NICE Medicines and prescribing centre

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Controlled drugs: safe use and management

NICE guideline

Methods, evidence and recommendations

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Draft for consultation

National Institute for Health and Care Excellence

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Disclaimer

This guideline represents the views of NICE and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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1 Introduction

1.1 Background and policy context

The term ‘controlled drug’ is defined by the Misuse of Drugs Act 1971 ("the Act") as ‘any substance or product for the time being specified in Part I, II or III of Schedule 2 of the Misuse of Drugs Act 1971’. Controlled drugs are subject to strict legal controls and legislation determines how they are prescribed, supplied, stored and destroyed. Controlled drugs are managed and used in a variety of settings by health and social care practitioners and by people who are prescribed them to manage their condition(s). Controlled drugs are closely regulated as they are susceptible to being misused and can cause harm. To ensure they are managed and used safely, legal frameworks for governing their use have been established.

Over the years there have been a number changes to legislation for managing controlled drugs as a result of controlled drugs related incidents including patient safety incidents. The Shipman Inquiry's Fourth Report made a number of recommendations to strengthen the prescribing of controlled drugs and for monitoring their movement from prescriber to dispenser to patient. In December 2004 the Government's response to the Shipman Inquiry, Safer Management of Controlled Drugs was published. The response accepted that systems could be strengthened provided that they did not prevent access to controlled drugs to meet patients' needs. Key changes included:

- reducing the validity of any prescription for controlled drugs in Schedule 2, 3 and 4 to be restricted to 28 days;
- healthcare organisations to appoint a controlled drugs accountable officer to ensure that the organisation has robust arrangements for the safe and effective management and use of controlled drugs;
- introduction of requirements that all healthcare providers holding stocks of controlled drugs should have and comply with the terms of an agreed standard operating procedure; and
- a duty of collaboration between local and national agencies, including professional regulatory bodies, police forces and the Care Quality Commission to share intelligence and agree joint action where there is evidence of misuse on controlled drugs issues.

As well as having robust governance arrangements for monitoring the use of controlled drugs, it is equally important to incorporate national patient safety alerts about controlled drugs into standard operating procedures for prescribing, dispensing and administering controlled drugs. There have been a number of reports of deaths and harms as a result of inadequate procedures in place for prescribing, dispensing and administering specific controlled drugs to patients. A 7 year review[1] of medicines-related safety incidents concerning controlled drugs reported to the National Reporting Learning System (NRLS) found the risk of death with controlled drug incidents was significantly greater than with medication incidents generally. Incidents involving overdose of controlled drugs accounted for 89 (69.5%) of the 128 incidents reporting of serious harm (death and severe harm).

Arrangements for the safe and effective use of controlled drugs have been established to encourage good practice as well as to detect unusual or poor clinical practice systems, criminal activity or risk to patients. These arrangements should not interfere with the appropriate use of controlled drugs and good clinical care. Safe governance principles should apply to all health and social care settings and individual practices where controlled drugs are prescribed, stored, administered or transported.

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

This guideline reviews the evidence available to support health and social care practitioners, and health and social care organisations, in considering the systems and processes required to ensure safe and effective use of controlled drugs. The guideline aims to bring together legislation, policy advice, good practice advice, published evidence together with committee experience and opinion in developing the recommendations.

These recommendations were developed using UK controlled drugs legislation and regulations, as amended and updated up until the end of 2015. Organisations and health and social care practitioners should refer to the most recent legislation and regulations (see the government's legislation website).

1.2 Legal framework

The law in relation to medicines for human use is complex. Marketing, licensing and dealing in medicinal products are governed by the Medicines Act 1968 and associated regulations, including the Human Medicines Regulations 2012 which have brought together in one place much of the previously existing law in this area. Compliance is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency sponsored by the Department of Health. The law on controlled drugs stems principally from the Act and associated regulations including the Misuse of Drugs Regulations 2001 ("the 2001 Regulations"). The Home Office leads on policy with regard to controlled drugs.

Controlled drugs are listed (grouped into "classes") in Schedule 2 of the Act.

The use of controlled drugs in medicine is permitted by the 2001 Regulations. Those Regulations, which are periodically amended, set out who is authorised to possess, supply and administer certain controlled drugs, which are listed in 5 Schedules to the 2001 Regulations according to the degree of control to which they are subject.

All controlled drugs are listed in 1 of 5 Schedules to the 2001 Regulations, according to their therapeutic usefulness, their potential for abuse and the perceived need for control. Controlled drugs within Schedule 1 have little or no therapeutic value, are addictive and have a high potential for abuse and are the most strictly controlled. Controlled drugs in Schedule 2 contain opioid drugs such as diamorphine as well as stimulants such as amphetamines. These drugs have a therapeutic value but are highly addictive and so their use is quite strictly controlled. There are special prescription requirements, and Regulations relating to record keeping, safe storage and destruction apply to controlled drugs in Schedule 2. Controlled drugs in Schedule 3 include barbiturates and some benzodiazepines. There is less strict control of controlled drugs in Schedule 3 compared with those in Schedule 2. Controlled drugs in Schedule 4 Part I contain most of the benzodiazepines; Part II contains the anabolic and androgenic steroids which have a potential for abuse. Controlled drugs in Schedule 4 are lightly regulated. Controlled drugs in Schedule 5 include preparations containing controlled drugs used in low strength and they can be sold over the counter under pharmacy supervision.

The relevant legislation is summarised briefly in Appendix F which is accurate at the time of publication. Relevant websites should be accessed for detailed, up-to-date information. Schedule 1 drugs are not included in the guideline as controlled drugs in this Schedule have no therapeutic use and are outside of the scope for this guideline.

1.3 Definitions

Controlled drugs

For the purpose of this guideline, the term ‘controlled drugs’ refers to controlled drugs in Schedule 2, 3, 4 and 5 of the 2001 Regulations. When a particular Schedule of controlled drugs is referred to, it will be specified in the text, for example, controlled drugs in Schedule 2.

Organisations

The term 'organisations' is used to include all commissioners and providers, unless specified otherwise in the text.

Commissioners are those individuals who undertake commissioning which is 'the process used by health services and local authorities to: identify the need for local services; assess this need against the services and resources available from public, private and voluntary organisations; decide priorities; and set up contracts and service agreements to buy services. As part of the commissioning process, services are regularly evaluated'.

Providers are organisations that directly provide health or social care services to people (for example, home care providers, social enterprises, community pharmacies, community health providers, GPs and other independent prescribers, dispensing doctors, voluntary agencies and charities). Where the guideline needs to distinguish between different providers, this will be made clear in the text.

Health and social care practitioners

The term 'health and social care practitioners' is used to define the wider care team, including but not limited to, home care workers, personal assistants, case managers, care coordinators, social workers, GPs, pharmacists and nurses. When specific recommendations are made for a particular professional or practitioner group, this is specified in the recommendation.

1.4 Person-centred care

This guideline offers best practice advice on the safe use and management of controlled drugs.

For the purpose of this guideline, the term ‘person’ or ‘patient’ may be used interchangeably depending on the context of use.

Patients and health professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their health professionals. If the person is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Health professionals should follow the Department of Health’s advice on consent. If a person does not have capacity to make decisions, health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards.

NICE has produced guidance on the components of good patient experience in adult NHS services. All health professionals should follow the recommendations in Patient experience in adult NHS services. In addition, all health and social care practitioners working with people using adult NHS mental health services should follow the recommendations in Service user experience in adult mental health.

1.5 Strength of recommendations

Some recommendations can be made with more certainty than others, depending on the quality of the underpinning evidence. The Committee makes a recommendation based on the trade-off between the benefits and harms of a system, process or an intervention, taking into account the quality of the underpinning evidence. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the person about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Person-centred care').

1.5.1 Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

1.5.2 Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the majority of people, a system, process or an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer…') when we are confident that a system, process or an intervention will not be of benefit for most people.

1.5.3 Interventions that could be used

We use 'consider' when we are confident that a system, process or an intervention will do more good than harm for most people, and be cost effective, but other options may be similarly cost effective. The choice of an intervention, and whether or not to have the intervention at all, is more likely to depend on the person's values and preferences than for a strong recommendation, and so the health professional should spend more time considering and discussing the options with the person.

2 Development of a NICE guideline

2.1 What is a NICE guideline

NICE guidelines make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health, and managing medicines in different settings, to providing social care and support to adults and children, safe staffing, and planning broader services and interventions to improve the health of communities. They aim to promote individualised care and integrated care (for example, by covering transitions between children's and adult services and between health and social care).

NICE guidelines cover health and social care in England and use the best available evidence; they involve people affected by the guideline and advance equality of opportunity for people who share characteristics protected under the Equality Act (2010).

In addition to the recommendations, guidelines also summarise the evidence behind the recommendations and explain how the recommendations were derived from the evidence. Many guideline recommendations are for individual health and social care practitioners, who should use them in their work in conjunction with judgement and discussion with people using services. Some recommendations are for local authorities, commissioners and managers, and cover planning, commissioning and improving services. Health professionals should take NICE guidance fully into account when exercising their clinical judgement, but it does not override their responsibility to make decisions appropriate to the circumstances and wishes of the individual person. The reasons for any differences should be documented.

Predetermined and systematic methods are used to identify and evaluate the evidence.

The guidelines are produced using the following steps:

- the guideline topic is referred to NICE from the Department of Health
- stakeholders register an interest in the guideline and are consulted throughout the development process
- NICE prepares the scope (stakeholders can comment on the draft at a scoping workshop and through a 4-week consultation)
- NICE establishes a Committee (through a formal application and selection process)
- a draft guideline is produced after the Committee assesses the available evidence and makes recommendations
- there is a consultation on the draft guideline
- the final guideline is published.

NICE produces a number of different versions of this guideline the:

- ‘full guideline’ contains all the recommendations, plus details of the methods used and the underpinning evidence
- ‘Short guideline’ lists the recommendations
- ‘information for the public’ is a summary of the recommendations written in plain English for people without specialist knowledge
- ‘NICE Pathways’ brings together all related NICE guidance.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk.

2.2 Remit

The topic for this guideline was identified through the NICE topic selection process. The NICE Medicines and Prescribing Centre developed the guideline.

2.3 Who developed the guideline

A multidisciplinary Committee comprising of health and social care practitioners, members from relevant national organisations and lay members developed this guideline (see Guideline developers for more information).

The National Institute for Health and Care Excellence (NICE) supported the development of this guideline. The Committee was convened by the NICE Medicines and Prescribing Centre and was chaired by Dr Tessa Lewis, in accordance with guidance from NICE and Developing NICE guidelines: the manual (2014).

The Committee met regularly during the development of the guideline. At the start of the guideline development process all Committee members declared interests in line with the NICE Conflict of interest policy, this included any consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent Committee meetings, members declared any new or changes to interests previously declared. If a member's declared interest could be a conflict in the development of the guideline, the Chair asked the member to either withdraw completely or for part of the discussion in line with the NICE Conflict of interest policy and Developing NICE guidelines: the manual (2014) (see chapter 3). The details of declared interests and the actions taken are shown in appendix A.

Staff from the NICE Medicines and Prescribing Centre provided methodological support and guidance for the development process. The team working on the guideline included an assistant project manager, systematic reviewer (senior adviser), health economist, information scientists and a project lead (associate director). They undertook systematic searches of the literature, appraised the evidence, conducted data analysis and cost effectiveness analysis where appropriate, and drafted the guideline in collaboration with the Committee.

2.4 Purpose and audience

The purpose of this guideline is to provide recommendations on the systems, processes or interventions for the safe use and management of controlled drugs.

This guideline is for:

- Health professionals providing care for people who require controlled drugs as part of their treatment (for example, GPs, pharmacists and nurses).
- Social care practitioners providing care for people receiving social care (for example, home care workers, personal assistants and social workers).
- Commissioners of services where controlled drugs are used (for example, local authorities and clinical commissioning groups).
- Providers of services where controlled drugs are used (for example, substance misuse services, ambulance services, home care providers, community pharmacies, community health providers, GPs and other independent prescribers, dispensing doctors, voluntary agencies and charities).

The guideline may also be relevant for:

- People using services and their families or carers and the public.
- Individual people and organisations delivering non-publicly funded services.

- Health and social care regulators.
- Secure environments.
- Police.
- Armed forces.
- Some voluntary services using controlled drugs.

It is anticipated that health and social care providers and commissioners of services will need to work together to ensure that people that use controlled drugs as part of their treatment, benefit from the recommendations in this guideline.

2.5 What this guideline covers

This guideline covers all settings, including people's own homes, where publicly funded health and social care is delivered and includes the following:

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

For further details please refer to the scope in appendix B and review questions in appendix C.2.

2.6 What this guideline does not cover

The guideline does not cover: specific clinical conditions or named medicines, although on occasion the evidence identified to answer a review question included a patient population who may have had a specific clinical condition for example, people with addiction to controlled drugs.

The guideline does not cover care home settings as this is covered by Managing medicines in care homes (2014) NICE guideline SC1.

For further details please refer to the scope in appendix B and review questions in appendix C.2.

2.7 Related NICE guidance

2.7.1 Published NICE guidance

- Medicines optimisation (2015) NICE guideline NG5
- Managing medicines in care homes (2014) NICE guideline SC1
- Needle and syringe programmes (2014) NICE guideline PH52
- Neuropathic pain - pharmacological management: The pharmacological management of neuropathic pain in adults in non-specialist settings (2013) NICE guideline CG173
- Patient Group Directions (2013) NICE guideline MPG2
- Social anxiety disorder: recognition, assessment and treatment (2013) NICE guideline CG159
- Developing and updating local formularies (2012) NICE guideline MPG1

- Opioids in palliative care: safe and effective prescribing of strong opioids for pain in palliative care of adults (2012) NICE guideline CG140
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Attention deficit hyperactivity disorder: Diagnosis and management of ADHD in children, young people and adults (2008) NICE guideline CG72
- Naltrexone for the management of opioid dependence (2007) NICE guidance TA115
- Methadone and buprenorphine for the management of opioid dependence (2007) NICE guidance TA114
- Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents (2006) NICE guidance TA98
- Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia (2004) NICE guidance TA77

2.7.2 NICE guidance in development

- Care of the dying adult NICE guideline (publication expected December 2015)
- Managing medicines for people receiving social care in the community NICE guideline (publication expected April 2017)
- Physical health of people in prison NICE guideline (publication expected November 2016)

3 Methods

This chapter sets out in detail the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guideline was developed in accordance with the methods outlined in Developing NICE guidelines: the manual (2014).

At the start of guideline development, the key issues listed in the scope were translated into review questions. Each review question in this guideline is presented in a separate section that includes:

- An 'evidence review':
- summary of included studies
- Health economic evidence
- Evidence statements
- Evidence to recommendations
- Recommendations and research recommendations.

Additional information is provided in the appendices for each review question, including:

- Evidence tables
- GRADE profiles

3.1 Developing the review questions and outcomes

3.1.1 Review questions

Review questions were developed in a PICO (patient, intervention, comparison and outcome) format and intervention reviews were carried out. For each review question a review protocol was developed. The review protocols then informed the literature search strategy for each review question. The methods used are outlined in chapter 4 of Developing NICE guidelines: the manual (2014).

During the scoping phase 5 review questions were identified. These were all questions to identify the effectiveness and cost effectiveness of interventions. Review questions are usually best answered by randomised controlled trials (RCTs), because this is most likely to give an unbiased estimate of the effects of an intervention. However, in line with the Developing NICE guidelines: the manual (2014) the best available evidence on which to produce the guideline may include evidence other than RCTs.

The Committee discussed the draft review questions at Committee meetings and agreed that minor changes were needed to several outlined in the final scope document; see table 1.

Table 1 Summary of changes made to review questions from the final scope

Review question wording in scope	Final review question
In line with legislation and regulation for scheduled 2, 3, 4 and 5 controlled drugs, what interventions, systems and processes are effective for **secure prescribing** to reduce controlled drugs related incidents, including patient-safety incidents?	In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of drugs Regulations 2001, what interventions, systems and processes are effective for **secure prescribing** to reduce controlled drugs related incidents, including patient-safety incidents?
In line with legislation and regulation for	In line with legislation and regulation for

Review question wording in scope	Final review question
scheduled 2, 3, 4 and 5 controlled drugs, what interventions, systems and processes are effective for **obtaining and supplying** (including dispensing and requisitions) controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?	Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective for **obtaining and supplying** (including dispensing and requisitions) controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?
In line with legislation and regulation for scheduled 2, 3, 4 and 5 controlled drugs, what interventions, systems and processes are effective for **administering** controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?	In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective for **administering** controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?
In line with legislation and regulation for scheduled 2, 3, 4 and 5 controlled drugs, what interventions, systems and processes are effective for **handling** (including, storing, transporting, possessing, disposing and destroying) of controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?	In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective for **handling** (including, storing, transporting, possessing, disposing and destroying) of controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?
In line with legislation and regulation for scheduled 2, 3, 4 and 5 controlled drugs, what interventions, systems and processes are effective for **monitoring** of the use of controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?	In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective for **monitoring** of the use of controlled drugs to reduce controlled drugs related incidents, including patient-safety incidents?

The Committee agreed to add in for clarity the regulation to which the Schedules of controlled drugs are defined. In total, 5 review questions were finalised by the Committee.

3.1.2 Writing the review protocols

A review protocol was developed for each review question. The final review protocols can be found in appendix C.2.

Review protocols outline the background, the objectives and planned methods to be used to undertake the review of evidence to answer the review question. They explain how each review is to be carried out and help the reviewer plan and think about different stages. They also provide some protection against the introduction of bias and allow for the review to be repeated by others at a later date.

Each review protocol includes:

- The review question
- Objectives of the evidence review
- Type of review
- Language
- Legislation and regulation
- Policy and guidance
- Study design/evidence type
- Status

- Population
- Intervention
- Comparator
- Outcomes
- Other criteria for inclusion or exclusion of studies
- Search strategies
- Review strategies
- Identified papers from scoping search and Committee experience that address the review question

Additionally, for each review protocol the Committee considered how any equality issues could be addressed in planning the review work.

Each review protocol was discussed and agreed by the Committee. This included the Committee agreeing the critical and important outcomes for each review question. These are shown in the review protocols.

3.2 Searching for evidence

3.2.1 Clinical literature searching

Scoping searches were undertaken in August 2014 in order to identify previous guidelines, technology assessment reports, and key published documents and reports relevant to the topic. A list of sources searched can be found in appendix C.1.

Systematic literature searches were carried out by an information specialist from NICE guidance information services between February 2015 and April 2015 to identify published evidence relevant to the review questions. The evidence search strategies can be found in appendix C1.2. Searches were carried out according to the methods in the Developing NICE guidelines: the manual. Databases were searched using relevant medical subject headings and free-text terms. Studies published in languages other than English were not reviewed. The following databases were searched for all questions: MEDLINE, Embase, PsycINFO, PubMed and the Cochrane Library. Citation searches were also undertaken in Web of Science and Google Scholar. No papers published after the date of the search were considered in the evidence review.

