



# Controlled Drugs in Perioperative Care

# 2006

Published by  
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January 2006

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The working party gratefully acknowledges the assistance of the Royal College of Nursing and the Royal Pharmaceutical Society of Great Britain who reviewed and commented on the document

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## SUMMARY OF THE RECOMMENDATIONS

1. Local guidelines should be established to promote good, safe and legal practice for handling controlled drugs. These must ensure compliance with the Medicines Act, the Misuse of Drugs Act, the Misuse of Drugs (Safe Custody) Regulations and the Misuse of Drugs Regulations.
2. When patient controlled analgesia or other infusion devices are being used, it is best practice to use pre-filled syringes rather than make up a solution by diluting ampoules.
3. The Misuse of Drugs Regulations should be amended to take account changes in the roles and titles of staff in modern clinical practice. The terms 'sister or acting sister' which are widely referred to are now archaic and should be changed. The Association recommends that ODPs should be able to be responsible for possessing and issuing controlled drugs and that senior ODPs could also have the authority to order controlled drugs.
4. Although controlled drugs must be stored in a secure place this must allow an appropriate level of access and availability for immediate clinical use.
5. Unused controlled drugs must be disposed of in an approved manner and this should be included in local guidelines.
6. The sharing of the contents of any ampoule between patients is poor practice.

## **SECTION 1. INTRODUCTION**

When the Association of Anaesthetists of Great Britain and Ireland (AAGBI) published a document (1981) on controlled drugs, their use as far as anaesthetists were concerned was essentially confined to the anaesthetic rooms and operating theatres. In addition, the quantities of drugs used were relatively modest.

The situation was different by the time these guidelines were revised in 1994 and developments in clinical practice have continued. Nowadays patients may receive large doses of opioids as a major part of their anaesthetic, there is a wide range of controlled drugs available and the responsibility of anaesthetists in prescribing and administering controlled drugs has extended not only into the recovery room and Intensive Therapy Unit, but also to acute and chronic pain services in all parts of the hospital and home care. An additional factor is the issue of substance abuse. Because of these extended uses of controlled drugs, particularly in relationship to acute pain services, a much wider range of preparations is necessary to meet these requirements, e.g. the development of Patient Controlled Analgesia (PCA).

This publication recommends what the Association considers best practice for the safe preparation, distribution and disposal of controlled drugs to meet current clinical demands in peri-operative care.

## SECTION 2. MEDICINES ACT 1968

The Medicines Act 1968, together with its secondary legislation, provides a regulatory scheme of licences, registrations and exemptions which control all aspects of the production and distribution of all medicinal products.

A **Product Licence** is issued when the Medicines and Healthcare products Regulatory Agency (MHRA) is satisfied regarding a product's inherent safety, quality and efficacy for the indicated purpose.

A product licence specifies not only the nature of the drug, but also its pharmaceutical form, strength and packaging. Thus, for example, an ampoule of morphine sulphate 30mg may be a licensed product, but, if used to make and supply a pre-filled syringe or PCA device, the resulting product will be unlicensed.

As part of the application for a Product Licence, the manufacturer will have to submit evidence regarding the stability of the product which will then be assigned a shelf-life.

**The Association of Anaesthetists of Great Britain and Ireland recommends that wherever a pre-filled syringe or PCA device is marketed as a licensed medicinal product, it should be used in preference to an equivalent but unlicensed product.**

A **Manufacturer's Licence** is issued when the Licensing Authority is satisfied that an applicant can manufacture medicinal products to acceptable standards, so as to ensure the safety, quality and efficacy of those products. A manufacturer's licence enables the holder to produce either a licensed medicinal product or an unlicensed special. A manufacturer's licence may be granted to commercial organisations and to some NHS hospitals.

**Specials** are medicinal products in respect of which a Product Licence is not in existence but which have been made by the holder of a Manufacturer's Licence to the order of a medical practitioner.

