Safer Management of Controlled Drugs

Guidance on Standard Operating Procedures for Northern Ireland

Department of Health, Social Services and Public Safety

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Guidance on Standard Operating Procedures (SOPs) for Controlled Drugs

Introduction

1. The purpose of this guidance is to promote the safe, secure and effective use of all controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. Strengthened measures have been introduced to make sure controlled drugs are managed safely. These governance arrangements need to be implemented in a way that supports professionals, and encourages good practice around the management and use of these important medicines when clinically required by patients.

2. This Department has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006[1]. These will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[2] ("Regulations") made under the Health Act 2006 will require each Designated Body to appoint an Accountable Officer, responsible for the safe and effective use of controlled drugs in their organisation. The Regulations also introduce Standard Operating Procedures (SOPs) for the use and management of controlled drugs, as one of the practical measures that will help to ensure good practice throughout the health and social care system.

3. The Regulations require Accountable Officers to ensure that his or her organisation, or a body or person acting on behalf of, or providing services under contract with his or her organisation, has adequate and up to date SOPs in relation to the use of controlled drugs.

4. The Standard Operating Procedures must in particular cover the following matters as stated in the Regulations:

    - who has access to the controlled drugs
    - where the controlled drugs are stored
    - security in relation to the storage and transportation of controlled drugs as required by Misuse of Drugs legislation
    - disposal and destruction of controlled drugs
    - who is to be alerted if complications arise
    - record keeping, including maintaining controlled drugs registers under Misuse of Drugs legislation and maintaining a record of Schedule 2 controlled drugs that have been returned by patients.

[1] Health Act 2006
[2] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Definition

5 A SOP is an unambiguous document, describing the responsibilities and the procedures necessary to safely and accountably manage any set of processes, in this case around the total management of controlled drugs. A SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of controlled drugs in an individual setting. The responsibilities should be assigned to individuals where possible to ensure accountability.

6 This guidance is intended to provide base line advice on the areas that might be considered for inclusion in the SOP. Different health and social care settings may have practice areas in addition to those outlined below.

Principles

7 Why are SOPs needed for controlled drugs?

- To improve governance of controlled drugs within the organisation
- To ensure practice is in line with the regulatory frameworks
- To improve clarity and consistency for all staff handling controlled drugs
- To define accountability and responsibilities and clarify where responsibility can be delegated
- As a training tool for new and existing staff.

Validation within the organisation

8 A large organisation will require an overarching policy for SOPs, and smaller organisations such as GP practices will need to have an appropriate process in place to agree, adopt and review SOPs for use.

9 SOPs will need to be agreed at a senior level on behalf of the organisation, usually through the Accountable Officer for designated organisations (as defined in the Health Act Regulations and will include the HSC Board, Trusts, Northern Ireland Ambulance Service and Independent Hospitals) and/or involving other relevant stakeholders such as senior practitioners, senior partners, senior pharmacists, prescribing advisers, medical advisers, superintendent pharmacists, and Clinical Governance Leads as appropriate to the organisation.

10 A common template needs to consider inclusion of the following:

- Organisation/Area/Service to which the SOP applies
- Objective/purpose
- Scope
- Stages of the process for example other committees that need to agree such a document
- Responsibilities
- Other useful information such as interaction with other SOPs, what to do if circumstances change
- Validation by organisation and date
- Review period. e.g. one, two or three years
- Lead author and named people contributing to SOP

11 The SOP policy should take account of:

- Training considerations for new and existing staff including ownership and awareness training
- The review criteria, for example:
  - After a given time period
  - Following a critical incident, to include the learning from such incidents
  - Significant change in legislation or best practice
  - Where a specified named person is included in a SOP then the SOP will need to be changed if personnel circumstances change.
- Cascade mechanism of changes to all staff
- Staff responsibilities – requirement to notify variation/inability to follow SOP
- Opportunity to comment and be part of review process.

Scope of SOPs

12 SOPs are needed for every stage of the controlled drug's journey from procurement (ordering, receipt, and transport), safe storage, supply, administration, destruction and guidance for dealing with an incident. Most will require multi-disciplinary collaboration.

13 The organisation will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.

14 The following is to assist in identifying the steps in handling controlled drugs that need to be considered in the SOP and what is appropriate for each organisation.

15 SOPs need to be accessible to staff at all times.

Areas to consider

Receiving into organisation/unit/individual practitioner

Activity	Detail	Comment
Ordering	Assessment of necessity for a licence/authority to produce, supply or possess the stock of controlled drugs.	Refer to Home Office web-site Refer to DHSSPS web-site Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care"
	Format of requisitions including descriptions of other forms and stationery to be used	See Reg 14 of Misuse of Drugs (Northern Ireland) 2002 [MDR (NI) 2002]
	Named person(s) (consider deputy/locum) with authority to order	See Reg 14 of MDR (NI) 2002
	Organisational tendering processes	
Transport and secure transfer of stock	Ensure secure arrangement in place, particularly if not from wholesaler/manufacturer	To be risk assessed depending upon the drugs, amounts, frequency and distance of movement
Receipt	Personnel authorised within organisation to receive	
	Physical check of order for accuracy and completeness	Who is responsible for this and what happens if a deficiency is identified?
	Record keeping of receipt	Is a Proof of Delivery provided? How is the invoice stored and for how long? Refer to DHSS guidance – Good management, good records.
	Security on receipt	Who, where and when is responsible for this once the consignment is accepted?

