

Medicines Management Policy

Standard Operating Procedure

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Introduction

This policy is for the safe and secure handling of medicines within a dental practice setting. It has been written in accordance with: -

- The Medicines Act (1968)
- The Misuse of Drugs Act (1971)
- The Human Medicines Regulations 2012
- The Resus Council UK

Hassan Bhojani has overall responsibility for the medicine's management throughout the dental practice.

Competence

The degree of competence of the practitioner in the administration of medicines depends on the nature of that person's training and experience. Any practitioner who prescribes medicines is fully responsible for their actions. A practitioner who feels ill-prepared for any aspect of ordering, handling, prescribing, dispensing, or administering medicines must not perform these tasks until they are confident about their own competence. Medicines (including controlled drugs) may only be purchased from a recognised dental wholesaler.

Other DCPs involvement in the handling of medicines should be appropriately trained to do so, this involved the stock control, retrieval, logging, and general handling of medication held within the premises. Practitioners should only allow competent DCP's to assist in the process.

Responsibilities

Hassan Bhojani has overall responsibility for the custody of controlled drugs and medicines. In addition, Hassan Bhojani is responsible for ensuring that all members of staff adhere to the contents of this policy.

In the event of Hassan Bhojani not being present the responsibility for the correct management of drugs and medicines will reside with a member of the team. All controlled drugs and medicines (including prescription pads) must always be strictly monitored.

Custody of Keys

Prescription pads, medicines or drugs are locked away. Anyone requesting any of these items will be required to log and sign for them. Keys for this storage area are held by the management team. No persons other than the management team have access to this.

Storage of Medicines / Controlled Drugs

We review our guidance from the Royal Pharmaceutical Society (RPS)

Practice must ensure that Medicine storage meets national guidance and regulatory requirements. Governance arrangements are established using the four principles and audit trails are in place to underpin the storage of medicines. In brief those four principles are- 1. Establish assurance arrangements. 2. Ensure capacity and capability. 3. Seek assurance and 4. Continually Improve.

- A risk management approach determines storage systems which reduce the risk of accidental access as well as unauthorised intentional access, whilst balancing the need for urgent or immediate access in clinical emergency situations.
- The storage of Schedule 2 controlled drugs (and where appropriate Schedule 3) meets the minimum requirements specified in legislation (where applicable) and prevents unauthorised access.
- Medicines with differing routes/methods of administration, or which look alike/sound alike are stored separately or segregated to minimise selection errors.
- Medical gases in cylinders are stored safely and securely to mitigate the following health and safety and diversion risks:

- cylinders are heavy and can cause severe injuries if mishandled.
- cylinders contain compressed gas at high pressure and can cause severe injury or death if damage leads to sudden escape of gas.
- oxygen supports combustion and increases the risk of fire.
- other gases may cause suffocation if used inappropriately or may be subject to theft, diversion, and abuse.
- Small size medical gas cylinders (e.g., size C, CD) are stored horizontally on shelves or in wall-mounted fittings. Larger cylinders are stored in a cage or secured to a fixed structure by a safety chain, always.
- Areas where oxygen is stored or used display appropriate signage.
- All medicines, including intravenous fluids and frequently used small volume injections in ampoules (such as local anaesthetic cartridges, sodium chloride 0.9% and water for injection) are stored in their original packaging and not loose or decanted. Where this is not possible, risk assessments are undertaken and reviewed regularly.
- Non-medicines and chemicals such as disinfectants that may be accessed by people who would not otherwise have access to medicines are stored separately from medicines.
- Cupboards for the storage of medicines comply with the current British Standard 2881.
- Locks for cupboards (except patients' medicine cabinets/lockers) comply with the current British Standard as a minimum. The current British Standard is BS 3621.
- Bulk flammable solutions are stored in lockable metal cupboards. A risk assessment is undertaken to determine whether a fire-resistant cabinet is required - this may not be required for small quantities in clinical areas.
- Access is controlled (by key or other means) to cupboards, trolleys, and rooms where medicines are stored.
- Risk assessments are undertaken to determine the number of key copies and safe custody arrangements for these that are appropriate for the healthcare setting.

