Controlled Drugs: Implementing the NICE Guidance on Safe Use and Management

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General Practitioner, Medical Adviser
Jan 2017
Controlled Drugs: Implementing the NEW NICE Guidance on Safe Use and Management

- NICE recommendations (organisations, professionals)
- Current issues & moving forward
- Case scenario
Case scenario

Mrs J is 49yrs old with intractable back pain, and fibromyalgia, past knee operation. She has asthma. She attended pain clinic in 2014, DNA physio.

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What issues or considerations does this scenario raise for you or your organisation?
Question 1.
Estimate the morphine dose equivalence of (i) Fentanyl 50mcg (ii) Buprenorphine 5mg

Recommendation 1.5.6:
‘Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered’.
Controlled drugs: safe use and management of controlled drugs: NICE guideline NG46

Published April 2016
Overview

NICE guideline on controlled drugs (CDs) covers 5 key areas:

- **Prescribing**
- **Obtaining and supplying CDs**
  - dispensing and requisitions
- **Administration**
- **Handling**
  - storage, transport, possession, disposal and destruction of CDs
- **Monitoring**
  - prescribing analysis, reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback of incidents to other health professionals
Evidence reviews & recommendations

- Little evidence identified for systems and processes used for the safe use and management of CDs
- 6 pieces of legislation, 18 UK national policy documents, 2 guidelines, 3 studies, 2 audit reports and professional guidance were included as evidence
- Committee expertise and consensus required
Challenges

• Level of detail
• Legislation
  – versus changes in NHS structure
  – interpretation of amendments
  – exemptions to regulations
  – setting specific requirements
• Terminology
• Setting-specific recommendations
  – such as GP, community pharmacies, hospitals, prisons and urgent care
Recommendations (1)

- 76 recommendations in total
- **Full guideline** provides the rationale behind each recommendation
- **NICE version** lists all the recommendations
- **NICE pathway** interactive, visually represents all of the recommendations, links with other relevant NICE guidance
- **Information for the public**
- **Baseline assessment tool**
NICE pathway

Controlled drugs: safe use and management overview

Safe use and management of controlled drugs

- Organisations
- Health professionals
- NHS England lead controlled drugs accountable officers
- Non-healthcare settings

Related NICE pathways

- NICE pathway on medicines optimisation
- NICE pathway on patient experience in adult NHS services
NICE bites (May 2016): No 87

Controlled drugs: safe use and management

1. A summary of prescribing recommendations from NICE guidance.
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<td>Developing and establishing systems and processes for organisations</td>
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<td>Designed bodies must appoint a controlled drug accountable officer, who will quality assure processes for managing controlled drugs in their organisation, in line with Regulation 6 of the 2013 Regulations. (111)</td>
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<td>Consider appointing a nominated person in organisations that are not required by legislation to appoint a controlled drug accountable officer, i.e.</td>
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<td>• share with the local NHS England and lead controlled drugs accountable officer and lead intelligence network members.</td>
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<td>Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs.</td>
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<td>Establish processes for developing, reviewing, updating, sharing and complying with controlled drug related standard operating procedures, in line with legislation and national guidance. Consider using a risk assessment when establishing processes.</td>
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<td>Designed bodies must put in place the minimum standard operating procedures for processes relating to prescribing, supplying and administering controlled drugs, including clinical monitoring for people who have been prescribed controlled drugs, in line with Regulation 11 of the 2013 Regulations.</td>
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<td>Ensure that national medicines safety guidance about controlled drugs, such as patient safety alerts, are incorporated into policy and acted on within a specified or locally agreed timeframe.</td>
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1.5.1 When making decisions about prescribing controlled drugs take into account:

- the benefits of controlled drug treatment
- the 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 naive
- evidence-based sources, such as NICE and the British National Formulary (BNF), for prescribing decisions when possible."
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Recommendations (2): Organisations

Key points

• Systems and processes for reporting controlled drug related incidents, ideally within 48 hours

• Governance arrangements should include:
  – responsibility and accountability
  – appointing Controlled Drug Accountable Officers (CDAOs) or nominated people
  – transporting CDs
  – destroying CDs

• Policies and processes should:
  – incorporate national medicines safety guidance
  – cover access to prescribing data for all controlled drugs
  – support prescribers and not create barriers
Recommendations (3): Organisations