Section 9 of the Medicines Act allows a medical practitioner to prepare or order a medicinal product for a particular patient. The practitioner assumes responsibility for all aspects of the safety of such products including compatibility of ingredients, their stability and sterility. The patient, or patients, must be named.

A shelf-life of several weeks or months may be appropriate for some Specials, but it is the responsibility of the manufacturer to ensure that the shelf-life is supported by suitable stability data. Notice must always be taken of expiry dates on all products.

**Prepared Medicines** are medicinal products in respect of which a Product Licence is not in existence but which have been made under the supervision of a pharmacist in a retail or hospital pharmacy, neither of which is the holder of a Manufacturer's Licence.

This activity is carried out under Section 10 of the Medicines Act which allows a pharmacist to prepare medicines in accordance with a prescription given by a medical practitioner or in anticipation of such a prescription.

Thus, a medicinal product may be classified as:

- a licensed medicine
- a special medicine
- a prepared medicine

Many injectable medicines, although supplied as licensed products, have to be reconstituted or diluted before administration to the patient and thus become prepared medicines. When this dilution is carried out by a registered prescriber, he or she is responsible for seeing that the procedure is performed properly and accurately.

The working party has given particular consideration to filled syringes and other devices which are either made up in advance or which remain with the patient for long periods of time and move with the patient from one clinical area to another. A common example are the medicines used for Patient Controlled Analgesia.

In order of preference, **the supply of pre-filled syringes and devices forming part of a PCA or similar system should be as follows:**

- (i) A licensed medicinal product wherever such an item is available.
- (ii) A 'special' produced in a licensed facility which may be a commercial supplier or hospital pharmacy.
- (iii) A prepared medicine made in a retail or hospital pharmacy, under the direct supervision of a pharmacist.
- (iv) Prepared by a trained member of staff near the patient according to a local protocol.



## **SECTION 3. ISSUE OF CONTROLLED DRUGS WITHIN THE OPERATING DEPARTMENT AND KEY HOLDING**

The Misuse of Drugs Regulations 2001 place the responsibility for the possession, safe custody and issue of controlled drugs within hospital wards and departments with the sister or acting sister in charge of that ward or department.

Over the last few years, staffing practice in operating departments and related areas has undergone considerable change; the titles “sister” and “acting sister” are often no longer used. However, in purely legal terms, responsibility for the safe custody and issue of controlled drugs rests with the most senior registered nurse on duty in the department.

Some operating departments have several operating theatres, each of which will have its own controlled drugs cabinet. The sister or acting sister in charge of the operating department is responsible for supplies from all the controlled drugs cabinets. To ensure controlled drugs are readily available, the sister or acting sister in charge may delegate control of access (key holding) to another registered nurse or a medical practitioner (e.g. anaesthetist) or an operating department practitioner (ODP). This access must be strictly controlled in practice and set out in locally agreed written guidelines. A registered nurse or an ODP may remove controlled drugs from a controlled drugs cabinet and return them to the cabinet on the specific authority of either the sister or a medical practitioner. However, the responsibility for all controlled drugs remains with the senior registered nurse on duty, even if the nurse decides to allow access by others.

As many operating departments are now staffed with ODPs and some are managed by ODPs, the Association of Anaesthetists of Great Britain and Ireland believes that the Misuse of Drugs Regulations 2001 should be amended so that ODPs may also be specifically authorised and be responsible for possessing and issuing controlled drugs. The terminology of ‘sister or acting sister’ is now archaic and should be amended.

## SECTION 4. GUIDELINES

The development of local guidance is essential. Such guidelines should:-

- recognise and adhere to the relevant legal requirements
- promote good, safe practice
- take account of local staffing arrangements
- not restrict the use of opioids in a manner which would be detrimental to patient care
- be understood and accepted by all staff

While individual hospitals should have their own local guidelines, there are a number of points which need to be considered. The Department of Health Report, Guidelines for the Safe and Secure Handling of Medicines, (Duthie Report 1988) may be of assistance.

### **Responsibility**

The system established for ordering and security should be that agreed between the senior pharmacist, the operating department manager and appropriate senior nursing staff. Current legislation states that controlled drugs may be requisitioned only by the sister or acting sister in charge of a department.