3.2.2 Health economic literature searching

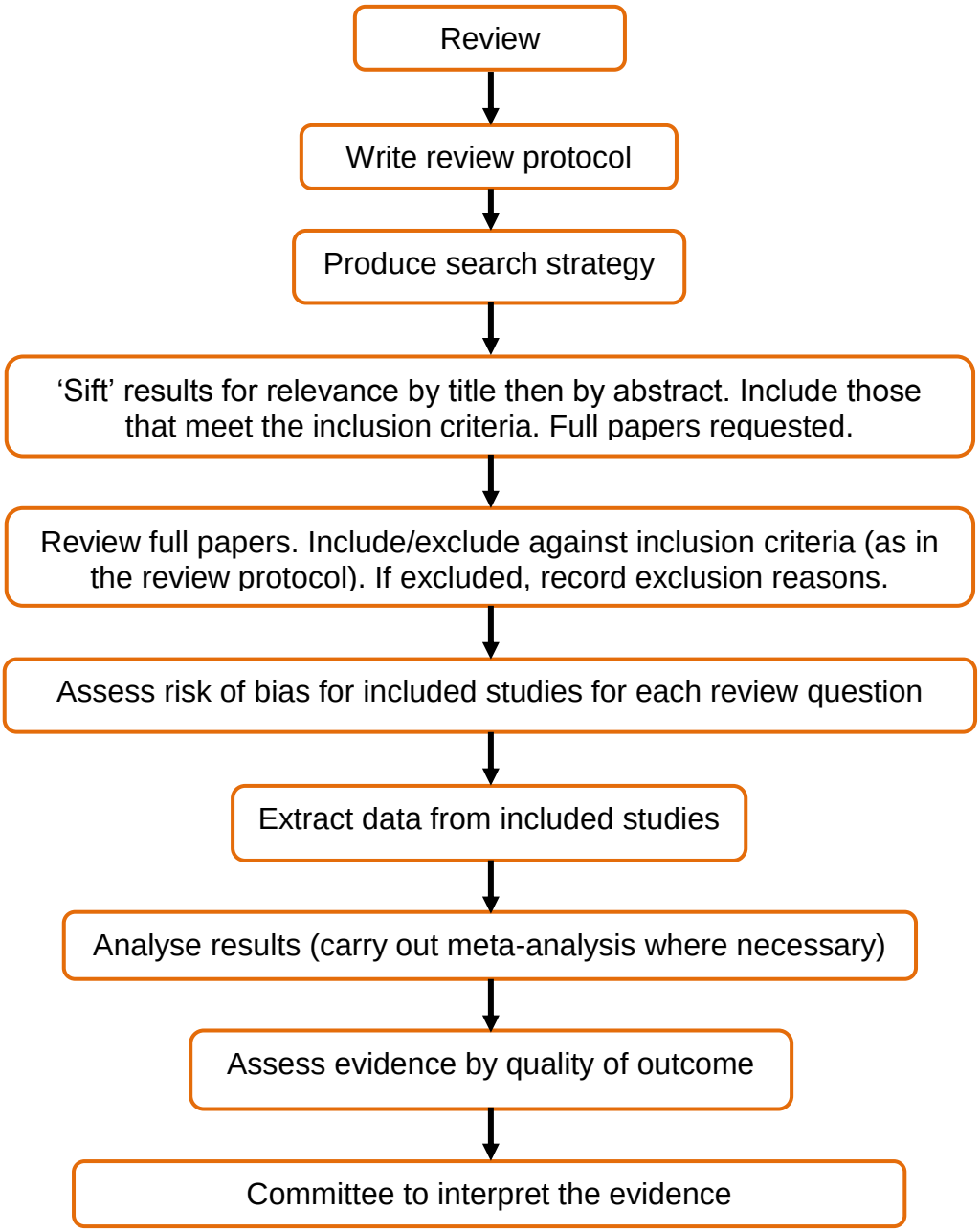
Systematic literature searches were carried out by an information specialist from NICE guidance information services between February 2015 and April 2015 to identify all published health economic evidence relevant to the review questions. The health economic evidence search strategies can be found in appendix C1.3. Searches were carried out according to the methods in the Developing NICE guidelines: the manual. Medline and Embase were searched using specific economic evaluation and quality of life search filters. DARE and the NHS Economic Evaluation Database (NHS EED) were searched using topic terms. Studies published in languages other than English were not reviewed. No papers published after the date of the search were considered in the evidence review.

3.3 Reviewing the evidence

The evidence retrieved from the search strategy was systematically reviewed for each review protocol. Evidence identified from the literature search was reviewed by title and abstract (first sift). Those studies not meeting the inclusion criteria were excluded. Full papers of the included studies were requested. All full text papers were then reviewed and those studies

not meeting the inclusion criteria were excluded (second sift). Relevant data from each included study was extracted and included in the 'Summary of included studies' table. These tables can be found in the relevant 'Evidence review' section. An overview of the systematic review process followed is outlined in figure 1.

Figure 1 Overview of the systematic review process



3.3.1 Inclusion and exclusion criteria

Selection of relevant studies was carried out by applying the inclusion and exclusion criteria listed in the review protocols (see appendix C.2). All excluded studies including reasons for exclusion can be found in appendix C.5. The Committee was consulted about any uncertainty and made the final decision for inclusion or exclusion of these studies.

3.3.2 Types of studies

Only evidence in the English language was considered. For all review questions the following types of studies were considered in the reviews:

- systematic reviews of RCTs
- RCTs
- observational studies (where RCTs not available).

National guidance from the UK, Europe and other countries with similar developed health systems, for example Australia, Canada and New Zealand, was used in the evidence reviews where relevant to the review question.

There were no systematic reviews of RCTs identified for this guideline. In the absence of RCT evidence, some review questions included non-NICE accredited guidance, qualitative studies, audit reports, questionnaires and/or professional guidance. National policy documents relating to patient safety were included as part of the evidence reviews for all the review questions.

Characteristics of data from included evidence were extracted into a standard template for inclusion in an evidence table, which can be found in appendix D. Evidence tables help to identify the similarities and differences between the types of evidence used, including the key characteristics of the study population and interventions or outcome measures or themes of good practice. This provides a basis for comparison. Each evidence table includes:

- Bibliographic reference
- Evidence/study type
- Evidence/study quality
- Research parameters
- Population
- Themes/intervention/systems/processes
- Limitations
- Additional comments

Characteristics of data from included national policy documents were also extracted into evidence tables. The evidence table includes:

- Source of evidence, for example NHS England, Medicines Healthcare products and Regulatory Agency (MHRA) or Care Quality Commission (CQC)
- Title of the alert/report
- Reason for the alert/report
- Actions outlines in the alert/report

All studies were quality assessed using the appropriate NICE methodology checklist; see appendix H in Developing NICE guidelines: the manual (2014). Other checklists were used to assess the methodology of audits and questionnaires; this included using the British Medical Journal critical appraisal checklist for a questionnaire study and the Healthcare Quality Improvement Partnership (HQIP) 'Criteria for high quality clinical audit'. The quality of the included international guidelines was assessed using the international criteria of quality for guidance development, as outlined by the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument.

3.3.3 Data analysis for the evidence reviews

Out of the 5 review questions, only 1 RCT that looked at an intervention was included for the review question on administering controlled drugs (see section on administration of controlled drugs). A meta-analysis was not carried out as there was only one RCT included. For this reason there was no assessment of heterogeneity.

Risk ratios (relative risk) were calculated for the dichotomous outcomes, such as retention in treatment for substance misuse. Mean differences were calculated for continuous outcomes, such as reduction in days of heroin use. GRADEpro software was used to calculate risk ratios and mean differences. Criteria such as the width of the confidence intervals and the number of events (as defined and reported in the study) were used to make judgements about imprecision and to assess the uncertainty of the results. When imprecision was apparent the quality of the evidence was downgraded (see table 3).

Data and outcomes extracted from national policy documents, professional guidance, questionnaires and audits were summarised as a short narrative or key points or themes in the 'summary of included references' table for each review question. Data was not combined for any of the reviews.

3.3.4 Appraising the quality of evidence by outcomes

Legislation and policy does not need quality assessment in the same way as other evidence, given the nature of the source. Recommendations from national policy or legislation are quoted verbatim in the full guideline, where needed.

Evidence was appraised for outcomes identified from the included RCT using 'Grading of Recommendations Assessment, Development and Evaluation (GRADE)' approach to assess the quality of evidence by outcomes. Developing NICE guidelines: the manual (2014) explains that 'GRADE is a system developed by an international working group for rating the quality of evidence across outcomes in systematic reviews and guidelines. The system is designed for reviews and guidelines that examine alternative management strategies or interventions, and these may include no intervention or current best management. For each outcome GRADEpro was used to assess the quality of the study, considering the individual study quality factors. Results of the analysis were presented in 'GRADE profiles' (see appendix D.2 for the GRADE profile).

The evidence for each outcome was examined separately for the quality elements listed and defined in table 2. Each element was graded using the quality levels listed in table 3. The main criteria considered in the rating of these elements are discussed below. Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall quality assessment for each outcome (table 4).

Table 2 Description of the elements in GRADE used to assess the quality of intervention studies

Quality element	Description
Risk of bias (study limitations)	Limitations in the study design and implementation may bias the estimates of the treatment effect. High risk of bias for the majority of the evidence decreases confidence in the estimate of the effect
Inconsistency	Inconsistency refers to an unexplained heterogeneity (as assessed by the I-squared or Chi-squared statistic studies) or variability in estimates of treatment effect across studies
Indirectness	Indirectness refers to differences between the population, intervention, comparator for the intervention and outcome of interest
Imprecision (random error)	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the

Quality element	Description
	effect
Publication bias	Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies

Table 3 Levels of quality elements in GRADE

Level	Description
None	There are no serious issues with the evidence
Serious	The issues are serious enough to downgrade the outcome evidence by 1 level
Very serious	The issues are serious enough to downgrade the outcome evidence by 2 levels

Table 4 Overall quality of outcome evidence in GRADE

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

For the evidence included for the review questions on prescribing, obtaining and supplying, handling and monitoring of controlled drugs (qualitative, audits and a questionnaire), the GRADE framework was not considered appropriate.

3.3.5 Evidence statements (summarising and presenting results for effectiveness)

Evidence statements for outcomes were developed to include a summary of the key features of the evidence. For each question, evidence statements for effectiveness of the intervention, system or process and cost effectiveness were produced to summarise the evidence. The Committee used these in their review of the evidence and to support their decision-making when linking evidence to recommendations. The wording of the statement reflects the certainty or uncertainty in the estimate of effect.

3.4 Evidence of cost effectiveness

The Committee needs to make recommendations based on the best available evidence of clinical and cost effectiveness. Guideline recommendations should be based on the estimated costs of the interventions or services in relation to their expected health benefits (that is, their 'cost effectiveness'), rather than on the total cost or resource impact of implementing them. Thus, if the evidence suggests that an intervention or service provides significant health benefits at an acceptable cost per person treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key issues addressed in the guideline was sought. The health economist undertook a systematic review of the published economic literature (see appendices C.1.3 and C.4 for details of the searches and search results), including critical appraisal of relevant studies using the economic evaluations checklist as specified in appendix H of Developing NICE guidelines: the manual (2014).

Economic modelling was not carried out for this guideline as there was no relevant evidence or information identified.

3.5 Developing recommendations

The Committee reviewed the effectiveness (including cost effectiveness) of evidence in the context of each of the 5 review questions to develop recommendations that would be useful to health and social care practitioners and commissioning and provider organisations.

The recommendations were drafted based on the Committee's interpretation of the evidence presented, where they considered the relative values of different outcomes, trade-offs between benefits and harms, quality of the evidence, costs of different interventions and other factors they may need to be considered in relation to the intervention.

For each review question, the effectiveness of the intervention, systems or process identified from the evidence was presented first, considering the net benefit over harm for the prioritised critical outcomes (as set out in the review protocols [see appendix C.2]). This involved an informal discussion, details of which are captured in the 'Evidence to recommendations' table for each review question.

The Committee then reviewed any cost effectiveness evidence where available and considered how this impacted on the decisions made after presentation of the clinical and cost effectiveness evidence. The recommendation wording considered the quality of the evidence and the confidence the Committee had in the evidence that was presented, in addition to the importance of the prioritised outcomes (the Committee's values and preferences).

Where the effectiveness (including cost effectiveness) of the evidence was of poor quality, conflicting or absent, the Committee drafted recommendations based on their expert opinion. Consensus-based recommendations considered the balance between potential benefits and harms, economic costs compared with benefits, current practice, other guideline recommendations, individual preferences and equality issues, and were agreed through discussion with the Committee.

The wording of the recommendations took into account the strength of the evidence and wording was based on the principles in chapter 9 of Developing NICE guidelines: the manual (2014). Some recommendations are strong in that the Committee believes that the vast majority of health and social care practitioners and people would choose a particular intervention if they considered the evidence in the same way that the Committee has. This is generally the case if the benefits of an intervention outweigh the harms for most people and the intervention is likely to be cost effective. Where the balance between benefit and harm is less clear cut, then the recommendations are 'weaker'; some people may not choose an intervention, whereas others would. Recommendations for practice that 'must' or that 'must not' be followed are usually included only if there is a legal requirement to apply the recommendation except occasionally when there are serious consequences of not following a recommendation (for example, there is a high safety risk).

3.5.1 Research recommendations

The safe use and management of controlled drugs is underpinned by legislation. Research recommendations for areas where there was no evidence were discussed however the Committee agreed not to make any research recommendations.

3.6 Validation process

3.6.1 Validation process

This guideline is subject to a 4-week public consultation. This allows stakeholders, members of the public and other NICE teams to peer review the document as part of the quality assurance process. All comments received from registered stakeholders within the specified deadline will be responded to. All comments received and responses given will be posted on the NICE website. See chapter 10 of Developing NICE guidelines: the manual (2014) for more information on the validation process for draft guidelines, and dealing with stakeholder comments.

3.6.2 Updating the guideline

The guideline will be updated in accordance with the methods described in chapter 15 of Developing NICE guidelines: the manual (2014).

Disclaimer

This guideline represents the views of NICE and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

3.6.3 Funding

NICE commissioned the NICE Medicines and Prescribing Centre to produce this guideline.

4 Guideline summary

4.1 Recommendations

Prescribing of controlled drugs (a)

When prescribing controlled drugs, there are many considerations that need to be taken into account, such as prescription writing requirements for controlled drugs in Schedule 2 and 3, clinical need and the person's values and preferences. Regulation 15 of 2001 Regulations specifies requirements for writing prescriptions for controlled drugs. In addition to working within the legal framework, prescribers need to use their clinical and professional judgment when prescribing controlled drugs to people.

Organisations

1. Develop processes that support prescribers who have been assessed as competent to prescribe controlled drugs. Processes should not place unnecessary barriers on prescribers.

Prescribers

2. When making decisions about prescribing controlled drugs take into account:
    - the benefits and risks of prescribing (for example, the risks of diversion in the person's home, overdose and access to the controlled drug by other people)
    - any other medicines the person is taking (including any other centrally acting medicine prescribed) and whether the person may be opioid naive
    - evidence-based sources for prescribing decisions when possible.
3. When prescribing controlled drugs:
    - document clearly the indication for the controlled drug in the person's care record
    - if appropriate, titrate the dose (up or down) until a good balance is achieved between clinical effect and side effects
    - take into account the person's ongoing clinical needs and whether dose reduction may be needed
    - discuss with the person the arrangements for reviewing and monitoring treatment for clinical and adverse effects.
4. Document and give clear instructions to the person taking or administering the drug, 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 controlled drugs prescribed in both sustained-release and immediate-release formulations.
5. When prescribing 'when required' controlled drugs:

- Document clear instructions for when and how to take or use the drug in the person's care record.
- Include dosage instructions on the prescription (including the maximum daily amount and how long the controlled drug should be used for) so that this can be included on the label when dispensed.
- Take into account any existing supplies the person has of 'when required' controlled drugs.

6. 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.
7. Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.
8. When prescribing, reviewing or changing controlled drug prescriptions, prescribers should follow local (where available) or national guidelines and take into account the:
    - 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.
9. Use a locally agreed opioid dose conversion table when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.
10. When prescribing a repeat prescription of a controlled drug for treating a long-term condition, take into account the controlled drug and the person's individual circumstances to determine the frequency of review for further repeat prescriptions.
11. When prescribing controlled drugs, advise people how to safely dispose of:
    - unwanted controlled drugs at a community pharmacy
    - used controlled drugs.
12. When prescribing controlled drugs outside of general practice, inform the person's GP of all prescribing decisions in line with the following 5 rules :
    - Confidential information about service users or patients should be treated confidentially and respectfully.
    - Members of a care team should share confidential information when it is needed for the safe and effective care of an individual.
    - Information that is shared for the benefit of the community should be anonymised.
    - An individual's right to object to the sharing of confidential information about them should be respected.
    - Organisations should put policies, procedures and systems in place to ensure the confidentiality rules are followed.

Record this information in the person's care record and use it to inform prescribing decisions.

13. Follow local processes for reviewing anticipatory prescribing of controlled drugs. Determine the type of review needed on a case-by-case basis, including the ongoing clinical need and the expiry dates of any controlled drugs already stored by the person.
14. When prescribing controlled drugs (for example, on a medicines or inpatient record) that are to be administered by different routes, prescribe each as a separate item.

Obtaining and supplying controlled drugs (b)

Regulation 14 of the 2001 Regulations sets out requirements for writing requisitions for controlled drugs in Schedule 2 and 3. Standard operating procedures need take into account the legal framework when obtaining and supplying controlled drugs.

Organisations

15. When obtaining stocks of controlled drugs in Schedule 2 and 3 from an external pharmacy, a requisition signed by a doctor or dentist employed or engaged in that organisation should be provided.
16. Requisitions of supplied controlled drugs should be kept by organisations for 2 years from the date on the requisition in line with Regulation 23 of the 2001 Regulations.
17. Controlled drugs registers must be kept for 2 years from the date of the last entry, in line with Regulation 23 of the 2001 Regulations.
18. Incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs.
19. Consider using a locally determined standard requisition form across the whole of an organisation when a mandatory form is not legally required for obtaining controlled drugs in Schedule 2 and 3 for use as stock. Include on the form:
    - the signature and printed name of the person ordering the controlled drug
    - the name of the care setting
    - the ward or department
    - the controlled drug name, form, strength, and for ampoules, the size if more than one is available
    - the total quantity of the controlled drug to be supplied
    - the date of the request
    - the signature of the person issuing the controlled drug from the pharmacy.
20. Hospital and prison pharmacies that are unable to supply the total quantity of a controlled drug requested by requisition should ensure that 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.

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

Health professionals

22. When obtaining controlled drugs for use in the community, health professionals must use a mandatory form for the requisitioning of controlled drugs in Schedule 2 and 3, in line with Regulation 14 of the 2001 Regulations and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015. [Note this does not come into effect until 30th November 2015]
23. Pharmacists or dispensing doctors who are unable to supply the total quantity, requested by prescription, of a controlled drug in Schedule 2 must make an entry in the controlled drugs register only for the quantity of the controlled drug supplied, in line with Regulation 19 of 2001 Regulations. They must then make a further entry in the register when the balance is supplied.
24. When dispensing more than one formulation (for example immediate-release and sustained-release formulations) of a controlled drug, discuss the differences between the formulations of the controlled drug with the person, and their family members or carers if appropriate, and check that they understand what the different formulations are for and when to take them.
25. When dispensing controlled drugs in Schedule 2 in advance of collection, only document the supply in the controlled drug register once they are collected by the person or their representative.
26. When supplying controlled drugs, advise people how to safely dispose of:
    - unwanted controlled drugs at a community pharmacy
    - used controlled drugs.
27. When the total quantity of a controlled drug cannot be supplied, inform the person receiving the drug, tell them when the rest will be available and ask them to collect it within 28 days of the prescription date.
28. When supplying controlled drugs to a person or their representative, take reasonable steps to check their identity and use professional judgement to address any concerns about them.

Administering controlled drugs (c)

Regulation 7 of the 2001 Regulations specifies who can administer controlled drugs in Schedule 2, 3, 4 and 5.

Organisations

29. Carry out a risk assessment to find out if standard operating procedures for administering controlled drugs should include additional safety measures, such as contacting other health professionals by telephone or

email, or arranging for another health professional to carry out a second check for:

- dose calculations
- the dose and route to be administered
- assessing the skills and competence of health and social care practitioners administering controlled drugs.

Health Professionals

30. Follow the relevant standards set by your professional regulator when administering controlled drugs to a person and when necessary check:
    - with the prescriber if you are concerned about 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.
31. Tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.
32. Record the following in the person's care record after administering controlled drugs:
    - name of the person having the dose administered
    - date and time of the dose
    - name, formulation and strength of the controlled drug administered
    - dose of the controlled drug administered
    - name and signature or initials of the person who administered the dose
    - name and signature or initials of any witness to administration.
33. Record the administration of the controlled drug and ensure the record is kept with the person to ensure continuity of care and to prevent:
    - doses being missed or duplicated
    - treatment being delayed.
34. 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 the correct dose to be administered.
35. Complete relevant training and assessment to confirm competence in setting up devices for continuous administration of controlled drugs. Seek specialist advice if needed.
36. When prescribing controlled drugs, involve the person's GP and any lead health professionals for other care teams in decisions about whether to use a device for continuous administration and record the decision in the patient's notes. If prescribing outside of normal working hours tell the GP about the decision the next working day.

Handling controlled drugs (d)

There are a number of regulations that apply to the handling of controlled drugs, including the Misuse of Drugs (Safe Custody) Regulations 1973, and the 2001 Regulations. Controlled drugs in Schedule 2 and 3 have additional restrictions placed on them and they are handled to allow their use to be monitored.

