

Guidelines

Controlled drugs in peri-operative care 2019



Association
of Anaesthetists

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Controlled drugs in peri-operative care 2019

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This document is endorsed by; The Royal College of Anaesthetists and The College of Operating Department Practitioners.

This guideline has been seen and approved by the Board of Trustees of the Association of Anaesthetists

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Summary

Previous guidelines [1] on controlled drugs in peri-operative care were issued by the Association of Anaesthetists (Association) in 2006. These new guidelines have been produced in response to changes in legislation and regulations and are aimed at the use of controlled drugs in the theatre and recovery environment. The death of an anaesthetist in 2014 led to the Coroner issuing a Report to Prevent Future Deaths [2, 3]. These guidelines are a consensus document produced by expert members of a Working Party established by the Association. The Working Party included representation from the Home Office, Medicines and Healthcare products Regulatory Agency (MHRA), Care Quality Commission (CQC), Royal College of Nursing, College of Operating Department Practitioners and Royal College of Anaesthetists (RCoA).

Recommendations

1. Local Standard Operating Procedures (SOPs) should be established to promote safe and legal practice for handling controlled drugs in theatre and recovery. These must reference current regulations and legislation, and be reviewed on a regular basis.
2. SOPs should set out arrangements for the storage of controlled drugs in theatres in line with the Misuse of Drugs (Safe Custody) Regulations [4] and take into account:
 - o secure and appropriate locking of the controlled drug cupboard at all times;
 - o prompt staff access to controlled drugs in theatres and availability for immediate clinical use;
 - o any additional storage requirement for controlled drugs of different strengths with similar packaging;
 - o security of the controlled drug cupboard keys (including any spare keys).
3. When patient-controlled analgesia or other infusion devices are being used, it is good practice to use pre-prepared syringes and bags in a standardised concentration (from a licensed manufacturer or prepared in an appropriate aseptic unit). Consideration should be given to the preparation and availability of these products out of hours, including the location of their storage and the staff competency required to perform this task.
4. Regarding disposal of unused or part-used open ampoules and syringes of controlled drugs:
 - o Ampoules and syringes should be emptied completely before being discarded;
 - o Disposal of controlled drugs should be in a container with an absorbent medium designed to denature them; if sharps boxes are used for disposal they should also contain an absorbent medium;
 - o It is poor practice to discard part-filled syringes and ampoules in the sharps bin;
 - o It is good practice to witness the disposal, even though there is no legal requirement to do so; the witness should be a registered health professional.
5. In keeping with the minimum requirements of Regulation 19 of the Misuse of Drugs Regulations 2001 and as recommended in the National Institute for Health and Care Excellence (NICE) guidance [5], recordkeeping for all Schedule 2 drugs in the controlled drugs register must be contemporaneous and should include:
 - o Patient's name, NHS or hospital number;
 - o Date and time of administration of drug;
 - o Amount of drug supplied;
 - o Amount of drug administered;
 - o Amount of drug disposed;
 - o Signatures of person supplying and person administering the drug;
 - o Signatures of person disposing of unused controlled drug and witness.
6. Regular departmental audit should be undertaken to ensure controlled drug doses recorded in the anaesthetic record or medicine record are congruent with the doses recorded in the controlled drugs register in theatre.

7. The sharing of the contents of a controlled drug ampoule between patients is poor practice and should be avoided [6].
8. There should be awareness among healthcare professionals of substance misuse and its early warning signs. The matter should be reported promptly and handled with great care and empathy.

What other guidelines are available on this topic?

Guidelines were published by the Association in 2006 [1] and NICE published guidance on safe use and management of controlled drugs in 2016 [5].

Why was this guideline developed?

There have been a number of changes in the regulations and legislation regarding controlled drugs since the last Association guidelines. Department of Health regulations came into force on 1 April 2013 [7] and cover England, Scotland, Wales and the Armed Forces. There are separate regulations for Northern Ireland [8].

How does this differ from existing guidelines?

The previous Association guidelines have been updated in light of changes in regulations and legislation. In addition, guidance is offered to define good practice and increase accountability when controlled drugs are administered in the peri-operative period.