Responsibility of individuals within the operating department are those of:

- (a) The sister or acting sister in charge for:
  - (i) ordering, receiving, checking, recording and storing stock;
  - (ii) recording the amount issued to medical staff;
  - (iii) returning unused ampoules to stock;
  - (iv) amending balances accordingly.

(b) Medical staff for:

- (i) signing for the controlled drugs received in the operating theatre controlled drugs register;
- (ii) properly recording in the patient's records the amount of drugs administered;
- (iii) returning any unopened ampoules;
- (iv) safe disposal of any unused controlled drugs that remain in an open ampoule or syringe.

(c) The pharmacist for:

- (i) supply of controlled drugs to each stock location;
- (ii) regular audit of local policies;
- (iii) checking controlled drug stocks and registers at least once every three months.

### **Issue of drugs from a register to anaesthetists or other prescribers**

- (a) When controlled drugs are issued, they must be checked by the prescriber with the nurse (or other designated person) and the controlled drugs register signed.
- (b) The same responsibility and recording procedures apply for the drawing up of controlled drugs for a PCA or other infusion regimen.

### **Ordering and Transfer of Drugs**

- (a) An agreed stock level and usage pattern should be decided between medical staff and those responsible for ordering.
- (b) If computer ordering systems are used, a printout signed by the sister is required to provide the necessary requisition.
- (c) Where ordering is carried out using computer technology, access to passcodes/terminals should be restricted to designated persons.

(d) Controlled drugs coming into the operating department should, ideally, be received at one central point and distributed from there to individual operating theatres, or be issued directly to the controlled drug stock in a specific theatre. There is no legal requirements for registers to be held at individual theatre level, but good practice and Department of Health guidance dictates that the theatre suite register should include a record of all drugs issued for administration to patients in the individual theatres.

### **Unused Controlled Drugs**

There should be a local protocol describing the procedure for the disposal of individual doses of controlled drugs which are prepared but not administered. The Department of Health is expected to issue guidance on the disposal of controlled drugs shortly.

## **SECURITY**

Controlled drugs must be stored in a secure place. The Misuse of Drugs (SafeCustody) Regulations 1973 define in great detail the type of cabinet or safe required and the type of steel, locks and hinges of which it should be made.

Neither the Misuse of Drugs Act 1971 nor the Safe Custody Regulations 1973 state that controlled drugs must be stored in a double-locked cabinet, with or without a red light. However, it is worth noting that a locked refrigerator is a complying receptacle.

Numerous amendments have added substances to, and subtracted others from, the comprehensive list of those that need or need not be stored in the controlled drugs cabinet. These relate to Schedule 2 drugs, i.e. the opioids and other potent analgesic agents. They are listed in the Appendix A. The pharmacist would be able to advise, should there be any doubts, as to whether a particular drug is subject to the Safe Custody Regulations.

## **SECTION 5. MULTIPLE DOSING**

Containers whose contents are designed to be used for more than one patient are labelled in such a way as to indicate that they are intended for multiple use. The contents of any other type of ampoule, whatever the size, should not be shared between patients.

Financial pressures and a simple wish not to be wasteful of resources often led anaesthetists to share the contents of one ampoule amongst multiple syringes. The possibility of mistakes in administration, cross infection and the admittedly theoretical risk of theft from an open ampoule are not over-ridden by the small cost benefit of using one large ampoule rather than several smaller ones. This should not be construed as including the preparation in pharmacy of individual prepared syringes.

## **SECTION 6. SOLUTIONS FOR INFUSION**

Opioid containing solutions are increasingly being used for parenteral PCA and epidural analgesia techniques. They commonly contain a solution of a single controlled drug in diluted format, or a mixture in combination with a local anaesthetic or other drug.