Organisations

37. Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs.
38. 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 of use
    - storage facilities needed
    - whether the security setting is low, medium or high risk
    - quantities of controlled drugs expected to be used
    - checking for discrepancies in stock balances at shift handover
    - frequency of staff turnover
    - accessibility for use by staff.
39. A separate controlled drugs register must be kept for each premise of an organisation where controlled drugs in Schedule 2 are stored, in line with Regulation 20 of 2001 Regulations.
40. When developing standard operating procedures for storing controlled drugs, ensure that they meet the needs of their service and take into account:
    - whether the security setting is low, medium or high risk
    - staff access to controlled drugs
    - the storage environment, including temperature and space in the controlled drugs cabinet
    - storage of stock and patients' own controlled drugs
    - any additional storage needs for controlled drugs with similar or 'lookalike' packaging and different strengths
    - the setting for use.
41. Consider developing standard operating procedures for risk assessing the use of controlled drugs in organisations where patients' own controlled drugs may be used and handled. The risk assessment may include:
    - self-administration or self-possession
    - storage requirements
    - record keeping
    - disposal.
42. Consider developing a standard operating procedure for carrying out stock checks of all controlled drugs entered into the controlled drugs register. The procedure should include:

- checking the balance in the controlled drugs register against current stock
- measurements of liquid balances and checks of remaining liquid stock when finishing a bottle
- the frequency of stock checks, which should be determined using a risk assessment and should be at least once a week
- recording stock checks in the controlled drugs register along with the date and signature of the health professional carrying out the check.

43. When developing standard operating procedures for transporting controlled drugs, take into account:
    - storage while in transit
    - security (for example, use of locked doctor's bags and ambulances)
    - record keeping, such as the movement of controlled drugs supplied for use at different locations
    - the supply process.
44. Do not routinely use couriers, taxis or equivalent services to transport controlled drugs or prescriptions for controlled drugs. If there are exceptional circumstances of urgent clinical need, use a delivery service that needs a signature on delivery to ensure that there is an audit trail.
45. Arrangements for destroying and disposing of controlled drugs must be in place and in line with the 2001 Regulations and the Controlled Waste (England and Wales) Regulations 2012, regardless of the source of supply.
46. When developing standard operating procedures for disposing of controlled drugs, including unwanted or expired stock and drugs returned by people, take into account:
    - the place of destruction
    - local agreement and records of authorised people to witness the destruction of controlled drugs.
47. Arrangements for witnessing the disposal of stock controlled drugs in Schedule 2, 3 and 4 must be in place and in line with Regulation 27 of the 2001 Regulations.
48. In organisations with internal pharmacies, use a risk assessment (see the Management of Health and Safety at Work Regulations 1999) to determine locally the most appropriate place for destroying controlled drugs. This should consider how close the place of destruction should be to where the drugs are used to help minimise risks of controlled drug-related and patient safety incidents.
49. Consider developing standard operating procedures based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died.
50. Non-healthcare settings, such as schools, should have systems and processes in place for storing, recording and transporting controlled drugs that belong to a person who is under their supervision.

Organisations and health professionals

51. Consider keeping records to provide an audit trail for the supply, administration and disposal of controlled drugs and the movement of them from one location to another.
52. When supplying dispensed controlled drugs to a person in police custody, check whether the custody staff have adequate arrangements and handling facilities for controlled drugs.
53. Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:
    - the person's preference for a lockable or non-lockable storage box
    - whether they are accessible to people who should and should not have access to them.
54. Assess if a person's method of storing their controlled drugs in their home could lead to an increased risk of controlled drug-related incidents, including patient safety incidents.
55. 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.
56. When a person has died in their home and controlled drugs need to be removed for destruction and disposal, 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.
57. When destroying and disposing of stock controlled drugs in Schedule 2, 3 and 4 (part I), health professionals must record the following, in line with Regulation 27 of 2001 Regulations:
    - the name, strength and form of the controlled drug
    - the quantity
    - the date of destruction
    - the signatures of the person destroying the controlled drugs and the authorised person witnessing the destruction.
58. Consider asking a second member of staff (preferably a registered health professional) to witness the destruction and disposal of a patient's returned controlled drugs.

59. 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 a witness.
60. When disposing of bottles of liquid controlled drugs containing irretrievable amounts:
    - consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin
    - remove labels and other identifiers from the container
    - dispose of the clean, empty container into the recycling waste.

Disposal of irretrievable amounts of controlled drugs does not need to be recorded.

Monitoring of controlled drugs (e)

Monitoring of controlled drugs includes analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback. The aim of the 2013 Regulations is to strengthen the governance arrangements for the use and management of controlled drugs in different care settings.

Organisations

61. Designated 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, as specified in Regulation 11 of the 2013 Regulations.
62. Designated bodies must appoint a controlled drugs accountable officer, who will quality assure processes for managing controlled drugs in their organisation, in line with Regulation 8 of the 2013 Regulations.
63. Organisations that are not required by legislation to appoint a controlled drugs accountable officer should consider appointing a nominated person. The nominated person should:
    - work in accordance with appropriate governance arrangements for the safe use and management of controlled drugs
    - make sure processes are in place for safe management and use of controlled drugs and the reporting and investigating of concerns
    - liaise with the local lead controlled drugs accountable officer and local intelligence network members.
64. Establish processes for developing, reviewing, updating, sharing and complying with controlled drugs-related standard operating procedures in line with legislation and national guidance. A risk assessment may be used when establishing processes.

65. Commissioners of healthcare services should include governance arrangements with clear lines of responsibility and accountability for controlled drugs in their contracts with provider organisations.
66. When multiple systems are used for reporting controlled drug-related incidents (for example, 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.
67. Consider including in local processes how to inform the controlled drugs accountable officer or nominated person of controlled drug-related concerns or incidents in a timely way, ideally within 48 hours.
68. Consider developing standard operating procedures for audits of controlled drugs 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.
69. Consider putting processes in place to access prescribing data for all controlled drugs to identify:
    - prescribing trends and potential risks of unintended use
    - the reasons for very high, increasing or very low volume prescribing.

Lead controlled drug accountable officers, controlled drugs accountable officers and nominated persons

70. Controlled drugs accountable officers must ensure that robust systems are in place for raising and reporting concerns or incidents about controlled drugs in a timely way (including those for starting investigations) in line with Regulations 11 and 13 of the 2013 Regulations.
71. Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should:
    - include other relevant local organisations, such as substance misuse, palliative care and out-of-hours services, in local intelligence networks
    - work with local intelligence networks in other areas when needed
    - notify the Care Quality Commission of poor engagement by those legally required to attend local intelligent network meetings.
72. Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should consider:
    - identifying barriers to reporting
    - identifying trends in incidents reported

- providing feedback of actions from controlled drugs-related incidents including patient safety incidents, and from occurrence reports to controlled drugs accountable officers
- sharing learning with their controlled drugs accountable officers, including trends or significant incidents, to support continuing professional development
- reporting organisations that submit occurrence reports infrequently or with insufficient detail to the Care Quality Commission.

73. An organisation's controlled drugs accountable officer or nominated person should review controlled drug-related concerns or incidents and take any action needed on a case-by-case basis.

5 Prescribing of controlled drugs (a)

5.1 Introduction

5.1.1 Legislation, regulation and policy

Controlled drugs are subject to legislative controls because there is a potential for them to be abused, diverted or cause harm. Over time several pieces of legislation, either as amendments to existing legislation or new, have been passed to strengthen the arrangements for the prescribing and governance of controlled drugs that underpin safe and effective practice.

A summary of the legal frameworks associated with controlled drugs can be found in Appendix F. See also Controlled Drugs and Drug Dependence.

The authority to supply and possess controlled drugs is set out in Regulations 8, 9, 10 and 11 of the 2001 Regulations. These are highly detailed and complex provisions. The Misuse of Drugs (Supply to Addicts) Regulations1997 requires doctors who prescribe, administer or supply diamorphine, cocaine or dipipanone for the treatment of addiction to have a licence to carry out this activity.

The 2001 Regulations defines the people who are authorised to supply and possess controlled drugs while acting in their professional capacities and lays down the conditions under which these activities may be carried out. The Misuse of Drugs (Supply to Addicts) Regulations1997requires doctors who prescribe, administer or supply diamorphine, cocaine or dipipanone for the treatment of addiction to have a licence to carry out this activity.

Health professionals who can prescribe controlled drugs as part of their practice are required to follow their professional regulatory guidance or code of practice in addition to legislation.

When prescriptions are written for Schedule 2 and 3 controlled drugs of the 2001 Regulations for example on an NHS prescription form or a discharge prescription, prescribers must comply with the prescription writing requirements of Regulation 15 of the 2001 Regulations see table 5 for key points. Prescriptions for Schedule 4 and 5 controlled drugs are exempt from the specific prescription writing requirements.

Prescriptions for Schedule 2, 3 and 4 controlled drugs of the 2001 Regulations are valid for 28 days. The 28 day period of validity runs from the date the prescription was signed unless the prescriber has specified a start date on the prescription. For instalment dispensing prescriptions, the first supply must be made within 28 days of the appropriate date and the remainder of the instalments must be dispensed only in accordance with the directions on the prescription.

Table 5: Key points of the prescription writing requirements for Schedule 2 and 3 controlled drugs

The prescription must:

- be written so as to be indelible;
- be dated;
- be signed by the person issuing it with his usual signature (or alternatively an electronic prescription form may be used);
- in the case of private (non-NHS) prescriptions:
  - be written on a private prescription form provided by the National Health Service Commissioning Board or an equivalent body (unless prescribed on an electronic prescription form)
  - specify the prescriber identification number of the person issuing it
  - except in the case of a health prescription, specify the address of the person issuing it;

- if issued by a dentist, have the words “for dental treatment only” written on it;
- specify the dose to be taken and
  - for preparations, the form and, where appropriate, the strength of the preparation, and either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied;
  - in any other case, the total quantity (in both words and figures) of the controlled drug to be supplied;
  - where the prescription is to be supplied by instalments, contain a direction specifying the amount of the instalments and the intervals to be observed when supplying.

Controlled drugs can be prescribed to a person on an NHS prescription form, a private (non-NHS) prescription form, a medicines or inpatient chart or a discharge prescription (further information can be found on the NHS Business Service Authority website).

NHS repeat dispensing scheme

Repeat dispensing schemes are an essential service under the NHS contractual framework for community pharmacists (England and Wales). As part of this service the doctor issues a repeatable prescription which gives the details of how many instalments and the frequency of instalments the pharmacist can dispense before the patient has to go back to the GP for a review. Repeatable prescriptions can be written for up to 1 year. Schedule 4 and 5 controlled drugs may be ordered on prescriptions issued under the repeat dispensing scheme, however Schedule 2 and 3 controlled drugs are not allowed on prescriptions issued under the repeat dispensing scheme.

Electronic systems used to prescribe controlled drugs

In primary care, electronic prescribing systems (also known as EPS) use prescriptions that are sent electronically from the GP surgery to a nominated pharmacy. Prescriptions for controlled drugs can be prescribed using EPS. For Schedule 2 or 3 controlled drugs the usual prescription writing requirements apply (see table 5). Electronic prescribing should take place under the established NHS EPS structure with its incorporated layers of security, including the use of an advanced electronic signature.

Some hospitals use electronic prescribing in the form of electronic inpatient or medicines charts, outpatient prescriptions or discharge prescriptions and this is a different type of electronic system to that described above. The usual legal prescriptions writing requirements apply where a prescription for a Schedule 2 or 3 controlled drugs is issued.

Private (non-NHS) prescribing

This guideline is written for the NHS in England, however, it is equally applicable to professionals providing healthcare in non-NHS settings. The law relating to prescribing applies to all NHS and non-NHS settings and good governance is equally relevant to non-NHS organisations.

The term ‘private prescriber’ is used to describe the situation when a private prescription is written, either by NHS or non-NHS practitioners, in either NHS or non-NHS settings.

Where a private prescription is written for a specified quantity of drugs and the prescriber endorses the prescription with the number of times the prescription should be repeated, this is known as a repeatable private prescription. This is not allowed for Schedule 2 and 3 controlled drugs. However, Schedule 4 and 5 controlled drugs can be prescribed on a repeat basis on a private prescription.

All private prescriptions for human use of Schedule 2 and 3 controlled drugs that are presented for dispensing in the community must be written on a standard prescription form

which must include the private prescriber's unique (6 digit) identification number issued specifically for their private prescribing activity.

5.2 Review question

In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective and cost effective for the **prescribing process** to reduce **controlled drugs related incidents**, including **patient-safety incidents**?

5.3 Evidence review

5.3.1 Evidence

The review protocols identified the same parameters for the review questions on prescribing and administration of controlled drugs. Therefore a single systematic search was carried out for these 2 review questions (see appendix C.1.2.6). A total of 37170 references were identified from the search. After removing duplicates the references were screened on their titles and abstracts and each included study was identified as being relevant for inclusion for review. Sixty two references were obtained and reviewed against the inclusion criteria as described in the review protocol for prescribing controlled drugs (appendix C.2.1). Overall, 61 references were excluded because they did not meet the eligibility criteria. A list of excluded references and reasons for their exclusion is provided in appendix C.5.1. From the searches, only 1 reference met the review protocol criteria for this review question and was included. This was an audit of opioid prescribing in hospitals, mainly by doctors. See appendix D.1 evidence table 8.The audit was quality assessed using, the Healthcare Quality Improvement Partnership (HQIP) 'Criteria for high quality clinical audit'.

In addition to the systematic search, national organisation websites such as NHS England, Medicines and Healthcare products Regulatory Agency (MHRA) and Care Quality Commission (CQC) were searched to identify any safety information for practice relating to prescribing controlled drugs. Information found from these sources included drug safety updates, patient safety alerts and CQC recommendations to avoid incidents that could harm people who take specific controlled drugs. These have been summarised in Appendix D.3 relevant national reports and alerts. As this information would be classed as national policy, quality assessment was not required. Table 6 summarises the references included for this review question. No other information was found from other secondary sources that were listed to be searched in the review protocol. A citation search was also carried out using the references included for the review question to identify any additional papers. The citation search did not identify any relevant papers to include for the review.

There was no outcome data to assess whether or not good practice points, standard operating procedures or checklists would help reduce patient-safety related incidents when prescribing controlled drugs.

1 **Table 6: Summary of included evidence**

Reference	Population	Aim of intervention, system or process	Findings
Humphries (1997) England	• Health professionals, mainly doctors in hospitals. • The prescribing of 3 intramusuclar opioid medicines (morphine, papaveretum and pethidine) was recorded by the ward pharmacists on 6 wards (2 general, 2 general surgical and 2 orthopaedic wards) over a 2 week period in 1994. • Re-audit carried out in 1995 (1 year later)	• To assess intramuscular opioid analgesic prescribing habits in a large district general hospital before and after the introduction of prescribing guidelines.	• At re-audit, there was a statistically significant decrease in the: ○ number of prescriptions that were inadequate for dose and frequency ○ number of prescriptions with inadequate frequency of prescribing. after introduction of the prescribing guidelines. • At re-audit, there was a statistically significant increase in the number of prescriptions that were correct for both dose and frequency according to the BNF and the prescribing guidelines.
National policy Reducing risk of overdose with midazolam injection in adults – Rapid Response Report. (December 2008)	• Healthcare organisations • Health professionals	• To alert healthcare organisations and staff of the risks and precautions when prescribing midazolam injection for conscious sedation.	• Healthcare organisations should: ○ assign overall responsibility to a senior clinician. ○ clarify guidance on the use of midazolam. ○ ensure that the risks are fully assessed and that staff involved in sedation techniques have the necessary skills. ○ ensure that sedation is covered by organisational policy.
National policy Reducing dosing errors with opioid medicines - Rapid Response Report. (July 2008)	• Healthcare organisations • Health professionals	• This is to alert all health professionals prescribing, dispensing or administering opioid medicines to the risks of patients receiving unsafe doses. • Every member of the team has a responsibility to check that the intended dose is safe for the individual patient.	• When prescribing, dispensing or administering these medicines the health professional or their clinical supervisor should: ○ confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. ○ ensure where a dose increase is intended, that the calculated dose is safe for the patient. ○ check the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, and

Reference	Population	Aim of intervention, system or process	Findings
			common side effects of that medicine and formulation. • Healthcare organisations should review local medicines and prescribing policies, including standard operating procedures, to reflect the guidance in the alert.
National policy Ensuring safer practice with high dose ampoules of diamorphine and morphine - Safer Practice Notice (May 2006)	• Healthcare organisations • Health professionals	• To alert healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine medicines.	• To review and improve measures for safer practice in prescribing, storing, administering and identifying high dose morphine and diamorphine injections.
National policy Drugs and driving: blood concentration limits to be set for certain controlled drugs in a new legal offence (July 2014)	• Health professionals	• The Department for Transport has introduced an offence of driving with certain controlled drugs above specified limits in the blood. .	• Advice for health professionals: ○ Any condition that requires medicinal treatment may itself pose a risk to driving ability if left untreated. Therefore it is important to advise patients to continue their treatment and to check the leaflet that comes with your medicine for information on how your medicine may affect your driving ability.
National policy Codeine for analgesia: restricted use in children because of reports of morphine toxicity (July 2013) Codeine: restricted use as analgesic in children and adolescents after European safety review (June 2013) Codeine-containing pain relief in children (December 2012)	• Health professionals	• Advice on the use of codeine for the relief of acute moderate pain to be used in children older than 12 years and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen alone.	• A list of factors to consider has been provided for health professionals when prescribing codeine. Additional details can be found on the hyperlink provided.

Reference	Population	Aim of intervention, system or process	Findings
National policy Buccal midazolam (Buccolam▼): new authorised medicine for paediatric use (October 2011)	• Health professionals	• Information provided for health professionals to take care when transferring from unlicensed formulations of midazolam to the licensed formulation of midazolam (Buccolam®).	• Health professionals should consider several factors when transferring patients to the licensed Buccolam® product when an unlicensed medicine other than Buccolam® has been used previously.
National policy Addiction to benzodiazepines and codeine (July 2011)	• Health professionals	• Drug safety update based on findings from 2 reports. Regional breakdown of long-term prescribing of benzodiazepines data showed very large variations in prescribing practice across England.	• Reminder for health professionals to prescribe benzodiazepines at the lowest effective dose for the shortest time possible. Maximum duration of treatment should be 4 weeks, including the dose-tapering phase.
National policy Methylphenidate: safe and effective use to treat attention deficit/hyperactivity disorder (ADHD) (March 2009)	• Health professionals	• A review was completed by the EMA concluded that the benefits of methylphenidate continue to outweigh the risks when used in its licensed indication.	• Health professionals prescribing and monitoring people who require treatment with methylphenidate should: ○ take in to consideration contraindications, ○ carry out pre-treatment screening, and ○ carry out on-going monitoring. Additional details can be found on the hyperlink provided for the drug safety update.
National policy Serious and fatal overdose of fentanyl patches (September 2008)	• Health professionals	• Advice provided to prevent unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source.	• Advice for health professionals, particularly those who prescribe and dispense fentanyl patches to give patients and carers' information on safe use of fentanyl patches.
National policy Codeine: very rare risk of side-effects in breastfed babies (November 2007)	• Health professionals	• Drug safety update based on a Canadian case report that described a breastfed neonate who died from morphine poisoning associated with maternal codeine used for episiotomy pain.	• Advice for health professionals includes providing the necessary information to all patients about the typical side-effects of opioids because most patients are not aware of their CYP2D6 status. Additional details can be found on the hyperlink provided for the drug safety update.
National policy Safer Use of Controlled Drugs – Preventing	• Health professionals	• Recommendations to prevent further patient safety incidents involving methadone.	The list of recommendations covers*: • competence

Reference	Population	Aim of intervention, system or process	Findings
harms from the use of methadone			• dosage and formulation • potential harms • co-prescribing with other opioids • supervised consumption.
National policy Safer Use of Controlled Drugs - Preventing harms from fentanyl and buprenorphine transdermal patches	• Health professionals	• Checklist provided to prevent patient safety incidents involving fentanyl and buprenorphine transdermal patches.	The checklist includes*: • co-prescribing with regular opioid doses • dosing and double checking of calculations • recording anatomical position of currently applied patches • prescribing by brand and giving adequate amount • provision of advice in accordance with the summary of product characteristics • considering symptoms of opioid withdrawal.
National policy Safer use of oral oxycodone medicines	• Health professionals	• Checklist to prevent patient safety incidents involving oral oxycodone medicine.	The checklist includes*: • second line use if morphine is not suitable or cannot be tolerated. • obtaining information of previous analgesics used • checking formulation, for example short acting or long acting • prescribing by brand and checking therapeutic duplication.
* Additional details can be found in the document (hyperlink provided). Abbreviations BNF British National Formulary; EMA European Medicines Agency.			

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Analysis of the evidence

There were no RCTs or other types of studies included for this review question and so data was not analysed using GRADE or Review Manager to calculate statistical significance. The evidence has been summarised in table 6 summary of included evidence as a narrative under 'findings'.