The controlled medicine held by the practice is Midazolam, which is listed as a Schedule 3 controlled drug under the Misuse of Drugs Regulations 2001. This is kept in the emergency drug kit for the management of status epilepticus and is not supplied to patients for use off the premises. As a schedule 3 controlled drug, it does not need to be stored in a controlled drug cabinet.

Ordering Controlled Drugs

From 30th November 2015 it is mandatory for all Schedule 2 and 3 controlled drugs to be ordered using the official requisition form FP10CDF[†]. These forms should be obtained from NHS Area Teams, even if the dentist has no NHS contract with the Area Team.

Labelling requirements

- The Dentists name and address
- Date of dispensing
- The patients name.
- Expiry date of the medicine
- The name of the medicine
- Directions for use
- The wording to the effect of "Keep out of reach of children" or "for external use only" (If relevant)
- Any special precautions

Stock Control

Practices should keep records of regular checks on both the emergency drug box and controlled drugs cupboard. There should be clear protocols agreed in relation to the identification of problems.

Disposal of controlled medicines

Controlled drugs that need disposal e.g., part used ampoules left over after a clinical procedure or stock that is out of date, unwanted or for some other reason unusable, must be destroyed and disposed of safely in accordance with Misuse of Drugs Regulations 2001.

- All patients should be told how to dispose of any medicines that are no longer required when they are prescribed them.
- Medicines should not be disposed of via the sewerage system or through domestic waste.
- Patients should dispose of their medicines by returning to the community pharmacist or their dental practice.
- Dental practices should dispose of their unwanted medicines by the blue pharmaceutical waste bins.
- All Schedule 2, 3 and 4 (Part 1) controlled drugs, including midazolam, must be denatured, or rendered irretrievable before they are disposed of
- Wherever practicable, controlled drugs should be denatured using denaturing kits. Where use of controlled drug denaturing kits is not possible or practicable, adsorbing a liquid preparation onto cat litter is acceptable. The used denaturing kit or cat litter and the empty ampoules should be disposed of in the pharmaceutical bin.
- Schedule 2 controlled drugs, require witnessed destruction by an individual authorised under the Misuse of Drugs regulations. It is not required to have a witness to the destruction of Schedule 3, 4 and 5 controlled drugs, but it is good practice to have another member of the practice as a witness.

Regulations surrounding disposal of controlled drugs?

Sorting and denaturing controlled drugs for disposal in dental practice must be covered by an Environment Agency exemption: Waste exemption: T28 sort and denature controlled drugs for disposal. Register for an exemption at

<https://www.gov.uk/guidance/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal>

A separate T28 exemption is required for each part of an organisation if they are in different postcode areas e.g., a practice based on two or more sites.

Schedule 2 controlled drugs require witnessed destruction by an individual authorised under Misuse of Drugs Regulations 2001. Dentists are unlikely to need to destroy Schedule 2 controlled drugs unless they hold, for example, morphine for use in the practice. Dentists should seek advice from their local Area Team Accountable Officer if they require Schedule 2 controlled drug destruction to be witnessed. Destruction of Schedule 3, 4 and 5 controlled drugs do not need to be witnessed by an authorised individual. Although destruction and disposal of Schedule 3 and 4 controlled drugs, including midazolam, does not require witnessing by an authorised individual all destruction and disposal carried out within the practice should be documented and witnessed internally to ensure robust stock reconciliation and audit trail.

Written Prescriptions

- The prescriber must have access to a current BNF.

- The prescription must be legible, signed, dated (it is both dentists and nurse's responsibility to ensure that the prescription is legible).
- The name of the drug, dose, form, route, and maximum frequency, in hours, of administration should be stated.
- Generic names should be used.
- Relevant medical history should always be checked before issuing a prescription (checking allergies to anti-biotics in particular).

