

Template Standard Operating Procedure For: Handling of Midazolam and other controlled drugs in Dental Practices
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Name of Dental Practice :	
Objectives	<ul style="list-style-type: none"> To ensure implementation of the regulations and guidance on safe and secure handling of midazolam and other controlled drugs (CDs)
Scope	<ul style="list-style-type: none"> To cover all aspects of obtaining controlled drug stock, handling, responsibilities, storage, access, stock checks and record keeping in Wirral dental practices
Target Group (Staff who are authorised to follow standard operating procedure)	<ul style="list-style-type: none"> Dentists and all staff within the practice who are involved in the handling of midazolam and other controlled drugs.
Cross reference related policies	<ul style="list-style-type: none"> Amendment to the Misuse of Drugs regulations 2001
Evidence to support procedure	<ul style="list-style-type: none"> Safer Management of Controlled Drugs: Changes to Requirements for Requisitions for the supply of schedule 1,2 and 3 Controlled Drugs <i>Department of Health January 2008</i> A guide to good practice in the management of controlled drugs in primary care (England) Third Edition <i>National Prescribing Centre December 2009</i> Safer Management of Controlled Drugs: Guidance on standard operating procedures for controlled drugs <i>Department of Health January 2007</i> The Safe Custody of Controlled Drugs. A professional practice quick reference guide. <i>Royal Pharmaceutical Society August 2011</i>

Procedure		
Activity	Rationale	Responsibility
1. Ordering Stock Controlled Drugs		
<ul style="list-style-type: none"> Practitioners must NOT use controlled drugs (CDs) dispensed for specific patients, to top up or replace their bags for home visits or practice stock. 	To comply with good practice. This is also a potential offence under the Theft Act 1968	Registered Dentist

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<ul style="list-style-type: none"> Registered dentists can order CDs from a dental wholesaler or local pharmacy by a written requisition. Registered dentists who wish to requisition CDs from a community pharmacy will need to apply for access to the PCT Private CD Dental Prescriber code (tel: 0151 643 5319). This code should be included as the Organisation Code on Part C of the CD requisition form (FP10CDF). When ordering CDs from a local pharmacy, a dedicated CD requisition form (FP10CDF) should be used. Dedicated requisition forms are available from Peter McMullen at the Stationery Department, Bevan House, Wavertree, Tel: 0151 296 7185, Fax: 0151 296 7189 The new forms have serial numbers and must be regarded as controlled stationery and locked away A record of the serial numbers of the forms received should be made. A record of date and name of dentist writing the requisition should also be kept <i>Only in exceptional circumstances, where the dedicated requisition form is not available, a requisition may be written on a non standard form, provided all the legal requirements are met</i> 	<p>A registered dentist is legally entitled to obtain controlled drugs from a wholesaler or pharmacy upon the production of a written requisition.</p>	<p>Registered Dentist</p>
<ul style="list-style-type: none"> The requisition may be in writing or computer generated Be signed by hand and dated by the registered dentist State the dentist's name and address of practice State the dentist's profession (it is good practice to include the dentist's registration number) Specify the drug, form and strength Specify the total quantity of the drug required Specify the purpose for which it is required , such as "for practice use" It is recommended that a copy of the requisition is retained 	<p>To comply with good practice and legal requirements</p> <p>To act as a check when CDs are received</p>	<p>Registered Dentist</p>
<ul style="list-style-type: none"> The original document must be issued to the wholesaler or pharmacy supplying CDs 	<p>Faxed or electronically transmitted requisitions are not currently permitted</p>	<p>Nominated staff member</p>
2. Receiving Stock from Wholesaler or Pharmacy		

