NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Controlled drugs: the safe use and management

Topic

Through the medicines practice guideline topic selection process, the safe use and management of controlled drugs was identified as a priority area for guidance development.

Who the guideline is for

Who should take action:

- Healthcare professionals.
- Social care practitioners.
- Providers of care services using controlled drugs in their organisation.
- Commissioners of care services using controlled drugs.
- Local authorities.

It may also be relevant for:

- People using services, families and carers and the public.
- Individual people and organisations delivering non-NHS healthcare services.
- Health and social care regulators.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE will carry out an equality impact assessment during scoping. The assessment will:

- list equality issues identified, and how they have been addressed
- explain why any groups are excluded from the scope, if this was done.

1 What the guideline is about

1.1 Who is the focus?

Groups that will be covered

- All health and social care practitioners.
- Organisations commissioning (for example clinical commissioning groups or local authorities), providing or supporting the provision of care of NHS and non NHS services using controlled drugs.
- Adults, young people and children (including neonates) using or taking controlled drugs, or those caring for these groups.

1.2 Settings

Settings that will be covered

- All settings where publicly funded health and social care is delivered.

Settings that will not be covered

- Care homes (this is covered by Managing medicines in care homes [2014] NICE guideline SC1).
- People's own homes, if care is being provided by home care agencies (this topic will be covered in a separate guideline).

1.3 Activities, services or aspects of care

Key areas that will be covered

1 Systems and processes that involve the use and management of controlled drugs in the following areas:
   - Prescribing (including advising patients on the safe use of controlled drugs)
   - Supply (including dispensing, obtaining)
   - Administration

- Recording
- Destruction
- Storage (safe custody)
- Transportation
- Possession
- Managing controlled drugs in specific settings (for example prisons)
- Information sharing.

Areas that will not be covered

1 Treatment of clinical conditions.

2 Unlicensed and 'off label' use of controlled drugs.

3 Shared care arrangements for controlled drug use across primary and secondary care.

4 Education and training of health and social care practitioners.

5 Needle exchange services (this is covered by Needle and syringe programmes [2014] NICE guideline PH52).

1.4 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out when appropriate. The Committee developing the guideline will take into account resource implications when making recommendations for good practice. Further detail on the methods can be found in developing NICE guidelines: the manual.

1.5 Key issues and questions

For the safe use and management of controlled drugs, robust systems and processes are needed. The main key areas relating to controlled drug use include: prescribing, dispensing, administering, handling and monitoring.

While writing this scope, we have identified the following key questions:

1 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safe prescribing to reduce medicines-related incidents, including patient-safety incidents.

2 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safely obtaining and supplying (including dispensing and requisitions) controlled drugs to reduce medicines-related incidents, including patient-safety incidents.

3 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safely administering controlled drugs to reduce medicines-related incidents, including patient-safety incidents.

4 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safe handling (including, storing, transporting, possessing and destroying) of controlled drugs to reduce medicines-related incidents, including patient-safety incidents.

5 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safe recording of controlled drugs to reduce medicines-related incidents, including patient-safety incidents.

6 In line with legislation and regulation for all controlled drugs, what interventions, systems and processes are effective for safe monitoring of use (including, analysing, reporting, sharing information, sharing learning, addressing concerns, feedback) of controlled drugs to reduce medicines-related incidents, including patient-safety incidents.

1.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1 Controlled drug related patient safety incidents[1], including but not limited to:
   - potentially avoidable medicines-related hospital admissions and readmissions
   - prescribing errors
   - dispensing errors
   - administration errors
   - monitoring errors
   - potentially avoidable adverse events
   - missed doses of medicines
   - near misses (a prevented medicines related patient safety incident which could have led to patient harm)
2 Patient reported outcomes such as misuse, quality of life, medicines adherence, concordance, compliance, patient experience and patient satisfaction.
3 Patient and practitioner relationships.
4 Health and social care practitioner reported outcomes such as satisfaction and collaborative working.
5 Process measures as reported in the study or guidance.
6 Controlled drug related incidents as reported in the study or guidance, including but not limited to:
   - diversion (obtaining controlled drugs to sell on)
   - health and social care practitioner misuse
   - inadequate storage
   - missing stock
   - record keeping.
7 Compliance with legislation and regulation.

1 Unintended or unexpected incidents that were specifically related to medicines use, which could have, or did, lead to patient harm.

