

# CD guidance for secondary care — ensuring procedures are fit for purpose

This week sees the publication by the Department of Health and the Royal Pharmaceutical Society of “Safer management of Controlled Drugs: a guide to good practice in secondary care (England)”. Robert Clayton, head of practice at the Society explains content of the document

New guidance from the Department of Health and the Royal Pharmaceutical Society — “Safer management of Controlled Drugs: a guide to good practice in secondary care (England)” — is designed to support the implementation of new legislation and governance arrangements and to provide good practice recommendations for those who are involved in the day-to-day management of CDs in secondary care and for those who are responsible for ensuring that CDs are managed safely and appropriately in their organisations.

The Shipman Inquiry uncovered gaps in the systems in the management and use of CDs and the reports arising from the inquiry made numerous recommendations related to health and social care. The Health Act 2006 introduced significant new legislation and governance arrangements relating to the management of CDs in both primary and secondary care.

There was also mounting concern among pharmacists working in secondary care that there was considerable variation in systems and processes for the management of CDs. Some areas such as patients’ own CDs, CDs in operating theatres, the use of CDs in paediatrics, the destruction of CDs and the audit trail for CDs in hospitals were identified as being specific problem areas where clarification and guidance were needed. Against this background the need for clear, authoritative guidance for the management of CDs in secondary care became apparent.

In autumn 2006, the Society was commissioned by Keith Ridge, Chief Pharmaceutical Officer for England, to prepare a document that would build on the guidance provided in “The safe and secure handling of medicines: a team approach” (the Revised Duthie report, March 2005), and incorporate the new legislation and governance arrangements, in particular, the role of the accountable officer. Another important part of the brief was to capture the areas of concern or risk that practitioners had identified along with the developments that have taken place to modernise working practices in recent years and the changing roles of health care professionals. All of these were to be built into the guidance within the framework of existing legislation.

## Consultation

A multidisciplinary stakeholder meeting (involving practitioners, regulators and representatives from the DoH and the Home Office) was held in November 2006 to identify the



key areas of risk and areas where guidance was needed. This was followed by two smaller meetings as the document began to take shape. Examples of good procedures and documents were also gathered from leading edge institutions. The final draft of the document was then subject to two further rounds of consultation for content and accuracy.

## Content

The final document contains numerous good practice recommendations and suggestions. It sets out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of CDs, while at the same time helping to ensure appropriate and convenient access for patients who require them. It is not designed to provide advice on the clinical choice or use of CDs.

The document has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of CDs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations or topics, such as CD stationery and the management of CDs that are patients’ own property, that do not obviously fit elsewhere.

This guidance applies to all areas of secondary care, including private hospitals and clinics. It has followed the style of the Duthie reports and used the term “should” for recommendations that relate to good practice and “must” for those governed by legal re-

quirements. Recommendations have also been inserted that “may” be followed as matters of good practice, if they are relevant to local circumstances.

The main points of interest are summarised below:

**Legislation and governance arrangements** There is a brief review of the legislation and governance arrangements for CDs. Two detailed appendices set out the schedules to the Misuse of Drugs Regulations and the responsibilities of the accountable officer. This section is extensively cross-referenced and hyperlinks have been inserted wherever possible so that users can easily locate key documents.

**Principles** There are a number of overarching principles that guide the use of medicines in general and CDs in particular. These underpin and inform the decisions that are made about the safe management of CDs within the current legal framework. As the guidance cannot cover every conceivable situation that might occur in practice, the inclusion of this list of principles is intended to provide users with a framework within which to work. It is perhaps noteworthy that the first principle mentioned is that “patients have timely access to the medicines prescribed for them”.

**Responsibilities of the accountable officer** The accountable officer is responsible for all aspects of the safe and secure management of CDs in his or her organisation.

This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing of the management systems and investigation of concerns and incidents related to CDs. The accountable officer role is new and, in order to support trusts in this aspect of implementation, we have included detailed guidance on the accountable officer's duties and responsibilities.

**Standard operating procedures** The guidance emphasises the importance of standard operating procedures (SOPs) because they represent a safeguard for both health care professionals and patients. Each of the activities that relates to CDs, regardless of where in the organisation they occur, must be described in an SOP. This is particularly important if tasks are delegated to others. Accountable officers are responsible for ensuring that there are adequate and up-to-date SOPs in place in relation to the management and use of CDs within their organisations.

**Pharmacy technicians** In recent years pharmacy technicians have taken on many of the supply functions in pharmacies. Now that many technicians are registered with the Royal Pharmaceutical Society, their position is strengthened. This is recognised and throughout the document reference is made to the tasks that could appropriately be delegated to registered technicians.

### **Operating department practitioners**

There has been considerable modernisation of practice in operating theatres in recent years. Many operating department practitioners are now registered with their professional body — the College of Operating Department Practitioners — and in some hospitals theatres are managed by operating department practitioners. Although it is still necessary to work within the Misuse of Drugs Regulations, the Society and the DoH have recognised these developments and the guidance clearly points out that functions such as key-holding and requisitioning of CDs can legitimately be delegated to operating department practitioners, ideally supported by a standard operating procedure.

**Disposal of CDs** Disposal of CDs must comply with Home Office guidance, Waste Management Regulations and Environment Agency guidance in addition to good governance measures. Therefore explicit guidance on disposal of CDs has been included. Fortunately the number of people who can now act as authorised witnesses to the destruction of CDs (for those situations where an authorised witness is required by the Misuse of Drugs Regulations) has increased considerably. As a result the problems experienced by pharmacies while waiting for an authorised witness have been lessened. In order to make the guidance more user-friendly, a

quick-reference table for disposal has been included to show the acceptable methods of disposal for CDs in common situations.

**Product journey diagram** A product journey flow chart has also been included as an additional means of signposting users to the correct section of the document. Each stage in the flow is cross-referenced to the relevant paragraphs in the text. This was done because stakeholders pointed out that, for many people, this is an easier way to navigate a document than the conventional contents list.

### **Conclusion**

Pharmacists should play a leading role in the safe management of medicines in general and CDs in particular. This guidance will help pharmacists in secondary care contribute to the effective management of CDs in their organisations. Robust governance arrangements for CDs have recently been introduced into the primary care sector in the wake of the Shipman Inquiry and it is important that the secondary care sector is seen to have similarly robust arrangements in place. The Society and the DoH believe that this document will support these developments and hope that accountable officers will see this as an opportunity to review processes and procedures in their organisations to ensure that they are robust and fit for purpose.

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