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<ul style="list-style-type: none"> If a messenger is sent to collect the CD they must carry a bearer's note, signed and dated by the registered dentist, stating they are authorised to collect the CD. 	To comply with good practice/ legal requirements	Nominated staff member
<ul style="list-style-type: none"> The supplier of CDs should provide a delivery note for the dentist or authorised messenger to sign The dentist or messenger must check the CDs supplied at the point of receipt, checking the drug name, form, strength, quantity, expiry date and that the CDs are in good condition then sign the delivery note for receipt of the CDs. 	To comply with good practice It is the responsibility of the dentist to ensure that the correct item has been supplied	Nominated staff member
<ul style="list-style-type: none"> The dentist or messenger must then transport the controlled drugs directly to the dental practice. It is recommended that the CDs are transported in the boot of the car 	To comply with good practice For maximum security	Nominated staff member
3. Entering stock CDs into Dental Practice Stock		
<ul style="list-style-type: none"> On receipt of CDs into the dental practice, the CDs must be immediately stored securely and away from access by patients or other members of the public. This task may be delegated, but the dentist retains full accountability for this process. It is recommended that the copy of the requisition and the delivery note are stapled together and kept for at least 5 years 	To comply with legal requirements Legally, copies of requisitions should be kept for a minimum of 2 years, however cases often come to court much later than the mandatory 2 years	Nominated staff member or dentist
4. Storage of CDs		
<p>Midazolam is exempt from the safe storage requirements outlined in the 1973 regulations, however it is recommended that it is stored away from public areas that may be accessed by patients and you may wish to maintain storage under safe custody</p> <p>Some other CDs that may be kept by dental practices (eg temazepam) are subject to safe keeping requirements. If any of these are kept, the following considerations apply:</p> <ul style="list-style-type: none"> Practice stocks of CDs must be stored in a locked cabinet or safe that must be bolted to a solid wall or floor. It is highly recommended that the cabinet or safe complies with The Misuse of Drugs Act Regulations 1973 (New CD Cabinets purchased should therefore be designed specifically for the purpose of storing CDs) 	To comply with legal requirements and good practice	Designated practitioner who may be a dentist or a nurse

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<ul style="list-style-type: none"> • Access must be limited to Designated Practitioners who must be a registered nurse or dentist • Stocks of CDs should be kept to a minimum • CDs must be kept in the container issued by the supplying pharmacy or wholesaler • CD cabinets should not be used to store valuables, but should be used exclusively for the storage of CDs and related pharmaceuticals • The dentist or a delegated staff member must undertake a monthly stock check of CDs 	<p>To reduce the risk of error and to comply with Safer Practice Notice No 12</p> <p>To check for out of date stock</p>	
5. Security of Related Stationery		
<ul style="list-style-type: none"> • All CD related stationery such as dedicated requisitions, prescription pads and CD registers and records must be kept locked away when not in immediate use. • The keys to the CD cabinet must be kept personally by the senior practitioner when on duty, out of hours the keys must be kept locked away only accessible to authorised staff. 	<p>To ensure security.</p> <p>To enable staff to locate key to access cupboard</p>	<p>Designated practitioner who may be a dentist or a nurse</p>
6. Disposal of Expired CD Stock		
<ul style="list-style-type: none"> • When stock CDs become expired they should be clearly marked –“date expired” and segregated from other stock. • Destruction of schedule 2 CDs must be witnessed by a PCT Prescribing Adviser, an authorised senior dental officer or a police constable. • Destruction of schedule 3-5 CDs must be witnessed by an appropriate member of staff within the practice eg a nurse • The destruction must be performed by the dentist, using appropriate CD destruction kits (a DOOP kit). The dentist and the authorised witness must both sign the CD register or other documentation that records the destruction. • The denatured CDs should then be disposed of with clinical waste for incineration. 	<p>To comply with legal requirements and good practice</p> <p>People authorised to witness destruction of stock CDs include PCT Prescribing Advisers who have been authorised to destroy CDs by the PCT Accountable Officer, Inspectors of the RPSGB and Police Constables</p>	<p>Registered dentist in conjunction with an appropriate witness</p>
7. Prescribing of Controlled Drugs		
<ul style="list-style-type: none"> • Dosages and frequencies for all controlled drugs must be written in full by the prescriber to aid correct administration. • Prescriptions for controlled drugs should not exceed 30 days supply except in justifiable exceptional circumstances. • If prescribing in excess of 30 days the reason should 	<p>To comply with legal requirements and good practice</p> <p>To comply with Department of Health recommendations</p>	<p>Registered Dentist</p>

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<ul style="list-style-type: none"> • be documented in the patient's notes • The standard FP10D prescription should be used to prescribe CDs on the NHS. Dentists may only prescribe CDs from the Dental Practitioners Formulary list (temazepam, diazepam, dihydrocodeine) • For non-NHS (Private) prescribing, Dentists may only prescribe schedule 2 or 3 controlled drugs as long as they meet the dental needs of the patient • All private prescriptions for schedule 2 and 3 CDs must be written on a prescription form FP10PCD. Access to the PCT Private CD Dental Prescriber code is authorised by the PCT Medicines Management Team (Fax No: 0151 643 5442, Tel No: 0151 643 5319). This process may take in excess of 4 weeks. • Other than in extreme emergencies prescribers should not prescribe for themselves or anyone with whom they have a close personal or emotional relationship 	<p>Pharmacists should challenge CD prescribing that has no recognised dental use Pharmacists cannot dispense Private CD prescriptions unless written on this form</p>	
8. Administration of Controlled Drugs		
<ul style="list-style-type: none"> • If administering CDs from dental practice stock, a record must be made to maintain an audit trail, including the date, name of patient, drug /dose/ quantity /route • The record should be signed by the practitioner administering the CD and whenever possible, a witness, who should be a practice employee. • The information must also be recorded in the patient's record and specify the date, time, strength, presentation and form of administration, dose administered as well as name and occupation of the person administering it. • A record of batch numbers and expiry dates is also recommended 	<p>To comply with good practice</p>	<p>Designated practitioner who may be a dentist or a nurse</p>
9. Advice to Patients		
<ul style="list-style-type: none"> • CD prescriptions must be presented to a pharmacy for dispensing as soon as possible • Medicines including CDs should be stored in a secure location, away from sources of direct heat or high humidity. Suitable temperatures for storage are 	<p>Prescriptions for Schedule 2 and 3 CDs are only valid for 28 days from the date of the prescription To reduce the risk of diversion and to ensure the</p>	<p>Patient or Carer</p>

