UKMi North West

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A summary of prescribing recommendations from NICE guidance

Controlled drugs: safe use and management

NICE NG46; 2016

This guideline covers systems and processes for using and managing CDs safely in all NHS settings **except** care homes.

Definition of terms

CD	controlled drug
IR	immediate release
SR	sustained release
SOP	standard operating procedure

Healthcare professionals providing CDs

Prescribing

- When making decisions about prescribing CDs take into account:
  - benefits of treatment and risks of prescribing, including dependency, overdose and diversion,
  - all prescribed and non-prescribed medicines the person is taking (particularly any centrally acting agents) and whether the person may be opioid naïve,
  - evidence-based sources e.g.NICE, BNF.
- When prescribing CDs**:**
  - document clearly the indication and regimen in the person's care record,
  - check the person's current clinical needs and, if appropriate, adjust the dose until a good balance is achieved between benefits and harms,
  - discuss with the person arrangements for reviewing and monitoring treatment,
  - be prepared to discuss the prescribing decision with other health professionals if further information is requested about the prescription.
- When prescribing **'when required' (prn)** CDs:
  - document clear instructions for when and how to take/use the drug in the person's care record,
  - include dosage instructions on the prescription (with maximum daily amount or frequency of doses) so that this can be included on the label when dispensed,
  - ask about and account for any existing supplies the person has.
- When prescribing, reviewing or changing CD prescriptions, prescribers should follow local (where available) or national guidelines and take into account:
  - appropriate route,
  - dose (including when dose conversions or dose equivalence is needed),
  - formulation (including changes to formulations).
- If guidance on prescribing is not followed, document the reasons why in the person's care record.
- Prescribe enough of a CD to meet the person's clinical needs for ≤30 days. If, under exceptional circumstances, a larger quantity is prescribed, the reasons should be documented in the person's care record.
- Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions to ensure that total opioid load is considered.
- When prescribing CDs outside general practice (e.g. in hospital or out of hours), inform the person's GP of all prescribing decisions and record this information in the person's care record so the GP has access to it. When sharing information take into account the 5 rules from; A guide to confidentiality in health and social care 2013.
- When prescribing CDs for inpatients (e.g. on a medicines or inpatient record) that are to be administered by different routes, prescribe each as a separate item and clearly state when each should be used to avoid administration errors.

Providing information and advice

For the person taking the CD or carer administering it

- Document and give clear information including:
  - how long the person is expected to use the drug,
  - how long it will take to work,
  - what it has been prescribed for,
  - how to use CDs when SR and IR formulations are prescribed together,
  - how it may affect the person's ability to drive (see Department for Transport; Drug driving and medicine: advice for healthcare professionals,
  - that it is to be used only by the person it is prescribed for,
- Advise the person that they or their representative may need to show identification when collecting CDs.
- Provide advice and information about how to store CDs safely. Discuss storage options taking into account:
  - the person's preference for a lockable or non-lockable storage box,
  - whether CDs will be accessible to other people,
  - whether the storage method could increase the risk of CD-related incidents, including patient safety incidents.
- When prescribing or supplying CDs in primary care for use in the community, advise people how to safely dispose of:
  - unwanted CDs at a community pharmacy,
  - used CDs.
- When supplying more than one formulation (e.g. IR and SR) of a CD, discuss the differences between formulations with the person, their family members or carers if appropriate, and check that they understand what the different formulations are for and when to take them.
- When the total quantity of a CD in Schedule 2, 3 or 4 cannot be supplied:
  - inform the person that only part of their supply is available,
  - tell them when the rest will be available,
  - ask them to collect it within 28 days of the date stated on the prescription.

For people having CDs administered

- Tell the person having the CD the name and dose of the drug before it is administered, unless circumstances prevent this.
- Provide advice on how different formulations of CDs are administered, and check that the person understands the advice. Ensure that appropriate equipment is available for the correct dose to be administered.

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Reviewing repeat prescriptions and anticipatory prescribing

- When prescribing a repeat prescription of a CD for treating a long-term condition in primary care, take into account the CD and the person's individual circumstances to determine the frequency of review for further repeat prescriptions.
- Follow locally agreed processes for reviewing anticipatory prescribing of CDs in primary care and palliative care services. Determine the type of review needed on a case-by-case basis, including ongoing clinical need and expiry dates of any CDs already stored by the person.