Key points

• Risk assess:
  – handling of CDs in schedules 3, 4 and 5
  – the most appropriate place for destroying CDs

• Develop standard operating procedures for:
  – CD prescriptions, supply, administration and clinical monitoring
  – storage, transport, destruction and disposal of CDs
  – CD balance checks and audits of CD registers and cabinets

• Record keeping:
  – requisitions
  – registers
  – invoices and destruction
Recommendation 1.3.1

Carry out a risk assessment to determine if controlled drugs in Schedule 3, 4 and 5 should be handled in the same way as controlled drugs in Schedule 2. The risk assessment may include:

- **frequency and quantities** of controlled drugs used
- storage facilities available
- whether the security **setting is low, medium or high risk**
- checking for discrepancies in stock balances at shift handover
- **frequency of staff turnover**
- staff access to controlled drugs
- any data from **relevant reported incidents**.
Recommendations (4): Health professionals

Key points

• When prescribing CDs:
  – Make and record prescribing decisions
  – Provide information and advice to the person
  – Review repeat prescriptions and **anticipatory for CDs**
  – Consider the balance of benefits, risks and harms

• When supplying CDs:
  – follow professional standards and carry out necessary safety checks
  – provide information and advice to the person
  – inform recipient and record **part supplies of stock CDs**
Recommendations (5): Health professionals

Key points

• Requisition requirements
  – Use of approved forms in the community compared to secondary care requisitions

• When administering CDs:
  – follow professional standards and carry out necessary safety checks
  – provide information and advice to the person
  – make records (including records of any remaining CDs)
  – set up continuous administration devices safely
Recommendations 1.7.2 & 1.7.3

1.7.2 Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.

1.7.3 Provide advice on how different formulations of controlled drugs are administered, and check that the person understands the advice. Ensure that appropriate equipment is available for correct dose to be administered.
Recommendations (6): Health professionals

Key points

• Destruction and disposal
  – Witnesses and records for stock or patient’s returned CDs (different for Schedule 2 CDs compared with Schedules 3 and 4)
  – Safe destruction and disposal (in organisations, pharmacies, from patient’s homes, irretrievable amounts)
Recommendation 1.7.8

For controlled drugs that are **left over after administration**, record in the controlled drugs register:

- the amount of controlled drug administered
- the amount of controlled drug to be disposed of after administration
- the signatures of the person disposing of the remaining controlled drug and any witness to the disposal.
Recommendation 1.8.1

Consider recording the destruction and disposal of controlled drugs that have been returned by people in a separate book for this purpose, and record:

- the date of receipt of the controlled drugs
- the date of destruction
- the signatures of the person destroying the controlled drugs and any witness.
Recommendation 1.8.10

When a person has died in their home and controlled drugs need to be removed for destruction and disposal in primary care consider:

- discussing the removal of controlled drugs with a family member or carer
- recording the action taken and details of the controlled drugs 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 controlled drugs, for safe disposal at the earliest opportunity.
Recommendations (7): NHS England lead CDAOs

Key points

• Work with local intelligence networks (LINs) in other areas when needed

• Consider including other relevant local organisations in the wider network part of the LIN
  – such as substance misuse, palliative care and out-of-hours services, and secure environments

• **Feedback to** and **share learning** with CDAOs

• Consider identifying trends in incidents reported and barriers to reporting
Recommendations (8): Non-healthcare settings

Key points

• Have systems and processes in place for storing, recording and transporting CDs that belong to a person who is under the organisation's supervision
Case scenario

Mrs J is 49yrs old with intractable back pain, and fibromyalgia , past knee operation. She has asthma. She attended pain clinic in 2014, DNA physio.

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Which recommendations would you need to consider for this scenario for you or your organisation?
Organisations should:

- Develop standard operating procedures relating to:
  - CD prescription, supply, administration and clinical monitoring
  - storage, transport, destruction and disposal of CDs
  - CD balance checks and audits of CD registers and cabinets

- Have governance arrangements in place for CD related processes

- Policies and processes should incorporate national medicines safety guidance and support prescribers and not create barriers to prescribing CDs

- Risk assess for handling CDs in Schedule 3, 4 & 5 in the same way as for Schedule 2.
Question 1.
Estimate the morphine dose equivalence of
(i) Fentanyl 50mcg (ii) Buprenorphine 5mg

Recommendation 1.5.6:
‘Use a recognised opioid dose conversion guide when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered’.