5.3.2 Health economic evidence

A systematic literature search (appendix C.1.3) was undertaken to identify cost effectiveness studies evaluating the systems, interventions and processes for the prescribing process to reduce controlled drugs related incidents, including patient-safety incidents.

This search identified 5,610 records, of which 5,594 were excluded based upon their title and abstract. The full papers of 16 records were assessed and all were excluded at this stage. The excluded studies and the reason for their exclusion are displayed in appendix C.7.1

5.4 Evidence statements

5.4.1 Evidence

An audit report of very low quality found a significant improvement in prescribing the correct dose and frequency of intramuscular opioid analgesics after the introduction of opioid analgesic prescribing guidelines to manage acute pain.

A number of key national alerts and reports based on patient safety incident reports concerning particular controlled drugs were found. These alerts and reports summarise how these incidents occurred and provide suggestions for potential avoidance of the incident. Health professionals are provided with advice on safe and effective prescribing and advice on providing the necessary information to patients when prescribing to avoid controlled drug-related patient safety incidents.

5.4.2 Economic evidence

No relevant economic analyses were identified in relation to the prescribing process to reduce controlled drug-related incidents, including patient safety incidents.

5.5 Evidence to recommendations

Table 7: Linking evidence to recommendations (LETR)

Relative values of different outcomes	The Committee discussed the relative importance of the outcomes and agreed that diversion, potentially avoidable adverse events, prescribing errors, quality of life, misuse, compliance to legislation and inadequate review were all critical and important when reviewing systems, processes or interventions for effective prescribing. The Committee was aware of the legislation that applies to prescribers when they prescribe controlled drugs. The national policy alerts and reports did not report any outcome measures because they provided prescribing advice for organisations and health professionals based on patient safety incidents that had already occurred. The Committee was also aware of the audit report by Humphries et al. that showed an improvement in prescribing the correct dose and frequency of intramuscular opioids when there is local guidance in place to guide safe prescribing.

Trade-off between benefits and harms of processes used to prescribe controlled drugs	The Committee considered a number of interventions, systems, processes and policies for this review question. The trade of between the benefits and harms of processes were discussed by the Committee. The Committee was aware that legislation and professional regulation guides the prescribing of controlled drugs and these are already put in place along with national prescribing guidance. The Committee was aware that some organisations have organisational processes that place restrictions on prescribing controlled drugs by certain professionals who are legally able to prescribe controlled drugs as part of their practice. The Committee heard that in some settings additional local arrangements prevent these health professionals, for example junior doctors and non-medical prescribers, from prescribing certain controlled drugs, therefore restricting access. The Committee discussed that providing the health professional has undergone the relevant training and has the skills and has been assessed as competent to prescribe controlled drugs safely, organisational processes should not be a barrier to these health professionals prescribing controlled drugs. The Committee highlighted that when prescribing controlled drugs to a person for treatment a balanced approach should be undertaken using clinical judgement, and taking into account that the presence of barriers could lead to patient harm. The Committee discussed that because of the nature of controlled drugs and the regulations associated with them, sometimes the general principles of good practice for prescribing can be overlooked as prescribers are often concerned about complying to regulations and associated accountability for how the controlled drug may be used by the person they prescribe it to (for example diversion, misuse or patient safety incidents). The Committee heard that rather than considering the clinical aspects of prescribing the controlled drug such as the clinical need, in some cases the technical aspects such as prescription writing requirements may affect the decision to prescribe a controlled drug. The Committee was concerned that this may affect the person's access to the controlled drug. The Committee was aware that in most cases, controlled drugs can be prescribed safely, providing that robust systems and processes are in place and that advice from local and national patient safety reports has been incorporated into them along with using prescribing guidelines. The Committee agreed that all medicines including controlled drugs should be prescribed in line with local and national prescribing guidance but that this should not replace clinical judgement.
Economic considerations	No economic evidence was identified for this review question.
Quality of evidence	The Committee was aware that legislation applies to the prescribing of controlled drugs and that guidance is also provided by national policy documents The Committee was also aware that the evidence presented was very low quality and limited to secondary care settings.. For this review question the recommendations were based on legislation, good practice advice from national policy documents and informal consensus by the Committee.
Other considerations: legislation, policy and practice	During its deliberations, the Committee recognised that there is variation in practice with: systems and processes used to prescribe controlled drugs in different settings and with the class of controlled drugs prescribed, for example opioids. The Committee discussed controlled drugs stationery, such as prescriptions or requisitions and agreed that as with all prescriptions, they should not leave such stationery unattended. The Committee agreed that this should be kept out of reach of people who are not authorised to access them and that they should be kept in a safe and locked place. The Committee explored and discussed a number of areas where prescribing practice relating to controlled drugs could be improved. These areas are detailed in the following text.

Good practice in prescribing controlled drugs

Shared-decision making

The Committee considered the national policy documents that were presented to them as part of the evidence review and discussed what good practice in prescribing is. As with all medicines prescribed for a person, the prescriber should take into consideration the person's values and preferences and the Committee referred to the shared-decision making recommendations in Medicines optimisation (2015) NICE guideline NG5.

The Committee recognised that in some groups of people there may be a risk of overdose, misuse or diversion with their controlled drug treatment and in these circumstances controlled drugs should be prescribed after a risk assessment, to prevent any controlled drug-related incidents, including patient safety incidents. The Committee indicated that the overall implications for prescribing controlled drugs to the person should be considered by the prescriber.

Clinical indication

The Committee highlighted that there have been cases in practice when the clinical indication is unclear, and controlled drugs have been prescribed to people when there is no evidence or documented reason to support their use. In these circumstances people who have been prescribed the controlled drug may be at risk of harm. As with all medicines there should be a clear indication for prescribing with reasons for its use documented in the person's care record along with arrangements for monitoring clinical and adverse effects. The Committee also discussed that controlled drugs are often prescribed for people with multimorbidities. The Committee agreed that when prescribing controlled drugs, consideration of other medicines that the person is taking needs to be taken into account, for example centrally acting medicines that may have an additive effect in terms of side effects increasing the risk of harm to the person from their medicines The Committee heard that a holistic approach is needed when prescribing medicines including controlled drugs. The Committee discussed that when considering the need for a controlled drug, where appropriate, prescribers should explore with the person non-pharmacological therapies where evidence for effectiveness supports their use. The Committee discussed that when initiating new controlled drugs, prescribers should consider titrating doses (up or down) of controlled drugs rather than using fixed-dose regimens.

The Committee also highlighted that the risks of potential opioid overdose to an opioid-naïve patient should also be considered (see section on calculating opioid equivalences). The Committee referred to the World Health Organization Information Sheet on opioid overdose that outlines some of the risk factors for opioid overdose and how they can be prevented. The Committee also referred to Opioids in palliative care (2012) NICE guideline CG140 that provides recommendations on safe and effective prescribing of strong opioids for pain in the palliative care of adults.

Providing information about controlled drugs

The Committee was aware of the rapid response report Reducing dosing errors with opioid medicines that advises prescribers to confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicine prescribed for the person when prescribing opioid analgesics, and agreed that these principles should be considered by prescribers to prevent dosing errors with controlled drugs and not just opioid analgesics. The Committee discussed that the harm associated with controlled drugs is greater to people who use them compared with other medicines and therefore agreed that good practice points need to be reinforced when prescribing controlled drugs.

The Committee discussed that prescribers should give and document clear

instructions about how the controlled drug should be taken to the person taking and/or administering the drug. The Committee agreed that instructions should include:

- how long the person is expected to need it,
- how long it will take to work
- what it has been prescribed for
- information about controlled drugs prescribed in both sustained release or immediate-release formulations.

The Committee further discussed good practice in prescribing 'when required' medicines. The Committee heard that there is often a lack of information provided to the person on how and when to take 'when required' controlled drugs and that there is a risk of controlled drugs-related patient incidents if comprehensive information has not been provided to the person. Although legislation for prescribing controlled drugs requires prescriptions to state the dose to be taken, in practice '1 to be taken as directed' is prescribed. The Committee discussed that this would not be helpful to some groups of people who take controlled drugs. The Committee agreed that when prescribing 'when required' medicine(s) the health professional prescribing the medicine should:

- document clear instructions for when and how to take or use the medicine in the person's care record (for example, 'when low back pain is troublesome take 1 tablet')
- include dosage instructions on the prescription (including the maximum daily amount and how long the controlled drug should be used for) so that this can be included on the label when dispensed.
- take into account any existing supplies the person has of 'when required' controlled drugs.

The Committee discussed that people prescribed controlled drugs should be informed by the prescriber about the nature of the medicine and that the medicine is controlled under legislation. Additional safe measures are required with controlled drugs, which include checking the person's identity before a supply is made. The Committee agreed that prescribers should inform people who are started on controlled drugs that they (or their representative) may need to provide identification when collecting controlled drugs. The Committee also discussed that prescribers should inform people about how to dispose unwanted or used controlled drugs to prevent unauthorised access. The Committee agreed that prescribers should advise people how to safely dispose of:

- unwanted controlled drugs at a community pharmacy
- used controlled drugs.

The Committee was aware that some controlled drugs are available in more than 1 formulation for example, immediate-release or sustained-release and that in some people both formulations may be prescribed, for example to manage pain. The Committee was also aware of different concentrations being available of low and high strengths of the same controlled drug. The Committee highlighted that in practice careful consideration needs to be given when prescribing, dispensing and administering immediate-release or sustained-release formulations and low or high strength concentrations of the same controlled drug because of the risk of controlled drug-related patient safety incidents to occur. The Committee discussed that health professionals should be aware of these differences and understand when to prescribe, dispense or administer different formulations and concentrations. They recognised that these differences in controlled drugs formulations may have different implications depending on the setting they are being used in, for example a high strength concentration may be used in palliative care or a low strength concentration may be used in substance misuse services. In addition to this, the Committee discussed how these differences are communicated to the person to ensure that they understand what they are for

and when to use them to prevent patient safety incidents.

Quantity of controlled drug to prescribe

The Committee discussed the quantity of controlled drugs to prescribe to a person for treatment. The Committee discussed that careful consideration should be given to the quantities prescribed, both to anticipate the person's requirements, for example over a weekend, and to reduce the amount of excess controlled drugs stored in the person's home. The Committee was aware that although it is not a legal requirement, in practice, prescriptions for Schedule 2, 3, and 4 controlled drugs are often limited to a quantity necessary for up to 30 days clinical need. This is also supported by a number of key documents such as, the National Prescribing Centre's A Guide to good practice in the management of controlled drugs in primary care, the Department of Health guidance on Safer management of controlled drugs: a guide to good practice in secondary care and the Department of Health Drug misuse and dependence: UK guidelines on clinical management'(2007, also known as the Clinical guidelines orange book). The Committee highlighted that there may be circumstances where there is a genuine need to prescribe quantities for more than a 30 days' supply. In these circumstances, the prescriber would need to ensure that this would not pose an unacceptable threat to patient safety and document the reason(s) in the person's care record.

Prescribing controlled drugs on a medicines chart or 'inpatient' chart.

The Committee discussed the prescribing of controlled drugs in secondary care, for example in a hospital setting, where medicines are often prescribed on a medicines chart or 'inpatient' chart. The Committee heard that different routes of administration for the same controlled drug for example, oral (PO), intravenous (IV) and intramuscular (IM) routes of morphine are often prescribed together on the medicines chart with a direction for 'route of administration' as 'PO/IV/IM' next to the name of the controlled drug along with frequency of administration as one item. The Committee discussed that this does not represent good practice in prescribing because it can lead to administration errors. For most controlled drugs, different routes of administration require different formulations and often different doses of the controlled drug. The Committee discussed that it would be good practice to prescribe different routes for administering the same controlled drug as separate items on the medicines chart rather than collating all the routes as a single item.

Review and follow up

The Committee discussed the importance of regularly reviewing and monitoring treatment in people who are prescribed controlled drugs. It referred to some of the patient safety incident reports that formed part of the evidence review and found that some incidents could be prevented through regular review and monitoring the treatment in people on controlled drugs. The Committee discussed that some controlled drugs may be initiated by a specialist in one care setting and then the prescribing responsibility may be transferred to the person's GP. The Committee further discussed that the person's overall care lies with the GP, supported by the specialist, if the person is also under their care, for example a pain specialist. The Committee heard examples of people:

- being left on high doses,
- receiving treatment that may not be relevant to the clinical condition anymore, for example pain management after surgery,
- being prescribed controlled drugs when they no longer require them.

The Committee suggested that this further supports the importance of why review of controlled drug treatment is necessary. The Committee discussed the frequency of review and decided that this should be determined on a case-by-case basis and documented in the person's care record. The Committee also discussed that people who are prescribed controlled drugs should be empowered to ask their prescribers for review of their treatment. The

Committee considered the following to be taken into account when prescribing, reviewing or changing controlled drug prescriptions:

- appropriate route
- dose (including when dose conversions or dose equivalence is needed)
- formulation (including where formulations are changed).

The Committee discussed the importance of prescribers following local (where available) or national guidelines when reviewing controlled drugs. The Committee heard that there may be some cases when prescribing is outside of local or national guidance. The Committee discussed the importance of documenting the rationale in the person's care record if prescribing is outside of local or national guidance.

Repeat management systems

The Committee discussed repeat prescription requests, for example some medicines that are required for regular treatment can be requested on a repeat prescription without a consultation, for example with their GP. The Committee heard that these repeat management systems are not subject to legislation and that controlled drugs are prescribed using this method for people who prescribed them for long-term treatment. The Committee also heard that there is variation in practice when setting a review date for a consultation for prescriptions issued in this way. The Committee agreed that health professionals who prescribe controlled drugs should not issue repeat prescriptions for long-term conditions without a review and that they should take account of the controlled drug and the person's individual circumstance when setting a review period as a more frequent review may be needed.

Calculating opioid equivalences

The Committee heard that in practice, some prescribers are unfamiliar with calculating opioid equivalences or total daily opioid doses, for example when converting an oral formulation to a patch or parenteral formulation, or a when converting a standard-release formulation to a slow-release formulation. The Committee indicated that prescribers should use locally (where available) or nationally approved dose conversion charts to do this. There are equivalent doses for opioid analgesics conversion charts in the 'Prescribing In Palliative Care' section of the British National Formulary (BNF). The Committee was aware that opioid conversion charts are used in palliative care and in most cases are embedded in palliative care guidelines or called 'palliative care opioid conversion charts'. The Committee was aware that using opioid conversions charts from palliative care guidelines could worry a patient who is not being treated with controlled drugs for that reason, for example they could be prescribed high dose opioids for chronic pain. The Committee agreed that whenever opioid treatment is prescribed, reviewed or changed, opioid conversion tables should be consulted to ensure that total opioid load is considered. A locally agreed dose conversion table can be used when changing doses.

Communication across all care settings

The Committee discussed how information about controlled drugs is communicated across care settings, for example initiation of a controlled drug by a specialist in secondary care. The Committee heard that in substance misuse services, controlled drugs are initiated by the substance misuse provider and this information is kept between the person receiving the treatment and the prescriber at the clinic and is not always shared with the person's GP. The Committee was concerned about this practice as it has the potential for a controlled drug-related patient safety incident. There is a risk of the person's GP prescribing other controlled drugs of the same class to them without knowing their full medical history along with a risk of misuse or 'doctor shopping' by a person who presents to several different prescribers requesting controlled drug prescriptions. The Committee also heard that there is variation in communication

about administered and prescribed doses of controlled drugs at admission and discharge in prisons. The Committee discussed the importance of confirming recent doses of controlled drugs and agreed that this would require robust communication and medicines reconciliation. The Committee was aware of the General Medical Council's good practice in prescribing standards for sharing information with colleagues and agreed that these principles could be used by non-medical prescribers when an episode of care or continuing care has been provided and information about medicines should accompany people (or quickly follow them, for example on emergency admission to hospital) when they transfer between care settings. The Committee also made reference to Medicines optimisation (2015) NICE guideline NG5 and agreed that the recommendations in the section 'medicines-related communication systems when patients move from one care setting to another' should be applied when people transfer between care providers and this includes doses of controlled drugs that have already been administered, for example methadone. From a patient safety perspective, the Committee agreed that the GP should be informed of all prescribing decisions relating to controlled drugs for their patients, and this information (in line with the 5 rules set out in the Health and Social Care Information Centre's A guide to confidentiality in health and social care [2013]) should be recorded in their care record, for example controlled drugs that are being prescribed by specialists or substance misuse services. The Committee also discussed and agreed that information should be recorded in the person's care record and this information should be used to inform prescribing decisions.

Anticipatory prescribing

The Committee recognised the importance of anticipatory prescribing for end of life care to ensure access to controlled drugs for people when they need them. The Committee referred to the good practice principles in prescribing controlled drugs discussed earlier and agreed they equally apply to prescribing controlled drugs for end of life care. The Committee was aware that prescriptions for controlled drugs for end of life care could be obtained from more than 1 source such as GPs, out-of-hours services and specialist palliative care teams.

The Committee discussed that the potential needs of people with deteriorating conditions need to be balanced with the safety of having large quantities of controlled drugs left in the person's home. The Committee discussed that this should encourage timely review of medicines particularly at the end of life. Professional advice and supporting information should be provided by the most appropriate health professional to ensure safety and maintenance of efficacy. The Committee also discussed it would be good practice to assess the clinical need and check for expired stock on a periodic basis. The Committee agreed that health professionals should follow local processes for reviewing anticipatory prescribing of controlled drugs and determine the type of review needed on a case by case basis including the ongoing clinical need and the expiry dates of any controlled drugs already stored by the person.

5.6 Recommendations & research recommendations

When prescribing controlled drugs, there are many considerations that need to be taken into account, such as prescription writing requirements for controlled drugs in Schedule 2 and 3, clinical need and the person's values and preferences. Regulation 15 of 2001 Regulations specifies requirements for writing prescriptions for controlled drugs. In addition to working within the legal framework, prescribers need to use their clinical and professional judgment when prescribing controlled drugs to people.

Organisations

1. **Develop processes that support prescribers who have been assessed as competent to prescribe controlled drugs. Processes should not place unnecessary barriers on prescribers.**

Prescribers

2. **When making decisions about prescribing controlled drugs take into account:**
   - the benefits and risks of prescribing (for example, the risks of diversion in the person's home, overdose and access to the controlled drug by other people)
   - any other medicines the person is taking (including any other centrally acting medicine prescribed) and whether the person may be opioid naive
   - evidence-based sources for prescribing decisions when possible.

3. **When prescribing controlled drugs:**
   - document clearly the indication for the controlled drug in the person's care record
   - if appropriate, titrate the dose (up or down) until a good balance is achieved between clinical effect and side effects
   - take into account the person's ongoing clinical needs and whether dose reduction may be needed
   - discuss with the person the arrangements for reviewing and monitoring treatment for clinical and adverse effects.

4. **Document and give clear instructions to the person taking or administering the drug, 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 controlled drugs prescribed in both sustained-release and immediate-release formulations.

5. **When prescribing 'when required' controlled drugs:**
   - Document clear instructions for when and how to take or use the drug in the person's care record.
   - Include dosage instructions on the prescription (including the maximum daily amount and how long the controlled drug should be used for) so that this can be included on the label when dispensed.
   - Take into account any existing supplies the person has of 'when required' controlled drugs.

6. **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.**

7. **Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs.**

8. **When prescribing, reviewing or changing controlled drug prescriptions, prescribers should follow local (where available) or national guidelines and take into account the:**
    - 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.

9. **Use a locally agreed opioid dose conversion table when prescribing, reviewing or changing opioid prescriptions to ensure that the total opioid load is considered.**

10. **When prescribing a repeat prescription of a controlled drug for treating a long-term condition, take into account the controlled drug and the person's individual circumstances to determine the frequency of review for further repeat prescriptions.**

11. **When prescribing controlled drugs, advise people how to safely dispose of:**
    - unwanted controlled drugs at a community pharmacy
    - used controlled drugs.

12. **When prescribing controlled drugs outside of general practice, inform the person's GP of all prescribing decisions in line with the following 5 rules[1] :**
    - Confidential information about service users or patients should be treated confidentially and respectfully.
    - Members of a care team should share confidential information when it is needed for the safe and effective care of an individual.
    - Information that is shared for the benefit of the community should be anonymised.
    - An individual's right to object to the sharing of confidential information about them should be respected.
    - Organisations should put policies, procedures and systems in place to ensure the confidentiality rules are followed.

    Record this information in the person's care record and use it to inform prescribing decisions.