Obtaining and supplying CDs

Standards and safety checks

- When supplying prescribed CDs:
  - follow relevant standards set by the professional regulator,
  - check with the prescriber about any safety concerns, such as whether the prescribed dose is safe for the person.
- When supplying CDs to a person or their representative, take reasonable steps to confirm their identity before providing the CD.
- If intending to supply dispensed CDs to a person in police custody, check whether custody staff have adequate arrangements and handling facilities for CDs.

Record keeping

- Keep records to provide an audit trail for the supply, administration and disposal of CDs, and the movement of them from one location to another.
- Ensure records of administration for CDs include the following:
  - name of the person having the dose administered,
  - date and time of the dose,
  - name, formulation and strength of the CD administered,
  - dose of CD administered,
  - name and signature/initials of the person administering the dose and any witness to administration.
- Ensure the record of administration of a CD for inpatients and people in the community is readily accessible to:
  - ensure continuity of care,
  - prevent doses being missed or duplicated,
  - avoid treatment being delayed.
- For CDs that are left over after administration, record in the CD register the:
  - amount of CD administered,
  - amount of CD to be disposed of after administration,
  - signatures of the person disposing of the remaining CD and any witness to the disposal.

Recording supplies in the CDs register

- When health professionals in primary care dispense CDs in Schedule 2 in advance of collection, they should document the supply in the CD register only after the drugs are collected by the person or their representative.
- Pharmacists or dispensing doctors unable to supply the total quantity of a prescribed CD in Schedule 2 must make an entry in the CD register for only the quantity of CD supplied (Regulation 19 of the 2001 Regulations). They must make a further entry in the register when the balance is supplied.

Part supplies

- Pharmacists in internal pharmacies (e.g. hospital and prison pharmacies) unable to supply the total quantity of a stock CD on a requisition should ensure the recipient is aware that:
  - a part supply has been made and no further supplies will be made for that requisition,
  - the quantity on the requisition has been amended to the amount actually supplied and is initialled or signed by the supplier.

Administering CDs

Standards and safety checks

- Follow relevant standards set by the professional regulator when administering CDs, and when necessary check with the prescriber about any safety concerns such as:
  - whether the prescribed dose is safe for the person,
  - whether other formulations have already been prescribed for the person,
  - whether the formulation is appropriate,
  - that any past doses prescribed have been taken.

Using continuous administration for CDs

- When prescribing CDs, involve the person's GP and any lead health professionals for other care teams involved in the person's care in decisions about whether to use a device for continuous administration. Record the decision in the patient's care record. If prescribing outside normal working hours, tell the GP about the decision the next working day.
- Health professionals who use devices for continuous administration of CDs should:
  - complete training in setting up the specific devices used by their service and have their competence confirmed,
  - seek specialist advice if needed when setting up devices for continuous administration.

Destruction and disposal

Stock CDs

- Health professionals required by the 2001 Regulations to maintain a CDs register must have an authorised person present to witness destruction of stock CDs in Schedule 2 (Regulation 27 of the 2001 Regulations).
- When destroying and disposing of stock CDs in Schedule 2, health professionals **must** record the following (Regulation 27 of the 2001 Regulations):
  - name, quantity, strength and form of the CD,
  - date of destruction,
  - signature of the authorised person witnessing the destruction,

  and **should** record the following:
  - signature of the person destroying the CDs.
- If legislation does not require a witness to be present when destroying stock CDs in Schedule 3 and 4 (part 1), consider having a witness present.
- If legislation does not require records to be kept of destruction and disposal of stock CDs in Schedule 3 and 4 (Part I), consider recording:
  - name, quantity, strength and form of the CD,
  - signatures of the person destroying the CDs and any witness to the destruction.
- For stock CDs, when disposing of bottles containing irretrievable amounts of liquid drugs:
  - consider rinsing the bottle and disposing of liquid into a pharmaceutical waste bin,
  - remove or obliterate labels and other identifiers from the container,
  - dispose of the clean, empty container into recycling waste.
- Disposal of irretrievable amounts of CDs does not need to be recorded.