2 Links with other NICE guidance

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to the safe use and management of controlled drugs:

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76

NICE guidance in development that is closely related to this guideline

NICE is currently developing the following guidance that is closely related to this guideline:

- Medicines optimisation. NICE guideline. Publication date to be confirmed.

2.1 NICE Pathways

When this guideline is published, the recommendations will be added to NICE Pathways. NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

3 Context

3.1 Key facts and figures

3.1.1 The National Reporting and Learning System (NRLS) was introduced in 2010 by the National Patient Safety Agency (NPSA) [2] as a single, national reporting system for patient safety incidents in England and Wales. Healthcare organisations report all patient safety incidents (including controlled drugs related patient safety

[2] In June 2012, the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to NHS England.

incidents) to the NRLS. These incident reports are analysed to identify common risks to patients and opportunities to improve patient safety. Resources are developed to disseminate actionable learning from patient safety incident reports.

3.1.2 There were a number of reports of deaths and harm due to the administration of high dose (30mg or greater) diamorphine or morphine injections to patients who had not previously received doses of opiates. In response to this in May 2006, the NPSA issued a Safer Practice Notice Ensuring safer practice with high dose ampoules of diamorphine and morphine, which aimed to ensure that look-alike packages of morphine or diamorphine were not misselected.

3.1.3 Up to June 2008 the NRLS had received reports of 5 deaths and over 4,200 dose-related patient safety incidents concerning opioid medicines. A rapid response report was disseminated to healthcare organisations to review local medicines and prescribing policies, including standard operating procedures, to reduce dosing errors with opioid medicines.

3.1.4 There were 498 patient safety incidents between November 2004 and November 2008 reported to the NRLS where the dose of midazolam injections prescribed or administered to the patient was inappropriate. Three of these incidents resulted in death. A rapid response report was issued providing healthcare organisations with guidance to prevent future patient safety incidents.

3.1.5 A 7 year review[3] of medicines-related safety incidents concerning controlled drugs reported to the NRLS found the risk of death with controlled drug incidents was significantly greater than with medication incidents generally. Incidents involving overdose of

[3] Cousins D, Gerrett D, Warner B (2013) A review of Controlled Drug incidents reported to the NRLS over seven years. Pharmaceutical Journal Vol 291

controlled drugs accounted for 89 (69.5%) of the 128 incidents reporting of serious harm (death and severe harm). Five commonly used controlled drugs were responsible for 113 incidents (88.4%) leading to serious harm. A detailed review of the 128 incident reports associated with serious harm found that only 1 incident had been referred to the Controlled Drug Accountable Officer (CD AO).

3.1.6 The Care Quality Commission (CQC) has a statutory duty to oversee the safe management arrangements for controlled drugs in England. In addition to ensuring that the regulations are implemented, the CQC produce annual reports describing developments for managing the risks associated with handling and using controlled drugs. The most recent report The safer management of controlled drugs, Annual report 2013 outlines national trends on the use and management of controlled drugs. This report shows that the number of controlled drugs dispensed in primary care was similar to the number in 2012 but the costs increased by 10%.

3.1.7 The NHS Business Services Authority (NHS BSA) provides information on costs and trends in prescribing in England and Wales. The NHS BSA produces 2 sets of reports for controlled drug monitoring:

- comparator charts available for the last 2 quarters' prescribing data
- analysis reports that can be accessed via the information services portal (username and password required).

These reports monitor the prescribing of schedule 2 and 3 controlled drugs allowing CD AOs to 'to highlight potential causes for concern within the prescribing of CDs through: demonstrating variance in the prescribing of controlled drugs between organisations, and by identifying prescribers or organisations exhibiting unusual prescribing behaviour'. The Health and Social

Care Information Centre (HSCIC) also produces an annual report showing prescribing trends for dentists which includes controlled drugs.

3.1.8 New regulations governing the management and use of controlled drugs came into force in April 2013 to ensure consistency with the new structure of the NHS. As a result of the implementation of the new regulations, all Local Intelligence Networks (LINs) have undergone changes to their core membership, procedures and reporting arrangements which are currently being re-established.