13. **Follow local processes for reviewing anticipatory prescribing of controlled drugs. Determine the type of review needed on a case-by-case basis, including the ongoing clinical need and the expiry dates of any controlled drugs already stored by the person.**

14. **When prescribing controlled drugs (for example, on a medicines or inpatient record) that are to be administered by different routes, prescribe each as a separate item.**

1 A guide to confidentiality in health and social care (2013) Health and Social Care Information Centre.

6 Obtaining and supplying controlled drugs (b)

6.1 Introduction

6.1.1 Legislation, regulation and policy

The 2001 Regulations specifies who can obtain and supply (and possess) controlled drugs for use in their practice, business or profession (see also Appendix F).

For the purpose of the guideline, the term 'obtaining' controlled drugs refers to purchasing from wholesalers or pharmacies for practice use or stock. The term 'supplying' controlled drugs includes dispensing and supplies made to people who buy over the counter controlled drugs in Schedule 5. It is important to distinguish between supplies of controlled drugs prescribed for individual people using a prescription and those obtained by health professionals such as doctors for stock for example, a doctor's bag. Any medicine prescribed to an individual must be supplied to, and used by, that person only. To obtain and supply controlled drugs, requisitions, prescriptions and midwife's supply orders can be used. Health and social care organisations must comply with legislation when obtaining and supplying controlled drugs.

Requisitions

A requisition is signed order that is used to obtain Schedule 2 and Schedule 3 controlled drugs for use as stock. There are differences in the information required on the requisition depending on the setting in which it is used.

Requisitions used in hospitals, care homes or prisons for obtaining ward, theatre or department stock from the organisation's own internal pharmacy must comply with the provisions in Regulation 14(6) of the 2001 Regulations. Other requisitions must comply with the provisions in Regulation 14(2) of the 2001 Regulations. See tables 8 and 9 for key information needed on requisitions.

Exemptions from these requirements for certain controlled drugs are set out in Regulation 14(7).

Table 8: Key information to include when persons listed in Regulation 14(4) of the 2001 Regulations requisition stock Schedule 2 and 3 controlled drugs used in the community

- Is in the form approved by the Secretary of State for the purposes of requisitioning Schedule 2 and 3 controlled drugs[1]
- The signature (handwritten) of the recipient (the person ordering the controlled drug)
- States the name, address and profession or occupation of the recipient
- Specifies the purpose for which the drug supplied is required and the total quantity to be supplied
- Where appropriate, satisfies the following requirements:
  - when given by the person in charge or acting person in charge of a hospital, an organisation providing ambulance services or care home, the requisition must be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home
  - when given by the master of a foreign ship, the requisition must contain a statement that the quantity of the controlled drug to be supplied is the quantity necessary for the equipment of the ship and signed by the proper officer of the port health authority within whose jurisdiction the ship is.

The supplier of the controlled drug should be reasonably satisfied with the identity and signature of

the person placing the order (as stated in Regulation 14(2)(b)). There may be exceptions to the requisition requirements (as stated in Regulation 14(2)(a)) when a controlled drug is required urgently.

[1] This corresponds to Regulation 14(2)(a)(v)) of the 2001 Regulations which is a recent addition to the Regulation which will not come into force until 30 November 2015

Table 9: Key information to include when persons identified in Regulation 14(6) requisition Schedule 2 and 3 controlled drugs of for use on wards, in theatre or in departments in a hospital, care home or prison

- Signature[1] and printed name of the recipient (the person ordering the controlled drug)
- Specifies the total quantity of the drug to be supplied[1]
- Name of hospital[2]
- Ward / department[2]
- Drug name, form, strength, ampoule size if more than one available[2]
- Date[2]
- Signature of person issuing the controlled drug from the pharmacy[2]

The supplier of the controlled drug should mark the requisition to show that it has been complied with and retain in the dispensary at which the drug was supplied and a copy of the requisition or a note of it should be retained or kept by the person who requisitioned the control drug.

[1]Requirements set out in Regulation 14(6) of the 2001 Regulations
[2]Safer management of controlled drugs: a guide to good practice in secondary care (England) October 2007

In England, a standard requisition form, FP10CDF for ordering Schedule 2 and 3 controlled drugs in the community is available, which aligns with the legal requirements. These forms can be obtained from NHS England area teams who hold stocks of controlled drug requisitions.

A requisition is not legally required before obtaining or supplying Schedule 4 or 5 controlled drugs.

Prescriptions

Controlled drugs can be supplied to people using different types of prescriptions; NHS prescription forms, hospital discharge and outpatient prescriptions, or on private prescriptions. Prescriptions for controlled drugs in Schedule 2, 3 and 4 are valid for 28 days from the date prescribed or start date as specified. These are dispensed by pharmacies or dispensing doctors (see also section on prescribing). The pharmacist or dispensing doctor must endorse prescriptions for Schedule 2 and 3 controlled drugs with the date of supply to the person. When a person collects a Schedule 2 controlled drug, proof of identity is required to establish whether the person collecting the medicine is the patient, the patient's representative or a health professional acting in his/her professional capacity on behalf of the patient. This applies to all prescriptions. Medicines or 'inpatient' records are not prescriptions but they form the authority to administer the medicine, for example a controlled drug, and must be signed by the prescriber.

Patient Group Directions (PGDs)

PGDs provide a legal framework that allow the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. In line with 2001 Regulations only certain controlled drugs are legally allowed to be included in a PGD. Legislation specifies

which registered health professionals are authorised to use controlled drugs in PGDs (see Patient Group Directions [NICE guideline MPG2].

Other care settings

There is additional guidance provided from the Home Office on licensing requirements to possess and supply controlled drugs, this includes out of hours services, NHS Ambulance Trusts, substance misuse services and prisons.

Record keeping

In community settings when requisitioning stock controlled drugs, requisitions are sent to the NHSBSA Prescription Services. However, this does not apply to requisitions submitted internally to an internal pharmacy such as a hospital pharmacy for ward/theatre/department stock (see also table 9).

In all care settings, the health professional supplying controlled drugs has the responsibility to ensure that the correct item has been supplied and that all appropriate records are made in the controlled drugs register (for Schedule 2 controlled drugs) as outlined in Regulation 19 and Regulation 20 of the 2001 Regulations. Regulation 24 of the 2001 Regulations goes into more detail of the nature of the documents to be retained for controlled drugs in Schedule 3 and 5, and who they must be retained by. Private (non-NHS) prescriptions for Schedule 4 and 5 controlled drugs are required to be retained for a period of 2 years under Regulation 23(3).See also the section on handling controlled drugs.

6.2 Review question

In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective and cost effective for **obtaining and supplying** (including dispensing and requisitions) controlled drugs to **reduce controlled drug-related incidents**, including **patient safety incidents**?

6.3 Evidence review

6.3.1 Evidence

The review protocols identified the same parameters for the review questions on obtaining and supplying, handling and monitoring of controlled drugs. Therefore a single systematic search was carried out (see appendix C.1.2) for these review questions. A total of 17,542 references were identified from the search. After removing duplicates the references were screened on their titles and abstracts and each included study was identified as being relevant for inclusion for review. Two hundred and nine references were obtained and reviewed against the inclusion criteria as described in the review protocol for obtaining and supplying of controlled drugs (appendix C.2.2). Overall, 208 references were excluded because they did not meet the eligibility criteria. A list of excluded references and reasons for their exclusion is provided in appendix C.5.2. From the searches, only 1 reference met the review protocol criteria for this review question and was included. This was a Canadian national guideline that provided additional practice points that could be applied to the UK, however, there were several limitations to this guideline, see appendix D.1 evidence table 1.

There was no evidence identified in the form of studies from the searches that looked at interventions, systems or processes that could be effective for obtaining and supplying controlled drugs. There were a number of non-UK national guidelines identified that could be included because they met the criteria in the review protocol. However, most of the non-UK

national guidelines were based on non-UK legislation and were excluded because they would not be applicable to the UK setting for obtaining and supplying controlled drugs.

The quality of the included Canadian guideline was assessed using the international criteria of quality for guidance development, as outlined by the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument.

In addition to the systematic search, national sources such as NHS England, Medicines and Healthcare products Regulatory Agency (MHRA) and Care Quality Commission (CQC) were searched to identify any safety information on practice relating to obtaining and supplying controlled drugs. Information found from these sources included drug safety updates, patient safety alerts and CQC recommendations to avoid incidents that could harm people who take specific controlled drugs. These have been summarised in appendix D.3 relevant national reports and alerts. As this information would be classed as national policy, quality assessment was not required. Table 10 summarises the references included for this review question. No other information was found from other secondary sources that were listed to be searched in the review protocol. A citation search was also carried out using the references included for the review question to identify any additional papers. The citation search did not identify any relevant papers to include for the review.

There was no outcome data to assess whether or not good practice points, standard operating procedures or checklists would help reduce patient safety incidents related to obtaining and supplying controlled drugs.

Table 10: Summary of included evidence

Reference	Population	Aim of intervention, system or process	Findings
Canadian guideline - Principles and guidelines for distribution of narcotic and other psychoactive drugs (1980)	• Health professionals in Canada	• To provide guidance to: ○ reduce diversion of legal drugs to the illicit market ○ protect the pharmacist ○ adhere to legislation and assist enforcement agencies.	• The relevant contact details of the person to report to should be known by the pharmacist when forged prescriptions are suspected. • Scrutinise prescriptions that are known to be drugs of abuse. • During dispensing the controlled drug container should not be left on a counter in open public view or reach. • After dispensing the controlled drug, it should be returned to the storage area as soon as possible.
National policy Ensuring safer practice with high dose ampoules of diamorphine and morphine - Safer Practice Notice (May 2006)	• Healthcare organisations • Health professionals	• To alert healthcare staff of the risks and precautions when prescribing, dispensing and administering higher doses of diamorphine and morphine medicines.	• To review and improve measures for safer practice in prescribing, storing, administering and identifying high dose morphine and diamorphine injections.
National policy Serious and fatal overdose of fentanyl patches (September 2008)	• Health professionals	• Advice provided to prevent unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source.	• Advice for health professionals, particularly those who prescribe and dispense fentanyl patches to give patients and carers information on safe use of fentanyl patches.
National policy Over-the-counter painkillers containing codeine or dihydrocodeine (September 2009)	• Pharmacies	• Introduction of additional warnings and tighter controls on the sales of over-the-counter medicines containing codeine or dihydrocodeine to minimise the risk of overuse and addiction to these medicines.	• Pharmacists asked to support the public health measures taken as advised in the document.
National policy Codeine-containing liquid over-the-counter medicines (October 2010)	• Pharmacies	• Codeine-containing over-the-counter liquid medicines should not be used for cough suppression in children and young people younger than age 18 years.	• Health professionals who can supply codeine-containing over-the-counter liquid should take this advice into account when requests for supply are made.
National policy Safer Use of Controlled Drugs	• Health professionals	• Recommendations to prevent further patient safety incidents	The list of recommendations covers*: • competence

Reference	Population	Aim of intervention, system or process	Findings
– Preventing harms from the use of methadone		involving methadone.	• dosage and formulation • potential harms • co-prescribing with other opioids • supervised consumption.
National policy Safer Use of Controlled Drugs - Preventing harms from fentanyl and buprenorphine transdermal patches	• Health professionals	• Checklist provided to prevent patient safety incidents involving fentanyl and buprenorphine transdermal patches.	The checklist includes*: • co-prescribing with regular opioid doses • dosing and double checking of calculations • recording anatomical position of currently applied patches • prescribing by brand and giving adequate amount • provision of advice in accordance with the summary of product characteristics • considering symptoms of opioid withdrawal.
National policy Safer use of oral oxycodone medicines	• Health professionals	• Checklist to prevent patient safety incidents involving oral oxycodone medicine.	The checklist includes*: • second line use if morphine is not suitable or cannot be tolerated. • obtaining information of previous analgesics used • checking formulation, for example short acting or long acting • prescribing by brand and checking therapeutic duplication.
* Additional details can be found in the document (hyperlink provided).			

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Analysis of the evidence

There were no RCTs or other types of studies included for this review question and so data was not analysed using GRADE or Review Manager to calculate statistical significance. The evidence has been summarised in table 10 summary of included evidence as a narrative under 'findings'.

Health economic evidence

A systematic literature search (appendix C.1.3) was undertaken to identify cost effectiveness studies evaluating the systems interventions and processes for obtaining and supplying (including dispensing and requisitions) controlled drugs to reduce controlled drugs-related incidents, including patient safety incidents.

This search identified 2,250 records, of which 2,236 were excluded based upon their title and abstract. The full papers of 14 records were assessed and all were excluded at this stage. The excluded studies and the reason for their exclusion are provided in appendix C.7.2.

6.4 Evidence statements

6.4.1 Evidence

There were no studies found that looked at interventions, systems or processes for obtaining and supplying controlled drugs.

Very low quality Canadian guidance provided some additional practice points to consider when dispensing controlled drugs.

A number of key national alerts and reports based on patient safety incident reports concerning particular controlled drugs were found. These alerts and reports summarise how these incidents occurred and provide suggestions for potential avoidance of the incident. Standard operating procedures and checklists seem to be the key requirements to have in place with regards to supplying controlled drugs. There was no information on obtaining controlled drugs.

6.4.2 Economic evidence

No relevant economic analyses were identified in relation to obtaining and supplying controlled drugs to reduce controlled drug-related incidents, including patient safety incidents.

6.5 Evidence to recommendations

Table 11: Linking evidence to recommendations (LETR)

Relative values of different outcomes	The Committee discussed the relative importance of the outcomes and agreed that dispensing errors, fraud, diversion, legislation, access to medicines (delays), practitioner misuse, monitoring use and reporting concerns (including concerns about patterns of prescribing were all critical and important when reviewing systems, processes or interventions for obtaining and supplying controlled drugs. The Committee was aware that organisations and health and social care practitioners must follow legal requirements when obtaining and supplying controlled drugs but was aware that legislation is different in different settings. The Committee was aware that the national policy documents included as evidence for this review question were issued as a result of reported patient safety incidents including errors, harm caused by controlled drugs and addiction

	to controlled drugs. However, there were no outcomes reported from the evidence presented to the Committee. The Committee discussed the variation in processes for obtaining and supplying controlled drugs in different settings but agreed that a standard process would not meet all the legal requirements in all care settings. The committee was also aware that the variation in practice can lead to different outcomes and that some processes may be more robust than others in reducing controlled drugs-related incidents including patient safety incidents. Furthermore a standard process would not meet the legislative requirements.
Trade-off between benefits and harms	The Committee considered a number of interventions, systems, processes and policies for this review question. The trade of between the benefits and harms of these were not discussed in detail by the Committee as systems and processes for obtaining and supplying controlled drugs are governed by legislation. From the national policy documents and evidence presented, the key theme was to have a robust process in place. In practice, many of these processes are already in place, however the Committee discussed that more clarity is required for individuals. The Committee felt that it is clear for some settings and not so clear for other settings. The Committee has developed recommendations to support legislation and good practice based on national guidance, good practice examples and expert opinion.
Economic considerations	No economic evidence was identified for this review question.
Quality of evidence	The Committee was aware of the legislation that applies to obtaining and supplying controlled drugs and that guidance is also provided by national policy documents The Committee was also aware that the evidence presented was very low quality. For this review question the recommendations were based on legislation, good practice advice from national policy documents and informal consensus by the Committee.
Other considerations: legislation, policy and practice	**Standard operating procedures** The Committee discussed the national safety alerts that have been issued as a result of reported patient safety incidents to the national reporting and learning system (NRLS) associated with a number of controlled drugs. The Committee was aware that advice from these alerts should be embedded into practice to prevent further patient safety incidents. The Committee was aware that improving learning from medicines-related patient safety incidents is important to guide practice and minimise patient harm and that Medicines optimisation [NICE guideline NG5] provides recommendations to support this. The Committee discussed and agreed that organisations should ensure that advice from national medicines safety guidance, such as patient safety alerts about controlled drugs are incorporated into standard operating procedures for controlled drugs. **Requisitions for controlled drugs in Schedule 2 and 3** The Committee was aware of the legal requirement to use a mandatory form in community settings in line with Regulation 14 of 2001 Regulations and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 for the requisitioning of controlled drugs in Schedule 2 and 3 controlled drugs. The Committee was also aware that the standardised requisition form can be used as an option to obtain or supply controlled drugs in the community as it aligns with the legal requirements. The Committee found the requirements for using a requisition to obtain or supply controlled drugs varied depending on the setting. The Committee also heard that when requisitions are required for obtaining or supplying controlled drugs in Schedules 2 and 3, although they include all the legally required information, different formats are used in different settings. The Committee was aware that that organisations that are not part of the community setting for example wards, theatres or departments in a hospital, or care home or prisons, are not required to use the mandatory requisition form. The Committee discussed that .these organisations should consider using a

locally determined standard requisition form across the whole organisation to obtain Schedule 2 and 3 controlled drugs as stock. The Committee further discussed the particulars of the form and agreed that it could include the particulars set out in table 9 of this review question.

The Committee discussed how requisitions are used in hospital settings. It heard that if hospitals have an internal (inpatient) pharmacy as part of their trust, then requisitions for controlled drugs in Schedules 2 and 3 do not need to be signed by a doctor. However, when the trust obtains Schedule 2 and 3 controlled drugs that are supplied by an external pharmacy, then the requisition must have an authorised doctor's signature as the pharmacy would be acting as a wholesaler since it is not part of the Trust. During its deliberations, the Committee recognised the complexities involved in obtaining and supplying controlled drugs, particularly where new organisations and settings have evolved. The Committee heard examples of retail pharmacy businesses, operating as separate organisations, but being based in hospital supplying controlled drugs. The Committee was aware that legislation is being interpreted differently with regard to whether a doctor or dentist employed at the organisation needs to sign the requisition in all circumstances. Legal advice received by NICE confirmed that there is no explicit requirement in the 2001 Regulations for requisitions from external supply to bear such signatures. However, the Committee discussed that having requisitions that have been signed by a doctor or dentist would reflect good practice.

Part supplies of controlled drugs against requisitions and prescriptions

There was no legislation or national policy guidance on part supplies of controlled drugs found during the evidence review. The Committee discussed how part supplies of controlled drugs are managed in hospitals and in community pharmacies. In hospital pharmacies when a requisition for a particular quantity of controlled drug cannot be fulfilled because not enough stock is available, for example, when a pharmacy is only able to supply 24 tablets for a requisition that states a quantity of 28 tablets, then the pharmacy will only supply 24 tablets and will not supply the remaining quantity of 4 tablets when the controlled drug is back in stock. The Committee heard that another requisition would need to be written if the recipient needed more. The Committee heard that when this happens, the requisition is updated by the pharmacy with the actual quantity supplied, but it was not clear who communicated this back to the person requesting the controlled drug. The Committee discussed and agreed that good practice would be represented by hospital and prison pharmacies that are unable to supply the total quantity of a controlled drug requested by requisition ensuring that 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.

The Committee was aware that prescriptions for controlled drugs are only valid for 28 days from the date it has been prescribed. The Committee discussed how part supplies are managed in community pharmacies when a prescription is not fully dispensed with the quantity prescribed. The Committee heard that most community pharmacies produce an 'owing' note to inform the person that only part of their controlled drug prescription has been dispensed and this is recorded in the controlled drugs register as 'part supply'. The person is informed by the pharmacist that they need to pick up the remaining amount within 28 days of the date on the prescription. The Committee also heard that once the remaining amount has been supplied, this is recorded in the controlled drugs register in addition to the other records. The Committee discussed that an entry in the controlled drugs register must be made only for the quantity of the controlled drug supplied as it would be in line with Regulation 19 of 2001 Regulations. A further entry in the register must be made when the balance is supplied.

Record keeping relating to controlled drugs

Requisitions

The Committee discussed the requirements for retaining requisitions once a supply has been made. The Committee was aware of the legal requirements to keep controlled drugs registers for 2 years from the date the last entry has been made in line with Regulation 23 of 2001 Regulations. The Committee was also aware that requisitions used to supply controlled drugs in Schedules 2 and 3 of 2001 Regulations in the community are required to be sent to the NHSBSA Prescription Services in primary care. The Committee discussed the requirements for the retention of requisitions used in settings such as hospitals. The Committee heard that in practice, requisitions are kept for 2 years from the date of request and this aligns with the controlled drugs register requirements that would also have a record of the supply against the requisition (for controlled drugs in Schedule 2).

The Committee found that there is guidance on the retention of pharmacy records that provides guidance based on legislation, where it exists, and broad consensus of best practice from the East of England Senior Pharmacy Managers Network. The document also covered pharmacists/technicians working in secure environments as well as those in community and hospital pharmacy settings. The Committee found that inpatient and outpatient controlled drug prescriptions should be kept for a minimum of 2 years and records of destruction of patients' own controlled drugs should be kept for a minimum of 7 years. The Committee also found that controlled drugs invoices are required to be kept for 6 years for the purpose of HM Revenue and Customs. The Committee was aware that the guidance is mainly for pharmacy records, but they agreed that the good practice guidance should be applied to the wider NHS when managing controlled drugs records.