CD schedules

The Misuse of drugs regulations 2001(and subsequent amendments) defines drugs into five schedules. See BNF:Controlled drugs and drug dependence

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Returned CDs
- Consider asking a second member of staff (preferably a registered health professional) to witness the destruction and disposal of a patient's returned CDs.
- Consider recording the destruction and disposal of CDs returned by people in a separate book and record the:
  - date of receipt of the CDs,
  - date of destruction,
  - signatures of the person destroying the CDs and any witness.
- When a person has died in their home and CDs need to be removed for destruction and disposal in primary care, consider:
  - discussing the removal of CDs with a family member or carer,
  - recording the action taken and details of the CDs listed in the person's medical record or notes,
  - having a witness to the removal,
  - any requirements of the coroner to keep medicines in the person's home for a period of time,
  - taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess CDs, for safe disposal at the earliest opportunity.

Requisitioning
- When obtaining CDs for use in the community, health professionals in primary care must use the approved mandatory form for requisitioning of CDs in Schedule 2 and 3 [(Regulation 14 of the 2001 Regulations) and Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015].
- When obtaining stocks of CDs in Schedule 2 and 3 from an organisation's contracted external pharmacy, a requisition signed by a doctor or dentist employed or engaged in that organisation must be provided (Regulation 14 of the 2001 Regulations).

Organisations providing CDs
- Organisations should agree governance arrangements with clear lines of responsibility and accountability for CDs in their contracts.
- Designated bodies must appoint a CDs accountable officer, who will quality assure processes for managing CDs in their organisation (Regulation 8 of the 2013 Regulations).
- CDs accountable officers must ensure robust systems are in place for raising and reporting concerns or incidents about CDs in a timely way (including systems for starting investigations) [Regulation 11 and Regulation 13 of the 2013 Regulations]). This should involve liaising with the following responsible bodies:
  - a designated body,
  - the Care Quality Commission,
  - NHS Protect,
  - a police force,
  - a relevant regulated body.
- Consider appointing a nominated person in organisations that are not required by legislation to appoint a CDs accountable officer, to:
  - work in accordance with appropriate governance arrangements for the safe use and management of CDs,
  - make sure processes are in place for safe use and management of CDs and the reporting and investigating of concerns,
  - liaise with the local NHS England lead CDs accountable officer and local intelligence network members.
- An organisation's CDs accountable officer or nominated person should:
  - review CD-related concerns or incidents and take any action needed on a case-by-case basis,
  - share information and learning throughout the organisation from CD local intelligence networks.

Policies and procedures
- Ensure that national medicines safety guidance about CDs, such as patient safety alerts, are incorporated into policy and acted on within a specified or locally agreed timeframe.
- Consider putting processes in place to access prescribing data for all CDs to identify:
  - prescribing trends and potential risks of unintended use,
  - the reasons for very high, increasing or very low volume prescribing.
- Ensure that prescribing policies support prescribers and do not create barriers that prevent health professionals who are competent to prescribe CDs from prescribing.

Standard Operating Procedures
- Develop a CDs policy and SOPs for storing, transporting, destroying and disposing of CDs.
- Establish processes for developing, reviewing, updating, sharing and complying with CDs-related SOPs, in line with legislation and national guidance. Consider using a risk assessment when establishing processes.
- Designated bodies must put in place the minimum SOPs for processes relating to prescribing, supplying and administering CDs, including clinical monitoring for people who have been prescribed CDs (Regulation 11 of the 2013 Regulations).
- Consider developing SOPs to risk assess the use of CDs in organisations providing inpatient care where patients' own CDs may be used and handled. Risk assessment may include:
  - self-administration or self-possession,
  - storage requirements,
  - record keeping,
  - disposal.

Storage
- When developing SOPs for storing CDs, ensure that they are in line with the Misuse of Drugs (Safe Custody) Regulations 1973, meet the needs of the service and take into account:
  - the setting for use and whether security setting is low, medium or high risk,
  - staff access to CDs,
  - the storage environment, including temperature and space in the CDs cabinet,
  - storage of stock (including unwanted or expired stock) and patients' own CDs,
  - any additional storage needs for CDs of different strengths with similar or 'lookalike' packaging.

Stock checks
- Ensure that a SOP is in place for stock checks of all CDs entered into the CDs register. The procedure should include:
  - checking the balance in the CDs register against current stock,
  - visual inspection of liquid balances, periodic volume checks and checks to confirm the balance on completion of a bottle,

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- having two people present to carry out stock checks, if possible,
- the frequency of stock checks, which should be based on the frequency of use and CD-related incidents , and risk assessment; for most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the circumstances,
- recording stock checks along with the date and signature of the health professional carrying out the check.