Introduction

Lapses in good practice in the handling of controlled drugs are a potentially serious matter. The death of an anaesthetist in 2014 [2] led to the Coroner issuing a Report to Prevent Future Deaths to the Chief Coroner [3] and disciplinary action against some staff members. A position statement was issued by the Association in May 2015 and a decision was taken to update the previous guidance [1] to take into account the changes in legislation and regulations relating to controlled drugs. These updated guidelines take into account NICE guidance [5] to highlight good practice regarding controlled drugs usage in the peri-operative period.

The legal framework and regulations

The management of controlled drugs in the UK is ruled by a complex set of regulations and pieces of legislation (see Appendices 1 and 2). Management is devolved to the nations of the UK and some provisions pre-date, others post-date, devolution. Exact comparisons are difficult, but in practice the process is very similar across the whole of the UK, with each nation having a comprehensive legal framework made up of national and UK-wide legislation and regulations.

The Misuse of Drugs Act 1971 [9] is the legislation that controls and classifies drugs that are 'dangerous or otherwise harmful' when misused. The Act applies to the whole of the UK and governs the criminal aspects of possession, supply, production, and import and export of controlled substances. The Act lists all controlled drugs in the UK and divides them into three classes (A, B and C) based on their harmfulness. These classifications are used to determine the penalty for illegal or unlicensed possession.

The Misuse of Drugs Regulations 2001 ('the 2001 Regulations') [10] classifies all controlled drugs into Schedules 1-5. These Regulations apply to England, Wales and Scotland; Northern Ireland has its own set of Regulations that mirror the 2001 Regulations. The Misuse of Drugs Act 1971 [9] and its associated regulations enable organisations to carry out legitimate activities involving controlled drugs, many of which are used in healthcare.

The Road Traffic Act (1988) has been amended by the introduction of new legislation - Section 5A [11]. It concerns driving while taking drugs identified in the regulations, which include some medicines such as morphine, methadone and several benzodiazepines, above specified limits in the blood. The limits that have been set for these drugs are set above therapeutic levels, therefore the vast majority of patients will be unaffected. There is a statutory defence in place if the drugs were lawfully prescribed, possessed and taken in accordance with all directions given, unless instructions not to drive were also given. At the time of writing, this legislation applies only in England and Wales. The new offence does not replace any existing offences of driving whilst impaired by drugs; including licensed medicines.

The Medicines Act 1968 [12], the Human Medicines Regulations 2012 [13] and subsequent amendments govern the control of medicines for human use; however, there is additional legislation and guidance for the management of controlled drugs:

- The Controlled Drugs (Supervision of Management and Use) Regulations 2006 and 2013 (the latter a technical update after other legislation);
- The Misuse of Drugs Act 1971 (England, Wales and Scotland) and amendments in 2015;
- *Safer Management of Controlled Drugs: a guide to good practice in secondary care (England)*, October 2007 [14] (a Department of Health circular);
- In 2016, NICE published guidance on safe use and management of controlled drugs [5]. While this is specifically guidance for England, Healthcare Improvement Scotland, the Welsh Assembly Government and the Department of Health for Northern Ireland have similar requirements.

The most recent, relevant changes are:

- Extension of prescribing of controlled drugs to most non-physician prescribers, the addition of ambulance services and prisons to the organisations that can possess and supply controlled

drugs, and the addition of paramedics and operating department practitioners to the list of healthcare professionals requiring a requisition in order to obtain stock for Schedule 2 and Schedule 3 controlled drugs;

- Requirement for healthcare organisations to appoint a Controlled Drugs Accountable Officer (CDAO) – a senior manager of their organisation, who should not routinely supply or handle controlled drugs themselves as part of their duties;
- Some drugs have been reclassified; most importantly for anaesthetists are ketamine to Schedule 2 (as for the strong opioids) and Sativex® (cannabinoid) to Schedule 4 Part I (Appendix 2);
- A requirement to witness and document destruction of part-used doses was suggested as good practice by the Department of Health [14] in 2007, but has gone unnoticed in many institutions.

