of GPs and community pharmacists were selected for interview and their arrangements for storing and recording the use of controlled drugs were examined. The findings from these interviews were used to devise questionnaires that were sent to all GP practices and community pharmacists not previously interviewed. The questionnaires sought information about their procedures and arrangements for storage of controlled drugs, for keeping of CDRs and for handling of patient returns and out of date drugs. The questionnaires sought views on the strengths and weaknesses of the present systems and also sought ideas as to how the systems could be improved.

5.17 Professor Baker explained the study findings to the Inquiry. So far as GPs were concerned, the arrangements for storage were variable; controlled drugs might be stored in a doctor's bag, a secure practice store or the practice dispensary. Several types of CDR were in use and doctors said that they were uncertain or confused as to their duties in this respect. Many said that they lacked any source of help or advice.

[1] published in abbreviated form in *Quality & Safety in Health Care* 2004; 13:21–25

Most GPs reported that their arrangements had not been inspected for many years, and many said that they would welcome an inspection.

5.18 As I have explained, the legislation allows a GP or pharmacist to accept the return of unused controlled drugs from patients for the purpose of destruction, without imposing any duty to record either the receipt or the destruction. The survey found that some practices accepted and encouraged the return to the practice of unused controlled drugs. The remainder would not accept them; they perceived problems with disposal and issues of ownership. Their policy was to advise patients or carers to return the drugs to a pharmacy.

5.19 The report recommended the provision of a local source of advice about good practice to pharmacists and GPs. It suggested that inspection arrangements should be put in place. It also encouraged greater support for police chemist inspection officers (CIOs).

5.20 Other witnesses giving evidence to the Inquiry confirmed that many GPs are uncertain about their duties and responsibilities with respect to controlled drugs. Dr Geoffrey Roberts, a former member of the Donneybrook practice and now Medical Director of a mental health trust in Warrington, told the Inquiry that, in his capacity as secretary of the LMC for Tameside, he had often received requests for advice about such matters as the destruction of unused controlled drugs following the death of a patient.

5.21 In 2001, Dr Clare Gerada, a Lambeth GP and Director and Chair of the RCGP National Advisory Group for Drug Misuse, while on secondment to the Department of Health (DoH), prepared a 'scoping study' entitled 'Controlled Drugs in Clinical Practice – Summary of Use and Controls'. In it, she reported that most practitioners are unclear about their roles and statutory responsibilities under the MDA 1971. As a result, compliance is poor, particularly in respect of the records kept of items administered personally from the doctor's bag. The position is made worse where several different doctors use the same emergency bag.

5.22 Mr David Young, an inspector for the RPSGB, confirmed that GPs have difficulty in understanding their responsibilities. He described an occasion when he was asked for advice by a group practice in Sheffield. The senior partner was concerned about the practice's arrangements for controlled drugs. They had had no guidance and did not know to whom to turn. They asked Mr Young to help them set up a CDR and to advise them on safe custody arrangements. Their existing arrangements would have permitted anyone working in the building, including cleaners, to have access to the drugs cupboard. Mr Young gave the help requested, although to do so was not part of his duties as a RPSGB inspector. When the system was set up, the senior partner asked Mr Young when he would come back to inspect its operation. That was not within his brief either and it is likely that the practice remains uninspected.

5.23 Very recently, in May 2004, the National Prescribing Centre published a preview edition of a new guide to good practice in the management of controlled drugs in primary care in England. This is a useful and comprehensive guide for general practitioners, pharmacists and others. The guide seeks to explain the current legal and regulatory frameworks and goes on to state what is regarded as good practice within those

frameworks. The publication of the guide is a very welcome development. It will be available on the DoH website and will be subject to regular revision in the light of future developments.

Dispensing Doctors

The Separation of Prescribing and Dispensing

5.24 The usual practice in respect of all prescription only medicines, including controlled drugs, is for a GP to write a prescription, which is taken by the patient or his/her representative to a pharmacy for dispensing. In general, the view has been taken that it is preferable for doctors to prescribe and for pharmacists to dispense. In that way, the pharmacist brings his/her separate expertise to bear upon the questions of whether the drug has been appropriately prescribed and whether the dosage is within normal limits.

