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ROYAL PHARMACEUTICAL SOCIETY





Safe Drug Management in Anaesthetic Practice

Overview

In 2016, the Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists (Association) jointly published a guidance document entitled 'Storage of drugs in anaesthetic rooms'.¹ It was produced in response to concerns expressed by anaesthetists that changes to drug handling and storage practices were compromising patient safety due to the fact that immediate access to emergency drugs was increasingly being restricted. The guidance document was well received but anaesthetists continue to express concerns about restrictions to their rapid access to emergency drugs occasioned by the implementation of regulations not primarily designed with the emergency management of crises that occur during anaesthesia in mind. Some have also asked that the guidance be extended beyond anaesthetic rooms to other areas where anaesthesia is administered, e.g. the Emergency Department and Labour Ward. This document has been produced in response to these patient safety concerns, and takes into account recently published guidance such as the RPS's revised 'Professional guidance on the safe and secure handling of medicines' documents.²

Since publication of the 2016 guidance, the RCoA and the Association have also received queries on issues relating to the welfare of healthcare professionals in relation to drugs used in anaesthetic practice, in particular from official bodies investigating the deaths of anaesthetists who used drugs to which they gained access at their places of work. This new guidance therefore seeks to include consideration of the safety and wellbeing of healthcare professionals by making recommendations that highlight to anaesthetists the risks relating to 'drugs of diversion', i.e. drugs that individuals might seek to appropriate for abuse, self-harm or sale, and that guide development of policies that ensure their safe use.

Scope

The scope of the guidance is the safe management of drugs used during anaesthetic practice in hospitals from the time of entry of drugs into the clinical area in which they are to be used to the time at which they are administered to patients or disposed of. This document builds on existing professional standards and guidance on the storage of medicines, and makes additional recommendations about access to drugs, their security and reconciliation.¹

Anaesthetic practice extends beyond operating theatres to many areas in the hospital, and this guidance seeks to be relevant to all these areas, including (but not limited to) the following:

- Cardiac catheter laboratory
- Critical care
- Emergency Department
- Endoscopy Department
- Labour Ward
- Radiology Department, to include CT and MRI scanners.

The guidance does not address issues covered by Controlled Drugs legislation, and seeks both to endorse and complement guidance issued by the National Institute for Health and Care Excellence (NICE), the Royal Pharmaceutical Society (RPS) and other bodies whose guidance is considered authoritative in the UK. The subject of drug error is not within the scope of this guideline, except where it overlaps with drug storage and access. This guidance does not cover prehospital emergency medicine.

Purpose

This guidance has been produced with three principles in mind:

- 1. Holding patient safety to be of paramount importance, and thereby ensuring timely access to drugs that are needed in the management of clinical emergencies.
- 2. Raising awareness of the risks of drugs used in anaesthetic practice to those who work with them, and supporting the development of a vigilant, supportive and caring culture that protects both healthcare workers and members of the public that they serve.
- 3. Providing clear guidance on standards against which regulators can inspect in order to ensure that hospitals provide a logical and consistent approach to the storage of drugs used in anaesthetic practice that protects patients, members of staff and the public.

Hierarchy of priorities

The guidance sets its priorities in this order:

- 1. Patient safety.
- 2. The safety of healthcare professionals.
- 3. The safety of the public.

The ideal is to develop policies and Standard Operating Procedures (SOPs) for areas in which anaesthesia is administered that equally promote all three priorities in this hierarchy. However, whenever there is concern that policies and procedures may compromise a higher priority, the policy or procedures should not be enacted until such time that all involved in creating them are satisfied that higher priorities are not compromised. A typical example of poor prioritisation would be the placement of drugs that may need to be accessed rapidly in an emergency in a locked cupboard to ensure that members of the public cannot access them.