Prescriptions

The Committee was aware that if a prescription for a controlled drug is dispensed, but is not due to be collected until a future date or time, the prescription can be assembled in advance. There was no legislation or national policy guidance found for this. The Committee heard that some pharmacies make records of controlled drugs in the controlled drugs register once they have been dispensed and are still waiting to be collected. The Committee discussed that this does not constitute good practice and also highlighted that this is an issue for automated systems that have an electronic controlled drugs register link to the pharmacy records. The Committee agreed that when dispensing controlled drugs in Schedule 2 in advance of collection, the supply should only be entered in the controlled drug register once it is collected by the person or their representative.

Supplying controlled drugs to people

There was no legislation or national policy identified for signatures required when collecting controlled drugs in Schedule 2 and 3. The Committee was aware of the best practice requirements for people to sign for controlled drugs in Schedule 2 and 3 when collecting them. This applies to NHS and private prescriptions. The Committee was also aware that people collecting controlled drugs, including those collecting them on behalf of others, are asked to sign the prescription on collection of the controlled drugs.

The Committee discussed the requirements to check the identity (such as asking to see a passport or valid driving licence) of the person collecting controlled drugs, particularly when this is a representative of the person. The Committee discussed that it is often difficult to confirm if the person's representative is genuine. The Committee also discussed and agreed that reasonable steps need to be taken to ensure that the controlled drug(s) supplied reach the intended recipient without delaying treatment. The Committee found that there are

	concerns about the risk of diversion when people collect controlled drugs on behalf of others. The Committee discussed that people for whom the controlled drug has been prescribed should authorise another person to act as their representative to collect their controlled drug. This may be by a letter of authority, which needs to be treated with caution because it can be open to abuse. The Committee heard that for substance misuse prescriptions that need to be collected by a third party, the prescriber would usually specify this on the prescription. **Advice for controlled drugs disposal** The Committee discussed how people who take controlled drugs are advised to dispose of their unwanted and used controlled drugs safely, for example returning used controlled drug patches to their pharmacist. The Committee agreed that good practice would be represented by health professionals providing people with advice about disposing of their unwanted controlled drugs safely at a community pharmacy. The Committee also discussed disposal requirements for different preparations and agreed that health professionals should provide people taking controlled drugs with advice on safe disposal of used controlled drugs.

6.6 Recommendations & research recommendations

Regulation 14 of the 2001 Regulations sets out requirements for writing requisitions for controlled drugs in Schedule 2 and 3. Standard operating procedures need take into account the legal framework when obtaining and supplying controlled drugs.

Organisations

15. **When obtaining stocks of controlled drugs in Schedule 2 and 3 from an external pharmacy, a requisition signed by a doctor or dentist employed or engaged in that organisation should be provided.**

16. **Requisitions of supplied controlled drugs should be kept by organisations for 2 years from the date on the requisition in line with Regulation 23 of the 2001 Regulations.**

17. **Controlled drugs registers must be kept for 2 years from the date of the last entry, in line with Regulation 23 of the 2001 Regulations.**

18. **Incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs.**

19. **Consider using a locally determined standard requisition form across the whole of an organisation when a mandatory form is not legally required for obtaining controlled drugs in Schedule 2 and 3 for use as stock. Include on the form:**
    - the signature and printed name of the person ordering the controlled drug
    - the name of the care setting
    - the ward or department
    - the controlled drug name, form, strength, and for ampoules, the size if more than one is available
    - the total quantity of the controlled drug to be supplied
    - the date of the request

- the signature of the person issuing the controlled drug from the pharmacy.

20. Hospital and prison pharmacies that are unable to supply the total quantity of a controlled drug requested by requisition should ensure that 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.

21. Unless legislation specifies otherwise, consider keeping:

- records of the destruction of a patient's own controlled drugs for a minimum of 7 years
- invoices for controlled drugs for 6 years.

Health professionals

22. When obtaining controlled drugs for use in the community, health professionals must use a mandatory form for the requisitioning of controlled drugs in Schedule 2 and 3, in line with Regulation 14 of the 2001 Regulations and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015. [Note this does not come into effect until 30th November 2015]

23. Pharmacists or dispensing doctors who are unable to supply the total quantity, requested by prescription, of a controlled drug in Schedule 2 must make an entry in the controlled drugs register only for the quantity of the controlled drug supplied, in line with Regulation 19 of 2001 Regulations. They must then make a further entry in the register when the balance is supplied.

24. When dispensing more than one formulation (for example immediate-release and sustained-release formulations) of a controlled drug, discuss the differences between the formulations of the controlled drug with the person, and their family members or carers if appropriate, and check that they understand what the different formulations are for and when to take them.

25. When dispensing controlled drugs in Schedule 2 in advance of collection, only document the supply in the controlled drug register once they are collected by the person or their representative.

26. When supplying controlled drugs, advise people how to safely dispose of:

- unwanted controlled drugs at a community pharmacy
- used controlled drugs.

27. When the total quantity of a controlled drug cannot be supplied, inform the person receiving the drug, tell them when the rest will be available and ask them to collect it within 28 days of the prescription date.

28. When supplying controlled drugs to a person or their representative, take reasonable steps to check their identity and use professional judgement to address any concerns about them.

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7 Administering controlled drugs (c)

7.1 Introduction

7.1.1 Legislation, regulation and policy

The Medicines Act 1968 (section 130) defines medicines administration as 'to give a medicine either by introduction into the body, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not.' Medicines can be administered to a person with consent for treatment or can be self-administered.

Regulation 7 of the 2001 Regulations specifies who can administer controlled drugs. There have been a number of amendments to Regulation 7 and the list of health professionals who can administer controlled drugs has been extended. This is summarised in table 12.

Table 12: Summary of health professionals who can administer controlled drugs

- Any person may administer to another any drug specified in Schedule 5.
- A doctor or dentist may administer to a patient any drug specified in Schedule 2, 3 or 4.
- Any person other than a doctor or dentist may administer to a patient, in accordance with the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4.
- Any person may administer any drug specified in Schedule 2, 3 or 4 in accordance with the directions of a doctor or dentist where that person is acting in accordance with a patient group direction[1].
- A supplementary prescriber acting under and in accordance with the terms of a clinical management plan may administer to a patient, without the directions of a doctor or dentist, any drug specified in Schedule 2, 3 or 4[2].
- Any person may administer to a patient, in accordance with the directions of a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, any drug specified in Schedule 2, 3 or 4[2].
- A nurse independent prescriber or a pharmacist independent prescriber may administer to a patient, without the directions of a doctor or dentist, any controlled drug which such nurse independent prescriber or such pharmacist independent prescriber respectively may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation[1].
- Any person may administer to a patient in accordance with the specific directions of a nurse independent prescriber or a pharmacist independent prescriber any controlled drug which such nurse independent prescriber or such pharmacist independent prescriber respectively may prescribe under regulation 6B provided it is administered for a purpose for which it may be prescribed under that regulation[1].
- A registered physiotherapist independent prescriber or registered chiropodist independent prescriber may administer to a patient without the directions of a doctor or a dentist, any controlled drug which such registered physiotherapist independent prescriber or registered chiropodist independent prescriber respectively may prescribe under regulation 6C provided it is administered for a purpose for which it may be prescribed under that regulation and by the method by which it was prescribed to be administered[3].
- Any person may administer to a patient, in accordance with the specific instructions of a registered physiotherapist independent prescriber or registered chiropodist independent prescriber, any controlled drug which such registered physiotherapist independent prescriber or registered chiropodist independent prescriber may prescribe under regulation 6C, provided it is administered for a purpose for which it may be prescribed under that regulation and by the method by which it was prescribed to be administered[3].

[1] The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012)
[2] The Misuse of Drugs (Amendment) Regulations 2005
[3] The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015)

Individuals who can administer controlled drugs to a person in line with legislation

Some controlled drugs can also be administered (and supplied see section 6 obtaining and supplying) by authorised registered health professionals when acting in accordance with a patient group direction (PGD), see also Patient Group Directions (NICE guideline MPG2) (2013).

Midwives may administer those controlled drugs, which they may lawfully possess under the Medicines Act (diamorphine, morphine, pethidine and pentazocine).

NHS employed ambulance paramedics serving at any approved ambulance station are able to administer diazepam 5 mg/ml injection and/or morphine sulphate injection (to a maximum of 20 mg) and morphine sulphate oral for immediate necessary treatment of sick or injured persons (see also on obtaining and supplying).

A family member or carer can, with consent, administer a controlled drug that has been individually prescribed for person. To ensure good patient care, home carers who are competent to administer medicines should also be assessed as competent to administer controlled drugs to a person. For administration of controlled drugs in care homes, see Managing medicines in care homes (NICE guideline SC1) (2014).

Record keeping

When controlled drugs have been administered to a person for treatment, a record should be made in the person's notes or administration record (if one is available). In addition, as outlined in Regulation 19 of 2001 Regulations, a record must be made in the controlled drugs register (CDR).

7.2 Review question

In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective and cost effective for **administering** controlled drugs to reduce **controlled drug-related incidents**, including **patient safety incidents**?

7.3 Evidence review

7.3.1 Evidence

The review protocols identified the same parameters for the review questions on prescribing and administration of controlled drugs. Therefore a single systematic search was carried out (see appendix C.1.2) for these 2 review questions. A total of 37170 references were identified from the search. After removing duplicates the references were screened on their titles and abstracts and each included study was identified as being relevant for inclusion for review. Sixty two references were obtained and reviewed against the inclusion criteria as described in the review protocol for administration of controlled drugs (appendix C.2.3). Overall, 61 references were excluded because they did not meet the eligibility criteria. A list of excluded references and reasons for their exclusion is provided in appendix C.5.3. From the searches, only 1 reference met the review protocol criteria for this review question and was included. This was a randomised controlled trial (RCT) that looked at the effectiveness of unobserved verses observed dosing of patients seeking treatment for heroin dependence. See appendix D.1 evidence table 6.

The study was quality assessed using the NICE methodology checklists for RCTs (see Developing NICE guidelines: the manual).

Appraisal of the quality of the study outcomes was carried out using GRADE. The reported outcomes from the RCT were analysed using GRADE (see appendix D.2 for grade profiles). The study reported dichotomous and continuous data where risk ratios and mean difference were calculated to show outcome effect (see table 14 for GRADE profile).

In addition to the systematic search, national organisation websites such as NHS England, Medicines and Healthcare products Regulatory Agency (MHRA) and Care Quality Commission (CQC) were searched to identify any safety information on practice relating to administration of controlled drugs. Information found from these sources included drug safety updates, patient safety alerts and CQC recommendations to avoid incidents that could harm people who take specific controlled drugs. These have been summarised in appendix D.3 relevant national reports and alerts. As this information would be classed as national policy, quality assessment was not required. Table 13 summarises the references included for this review question. No other information was found from other secondary sources that were listed to be searched in the review protocol.

Table 13: Summary of included evidence

Reference	Population	Aim of intervention, system or process	Findings
RCT Bell (2007) Australia	• Heroin users seeking treatment for addiction in specialist out-patient treatment centres. • N=119 • Aged over 18 years. • Opioid dependent with a history of at least 12 months' opioid use.	• To compare the effectiveness of treatment (buprenorphine-naloxone) with observation of dosing by randomising heroin users seeking treatment to either usual care (regular attendance for observed dosing) versus picking up the controlled drug medicine once per week for administration at home (unobserved dosing) over 3 months.	• Low quality RCT • No significant difference found in the following outcomes: ○ retention to treatment at 3 months ○ self-reported heroin use ○ QoL • There were 18 reports of diversion of trial medicines.
National policy Reducing risk of overdose with midazolam injection in adults – Rapid Response Report. (December 2008)	• Healthcare organisations • Health professionals	• To alert healthcare organisations and staff of the risks and precautions when administering midazolam injection for conscious sedation.	• Healthcare organisations should: ○ assign overall responsibility to a senior clinician. ○ clarify guidance on the use of midazolam. ○ ensure that the risks are fully assessed and that staff involved in sedation techniques have the necessary skills. ○ ensure that sedation is covered by organisational policy.
National policy Reducing dosing errors with opioid medicines - Rapid Response Report. (July 2008)	• Healthcare organisations • Health professionals	• This is to alert all health professionals prescribing, dispensing or administering opioid medicines to the risks of patients receiving unsafe doses. • Every member of the team has a responsibility to check that the intended dose is safe for the individual patient.	• When prescribing, dispensing or administering these medicines the health professional or their clinical supervisor should: ○ confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. ○ ensure where a dose increase is intended, that the calculated dose is safe for the patient. ○ check the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, and common side effects of that medicine and formulation. • Healthcare organisations should review local medicines and prescribing policies, including standard operating procedures, to reflect the guidance in the alert.
National policy Ensuring safer practice	• Healthcare organisations	• To alert healthcare staff of the risks and precautions when	• To review and improve measures for safer practice in prescribing, storing, administering and identifying high dose

Reference	Population	Aim of intervention, system or process	Findings
with high dose ampoules of diamorphine and morphine - Safer Practice Notice(May 2006)	• Health professionals	prescribing, dispensing and administering higher doses of diamorphine and morphine medicines.	morphine and diamorphine injections.
National policy Buccal midazolam (Buccolam▼): new authorised medicine for paediatric use (October 2011)	• Health professionals	• Information provided for health professionals to take care when transferring from unlicensed formulations of midazolam to the licensed formulation of midazolam (Buccolam®).	• Health professionals should consider several factors when transferring patients to the licensed Buccolam® product when an unlicensed medicine other than Buccolam® has been used previously.
National policy Serious and fatal overdose of fentanyl patches (September 2008)	• Health professionals	• Advice provided to prevent unintentional overdose of fentanyl due to dosing errors, accidental exposure, and exposure of the patch to a heat source.	• Advice for health professionals, particularly those who prescribe and dispense fentanyl patches to give patients and carers information on safe use of fentanyl patches.
National policy Codeine: very rare risk of side-effects in breastfed babies (November 2007)	• Health professionals	• Drug safety update based on a Canadian case report that described a breastfed neonate who died from morphine poisoning associated with maternal codeine used for episiotomy pain.	• Advice for health professionals includes providing the necessary information to all patients about the typical side-effects of opioids because most patients are not aware of their CYP2D6 status. Additional details can be found on the hyperlink provided for the drug safety update.
National policy Safer Use of Controlled Drugs – Preventing harms from the use of methadone	• Health professionals	• Recommendations to prevent further patient safety incidents involving methadone.	The list of recommendations covers*: • competence • dosage and formulation • potential harms • co-prescribing with other opioids • supervised consumption.
National policy Safer Use of Controlled Drugs - Preventing harms from fentanyl and buprenorphine transdermal patches	• Health professionals	• Checklist provided to prevent patient safety incidents involving fentanyl and buprenorphine transdermal patches.	The checklist includes*: • co-prescribing with regular opioid doses • dosing and double checking of calculations • recording anatomical position of currently applied patches • prescribing by brand and giving adequate amount • provision of advice in accordance with the summary of

Reference	Population	Aim of intervention, system or process	Findings
			product characteristics • considering symptoms of opioid withdrawal.
National policy Safer use of oral oxycodone medicines	• Health professionals	• Checklist to prevent patient safety incidents involving oral oxycodone medicine.	The checklist includes*: • second line use if morphine is not suitable or cannot be tolerated. • obtaining information of previous analgesics used • checking formulation, for example short acting or long acting • prescribing by brand and checking therapeutic duplication.
National policy Safer use of MS syringe drivers	• Healthcare organisations • Health professionals	• Checklist to prevent patient safety incidents involving MS syringe drivers.	The checklist includes*: • Introduction of ambulatory syringe drivers with safer design into practice • Take steps to reduce the risks of rate errors while MS syringe drivers remain in use based on a locally developed risk reduction plan which may include: ○ raising awareness ○ providing information to support users with rate setting ○ using lock-boxes.
* Additional details can be found in the document (hyperlink provided). Abbreviations QoL quality of life; EMA European Medicines Agency;			

Analysis of the evidence

Table 14: GRADE profile - Summary of the outcomes of the RCT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Observed dosing**	**Unobserved dosing**	**Relative (95% CI)**	**Absolute**		
Retention in treatment (follow-up mean 3 months; assessed with: Regular attendance to clinics)												
1[1]	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	None	33/58 (56.9%)[4]	37/61 (60.7%)[4]	RR 1.07 (0.79 to 1.44)[5]	42 more per 1000 (from 127 fewer to 267 more)	⊕⊕OO LOW	IMPORTANT
								0%		-		
Reduction in days of heroin use (follow-up mean 3 months; measured with: Change in number of self-reported days of heroin use and Opiate Treatment Index; Better indicated by lower values)												
1[1]	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	None	58	61	-	MD 3.5 higher (0.46 lower to 7.45 higher)	⊕⊕OO LOW	IMPORTANT

[1] Bell J et al 2007
[2] Inadequate concealment allocation, both groups not comparable.
[3] Small sample size
[4] intention-to-treat analysis
[5] Calculated using review manager. P value 0.6777

7.3.2 Health economic evidence

A systematic literature search (appendix C.1.3) was undertaken to identify cost effectiveness studies evaluating the systems interventions and processes for administering controlled drugs to reduce controlled drug-related incidents, including patient safety incidents.

This search identified 5,610 records, of which 5,594 were excluded based on their title and abstract. The full papers of 16 records were assessed and 1 study (Bell et al 2007) was included at this stage. The excluded studies and the reason for their exclusion are displayed in appendix C.7.3.

The Australian study by Bell and colleagues (2007) examined the costs and consequences of 2 administration methods for buprenorphine with naloxone for the treatment of heroin dependence. The control group (usual care) were required to attend a clinic to receive and take their medication (observed administration) in order to help ensure that the medication is taken as prescribed and help prevent illicit diversion. The intervention group were allowed to take home 1 week's supply of the same medication (unobserved administration) as the likelihood of illicit diversion is thought to be lower with the use for buprenorphine-naloxone than other medications for the treatment of heroin dependence. This study has a number of major limitations (see table 15) and is only partly applicable to the UK setting and the guideline as a whole.

1 **Table 15: Economic evidence profile**

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	Cost effectiveness	
Bell, J; Shanahan, M; Mutch, C et al 2007 A randomized trial of effectiveness and cost effectiveness of observed versus unobserved administration of buprenorphine–naloxone for heroin dependence. Addiction, 102, pp1899–1907	Major limitations[1, 2, 3, 4, 5, 6, 7, 8]	Partly applicable[9, 10, 11]	Authors state that this is a cost effectiveness analysis (CEA).	**Total cost:** Unobserved group: AU$2385 (95% CI 2079–2539) Observed group: AU$3862 (95% CI 3509–4127)	The primary measure of effectiveness was retention in treatment at 3 months and heroin use at 3 months. No significant differences were noted in outcome between the observed and unobserved cohorts.	Once all the costs and outcomes were combined, it cost (on average) an additional AU$1477 (95% CI 736.41, 2006.52) to achieve an equivalent change in heroin-free days in the observed compared to unobserved subjects.	No sensitivity analyses were conducted or reported by the study authors.

1 No economic model is defined
2 No time horizon is specified
3 It is unclear whether the sources of the estimates for treatment effects and resource use are from the best sources
4 No source is identified for unit costs
5 Potential conflicts of interest for two authors were reported
6 No sensitivity analyses were undertaken
7 It is unclear from the RCT study paper whether the study had sufficient power to detect the primary outcome of the study (20% difference in retention in treatment between the study arms) as the sample size calculated was initially 86 individuals per arm (final n=119)
8 There was a failure in blinding of the outcome assessor process in the RCT
9 Patient population (Adults seeking treatment for heroin dependence) is a subgroup under the care of the guideline population (health and social care staff)
10 Australian healthcare payer perspective adopted
11 No evidence of discounting in the study

7.4 Evidence statements

7.4.1 Evidence

Low quality evidence from 1 RCT showed no significant difference between observed and unobserved dosing groups for treating heroin users in retention to treatment and heroin use.

Low quality evidence from 1 RCT showed no significant difference between observed and unobserved dosing groups for treating heroin users in their quality of life.

A number of key national alerts and reports based on patient safety incident reports concerning particular controlled drugs were found. These alerts and reports summarise how these incidents occurred and provide suggestions for potential avoidance of the incident. Health professionals are provided with advice on safe administration and to provide any necessary administration instructions to patients to avoid controlled drug-related patient safety incidents.