Legislation in the Republic of Ireland

The Misuse of Drugs Acts 1971–2015 and the regulations and orders made in the Republic of Ireland regulate and control the import, export, production and supply of controlled drugs.

CQC assessment of the use of controlled drugs in theatres

In England, the CQC monitors safe and effective use of medicines, including controlled drugs as part of its inspection process; similar provisions apply to the devolved nations. Below is an outline of the areas reviewed:

- **Assessment of arrangements specific to controlled drugs:**
 - Security of controlled drug cupboards, access and keys;
 - Entries in theatre controlled drugs registers are clear, timely and signed and in accordance with the organisation's policy;
 - Unused portions of controlled drug preparations are handled safely, i.e. unused portions recorded and disposed of where possible;
 - Disposed of controlled drugs are denatured;
 - Medicines including controlled drugs are not drawn up in advance;
 - Frequent controlled drug checks are in place;
 - Controlled drug audits by pharmacy are in place;
 - Incident reports are completed for deviation from Trust policies, procedures and guidance;
 - Discrepancies and errors are investigated in a timely manner, with action plans and learning identified.
- **Policies/SOPs**
 - Whether organisation-wide medicines policies and/or SOPs are in place for controlled drugs, and that these are regularly reviewed and updated.
- **Pharmacy arrangements**
 - Whether there is oversight by the Chief Pharmacist and the pharmacy team. Involvement and input from the pharmacy team on the top-up of medicines and expiry date checks of controlled drugs.
- **Controlled Drugs Accountable Officer**
 - Whether the CDAO oversees all controlled drug arrangements, including SOPs, for all aspects of controlled drug management, reporting and escalation of controlled drug related incidents and concerns, and the arrangements for policy awareness/training/competency/safe use of controlled drugs by theatre staff.
- **Medication Safety Officer/Medical Device Safety Officer**
 - The CQC checks whether there is a medication safety officer appointed to link with the theatre team and the CDAO/pharmacy team around safe use of medicines and devices.
- **Implementation of relevant legislation and guidance**
 - Whether the organisation's controlled drugs policy takes account of relevant legislation, alerts and national guidance.

- **Controlled drugs usage in theatres**
 - Whether controlled drug usage is in accordance with the organisation's formulary/ drug and therapeutics committee guidelines and policies, and kept under review.
- **Training**
 - It checks whether training and competency assessment in the safe handling of controlled drugs is in place for all relevant staff.
- **Controlled drug audit and action plans**
 - The CQC assesses whether controlled drug governance arrangements are audited. Organisations should have regular audit and monitoring systems in place as part of their medicines management/governance policies. Action plans should be drawn up for when audits identify gaps in the arrangements for controlled drugs and progress on the action plan should be kept under review.
- **Reporting**
 - Whether there is open reporting of controlled drug related errors, discrepancies, concerns and incidents. These should be encouraged using a non-blame culture, investigated appropriately and learning disseminated.

Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment

- All operating departments should have an up-to-date SOP taking into account current legislation and regulations. This should be understood and followed by all staff working in theatres;
- The SOP should take account of local staffing arrangements;
- It is important that the use and availability of opioids and other controlled drugs are not restricted to such an extent that patient care is compromised. During a theatre session there should be appropriate access to the controlled drug cupboards and arrangements in place for custody of the controlled drug cupboard key. The key should always remain in the custody of the anaesthetic nurse/operating department practitioner or handed over to another registered and competent healthcare professional who should be present in theatre;
- Controlled drug ampoules/vials meant for single patient use should not be shared between patients [6]. This should not be construed as including the preparation in pharmacy of individual prepared syringes under aseptic precautions.

Responsibility for handling of controlled drugs

The healthcare professional in charge of each theatre has overall responsibility for:

- ordering, receiving, checking, recording and storing stock;
- recording the amount issued to medical staff;
- returning unused ampoules to stock;
- amending balances appropriately.

Record of administration

When a controlled drug is selected for a patient, the anaesthetic assistant/healthcare professional must ensure documentation of:

- name of patient with hospital/NHS number;
- date and time of dose administered;
- name, formulation and strength of controlled drug administered;
- dose of controlled drug supplied for administration;
- name and signature or initials of person/anaesthetist who administered dose;

Recording controlled drugs in the controlled drugs register must include:

- amount of controlled drug administered;
- amount of unused controlled drug to be disposed of after administration;

- signature of person disposing of unused controlled drug and any witness to disposal;
- suitable controlled drug registers, which are easily available.