3.1.9 There has been significant activity to help ensure the safe use and management of controlled drugs at a local and national level. However, ongoing activity and vigilance is required to sustain the positive developments that have been achieved since the change in the NHS structure. This guideline is needed to consider the following: changes to legislation and NHS structure; national polices; controlled drug related patient safety incidents; and evidence for effective interventions, to provide further clarity and good practice recommendations for the safe use and management of controlled drugs across all NHS settings. This guideline will support organisations to minimise harms associated with the use and management of controlled drugs by having robust systems and processes in place.

3.2 Current practice

3.2.1 Arrangements for controlled drugs have been established to encourage good practice in the management of controlled drugs as well as help to detect unusual or poor clinical practice, systems criminal activity or risk to patients. Organisations have variable systems and processes in place for obtaining, storing, supplying, recording, monitoring and disposing safely of controlled drugs, while at the same time helping to ensure appropriate and convenient access for those patients that require controlled drugs.

3.2.2 NHS England[4] CD AOs have a critical role in the management and safe use of controlled drugs, minimising harm to patients and feeding back local intelligence through LINs.

3.2.3 All healthcare professionals who prescribe, dispense or administer controlled drugs are required to work within the legal and their professional frameworks to ensure safe use of controlled drugs.

3.2.4 New NHS governance structures are in place to support the safe reporting of medicines-related patient safety incidents through the NRLS, NHS England and Medicines and Healthcare products Regulatory Agency (MHRA). This network discusses potential and recognised safety issues and identifies trends and actions to improve the safe use of medicines.

3.3 Policy, legislation, regulation and commissioning

Legislation, regulation and guidance

3.3.1 Since the Shipman Inquiry's Fourth Report in 2004, there have been significant legislative changes to the Misuse of Drugs Act 1971 introduced by the Government to strengthen the governance arrangements for controlled drugs.

3.3.2 Controlled drugs are defined and governed by the Misuse of Drugs Act 1971 and associated regulations. The Home Office is in charge of government policy on security-related issues including activities related to the Misuse of Drugs Act 1971. The Home Office controlled drugs list which includes the most commonly encountered drugs currently controlled under the misuse of drugs legislation and shows their respective classifications under both the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

[4] The NHS Commissioning Board was established in legislation in the Health and Social Care Act 2012 but is now known as NHS England.

3.3.3 The Misuse of Drugs Regulations 2001 and subsequent amendments set out who is authorised to supply and possess controlled drugs. Robust arrangements for the management and use of controlled drugs are required to minimise patient harm, misuse and criminality.

3.3.4 The Health Act 2006 and its associated regulations – principally the Controlled Drugs (Supervision of Management and Use) Regulations 2006 - required that all designated bodies (for example NHS trusts) appointed a CD AO to govern the use and management of controlled drugs and to share intelligence on controlled drug issues.

3.3.5 The Health and Social Care Act 2012 abolished PCTs from April 2013. This had a direct impact on the role of CD AOs and on PCT CD AOs who, in particular, had responsibility for leading controlled drug LIN meetings.

3.3.6 The Controlled Drugs (Supervision of Management and Use) Regulations 2013 carried forward the main provisions of the 2006 regulations and introduced new provisions to reflect the changes made to the structure of the NHS in England as a result of the Health and Social Care Act 2012.

3.3.7 The Department of Health's information about the Controlled Drugs (Supervision of management and use) Regulations (2013) provides support and additional information about the changes made to the regulations which came into effect on 1 April 2013. The supporting information continues to promote good governance concerning the safe management and use of controlled drugs in England and Scotland. Wales and Northern Ireland have their own equivalent but separate regulations which are unaffected by these changes.

3.3.8 The NHS England guidance The Controlled Drugs (Supervision of management and use) regulations 2013 Single Operating Model supports NHS England area teams in establishing their statutory

responsibility in relation to the Controlled Drugs (Supervision of management and use) Regulations 2013.

3.3.9 Professional and regulatory bodies, for example General Medical Council, Royal Pharmaceutical Society and Nursing and Midwifery Council, have good practice guidance to ensure those using controlled drugs work within the legal framework and ensure safe use and management.

3.3.10 Significant legislative changes that have been introduced over the years and the key documents outlined above will be used to inform this guideline. In addition, evidence will be used to identify robust systems and processes for the safe use and management of controlled drugs to develop good practice. This guideline will provide good practice recommendations that are in line with legislation and regulations, and that support health and social care practitioners to improve the safe use and management of controlled drugs.

4 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 3 November to 1 December 2014.

The guideline is expected to be published in March 2016.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.