5.25 There are two sets of circumstances in which this usual separation of functions does not apply. The first follows from the fact that all doctors are permitted to supply and administer prescription only medicines, including controlled drugs, to their patients for immediately necessary treatment, pursuant to regulation 19 of the National Health Service (Pharmaceutical Services) Regulations 1992 (the 1992 Regulations). These Regulations allow a doctor to provide emergency medication from his/her bag or practice stock. Regulation 19(b) permits a doctor to supply to a patient any appliance or drug that is personally administered.

5.26 The second set of circumstances arises because, under the 1992 Regulations, some doctors, practising in rural areas, are permitted to dispense as well as to prescribe drugs, even in circumstances where there is no emergency. This is a source of additional income for such doctors, which may be of some importance to a rural practice with a small patient list.

5.27 The 1992 Regulations provide that a PCT may authorise a GP to provide pharmaceutical services under the NHS to patients living in a **'controlled locality'** who would have serious difficulty in reaching a pharmacy. A controlled locality is a rural area. In a dispensing practice, the dispensing of medicines will take place on the practice premises under the authority of the GP. However, the GP usually delegates the work of dispensing to a pharmacist or dispenser (who may or may not be qualified) employed by the GP or the practice. In England, there are about 4800 dispensing GPs, about 15% of all practising GPs. Scotland, despite its geographically dispersed population, has only about 290, which represents about 8% of GPs in practice there.

5.28 All applications to provide NHS pharmaceutical services from a community pharmacy in England must be approved by the local PCT and, if the application relates to a controlled locality, it may be opposed by the local dispensing doctors. By regulation 4(4) of the 1992 Regulations, the application is to be granted only if the PCT is satisfied that it is necessary or desirable to do so in order to secure the adequate provision of services of the type proposed in the neighbourhood in which the pharmacy would be situated.

5.29 Regulation 4(4), which, in respect of a controlled locality, effectively places the onus on the applicant pharmacy to overcome any objections raised by the dispensing doctors, appears rather surprising. On the face of it, the determining factor is whether the existing pharmaceutical services are adequate. It seems that these include the pharmaceutical services provided by dispensing doctors. The fact that those pharmaceutical services may not be as safe for patients as those provided by a pharmacist independent of the prescribing doctor does not appear to be taken into account. It is generally recognised that the scrutiny that can be applied to a prescription by a qualified pharmacist, independent of the prescribing doctor, provides a better potential clinical safeguard than that provided by a dispenser or even a pharmacist who is employed by the prescribing doctor. These issues may be said to be beyond the scope of the Inquiry. However, there is another public interest reason, which does lie within the remit of the Inquiry, why pharmaceutical services provided by pharmacists may be preferable to those provided by dispensing doctors. An independent pharmacist is or should be a safety check on malpractice by a GP in connection with drugs of potential abuse. If Shipman had been a dispensing doctor, it would have been even easier than in fact it was for him to obtain his illicit supplies. It would have been extremely difficult for an employed dispenser to challenge any irregularity of which s/he became aware. I am not suggesting that there is any evidence that dispensing doctors are any more prone to acts of dishonesty in relation to controlled drugs than any other doctor. However, I do consider that there is a significant potential for abuse, particularly since CIOs have no authority routinely to inspect the dispensaries of dispensing GPs.

Conclusion

5.30 I have explained that, at present, many GPs are not complying with their duties under the MDR 2001, often as the result of ignorance, confusion and lack of advice rather than with any intention to default. Does this matter and, if it does, what should be done about it?

5.31 The general policy of the current legislation is that the keeping and use of controlled drugs should be subject to safe custody and record keeping requirements and that the arrangements and records should be subject to periodic inspection. That being so, there seems every reason why GPs, including dispensing doctors, should be subject to the same standards of inspection and enforcement as pharmacists. To achieve this, there must be improved sources of advice for GPs and a new or improved system of inspection. However, it is clear that the existing safe custody and record keeping requirements, even if fully enforced, will not deter or detect the activities of a doctor who, like Shipman, is determined to keep a secret supply of a controlled drug. Shipman did not keep a CDR but, even if he had kept one, it would not have contained entries relating to his illicit supplies. However good a system of inspection of his CDR and of his arrangements for keeping any legitimate supplies had existed, his illicit supplies would not have been found. In Chapter Fourteen, I shall discuss the improvement of inspection arrangements and the feasibility of measures that would detect activities such as Shipman's.