Medical staff (including anaesthetists) administering the drugs are responsible for:

- signing the controlled drugs register contemporaneously;
- recording in the patient's notes or anaesthetic record the amount of drug administered;
- returning any unopened ampoules;
- safe disposal of any unused controlled drugs that remain in opened ampoules or part-used syringes; it is good practice that this is witnessed by a registered healthcare professional.

The medicines management team/pharmacy department are responsible for:

- supply of controlled drugs to the appropriate location;
- regular audit of compliance with local guidelines;
- checking the controlled drug stocks and registers as required by the CDAO.

Checking controlled drug stock levels should be undertaken regularly in accordance with the local SOP by two registered healthcare professionals. Both must sign and date the checklist held within the register and any discrepancy should immediately be notified to the senior healthcare professional in the theatre suite. It is good practice to check balances at each issue of a controlled drug.

Transfer of controlled drugs

The transfer of controlled drugs from one theatre to another is poor practice and, ideally, should not occur. However, in cases of urgent clinical need a single dose may be given to a named patient in one theatre from the stock in another with all the required entries being made in the controlled drugs register of the issuing theatre.

Disposal of unused portions of controlled drugs

The local SOP should state how unused controlled drugs are disposed of – ideally this will be by use of a suitable denaturing container.

Good practice for controlled drugs used as infusions/patient-controlled analgesia/patient-controlled epidural analgesia

Controlled drug infusions

A controlled drug infusion that is pre-prepared under the strict conditions of a Marketing Authorisation holder (pharmaceutical companies and some NHS hospital pharmacies) is preferable to that prepared by a clinician. Examples of pre-prepared infusions include 50 ml morphine 1 mg.ml⁻¹ for use in patient-controlled analgesia, and 100 ml levobupivacaine 1mg.ml⁻¹ with fentanyl 2 µg.ml⁻¹ for use in an epidural infusion.

In some circumstances, due to instability of the controlled drug, it is not possible to use pre-prepared infusions (e.g. remifentanyl). Therefore, departments should take a pragmatic approach and accept clinician-prepared infusions (of agreed concentrations) in these circumstances. A SOP should be in place to cover this activity.

Preparation

If the medicine requires preparation, clinicians should do so under sterile conditions and follow the drug's Summary of Product Characteristics (SmPC). As well as the medicine insert, the SmPC for any licensed medicine can be found on the electronic Medicines Compendium website [15]. Alternatively, copies of authorised SmPCs can be found on the MHRA website [16].

Labelling

Labelling of controlled drug infusions should follow the relevant legislation and other Association recommendations (e.g. *Injectable drug labelling & packaging* [17] and *Best practice in anaesthesia by intravenous infusions* [18]; both under review at the time of writing).

For infusions that will not leave the theatre complex:

- Medicine and base fluid;
- Concentration.

For infusions set up in the theatre complex and to be continued on a ward:

- Medicine and base fluid;
- Concentration;
- Patient's name;
- Date and time of preparation;
- Initials of person preparing the infusion.

Disposal of part-used infusions

Controlled drugs that are used in theatre only should be disposed of in theatre prior to the patient leaving. It is good practice to have the disposal of the drug witnessed by another member of staff. All cannulae should be flushed once the medicines, including controlled drugs, have been disconnected.

Controlled drug infusions that leave theatre and recovery should be disposed of on the ward.

Record keeping

Controlled drug infusions used in theatre should be documented on the anaesthetic chart. Those infusions that are to continue after theatre must be prescribed on the patient's drug chart. Disposal of part-used controlled drug infusions should be recorded so that a clear audit trail can be kept. If the infusion is disposed of in theatre, the amount of drug given to the patient and the amount disposed of must be recorded in the controlled drug record book. On the ward, the amount disposed of should be recorded in the ward controlled drug record book or in the patient's medical records (e.g. on the patient-controlled analgesia chart), in line with organisational policy.