Template Standard Operating Procedure For: Handling of Midazolam and other controlled drugs in Dental Practices

<p>included in the patient information leaflet issued with the medicine.</p> <ul style="list-style-type: none"> • Consideration must be given to ensuring pets or vulnerable persons such as children do not have access to the medicines. Storage of CDs should also be out of sight from visitors to the home. • At the nearest opportunity any unused, unwanted, out of date CDs should be returned by the patient and or carer to the supplying pharmacy (or if inconvenient, any registered pharmacy) for appropriate destruction • The dental practice will not accept patient returned CDs. 	<p>medicines stay in good condition To avoid accidental ingestion</p> <p>It is an offence to be in possession of CDs that have not been prescribed for you.</p> <p>The supplying pharmacy will have the appropriate systems in place for disposal of CDs</p>	
10. Stock Reconciliation/ Reporting Concerns		
<ul style="list-style-type: none"> • CD stock reconciliation should be performed prior to administration of any controlled drug from stock and also at the end of each working week. • Expiry dates should also be checked at this point. • In the event of a discrepancy in the amount of CDs the discrepancy must be investigated by the Practitioner in Charge or Assigned Practitioner if he/she is not on duty. • The count should be double-checked. • Contact the dental practice manager to report the discrepancy. • In addition to the usual incident form, a completed incident form must be sent to the Accountable Officer for Controlled Drugs on the day of the incident. (Fax No: 0151 643 5442 Tel No: 0151 643 5319) • Once resolved a note should be made in the CD register correcting the discrepancy in the balance • When a discrepancy occurs, a record should be kept of the actions taken • If any member of the dental practice has concerns regarding any aspect of CD management they must contact the Accountable Officer for CDs at the PCT • All clinical incidents involving CDs including near misses must also be reported to the PCT Accountable Officer for CD 	<p>To comply with good practice</p>	<p>Practitioner in charge with another nurse or dentist</p>
11. Staff Training		
<ul style="list-style-type: none"> • All members of the dental practice who are involved 	<p>To comply with good</p>	<p>Dentists and all</p>

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<p>with the prescribing or handling of CDs must be trained to do so and be aware of the contents of this SOP and abide by it.</p> <ul style="list-style-type: none"> All practitioners are responsible to keep up to date with practice through programmes of CPD 	practice and legal requirements	practice staff who are involved in handling controlled drugs.
12. Self-assessment and CDs Declaration Statement		
<ul style="list-style-type: none"> Each Dental Practice is required to complete an annual declaration as requested by the PCT Accountable Officer, relating to the prescribing, management, usage and handling of CDs 	This is a requirement of the Health Act 2006	Authorised person within dental practice with responsibility for the management and use of CDs

Training

Specialist competencies or qualifications	Appropriately trained in the SOP
Continuing education & training	Update on SOP when SOP is reviewed
Risk Assessments	Controlled drugs are drugs of potential abuse.

Organisation

Organisation	NHS Wirral
Dental Practice	

Standard Operating Procedure Developed By

Pharmacist	Name: Helen Dingle Position: Prescribing Adviser	
	Signature: _____	Date: 06/09/12
Practice Lead	Name: Position :	
	Signature: _____	Date: _____
Authorisation		
Lead Pharmacist	Name: Julia Simms Position: Head of Medicines Management, Wirral PCT Accountable Officer, Wirral PCT	
	Signature: _____	Date: 06/09/12

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Standard Operating Procedure (SOP) peer reviewed by:-	
Forum	Members of the Primary Care Prescribing Committee NHS Wirral

Individual Authorisation

Practice employed staff named below based atDental Practice

I have read and understood the Standard Operating Procedure and agree to handle medicines in accordance with this procedure.

Name of Employee	Signature	Authorising Manager	Date