7.4.2 Economic evidence

Partially applicable evidence with major limitations built on single RCT data suggests that observed therapy with buprenorphine with naloxone has similar clinical outcomes but is more costly when compared to unobserved therapy.

7.5 Evidence to recommendations

Table 16: Linking evidence to recommendations (LETR)

Relative values of different outcomes	The Committee discussed the relative importance of the outcomes and agreed that potentially avoidable adverse events, administration errors, fraud, diversion, legislation, access to medicines (delays), record keeping and quality of life were all critical and important when reviewing systems, processes or interventions for the administration of controlled drugs. The Committee was aware that the national patient safety alerts and reports did not report any outcome measures as they provided administration advice for organisations and health professionals based on patient safety incidents that had already occurred. The study by Bell et al met the inclusion criteria of the review protocol, however the Committee felt that as it was conducted in a very specific population this could not be generalised to develop a recommendation for administration of all controlled drugs. The Committee discussed that systems, processes or interventions for administration should ensure that the person having the controlled drug does not experience any controlled drug-related patient safety incidents associated with administration, for example serious harm such as opioid overdose. In addition to this, the Committee further discussed the importance of preventing controlled drug-related incidents, for example diversion during administration.
Trade-off between benefits and harms	The Committee was aware of Regulation 7 of the 2001 Regulations that specifies who can administer controlled drugs. The Committee was also aware of standard operating procedures being in place for administering medicines (including controlled drugs) within some organisations, for example hospitals. These procedures may help to prevent controlled drug-related incidents, including patient safety incidents. The Committee agreed that the benefits of having these procedures in place would outweigh the harms, providing they do not delay access to medicines or act as a barrier to the provision care. The resource impact of some of the processes and interventions considered for this review question were discussed in the relevant text where the Committee

	found that there may be a change in practice.
Economic considerations	The Committee agreed that the economic evidence presented to them was not applicable to the general population using controlled drugs as it was based on a specific group of people. In addition to this, the Committee recognised that although the study suggested that observed therapy with buprenorphine with naloxone is more costly than unobserved therapy, in practice this may always be the case as observed therapy requires more resources. The Committee referred to the NICE technology appraisal (TA114) on methadone and buprenorphine for the management of opioid dependence (2007), which recommends daily administration of methadone and buprenorphine, under supervision for at least the first 3 months, with supervision relaxed only when the person's compliance is assured.
Quality of evidence	The Committee was aware of the legislation that applies to the administration of controlled drugs and that guidance is also provided by national policy documents (patient safety alerts and reports). The Committee was also aware that the evidence presented was low quality and limited to substance misuse services provided in Australia. For this review question the recommendations were based on legislation, good practice advice from national policy documents and informal consensus by the Committee.
Other considerations: legislation, policy and practice	The Committee referred to the review question on monitoring controlled drugs and the recommendation for organisations to have standard operating procedures for administration of controlled drugs. The Committee discussed that these standard operating procedures may vary in different care settings with different staff undertaking an administration role (for example health or social care practitioners), the context of use and the resources available to carry out administration and related activities, for example the number of staff available to administer a controlled drug. **Process of administration** Checking prior to administration The Committee was aware that health professionals who administer controlled drugs have a responsibility to work within the standards set by their professional regulator and to comply with local policies and procedures for the administration of medicines. The Committee heard that in practice there is variation in checking 'unusual doses' of controlled drugs with the prescriber before administering them. The Committee discussed what may affect the processes for querying 'unusual doses' of controlled drugs prior to administration, such as inter- or intra- professional relationships for example working relationships between health professionals, accessibility to the prescriber and the settings in which they are prescribed. The Committee heard that in practice, in some settings, it is not always clear who originally started the prescription for the controlled drug and that some prescriptions have the name of the service provider documented instead of the prescriber. The Committee recognised that these problems may act as a barrier for checking doses before administration and was concerned that in some cases it may lead to controlled drug-related patient safety incidents such as delayed or missed doses. The Committee referred to the rapid response report on Reducing dosing errors with opioid medicines and echoed that every member of the team providing care has a responsibility to check that the intended dose is safe for the person. The Committee further stated that knowledge of different formulations and previous doses of controlled drugs is essential for the safe use of these medicines. For example if a sustained-release formulation of a controlled drug has already been given and another dose of a sustained-release formulation of the same controlled drug has been prescribed. From the evidence provided from national patient safety alerts and reports, the Committee found that in addition to the rapid response report on Reducing dosing errors with opioid medicines mentioned above, guidance from the Care

Quality Commission (CQC) on Preventing harms from fentanyl and buprenorphine transdermal patches advises on double checking calculations of doses of controlled drugs before administration. The Committee was aware that in some settings calculations of doses and also measurements of liquid doses are checked by another health professional. The Committee heard that in some settings, for example in out-of-hours services, or where the practitioner is working as a 'lone worker' it would be difficult to get another person to check a calculated or measured dose before administration. The Committee discussed that some organisations have a system in place where the calculation can be checked over the telephone with another health professional, for example by calling a community pharmacy, medicines information centre, specialist clinic or using emails. The Committee also found that some organisations have a process for double checking calculations, measurements of liquids and doses administered incorporated into their standard operating procedures for administration. The Committee recognised that having a second person to check may not always be practical and that it may not always provide a safety net, but be a barrier to access to medicines. The Committee discussed whether organisations should carry out a risk assessment to determine if the introduction of these measures is necessary, within their organisation. In addition to this, the Committee also discussed and agreed that the health professional should practice within their competence and should always act in the best interests of the person.

Supervised consumption of controlled drugs

The Committee discussed supervised consumption of certain controlled drugs, for example methadone. The Committee was aware that some pharmacists who supervise people self-administering controlled drugs involve the person in the process by showing them the medicine and the quantity they are getting as a safety check before offering this to the person to take. The Committee then went on to discuss how people are involved in checking their controlled drugs when they are administered in hospital and agreed that in some cases it may not be appropriate to inform the person about the controlled drug being administered, for example when emergency treatment is needed after an accident or when the person is not conscious. The Committee agreed that health professionals should tell the person having the controlled drug the name and dose of the drug before it is administered, unless the circumstances prevent this.

Administration of different formulations and equipment

The Committee discussed the national patient safety alerts and reports that provide advice for the administration of different formulations of controlled drugs, for example buccal or parenteral formulations and transdermal patches, for health professionals to give to people who use them. The Committee referred to its recommendations for the review question on obtaining and supplying controlled drugs that recommends incorporating advice from national patient safety alerts about controlled drug-related patient safety incidents into standard operating procedures. In addition to this, the Committee heard that in some cases, people do not always have access to the appropriate equipment to measure and administer doses of controlled drug. An example of this would be administering highly concentrated liquids that would require a small volume to be administered using an appropriately graduated syringe so that the volume can be accurately measured. The Committee discussed and agreed that equipment should be available in all organisations that use controlled drugs to measure the required dose in the most accurate and safest way. The Committee also discussed that people who self-administer their controlled drugs or social care practitioners who administer controlled drugs to the person should be provided with advice on safe administration of different formulations along with the right equipment to administer their controlled drugs.

Records

Information to record

Legislation, regulation and evidence from national policy alerts and reports show that health and social care practitioners have a responsibility to make records of medicines administration. The Committee was aware that in some settings there may be 2 people involved in witnessing and administering controlled drugs to a person and documenting administration in the person's care record. The Committee was aware that the Nursing and Midwifery Council (NMC) standards for medicines management state that a clear, accurate and immediate record of all medicines administered should be made and a second signatory is required within secondary care and similar care settings for the administration of controlled drugs. In other settings, for example in primary care, obtaining a secondary signatory should be based on a local risk assessment. The Committee discussed that these principles could be used by other health or social care practitioners who administer controlled drugs to a person as part of their practice or care. The Committee discussed the information to record in the person's care record when a controlled drug has been administered to them. The Committee was also aware of the Department of Health guidance Safer management of controlled drugs. The Committee discussed that this information could be adapted and used in other care settings as well as in secondary care as good practice. The Committee agreed that when administering controlled drugs, a record must be made in the person's care record(s), which should include, but not be limited to the:

- name of the person having the dose administered
- date and time of the dose
- dose of the drug administered
- name, formulation and strength of the drug administered
- name and signature or initials of the person who administered the dose
- name and signature or initials of the witness (if there is a second person witnessing administration).

Record of administration

The Committee heard that in settings where records of administration are used for example in hospital, these records are sent to the pharmacy so that medicines can be ordered. The pharmacist can carry out a clinical check to ensure the dose, route and frequency of the medicine is appropriate for the person. The Committee highlighted that this practice of sending records of administration to pharmacies takes the record away from the patient and can put the patient at risk of incidents such as delayed and omitted doses and where controlled drugs for pain are concerned put the patient at risk of withdrawal symptoms. The Committee discussed the National Patient Safety Agency (NPSA) alert on Reducing harm from omitted and delayed medicines in hospital. In addition the Committee added that processes used to manage medicines should include the need to keep records of administration with the patient, and should be part of the system improvements to reduce harms from omitted and delayed medicines as outlined in the NPSA alert. The Committee was aware that in June 2012, the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to NHS England. The Committee discussed that the record of administration should stay with the person having the controlled drug administered to ensure continuity of care to prevent:

- doses being missed or duplicated
- treatment being delayed.

Continuous administration devices

The Committee referred to the CQC's advice on the Safer use of MS syringe drivers and discussed how there is variation in practice depending on the training that the health professionals using continuous administration devices

	(such as syringe drivers) have had. The Committee heard that this is a particular problem in services providing out of hours care when health professionals who have not had the necessary training are asked to set up the syringe driver. The Committee found that a number of controlled drug-related patient safety incidents have occurred as result of syringe drivers: • being set up with the incorrect rate setting • failing to deliver the infusion • being programmed to infuse at a rate that is too fast or too slow the syringe being incorrectly inserted. The Committee discussed that it would be in the person's best interest and good practice for health professionals to be trained and assessed as competent before they use a syringe driver to administer controlled drugs. The Committee heard that when devices for continuous administration of controlled drugs are set up out of hours, there is variation in practice in how this is communicated with the person's GP and other care teams the person may be under (for example, palliative care). The Committee discussed that in some areas information about a continuous administration device being set up may not be shared with the person's GP or that the decision to start administration of a controlled drug using the device may not be documented in the person's care record by the care team. The Committee raised a number of concerns about this and agreed that it is in the person's best interests to have clear communication about the use of devices for continuous administration of controlled drugs to prevent any patient safety incidents from occurring as a result of poor communication and lack of monitoring arrangements. The Committee therefore concluded that when setting up a device for continuous administration of controlled drugs the health professional should involve the person's GP and any other lead health professional for any other care teams involved in the persons care in the decision to start controlled drugs through a continuous administration device. The decision should be recorded in the patient's notes before staring treatment.

7.6 Recommendations and research recommendations

Regulation 7 of the 2001 Regulations specifies who can administer controlled drugs in Schedule 2, 3, 4 and 5.

Organisations

29. **Carry out a risk assessment to find out if standard operating procedures for administering controlled drugs should include additional safety measures, such as contacting other health professionals by telephone or email, or arranging for another health professional to carry out a second check for:**
    - dose calculations
    - the dose and route to be administered
    - assessing the skills and competence of health and social care practitioners administering controlled drugs.

Health Professionals

30. **Follow the relevant standards set by your professional regulator when administering controlled drugs to a person and when necessary check:**
    - with the prescriber if you are concerned about 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.

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

32. Record the following in the person's care record after administering controlled drugs:

- name of the person having the dose administered
- date and time of the dose
- name, formulation and strength of the controlled drug administered
- dose of the controlled drug administered
- name and signature or initials of the person who administered the dose
- name and signature or initials of any witness to administration.

33. Record the administration of the controlled drug and ensure the record is kept with the person to ensure continuity of care and to prevent:

- doses being missed or duplicated
- treatment being delayed.

34. 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 the correct dose to be administered.

35. Complete relevant training and assessment to confirm competence in setting up devices for continuous administration of controlled drugs. Seek specialist advice if needed.

36. When prescribing controlled drugs, involve the person's GP and any lead health professionals for other care teams in decisions about whether to use a device for continuous administration and record the decision in the patient's notes. If prescribing outside of normal working hours tell the GP about the decision the next working day.

8 Handling controlled drugs (d)

8.1 Introduction

8.1.1 Legislation, regulation and policy guidance

For the purpose of this guideline, the term 'handling' includes possessing, storing, recording, transporting, disposing and destroying of controlled drugs. Table 17 below summarises legislation and regulations that apply to the handling of controlled drugs (see also Appendix F). In addition, the Home Office have published General security guidance for controlled drug suppliers that provides advice on security measures that are appropriate for premises licensed to use controlled drugs and includes information about storing and transporting controlled drugs.

Table 17: Summary of legislation that applies to handling of controlled drugs

	Legislation/Regulation	Additional notes
Possession	Misuse of Drugs Act 1971 Misuse of Drugs Regulations 2001,	• A person may not legally have a controlled drug in their possession unless permitted as outlined in Regulations. • Unauthorised possession of a controlled drug is a criminal offence.
Storage	Misuse of Drugs (Safe Custody) Regulations 1973	• Apply to all controlled drugs except for those listed in Schedule 1 to these Regulations. • Set down storage requirements in relation to safes, cabinets and rooms to store controlled drugs. • Set down storage requirements in respect of the different premises upon which controlled drugs may be stored
Recording	Misuse of Drugs Regulations 2001	• Regulations 19, 20, 21 and 22 impose record-keeping requirements upon those identified in Regulations 5 and 8 as authorised to supply certain controlled drugs. • Records in respect of controlled drugs must be kept in a controlled drugs register (CDR). • All health professionals who hold personal controlled drugs as stock must keep their own CDR, and they are responsible for keeping this accurate and up to date. • Regulation 20 requires a separate CDR to be kept for each set of premises by the person who carries on his business or occupation (for example, not just the main surgery). The CDR must be kept at the premises to which it relates and be available for inspection at any time. • The CDR must be kept for a minimum of 2 years after the date of the last entry, once completed and not be used for any other purpose. • As an alternative to a bound book, an electronic CDR may be used.
Transporting	Misuse of Drugs Act 1971 Misuse of Drugs Regulations 2001	• When controlled drugs are in transit, responsibility for their security remains with the owner (normally the supplier) and does not transfer to either the courier or the customer until the drugs arrive at their destination and are signed for. See also 'Safe custody of controlled drugs in transit guidance'. • A person representing a patient is allowed to return

	Legislation/Regulation	Additional notes
		controlled drugs which were prescribed to that patient to any doctor, dentist or pharmacist for destruction. • The Home Office Drugs Licensing and Compliance Unit issues import and export licences for commercial transactions, as well as having responsibility for the Open General Licence and issuing personal import and export licences for people travelling to and from the UK with their prescribed controlled drugs.
Destroying & disposing	Misuse of Drugs Act 1971 Misuse of Drugs Regulations 2001	• Health professionals and service providers required by law to maintain a CDR for controlled drugs are not allowed to destroy controlled drugs in Schedules 1, 2, 3 or 4 without the destruction being witnessed by an authorised person. • When a controlled drug listed in Schedules 1, 2, 3 or 4 is destroyed by such a person, details of the destruction must be recorded.

There is guidance from NHS England on methods of denaturing controlled drugs.

8.2 Review question

In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective and cost effective for **handling** (including, storing, transporting, possessing, disposing and destroying) of controlled drugs to reduce **controlled drugs-related incidents**, including **patient safety incidents**?

8.3 Evidence review

8.3.1 Evidence

The review protocols identified the same parameters for the review questions on obtaining and supplying, handling and monitoring of controlled drugs. Therefore a single systematic search was carried out (see appendix C.1.2) for these review questions. A total 17,542 references were identified from the search. After removing duplicates the references were screened on their titles and abstracts and each included study was identified as being relevant for inclusion for review. Two hundred and nine references were obtained and reviewed against the inclusion and exclusion criteria as described in the review protocol for the handling of controlled drugs (appendix C.2.4).

Overall, 204 references were excluded because they did not meet the eligibility criteria. A list of excluded references and reasons for their exclusion is provided in appendix C.5.4. Non-UK based national guidelines that were solely based on legislation were excluded on the basis that the UK have their own legislation and the guideline would not be applicable to the UK setting for the handling of controlled drugs.

From the searches, a total of 5 references relevant to the review question were identified. One qualitative study was identified that involved interviewing and sending out questionnaires to general practices to identify systems and processes relating to the storage, recording and disposal of controlled drugs. There were no other studies identified that looked at interventions, systems or processes that could be effective for handling controlled drugs. However, there was an audit report that looked at how clinical staff in a hospital handled controlled drugs and also professional guidance from the Royal Pharmaceutical Society that provided information on maintaining and reviewing controlled drugs balances. Both of these were included as they looked at systems and processes for disposing controlled drugs and

controlled drug stock management as specified in the review protocol. In addition to this, 2 non-UK based national guidelines were included (American and Canadian) as they provided additional practice points on record keeping, safe keeping of stationery used to prescribe controlled drugs and carrying out inventories for controlled drugs. There were several limitations to these guidelines, see appendix D.1 evidence tables 1 and 2.

The qualitative study was assessed using the NICE methodology checklist for qualitative studies. In addition, the questionnaire used in the study was also appraised using the British Medical Journal critical appraisal checklist for a questionnaire study. To assess the quality of the audit report, the Healthcare Quality Improvement Partnership (HQIP) 'Criteria for high quality clinical audit' was used. The professional guidance was not assessed for quality as this is based on legislation and policy. The quality of the included international guidelines was assessed using the international criteria of quality for guidance development, as outlined by the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument. See appendix D.1 evidence tables.

In addition to the systematic search, national sources such as NHS England, Medicines Healthcare products and Regulatory Agency (MHRA) and Care Quality Commission (CQC) were searched to identify any safety information on practice relating to obtaining and supplying of controlled drugs. Information found from these sources included drug safety updates, patient safety alerts and CQC recommendations to avoid incidents that could harm people who take specific controlled drugs. These have been summarised in Appendix D.3 relevant national reports and alerts. As this information would be classed as national policy, they did not need to undergo quality assessment. Table 18 summarises the 2 relevant references included for this review question that met the inclusion criteria. No other information was found from other secondary sources that were listed to be searched in the review protocol. A citation search was also carried out using the references included for the review question to identify any additional papers. The citation search did not identify any relevant papers to include for the review.

There was no outcome data to assess whether or not good practice points, standard operating procedures or checklists would help reduce patient safety incidents related to handling controlled drugs.

Table 18: Summary of included evidence

Reference	Population	Aim of intervention, system or process	Findings
Investigation of systems to prevent drug diversion of opiate drugs in general practice in the UK. Barker R et al. (2004)	General practitioners (GP)	This study highlighted the systems used by GPs for handling and monitoring controlled drugs. N= 142	Various approaches used to record controlled drugs in various formats, in some cases lack of compliance to regulations. Storage of controlled drugs varied amongst practices, some stored in more than one place. This includes storage of outdated controlled drugs. Variety of policies on the destruction and disposal of unused controlled drugs and patient returned controlled drugs.
Audit report Ahmed I et al. (2007)	Health professionals working within secondary care in the UK	Questionnaire used to audit the methods and procedures followed by the staff who were involved in the use and disposal of controlled drugs. N=200	There was some variation in practice found when disposing of controlled drugs in the hospital by clinical staff. 53.2% of all staff were aware of a guideline or protocol (either local or national) for disposal of controlled drugs 60.3% felt there was a need for guidelines in this area.
Professional guidance Royal Pharmaceutical Society: Maintaining running balances of stock in controlled drug registers. (2005)	Pharmacists and other health professionals who supply controlled drugs in the UK	Maintenance of a running balance of stock in controlled drug registers as a matter of good practice.	Review of current procedures and develop standard operating procedures to maintain running balances. When developing standard operating procedures for the reconciliation process, consideration should be given to a number of factors, including the volume and frequency of controlled drugs dispensing, dispensary workflow and staffing arrangements. Standard operating procedures should clearly define the action that should be taken if a discrepancy between the theoretical and actual balance of stock arises.
American guideline Technical assistance bulletin on use of	Organised health care settings in America.	To ensure compliance with American law.	The following practice points have been issued relating to : • Record keeping of all controlled drugs

Reference	Population	Aim of intervention, system or process	Findings
controlled substances in organised health care settings. (1993)			• Physical inventory of all controlled drugs and audit. • Handling of controlled drugs within an operating/theatre room.
Canadian guideline Principles and guidelines for distribution of narcotic and other psychoactive drugs. (1980)	Health professionals in Canada	To provide guidance to: • reduce diversion of legal drugs to the illicit market • protect the pharmacist • adhere to legislation and assist enforcement agencies.	Practice points relating to handling: • Strict control of prescription pads should be exercised and encouragement should be given to practitioners, hospital, clinics, etc. • Many pharmacies have found that an inventory of narcotics and controlled drugs, renewed at regular intervals, has greatly facilitated the reporting of drug losses.
National policy Reducing risk of overdose with midazolam injection in adults – Rapid Response Report. (December 2008)	Healthcare organisations Health professionals	This is to alert healthcare providers and health professionals about incidents and deaths resulting from inappropriate midazolam doses prescribed or administered to the patient.	Health organisations should: • have an organisational policy in place for sedation • restrict the storage and use of high strength midazolam to clinical areas/situations where its use has been risk-assessed and replace the storage and use of high-strength midazolam with low-strength midazolam in other clinical areas.
National policy Ensuring safer practice with high dose ampoules of diamorphine and morphine - Safer Practice Notice. (May 2006)	Healthcare organisations Health professionals	This document alerts the NHS in England and Wales to review and improve measures for safer practice in prescribing, storing, administering and identifying high dose morphine and diamorphine injections.	The main risks identified include: lookalike or similar packaging for different strengths of diamorphine and morphine ampoules; poorly differentiated outer cartons and ampoules; higher and lower strength ampoules of diamorphine and morphine stored together in clinical areas in both primary and secondary care. All NHS organisations to put measures in place to protect patients from simple but potentially fatal mistakes.