(i) fentanyl 50microgram patch, change every 72hrs approx. equivalent to morphine120mg /24hrs (BNF)

(ii) buprenorphine ‘5’ (5micrograms/hour) patch approx. equivalent to oral morphine12mg/24hours (BNF)
**Acute**

- **Diazepam** 2mg tablets *one three times a day* (56)
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**Repeat**

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**Question 2.**
What needs to be considered when prescribing controlled drugs and at medication review?
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What needs to be considered when prescribing controlled drugs and at medication review?
Recommendation 1.5.1

When making decisions about prescribing controlled drugs take into account:

- the benefits of controlled drug treatment
- the 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 naive
- evidence-based sources, such as NICE and the British national formulary (BNF), for prescribing decisions when possible.
Recommendation 1.5.2

When prescribing controlled drugs:

• document clearly the **indication** and regimen for the controlled drug 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 harm

• discuss with the person the 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
Recommendation 1.5.5

Prescribe enough of a controlled drug to meet the person's clinical needs for no more than 30 days. If, under exceptional circumstances, a larger quantity is prescribed, the reasons for this should be documented in the person's care record.
Other considerations

- Frequency of issued scripts e.g. acutes
- Total opioid load when viewing a months actual issues
- Over-rides: Safe repeat prescribing process?
- Medicines pattern: Centrally acting load
- Depression /alcohol/ social considerations
- Did not attend physio
- Referral?
Question 3.
What information should be provided to the patient about usage, collection, storage & disposal?
Take into account…

- **Usage**: Rec 1.5.9 includes duration of use, time taken to work, sustained release vs. immediate release preparations, ability to drive.

- **Collection**: Rec 1.5.10: showing ID when collecting CDs from a pharmacy

- **Storage**: Rec 1.8.2 discussing storage options, use of lockable/non-lockable storage box
Disposal: Recs 1.5.11/1.6.6 safe disposal of unwanted/used CDs at a community pharmacy

- **Serious and fatal overdose of fentanyl patches** - MHRA received reports of unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source (Sept 2008).

- **Reminder issued in 2014:**
  - When applying the patch, choose the application site carefully (see instructions on the labelling and in the leaflet that came with the patch).
  - Check that the patch is stuck on securely, especially the edges.
  - When disposing of the patch, fold it as soon as it is removed so that the sticky side sticks firmly to itself. Dispose of the folded patch safely so that it is not picked up by others (especially children).
Recommendation 1.8.10

When a person has died in their home and controlled drugs need to be removed for destruction and disposal in primary care, consider:

• discussing the removal of controlled drugs with a family member or carer
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• 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 controlled drugs, for safe disposal at the earliest opportunity.
GP Quiz

1. Estimate the morphine dose equivalence
2. What do you discuss at medication review?
3. What information should be provided to the patient… about usage, collection, storage & driving
4. Returned medicines & disposal after death
5. Practice systems and processes
   incl. frequency of stock checks, nominated CD lead, review of anticipatory prescribing
GP measures:

- NICE Key therapeutic topics – hypnotics
- AWMSG National Prescribing Indicators 2016/17
  - Hypnotic and anxiolytic ADQs per 1,000 STAR-Pus
  - Tramadol DDDs per 1,000 patients
  - Gabapentin and pregabalin DDDs per 1,000 patients
Strong opiate & tramadol prescribing review
Aneurin Bevan Health Board, Rachel Brace Independent Prescriber

Task & Finish Group
• Consultant Psychiatrist - substance misuse services lead
• Consultant Anaesthetist - pain services lead
• Primary Care Pharmacists
• Secondary Care Pharmacists
• GPs

Two-pronged approach across primary & secondary care
Patient goals
Safe use and management of controlled drugs summary

• Complex guideline covering most settings
• Links to useful documents and websites where further specific information about CDs is required
• Brings together legislation, policy advice, good practice advice
• Implementation
  – Implementation considerations varies with each organisation
  – Risk assessment completed by the right people? Opinion of frontline people?
  – Case-based peer discussion

“Support patients and prescribers so that medicines are appropriate and reviewed holistically”