Destruction of unused controlled drugs

Unused part doses of controlled drugs should be disposed of safely and made irretrievable by emptying the contents of the syringe, ampoule or other container. This should be achieved by using an absorbent gel which denatures the controlled drug. Disposing into a sharps bin where waste is incinerated is acceptable but not ideal. It is good practice to have an absorbent gel in the sharps bin to avoid pooling of controlled drugs at the bottom of the bin. This disposal should, ideally, be witnessed by practitioners who are signing for the controlled drugs in the controlled drugs register.

Safety and wellbeing of healthcare staff

There is a three times greater frequency of substance abuse in anaesthetists compared with other medical practitioners [19], possibly due to ease of access to opioids. It affects all grades of staff. An Association guideline on identification and management of this problem was published in 2011 (currently under review) [20], and another by the Australian and New Zealand College of Anaesthetists in 2013 [21].

Sadly, the first presentation of substance use disorder in an anaesthetist may be their death, from either deliberate or accidental overdose. Those that are recognised without such a dramatic outcome often present with intoxication and witnessed use, rather than behavioural signs. Direct evidence of abuse, such as observed use, requires immediate action. Indirect signs that should raise concern include:

- Evidence of controlled drugs or intravenous equipment in non-workspace environment;
- Inconsistencies in drug charts, unaccountable or missing drugs, or a consistent pattern of disproportionate postoperative pain in patients;
- Behavioural changes including unexplained absences, mood swings, being found in strange places or working additional shifts. In addition, offering to draw up drugs for others, withdrawal from family and friends, collapse or alteration of conscious level which is unexplained or implausibly explained, adoption of dress which would tend to disguise injection marks, e.g. long sleeve gowns;
- Deterioration in performance (often a late feature).

Substance use disorder should be treated as a health issue, not misconduct, and the practitioner involved should be treated as a patient rather than as a colleague. With appropriate support and cooperation, some anaesthetists can return to practice. A study showed that over 75% of anaesthetists return to full practice if they fully cooperate with treatment and supervision [22].

Audit and quality improvement tools

Regular audit of practice in theatres against standards recommended in the RCoA audit recipe book [23] should be undertaken (see Appendix 3).

Audit standards should include:

- 100% staff awareness of and adherence to existing guidelines/SOP in theatres;
- No evidence of incorrect disposal of controlled drugs;
- 100% accurate and correct record keeping in controlled drugs registers.

Quality improvement projects should be carried out:

- to promote increased awareness of the importance of witnessing disposal of part-used ampoules and syringes of controlled drugs in theatres;
- to promote the importance of denaturing controlled drugs at the point of disposal.

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Appendix 1: Controlled drugs legislation and the role of the Controlled Drugs Accountable Officer

The legislation

The management of controlled drugs is governed by two key sets of legislation, the Misuse of Drugs Act 1971 [9] and supporting regulations (Home Office legislation) and the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (Department of Health legislation) [24]. The main purpose of the Misuse of Drugs Act is to prevent the misuse of controlled drugs by imposing restrictions on their possession, supply, manufacture, import and export. The Department of Health regulations set out strengthened governance arrangements for controlled drugs used as medicines.

Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001

The Misuse of Drugs Act 1971 is the legislation that controls and classifies drugs that are 'dangerous or otherwise harmful' when misused [9].

Many controlled drugs are also essential to modern clinical care and their legitimate, clinical use is governed by the Misuse of Drugs Regulations 2001, which categorises them into five schedules based on their therapeutic usefulness, the need for legitimate access and potential harms when misused [10]. The more harmful a drug can be when misused, the higher the schedule and the stronger the regime around its availability.

Controlled Drugs (Supervision of Management and Use) Regulations 2013

The Shipman Inquiry was an independent public inquiry set up in 2000 to examine the issues arising from the case of Harold Shipman. The inquiry's fourth report *The Regulation of Controlled Drugs in the Community* was published in July 2004 [25] and focused on the methods Shipman used to divert large quantities of controlled drugs for his own purposes, and considered how he was able to do it for so long without being detected. It concluded there were serious shortcomings in the systems for regulating the governance of controlled drugs. In response, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced and came into force in England on 1 January 2007. They have now been superseded by the Controlled Drugs (Supervision of Management and Use) Regulations 2013, which came into force on 1 April 2013 to reflect changes in the NHS [24].