### **Preparation**

As described in Section II of this document, the Association of Anaesthetists of Great Britain and Ireland recommends that, wherever possible, the best practice is that such pharmaceutical preparations should be purchased from a manufacturer, or prepared under sterile conditions in a hospital pharmacy. This practice is preferable to preparing the solution on an individual basis in the operating department or ward, for the following reasons:-

- (a) sterility is guaranteed, which is especially important as the solution may be administered over several days.
- (b) the solution will be clearly labelled, showing the constituent drug(s), concentration(s), diluent, date of manufacture and expiry date.

Hospitals without a licensed manufacturing facility may prefer to obtain ready prepared PCA and epidural solutions from a Manufacturers' Licence holder. This may be another local hospital.

On rare occasions, it may be clinically advisable to administer an unusual mixture or concentration of drugs. In such cases, it would prudent for the reasons for this to be documented in the patient's notes and for senior staff to be aware of the situation.

### **Storage**

Once prepared, it is recommended that PCA and epidural solutions of controlled drugs should be supplied in individually sealed bags to suitable locations such as operating theatres, recovery rooms and labour wards and post operative wards. Prepared solutions must be accounted

for in the ward controlled drug register in the same manner as controlled drugs.

Solutions must be stored in a complying locked cabinet in each location.

Bags of solution for epidural administration need to be clearly identifiable and must be stored separately from those for intravenous infusion. Serious harm to patients can result from the inadvertent parenteral administration of solutions intended for epidural administration.

## **SECTION 7. DISPOSAL OF CONTROLLED DRUGS**

A controlled drug ceases to be classified as such once it is denatured, dissipated, is not re-usable or has been rendered irretrievable. All drugs, once disposed of, should be unrecognisable as such. Syringes containing residual unused controlled drugs should be emptied before being discarded.

All unused, unopened or out of date products must be returned to the issuing pharmacy for recording and disposal in accordance with the law.

### **Sites outside the operating department**

It is common practice for infusions of controlled drugs to be set up in the operating theatre or recovery area. These infusions may then accompany the patient to the ward. Unused volumes of these infusions should be disposed of on the ward, thus avoiding unnecessary transport of controlled drugs (and consequent security implications) around the hospital.

It is impractical to record the disposal of these volumes in the controlled drugs register at their site of issue, which may be different from the site of disposal. In the ward, disposal should be recorded and a "disposals" page in the controlled drug register should record the site of drug issue and the volume of drug discarded.



## APPENDIX

The Misuse of Drugs Act provides the basis of control for certain drugs. It contains three sets of regulations.

1. **The Misuse of Drugs Regulations** defines five schedules of drugs.

**Schedule 1** contains drugs with no recognised medical use, which are the most tightly controlled. These include hallucinogens, raw opium and coca leaf.

**Schedule 2** is the most important and covers pharmaceutical opioids and amphetamines. It is the most relevant to this document and the routine practice of anaesthesia.

**Schedule 3** contains barbiturates and some slimming preparations.

**Schedule 4** contains benzodiazepines.

**Schedule 5** includes products containing low concentrations of drugs which would be in Schedule 2 if in a stronger preparation.

There have been various amendments since 1985.

2. **The Safe Custody Regulations**, followed by several recent amendments, refers to Schedules 2 and 3, but then actually exempts many of the Schedule 3 drugs.

A list of the commonly used Schedule 2 drugs include:-

Alfentanil

Cocaine

Diamorphine

Fentanyl

Methadone

Morphine

Pethidine

Remifentanil

3. **The Misuse of Drugs (Notifications of a Supply to addicts) Regulations**. Not relevant to this publication.

## REFERENCES

Report of a Working Party on the use of Controlled Drugs in Operating Theatres. Association of Anaesthetists of Great Britain and Ireland 1981 (revised 1994)

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Guidance to NHS Hospitals on the licensing requirements of the Medicines Act. Published by the Medicines Control Agency now the Medicines and Healthcare products Regulatory Agency (MHRA).

Misuse of Drugs Act 1971 and its secondary legislation:

The Misuse of Drugs Regulations 2001

The Misuse of Drugs (Safe Custody) Regulations 1973

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