Audits
- Develop SOPs for audits of CDs registers and cabinets that include, but are not limited to:
  - identifying the person responsible for auditing,
  - the frequency of audits,
  - reporting and managing discrepancies between stocks and records.

Transport
- SOPs for transporting CDs should take into account:
  - storage while in transit,
  - security e.g. use of locked doctor's bags and ambulances,
  - record keeping, such as the movement of CDs supplied for use at different locations,
  - the supply process.
- Ensure governance arrangements and processes are in place for safe transport of CDs or prescriptions for CDs if couriers, taxis or equivalent services are used.

Administering
- Ensure that SOPs for administering CDs include sufficient safety measures to minimise the risk of administration errors.
- Safety measures may include:
  - asking for advice from other health professionals (this could be by telephone or email),
  - arranging for another health professional to carry out a second check of dose calculations and route for administration.

Disposal
- Arrangements for destroying and disposing of CDs must be in place and in line with 2001 Regulations and the Controlled Waste (England and Wales 2012), regardless of source of supply.
- When developing SOPs for disposing of CDs, including unwanted or expired stock and drugs returned by people, take into account:
  - place of destruction,
  - local agreement and records of authorised people to witness the destruction of CDs.
- Consider developing SOPs in primary care organisations based on local arrangements for destroying and disposing of CDs that belonged to a person who has died.

Records
Requisition forms
- Requisitions of supplied CDs should be kept by organisations for 2 years from the date on the requisition (Regulation 23 of the 2001 Regulations).
- In organisations with an internal pharmacy, consider using a locally determined standard requisition form across the whole of an organisation when a mandatory form is not legally required for obtaining stock CDs in Schedule 2 and 3. Include on the form the:
  - signature and printed name of the person ordering the CD,
  - name of the care setting,
  - ward, department or location,
  - CD name, form, strength, and for ampoules, the size if more than one is available,
  - total quantity of the CD to be supplied,
  - date of the request,
  - signature of the person issuing the CD from the pharmacy.

CD registers
- A separate CDs register must be kept for each of the premises of an organisation where CDs in Schedule 2 are stored (Regulation 20 of the 2001 Regulations).
- CDs registers must be kept for 2 years from the date of the last entry,(Regulation 23 of the 2001 Regulations)

Invoices and destruction of CDs
- Unless legislation specifies otherwise, consider keeping:
  - records of the destruction of a patient's own CDs for a minimum of 7 years,
  - invoices for CDs for 6 years.

Risk assessments
- Carry out a risk assessment to determine if CDs in Schedule 3, 4 and 5 should be handled in the same way as CDs in Schedule 2. The risk assessment may include:
  - frequency and quantities of CDs used,
  - storage facilities available,
  - whether the security setting is low, medium or high risk,
  - quantities of CDs expected to be used,
  - checking for discrepancies in stock balances at shift handover,
  - frequency of staff turnover,
  - staff access to CDs,
  - any data from relevant reported incidents.
- In organisations with an internal pharmacy or dispensing doctors, use a risk assessment (see Regulation 3 of the Management of Health and Safety at Work Regulations 1999) to determine locally the most appropriate place for destroying CDs. This should take into account how close the place of destruction should be to where the drugs are used to help minimise risks of CD-related incidents.

CD-related incidents
- When multiple systems are used for reporting CD-related incidents (e.g. local and national systems and occurrence reporting), consider developing a local process that coordinates these systems within the organisation. This may include:
  - reviewing arrangements regularly to reflect local and national learning,
  - carrying out risk assessments of incidents,
  - sharing learning.
- Include in local processes for reporting CD-related concerns or incidents:
  - how to inform the CDs accountable officer or nominated person,
  - reporting incidents in a timely way, ideally within 48 hours.
- An organisation's CDs accountable officer or nominated person should:
  - review CD-related concerns or incidents and take any action needed on a case-by-case basis,
  - share information and learning throughout the organisation from CD local intelligence networks.

Governance and safety in the use of CDs
- Role of NHS England CD accountable officers – see NICE pathway

Recommendations – wording used such as 'offer' and 'consider' denote the strength of the recommendation.

Drug recommendations – the guideline assumes that prescribers will use a drug's Summary of Product Characteristics (SPC) to inform treatment decisions.