Activity	Detail	Comment
Storage	Security and key/code security Personnel with access	Refer to Safe Custody Regulations. Does the storage meet the legislative requirements? Is key storage secure and is access limited to nominated individuals? Is there an updated list of those with authority to access?
	Appropriateness for product e.g. temperature	
	Out of Hours access	Can the person lawfully supply a controlled drug under the legislation? Refer to Guidance on Out of Hours procedures.
	Contingency for extended closure	Where are the drugs stored? Who has responsibility?
Register entry	Ensure entries are made in accordance with legislation and best practice guidance.	Who makes entries? When are entries made?
Stationery	Arrangements for controlled stationery including ordering and disposal	Who is responsible? Is a list of who holds what stationery maintained?
Audit	Regular(need to specify when) checks/audits Personnel involved.	To be risk assessed on drugs, amounts held and frequency of transactions. Is there a standard report format
Discrepancies	Action to take if any discrepancies noted	Cross check register entries and physical stocks. Formal investigation to be undertaken by whom and within what time scale.
	Identify chain of interested parties.	Who is to be informed and timescale for reporting. Who is accountable within the organisation? Do the police or other regulatory bodies need to be informed? Role of Accountable Officer.
Process for reconciliation when necessary	Standard format of report. Retention period of report.	Does the organisation have this? Where and how long is it stored?

Transfer within organisation/to practitioners

Activity	Detail	Comment
Request	Prescription	See Regs 15 and 16 of MDR (NI) 2002
	Signed order (correct stationery) by known signatory	See Reg 14 of MDR (NI) 2002
	Checking authority to order	Supplier able to check against specimen signature
Assembly and supply	Authorised personnel (responsible person)	Training/competency/qualifications
	Labelling issues	
	Register entry	
Hand over	Record keeping	To whom
Transport	Authorised personnel	Some organisations may require specific SOPs relating to transport.
	Audit trail on leaving department	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Security	
Audit trail by receiving unit	Personnel authorised to receive	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Record keeping of receipt	
	Security on receipt	

Prescribing

Activity	Detail	Comment
Prescribing	Authority to prescribe	Refer to legal position of who can prescribe which controlled drugs. Supplementary prescriber status, existing and new independent prescribers, private or NHS.
	Prescription stationery	Hospital charts
		HS21 types including SP1 and SP2
	Private prescribing	Prescriber Identification Number – PCD1
	Local restrictions	

Administration

Administration	Authority to prescribe	Consider supplementary prescriber status, existing and new independent prescribers
	Authority to administer	PGD considerations, legal and clinical check
	Assembly	Removal from cupboard/store
		Reconstitution/assembly
		Trained personnel
	Patient	Verification of patient/treatment. Use of clinical notes.
	Register Entry	Entry in patient's notes
	Special precautions	IV, calculations
	Patient specific documentation	
	Disposal/recording arrangements for any unused portion	Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care" Refer to NMC Standards and Professional Guidance.

Records and Register

Record keeping	Record document management	Refer to DHSS guidance – Good management, good records.
	Retention of hard copies/back-up of records	Time period/location/responsible person
	Supplier of register	Contact details of supplier of register
	Record keeping (legal)	Requirements under Misuse of Drugs(Northern Ireland) Regulations 2002
	Record keeping	Patient returned controlled drugs – PDRCs Where is information recorded? By who? Storage of records?

Individual patient supplies

Supply to patient	Authority to supply	Legal and clinical check of prescription
	Assembly and supply	Removal from cupboard
		Training, competency/qualifications
		Standards of equipment used
		Authorised personnel (responsible person)
		Labelling
	Patient/representative	Verification of patient/treatment. Use of clinical notes.
		ID arrangements
	Delivery service	Transfer to delivery driver. Procedures on delivery to patient, consider if patient not at home, counselling.
	Register entry	
	Prescription forms	Arrangements for sending to the Business Services Organisation

Disposal

To include agreed record keeping requirements

Disposal	Unused portions (e.g. ampoules, syringe driver)	How is this undertaken and by whom?
	Out of date stock (ward and pharmacy)	How is this undertaken and by whom?
	Excess stock	Disposal
		Legal return to stock
	Patient Own	
	Denaturing	What is the process for this and what happens to clinical waste?
	Record keeping	
	Authorised witnesses if required	
	Disposal	Carrier and destination? Contact name, address and telephone number.

Illicit substances

Illicit substances	Removal	Who may lawfully undertake this activity?
	Storage	Where are drugs held until removal?
	Recording	How are they recorded?
	Reporting	Relevant contact numbers

Incidents

Incidents	Reporting mechanisms	Who has investigative responsibility? How is this documented?
	Review procedures	On-going reviews held when? Need to review in light of experience.

Audit of SOP

Audit	By whom	
	Format	
	Frequency	
	Reporting route	
	Record management	