The Department of Health has also published information about the regulations to support the changes made in legislation [7].

The role of the Controlled Drugs Accountable Officer

The 2013 regulations require healthcare organisations such as NHS Trusts and independent hospitals to appoint a CDAO who has responsibility for all aspects of controlled drugs management within their organisation. They must ensure every aspect of controlled drugs management is set out in appropriate and up-to-date SOPs and that these are followed in practice. This includes:

- procurement and storage arrangements;
- monitoring and oversight to ensure safe practices are in place for prescribing and administration;
- ensuring controlled drugs are used appropriately;
- ensuring relevant individuals are trained;
- ensuring there are effective routes for reporting controlled drug related concerns.

Each area team of NHS England is also required to appoint a lead CDAO with responsibility for controlled drug concerns across their geographical area. As part of this responsibility, all CDAOs within their geographical area are required to submit a quarterly occurrence report of controlled drug incidents from within their organisation so that the area team CDAO can identify trends of

concern. For the purpose of sharing controlled drug concerns and good practice initiatives, the area team CDAOs are required to set up controlled drugs local intelligence networks for their area. While they can determine the specific membership, the network should largely comprise CDAOs from across the area, Clinical Commissioning Group representatives and the relevant regulators and agencies as set out in the regulations.

Details of all CDAOs in England are held in the CDAO register, published on the CQC website [26].

Not all healthcare organisations are required to appoint a CDAO; however, those organisations that fall outside of the 2013 regulations must still comply with the Misuse of Drugs Regulations 2001 [10] and must have arrangements in place to ensure the safe and secure management of controlled drugs and the reporting of controlled drug concerns. To achieve this, they should consider nominating a lead person to ensure controlled drug governance arrangements are in place within their organisation.

Appendix 2: Schedules 1-5 controlled drugs

Access to controlled drugs for legitimate medicinal (or exceptionally for industrial purposes) is permitted through the Misuse of Drugs Regulations 2001 [10]. The regulations establish a regime of control around prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal. The purpose of these restrictions is to prevent the diversion and misuse of controlled drugs for patient and public protection.

All controlled drugs are listed in Schedules 1 to 5 of the Misuse of Drugs Regulations 2001 (Table 1). All controlled drugs (with the exception of gamma-butyrolactone, which is not scheduled due to wide use in industry) are listed in one of five schedules to the regulations, based on an assessment of their medical therapeutic usefulness together with their potential harm when misused. Schedule 1 covers drugs that have no therapeutic value and are mainly used for research under a Home Office licence. Schedule 2 controlled drugs are subject to the greatest restrictions and Schedule 5 the least.

Human medicines only contain controlled drugs in Schedules 2, 3, 4 and 5. This means that (appropriately registered) doctors have the authority to supply all but Schedule 1 controlled drugs. Legal possession and supply of Schedule 1 controlled drugs requires a Home Office licence.

Schedule 2 controlled drugs have therapeutic value but are highly addictive and may be subject to abuse. Their use is strictly controlled, including special prescription, storage, destruction and record keeping requirements. Drugs routinely used for anaesthesia fall into this schedule.

Schedule 3 includes barbiturates and some benzodiazepines. While less rigorously controlled than drugs in Schedule 2, they are also subject to special prescription writing and record keeping requirements as per regulation 22. Some are also subject to special storage requirements. Both Schedule 2 and Schedule 3 drugs are subject to the mandatory requisition form which was introduced in 2015.

Schedule 4 is divided into two parts: Part 1 contains most of the benzodiazepines and Part 2 contains the anabolic and androgenic steroids. There are some prescription requirements for Schedule 4 drugs. As per Regulation 16(5) a person shall not supply a controlled drug in Schedule 4 on a prescription later than 28 days after the prescribed date.

Schedule 5 includes preparations containing substances such as codeine or morphine, which are used in such low strength that they present little or no risk of misuse. There are no additional special controls on Schedule 5 drugs.