Recommendations

- Local SOPs should be developed and implemented for the safe storage and management of drugs used in anaesthetic practice. These SOPs should support the three priorities identified in the above hierarchy: patient safety, the safety of healthcare professionals and the safety of the public. The SOPs should be appropriately risk-assessed and agreed by a group that should include but is not limited to: pharmacists, anaesthetists, nurses, operating department practitioners (ODPs) and clinical managers, and should be ratified by the organisation's medicines management committee or equivalent. The Accountable Officer for Medicines within the organisation should endorse them. Local SOPs can contain elements generic to the organisation but should also address location-specific drug management issues.
- Anaesthetists should identify drugs that must be immediately available during clinical practice (Immediately Available Drugs or IADs). Although some of these drugs will be common to all anaesthetic departments, some will be location-specific, patient-specific, procedure-specific or anaesthetic-specific. It is therefore likely that there will be a small number of "universal IADs" for all anaesthetics, such as a neuromuscular blocking drug and a vasoconstrictor, to which the anaesthetist may add additional drugs specific to the location, patient, procedure or anaesthetic. IADs should accompany the anaesthetist and patient in or on a container that can be immediately accessed, i.e. there should be no lock that needs actuation by a key, code or radiofrequency identification (RFID) badge, although a tamper-evident, sealed container that requires no instruments such as scissors to open is acceptable.

- 3 Some clinical areas such as Emergency Department resuscitation rooms or Labour Ward operating theatres will require a selection of IADs for the anaesthetist's use that will be stored in a room that is often unoccupied. These drugs should be stored in a container that can be immediately accessed, as in (2) above. Local SOPs will determine the manner and location of storage of these drugs, e.g. in a tamper-evident container in a closed but unlocked cupboard.
- Some drugs that are not subject to Schedule 2 of the Misuse of Drugs Regulations 2001, such as midazolam (Schedule 3), are treated by many hospitals as Schedule 2 drugs, and written records are kept of their storage, prescription and use.³ The Working Party supports this practice as a way of protecting healthcare professionals and patients. Some drugs that are not listed in any Controlled Drug schedule may be drugs of diversion, e.g. propofol, potassium and neuromuscular blocking drugs. The Working Party encourages hospitals to consider the development of SOPs for the storage, management and reconciliation of these drugs that balance the practicality of changes to their storage and management, the likely urgency of the need for these drugs and the protection of healthcare professionals. The SOPs should also cover the disposal of these drugs and should consider whether drug disposal should be witnessed and recorded by a second healthcare practitioner.
- Physical barriers to access to drugs of diversion can be readily circumvented, and departments in which these drugs are stored and used should develop a vigilant, open, supportive and caring culture that encourages awareness of the risks for healthcare professionals and finds ways of identifying and managing those at risk. Departments should support, encourage and empower all staff members to speak up when they see something related to drug access and usage that does not seem right.
- 6 No workable modification to anaesthetic practice that enables the anaesthetist to continue to deliver anaesthesia safely will fully protect the anaesthetist or other healthcare workers who decide to divert drugs from the clinical area. Limiting access to and enforcing reconciliation of some drugs will not always prevent theft and diversion but may act as a barrier to ready access at times when extreme stress can lead to sudden, self-destructive impulses.
- 7 In common with the RPS's professional guidance on the safe and secure handling of medicines, the Working Party strongly recommends the use of drugs prepared in prefilled syringes.² The presentation of IADs in this format is particularly advantageous, as the majority of prefilled syringes are tamper-evident and would therefore not need storage in tamper-evident containers, the contents of which may be difficult to visualise and access.
- Regular review and audit of the SOPs for the storage, management, and ease of rapid access when necessary, of drugs used in anaesthetic practice should be conducted, with the results being reviewed by multidisciplinary groups responsible for drug management in these areas, and shared with all those involved in drug administration. Revisions should be made to the SOPs when such review indicates that change is necessary. In addition, an effective incident reporting system should be available that allows the reporting, assessment and remediation of adverse issues encountered with gaining access to drugs.
- **9** The Working Party supports the use of effective access control systems for all routes that allow entry to areas in which anaesthesia is administered, limiting access to only those with legitimate reasons for access.

References

- 1 Storage of drugs in anaesthetic rooms, RCoA and Association of Anaesthetists, London 2016 (bit.ly/2ZKS3F0)
- 2 Professional guidance on the safe and secure handling of medicines, Royal Pharmaceutical Society 2018 (bit.ly/3hj2V2K)
- 3 The Misuse of Drugs Regulations 2001, The National Archives 2001 (bit.ly/30qve8U)

Further reading

The Working Party supports the statements made by the following organisations:

- Statement on security of medications in the operating room. American Society of Anesthesiologists, 2018 (bit.ly/3jX1KYc)
- Guideline for the safe management and use of medications in anaesthesia. Australian and New Zealand College of Anaesthetists, 2020 (<u>bit.ly/3bFD5Ex</u>)
- Statement on keeping resuscitation drugs locked away. Resuscitation Council UK, 2016 (htbit.ly/35ivdaY)

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