Duraphat Toothpaste

Sodium fluoride dental paste 0.619% (2800ppm) or 1.1% (5000ppm) are a high strength fluoride toothpaste containing either 2800ppm (parts per million) fluoride or 5000ppm fluoride. These are also known or prescribed as the brand Colgate Duraphat®

High strength fluoride toothpastes, fluoride mouthwashes and fluoride tablets for the indication of prevention of dental caries are not recommended for GP prescribing as acute or repeat FP10 prescriptions, and should only be prescribed by dentists, where appropriate (please see list of items detailed below).

It is recommended that the prescribing and continuation of these fluoride dental products should remain under the close supervision of a dentist who can manage the patient's oral health. The dentist is best placed and the most appropriate clinician to monitor and assess both the benefits and adverse effects of treatment including the risk of patients developing fluorosis.

NHS dentists can issue NHS prescriptions (FP10D) for medicines, where appropriate, from the Dental Practitioners' Formulary (DPF). Private dentists can issue private prescriptions. In some circumstances, dentists can sell prescription only medicines (i.e., sodium fluoride toothpaste) directly to patients.

Delivering better oral health an evidence based toolkit for prevention chapter 2 provides useful guidance for dental teams prescribing Duraphat - [Chapter 2: Summary guidance tables for dental teams - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention/chapter-2-summary-guidance-tables-for-dental-teams)

How long are controlled drug prescriptions valid for?

NHS and private prescriptions for Schedule 2, 3 and 4 controlled drugs are valid for 28 days after the appropriate date on the prescription. The appropriate date is either the date the prescription was written and signed, or any other date indicated on the prescription (by the prescriber) as a date before which the drugs should not be supplied – whichever is later. Prescriptions for Schedule 5 controlled drugs and noncontrolled drugs are valid for six months.

Record Keeping

Since the practice stores and dispenses prescription medicines, the requirements in relation to record-keeping largely apply.

Another controlled drug we use is a Schedule 3 drug (Midazolam). Records of controlled drug purchases are kept (in the form of invoices) as part of the normal practice accounting system and are retained for more than 2 years.

We maintain records of prescriptions issued as part of individual patient clinical records.

Adverse Drug reactions

Any drug may produce unwanted or adverse reactions. Recording of these incidents should be recorded on the patients' clinical notes. The BNF provides details on the type of medicines and reactions which should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).

Web site <http://www.bnf.org/>. This scheme is known as the "Yellow card Scheme" and can be used by all individuals to report adverse reactions.

Recall of prescribed Medicines

The practice monitors MHRA and safety alerts on a weekly basis and is signed up to receive alerts. If an alert was launched in relation to a medicine prescribed by the practice, the practice would refer to the internal prescribing log which would give clear indication of all patients affected by the recall, the practice would then contact the patient immediately to recall the prescription to the pharmacy. The patient would be requested to re-attend the practice for a suitable alternative medication to be prescribed.

Medicine refrigeration

Where practices are required to store medications in the refrigerator (Glucagon being a prime example) The refrigerator should be monitored daily when in use, a maximum/minimum thermometer is recommended for this purpose. The range should be between 2-8 degrees Celsius. Practices can opt to log once daily or best practice standards would be twice daily- AM & PM. Records should be retained as evidence.

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Change History

Version	Status	Date	Author / Editor	Details of Change (Brief detailed summary of all updates/changes)
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0.2	Draft	07.09.22	PG	Document checked and following changes/new guidance added- Page 2- Updated Introduction Page 3 – Update to storage of Medicines guidance Page 5- NEW- Ordering controlled drugs Page 5 – NEW – Labelling requirements Page 6 – NEW stock control Page 8 – NEW- How long to store prescriptions Page 9 – NEW Recall of prescribed medicines guidance Page 9 – NEW Refrigeration of medicines guidance
0.3	Final	28.3.23	PG	Finalised Policy ready for launch
0.4	Final	26/6/24	PG	Update of broken Gov.uk link for registering exception

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