The Misuse of Drugs (Safe Custody) Regulations (1973 [4]) represents minimum standards for the physical storage of controlled drugs and preparations containing controlled drugs in applicable schedules. These regulations are applicable to all drugs in Schedule 2 to the Misuse of Drugs Regulations 2001 [10] (i.e. those commonly used in anaesthesia) and to some drugs in Schedule 3, e.g. buprenorphine and temazepam.

Table 1 Schedules 1 to 5 of the Misuse of Drugs Regulations 2001 (drugs referred to are examples, not all the scheduled drugs)

Schedule	Designation	Requirements
1	No recognised medicinal or therapeutic uses Used mainly in research	Home Office licence for 'research or other special purpose'
2	Strong opioids Morphine, diamorphine, fentanyl, alfentanil, remifentanil, cocaine, pethidine, oxycodone, ketamine	Requisition Recording in controlled drugs register Safe custody Prescription Witnessing of destruction of expired stocks
3	Midazolam (exempt from safe custody) Tramadol Temazepam Buprenorphine Gabapentin Pregabalin	Requisition Safe custody (unless exempt) Prescription Record keeping requirements
4 (Parts I and II)	Benzodiazepines Steroids and human growth hormone	None: no simple possession offence for Part II
5	Weak preparations of opiates, any morphine containing preparation with not more than 0.2% morphine Oramorph® (morphine sulphate 10 mg in 5 ml)	None: no simple possession offence as per DS22

Appendix 3: Audit tool guidance

Standard (100% compliance)	Justification	Outcome
Appointed Controlled Drug Accountable Officer	LEGAL	YES/NO
Local standard operating policy for controlled drugs	BEST PRACTICE	YES/NO
Evidence of an internal audit process	BEST PRACTICE	YES/NO
Evidence of a structure/process to report concerns		
Evidence of near misses or internal minor incidents	BEST PRACTICE	YES/NO
Evidence of major issues, unexplained discrepancies or illegal activity		
Metal, fixed cupboard used only for this purpose	LEGAL	YES/NO
Keys for the cupboard kept by an appropriate (available) person who does not administer the drugs.	LEGAL	YES/NO
Other unused keys kept in a secure location		
Ordering of drugs complies with regulations that enable an institutional register of controlled drugs to be maintained, including two people checking	LEGAL	YES/NO
Transfer of drugs from location to location is secure and clear documentation is maintained	LEGAL	YES/NO
A theatre controlled drug register is kept and includes:		YES/NO
1. Each preparation of drug considered separately		YES/NO
2. Stock counts maintained		YES/NO
3. Chronological order, with date and time		YES/NO
4. Name of each patient and ID number		YES/NO
5. Amount supplied (S) having two signatures	LEGAL AND BEST PRACTICE	YES/NO
6. Amount administered (A) with at least one signature. (Witness to this administration can be omitted where there is no reliable way to gain a witness)		YES/NO
7. Amount destroyed (D) (only needed if a discard takes place, two signatures required)		YES/NO
8. Corrections to the record should be kept to a minimum. Any corrections should follow the principles of good record keeping (still legible, signed, footnotes)		YES/NO
Medical record keeping;		
1. Entries made in a contemporaneous manner	LEGAL AND BEST PRACTICE	YES/NO
2. Drug, dosage and time of administration		
Unused drugs should be discarded in a way that ensures that drug is unrecoverable. (drug gel, absorbent mat)	BEST PRACTICE	YES/NO
The drug from one ampoule/vial should not be shared between patients.	BEST PRACTICE	YES/NO
Infusions of controlled drugs		YES/NO
1. Market authorisation holder prepared stock (PRE-MADE) or SOP agreed clinician preparation of infusions		YES/NO
2. Appropriate infusion labels (internal use to the department require drug and dose as a minimum, infusions being moved external to the department need date, times, name, location, drug, dose, duration, route and signatures)	BEST PRACTICE	YES/NO
3. Prescriptions and discard tracking of infusions which leave the department is required		YES/NO
Evidence of a policy dealing with potential substance misuse by practitioners	BEST PRACTICE	YES/NO

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