Analysis of the evidence

There were no RCTs or other types of studies included for this review question and so data was not analysed using GRADE or Review Manager to calculate statistical significance. The evidence has been summarised in table 18 summary of included evidence as a narrative under 'findings'.

8.3.2 Health economic evidence

A systematic literature search (appendix C.1.3) was undertaken to identify cost effectiveness studies evaluating the systems interventions and processes for the handling (including, storing, transporting, possessing, disposing and destroying) of controlled drugs to reduce controlled drugs-related incidents, including patient safety incidents.

This search identified 2,250 records, of which 2,236 were excluded based upon their title and abstract. The full papers of 14 records were assessed and all were excluded at this stage. The excluded studies and the reason for their exclusion are provided in appendix C.7.4.

8.4 Evidence statements

8.4.1 Evidence

A very low quality study found that there is variation within general practices when handling controlled drugs.

An audit report of very low quality found some variation in practice when disposing of controlled drugs in the hospital by clinical staff.

Professional guidance issued by the Royal Pharmaceutical Society advises that maintaining running balances of controlled drug stocks should be carried out as a matter of good practice, and standard operating procedures for this should be clearly defined.

Very low quality American guidance and Canadian guidance provided some additional practice points to consider when handling controlled drugs and on the stationery used to prescribe them.

A number of key national alerts and reports were found based on patient safety incident reports concerning particular controlled drugs. Some of these alerts and reports summarise how these incidents occurred and many of them provide recommendations on how they can be prevented. Key requirements from these documents include having organisational policies in place for managing procedures that require controlled drugs and ensuring that high-strength and low-strength preparations of the same controlled drugs are differentiated and stored in a way to minimise risk from selecting the incorrect strength.

8.4.2 Economic evidence

No relevant economic analyses were identified in relation to the handling (including, storing, transporting, possessing, disposing and destroying) of controlled drugs to reduce controlled drug-related incidents, including patient safety incidents.

8.5 Evidence to recommendations

Table 19: Linking evidence to recommendations (LETR) for storage of controlled drugs

Relative values	The Committee discussed the relative importance of the outcomes and agreed that

of different outcomes	unauthorised access, disposal, destroying, missed doses or delay of medicines, quality of life, and patient reported missed/delayed doses were all critical and important when reviewing systems, processes or interventions for the safe handling of controlled drugs. The Committee was aware of the various pieces of legislation that underpins the activities related to the handling of controlled drugs. Organisations and health and social care practitioners must follow relevant legislation and regulations when making arrangements to handle controlled drugs. The Committee was aware that 2 national policy documents included as evidence for this review question were issued as a result patient safety incidents reported to the NRLS, such as death and harm caused by controlled drugs, and addiction to controlled drugs. The Committee discussed good practice in different settings for handling controlled drugs, in addition to that required by legislation, to prevent controlled drug-related incidents including patient safety incidents.
Trade-off between benefits and harms	The Committee discussed that most health and social care settings already have policies in place for handling controlled drugs. The Committee highlighted that despite standard operating procedures being in place for handling controlled drugs there were some grey areas that need clarifying. These were discussed by the committee and majority of the recommendations made for this review question are based on good practice and other national guidance that already exists. In addition, the Committee was aware that the Care Quality Commission provide primary and secondary care providers with self-assessment tools to assess their organisations arrangements for controlled drugs governance and identify areas requiring improvement. The Committee agreed that the development of policies and standard operating procedures underpinned by risk assessment will facilitate the safe management and use of controlled drugs in various settings.
Economic considerations	There was no economic evidence identified for this review question.
Quality of evidence	The Committee was aware that the handling of controlled drugs is underpinned by legislation, and guidance is also provided by national policy guidance. The Committee was also aware that the evidence presented to them was of very low quality. For this review question the recommendations were based on legislation, good practice advice from national policy documents and informal consensus by the Committee.
Other considerations: legislation, policy and practice	The Committee was aware of the relevant legislation that covers storage and possession (summarised in section 8.1.1). Where specific legislation exists for the setting discussed, this will be included in the text. The committee was also aware from the evidence presented that there is variation in practice when storing controlled drugs. **Storage and possession** **Storage of controlled drugs in different Schedules of 2001 Regulations** The Committee considered the different legal requirements for controlled drugs in different Schedules of 2001 Regulations. The Committee was aware that most emphasis is placed on Schedule 2 controlled drugs, as these are subject to the highest level of control under legislation. The Committee found that for Schedule 3, 4 and 5 controlled drugs, there is no legal requirement to handle them in the same way as a Schedule 2 controlled drug. However, there are some settings, for example in hospital, where Schedule 3, 4 and 5 controlled drugs are managed in the same way as Schedule 2 controlled drugs to ensure a higher level of governance. The Committee discussed whether all controlled drugs in Schedules 3,

4 and 5 should be managed in the same way as controlled drugs in Schedule 2, and the possible limitations in some settings, because of controlled drugs storage facilities, resources, time and accessibility. The Committee also discussed that it may be worth carrying out risk assessments for settings to identify any risks, for example, diversion or patient safety incidents. The risk assessment may include frequency of use (for example a dentist using large quantities of midazolam may decide to handle this as a Schedule 2 controlled drug), storage facilities for controlled drugs (for example the size of the controlled drug storage cupboard), type of setting (for example secure environments [high risk] or community pharmacy [low risk]), staff turnover (for example in out of hours services), quantity of controlled drug stock and accessibility for use.

Storage of controlled drugs stationery

The Committee considered the storage of controlled drugs stationery, for example prescription forms. The Committee was aware inadequate systems for keeping prescription forms safe can lead to theft of prescription forms and their subsequent misuse. The Committee heard that prescription forms should be treated as 'blank cheques' which, in the wrong hands, can lead to a misuse of NHS resources. The Committee referred to the Security of prescription forms guidance produced by NHS Protect and agreed that organisations and health professionals should implement local systems and processes to prevent theft and misuse of prescription forms and other controlled drugs stationery. The Committee also discussed the management of prescription forms when prescribers visit patients at home. The Committee heard that prescribers working in the community should take suitable precautions to prevent the loss or theft of prescription forms, such as ensuring prescription pads are carried in a lockable carrying case (for example a doctor's bag) or are not left on view in a vehicle. The Committee discussed that prescription forms, if left in a vehicle, should be stored in a locked compartment such as a car boot and the vehicle should be fitted with an alarm in line with the guidance from NHS protect. The Committee recognised that it would be good practice for prescribers to record the serial numbers of any prescription forms or pads they are carrying on home visits before leaving the practice premises and to carry only a small number of prescription forms.

GP practices, out of hours and urgent care services

GP practices

The Committee was aware of Regulation 20 of 2001 Regulations about having a separate controlled drugs register for each premise (for example GP practices with a main practice and satellite practices), where controlled drugs in Schedule 2 of 2001 Regulations are stored.

The Committee discussed that there is variation in how controlled drugs are stored among GP practices and that some store controlled drugs in more than one place (Barker R et al.). Some GPs have a stock of controlled drugs stored in their 'doctor's bag' for use when making home visits. In addition to this, the GP practice may also hold controlled drug stocks that are accessible to GPs to add to their doctor's bag or for GPs who do not personally carry controlled drugs. The Committee also noted that some GP surgeries have a single controlled drugs register and one place for storage of controlled drugs for use across a number of branch surgeries. It discussed that when Schedule 2 controlled drugs stocks are moved from the place of storage to the place of use there is a risk of breaking the audit trail

The Committee heard that locum GPs may have their own doctor's bag containing controlled drugs along with their own controlled drugs register. The Committee discussed and agreed that locum GPs taking practice stock of controlled drugs for their doctor's bag does not constitute good practice.

Out-of-hours/Urgent care

The Committee discussed how controlled drugs are stored and used in out-of-hours services. Doctors working in out of hours have access to controlled drug stock for use when working in that setting. When transferring controlled drugs in Schedule 2 of 2001 Regulations from the place of stock storage to the doctor's bag and vice versa, a record is made in a 'mini controlled drug register' in addition to signing them out of the main controlled drug register. The Committee also heard that some private organisations track the contents of all out-of-hours doctor's bags, and include controlled drugs from all Schedules. The Home Office requires movement and use of controlled drugs to be closely audited under a Home Office licence to store and supply controlled drugs in all Schedules. The Committee agreed that as an example of good practice and these principles could also apply in settings that do not require a Home Office licence.

The Committee was concerned that some GP practices may have multiple systems in place for storing, transferring and recording controlled drugs. The Committee discussed that there should be some form of audit trail or 'mini controlled drugs register' similar to that used by out of hours doctors to document when controlled drugs stock has been transferred to a doctor's bag or administered to a person, allowing any discrepancies to be resolved in a timely manner.

Hospital settings

The Committee discussed whether people should have access to their own controlled drugs when needed, for example to manage their pain during an inpatient stay. The Committee was aware that some organisations have policies in place for self-medication, and this should involve risk assessment of all medicines including controlled drugs and storage of patients' own medicines. The Committee discussed that patients' own controlled drugs should be checked for suitability according to the organisation's local procedure for patients' own drugs to ensure they are suitable. The Committee was aware that organisations (for example prisons, hospices and hospitals) that provide inpatient care supply a lockable storage beside the bed or in the bedside locker for patients' own medicines to be stored safely when they self-administer. The Committee discussed that a standard operating procedure could be put in place for risk assessing the handling of patients' own controlled drugs that includes:

- self-administration and/or self-possession
- storage requirements
- record keeping of the controlled drugs
- disposal.

Patients' homes

The Committee was aware of deaths that have occurred as a result of unsafe storage of controlled drugs in people's own homes. The Committee heard that the way in which controlled drugs are stored may affect specific patient groups, examples include people with dementia, mobility problems and substance misuse or those where there is a risk of diversion. It discussed whether a risk assessment may be beneficial for 'at risk' groups of people to support them with any necessary storage arrangements. The Committee heard that some substance misuse clinics provide lockable storage boxes for safe storage to minimise the risk of harm to others. The Committee agreed that health professionals should consider assessing if a person's method of storing their controlled drugs in their home could lead to controlled drug-related incidents including patient safety incidents.

The Committee discussed how people who receive controlled drugs as part of routine care, as anticipatory end of life medicines or for substance misuse should

be informed of how to store controlled drugs in a safe way to avoid harm and diversion. The Committee further discussed that when controlled drugs are prescribed and supplied, health professionals should provide advice and information on how to store controlled drugs safely for people who are prescribed them and consider discussing with the person the options for storing their prescribed controlled drugs, taking into account:

- the person's preference for a lockable or unlockable storage box
- whether they are accessible to people who should and should not have access to them.

Secure environments

The Committee was aware of the legislation for handling controlled drugs in secure environments such as prisons, young offender institutions, immigration removal centres and secure hospitals. The Committee heard that some custodial establishments apply processes for handling controlled drugs that are similar to those used in hospitals, because they have similar operational arrangements. The Committee were aware of different settings having different levels of security; low, medium or high, and how risk assessment can be applied using these levels of security when handling controlled drugs in these environments. The Committee discussed how people in prisons access their controlled drugs. It heard that the Prison Service Instruction (PSI) for clinical services for substance misusers states that administration and consumption of controlled drugs and other medicines subject to misuse within prison must be directly observed and controlled drugs in Schedule 2 and 3 of 2001 Regulations are not permitted in possession without completion of a risk assessment.

The Committee heard that some secure environments have developed medicines policies and procedures to navigate their way through the complexities of the 2001 Regulations in order to ensure that practice is compliant with the law.

The Committee found that there is guidance from the Home Office for handling controlled drugs for people in police custody. The Committee heard that the custody officer (generally a police sergeant) is responsible for the safekeeping of all medicines including controlled drugs. Controlled drugs must be held in a locked receptacle to prevent unauthorised access. The Committee discussed that people who are in police custody should be provided with the same standard of clinical treatment as given to a person in a non-custodial setting. The Committee found that a police officer may not administer or supervise the self-administration of prescribed controlled drugs in Schedule 2 and 3 of 2001 Regulations and that it can only be carried out under the personal supervision of the registered medical practitioner authorising their use or other appropriate health professional. The Committee also found that the custody officer may supervise the self-administration of, or authorise other custody staff to supervise the self-administration of, controlled drugs listed in Schedule 4 or 5 of 2001 Regulations if the officer has consulted the appropriate health professional authorising their use and both are satisfied self-administration will not expose the person in custody, police officers or anyone else to the risk of harm or injury. The Committee discussed the arrangements for storing controlled drugs in this setting and highlighted that it would be good practice for health professionals who have supplied dispensed controlled drugs to a person in police custody to check if possible, whether the custody staff has adequate arrangements and handling facilities for controlled drugs.

Other settings

The Committee discussed how controlled drugs are handled in non-healthcare settings such as day care or schools and found that there is variation in the way that controlled drugs are stored, records made (for example of receipt, destruction, losses or administration) and transported (for example school trips) in these

settings. The Committee agreed that some guidance to these settings would be useful and would support them to handle controlled drugs to prevent controlled drugs-related incidents, including patient safety incidents, as in practice it is often not clear. The Committee was aware that where controlled drugs have been prescribed for the person, it is their property and they carry responsibility for ensuring that they are handled in a safe way and kept out of reach from children. Records of controlled drugs are not required to be made when a person is being transported from their home to another setting. The Committee heard that the Department for Education have guidance for supporting pupils in schools with medical conditions which specify that schools should have arrangements in place to manage medicines including controlled drugs and they need to comply with the requirements of the Misuse of Drugs Act and its associated regulations. The Committee discussed that the principles that apply in health and social care settings may apply to non-healthcare settings such as schools. The committee discussed day care settings and agreed this would be a social care setting and this would be covered by other guideline recommendations for organisations across health and social care.

Stock management

In addition to considering the storage requirements of controlled drugs in various settings, the Committee discussed how the same formulations of controlled drugs in different strengths are stored in response to the patient safety alerts. It heard that it is common practice to store these different strengths away from each other, and that this practice is carried out with other medicines of different strengths and with 'lookalike' packaging. The Committee agreed that storage of controlled drugs that are available in more than 1 strength or have lookalike packaging should be stored in a way to avoid confusion and incorrect selection, and this could form part of the overall procedure of handling controlled drugs.

The Committee also considered the need to store reversal agents for emergency management of poisoning or overdose from controlled drugs so that they are accessible. It heard that this may vary in different settings and that some areas do have policies for this. The Committee considered if this could be a cost pressure to the NHS and agreed that is was important to have stocks of reversal agents in settings where controlled drugs are being administered or taken. For example ambulance services keep stocks of reversal agents even though in most cases they only have small stocks of controlled drugs. The Committee highlighted the importance of organisations having procedures in place to manage controlled drug-related poisoning and overdose.

In reviewing the different settings above and the ways in which they store controlled drugs, the Committee summarised and agreed by consensus the following when storing controlled drugs:

- whether the security setting is low, medium or high risk
- staff access to controlled drugs
- the storage environment, including temperature and space in the controlled drugs cabinet
- storage of stock and patients' own controlled drugs
- any additional storage needs for controlled drugs with similar or 'lookalike' packaging and different strengths
- the setting for use.

Transport considerations

The Committee was aware of the relevant guidance documents from the Home Office relating to transport of controlled drugs (see section 8.1.1). There was no evidence covering interventions, systems or processes for transporting controlled

drugs.

The Committee discussed from their experience, there is variation in practice in the way controlled drugs are transported within organisations and to other settings. The Committee suggested that legislation does not take account of all organisational structures within the NHS. For example a retail pharmacy contracted to supply controlled drugs to a hospital or an inpatient pharmacy supplying the wards within a hospital. The Committee recognised the developments that have taken place to modernise working practices to align with the emergence of new organisational structures delivering health and social care services. The Committee agreed that it would be good practice for organisations that transport controlled drugs (within the organisation or to an external organisation) to consider having standard operating procedures in place that take into account:

- storage while in transit
- security (for example, use of locked doctor's bags and ambulances)
- record keeping, such as the movement of controlled drugs supplied for use at different locations
- the supply process.

The Committee highlighted that some pharmacy services transport controlled drugs using courier services where there is no audit trail. In most cases the courier involved in transporting the controlled drugs is not aware of what is being transported and there is no guarantee of delivering the controlled drug to the recipient securely. In some cases prescriptions for controlled drugs are also posted, for example for the treatment of drug addiction when prescriptions are often posted to pharmacies. The Committee discussed the potential for diversion and misuse of prescriptions if there is no audit trail. The Committee agreed that controlled drugs and prescriptions for them should not routinely be transported by courier, taxi or equivalent services, except in exceptional circumstance of urgent clinical need when they should be sent by delivery service that requires a signature on delivery to ensure there is an audit trail up to delivery.

The Committee discussed transporting controlled drugs in a 'doctor's bag' when carrying out home visits. The Committee was aware that a doctor's bag is a locked bag, box or case used for carrying medicines including controlled drugs which should be kept locked at all times, except when in immediate use. The Committee discussed Regulation 5 of the Misuse of Drugs (Safe Custody) Regulations 1973 and recognised that this would apply to a doctor's bag when once locked, it would be a suitable receptacle for storing controlled drugs. The Committee also highlighted that the person in lawful possession of this bag, or an individual authorised by them, must always retain the keys where used. The Committee heard that although regulations specify that a receptacle that is locked is suitable for storing controlled drugs, a locked car is not suitable for storing controlled drugs in this situation.

Disposal and destruction

The Committee was aware of the relevant legislative requirements that apply to disposal and destruction of controlled drugs (see section 8.1.1). From the evidence presented, the Committee found variation in practice with the disposal and destruction of controlled drugs. This includes stock of controlled drugs that are expired, no longer required, used and patients' own controlled drugs that are no longer required by them.

Disposal of stock controlled drugs that are used for administration or supply by the service provider

Organisations with an internal (inpatient) or external pharmacy

The Committee discussed how controlled drugs are destroyed in various settings. The Committee was aware that it is common practice for service providers with a pharmacy as part of their legal entity (for example a pharmacy that is part of the hospital) to send expired stock controlled drugs to their pharmacy for disposal. Some service providers provide denaturing kits for use on wards to destroy controlled drugs.

The Committee heard that there was sometimes uncertainty about who is responsible for disposing of and destroying controlled drugs when they have been supplied to a hospital by an external pharmacy. The Committee was aware that legislation available for this circumstance is often misinterpreted. The Committee heard that legislation must be followed when there is a contractual arrangement between an external pharmacy and the hospital. The Committee heard that for controlled drugs waste, the pharmacy or hospital (or other organisation) needs to register for a T28 exemption. This allows the pharmacy or hospital to destroy controlled drugs returned by patients and its own stock controlled drugs under certain conditions (own stock requires an authorised witness under other legislation). The external pharmacy, even if it is inside the hospital building cannot accept controlled drugs for disposal from the hospital that they supplied to, because the hospital is the place of production and legally that is where they should be denatured. In addition, the Committee heard that if a building is occupied by the same entity, and it occupies one postcode, it only needs one T28 exemption. For example, controlled drugs can be moved around a hospital building because it usually occupies one postcode, however they can't be moved from an outlying hospital to a main hospital unless they have a waste carrier's licence, because the T28 exemption doesn't allow transportation of waste. A separate T28 exemption is required for parts of an organisation that occupy more than one postcode. To clarify this, the Committee agreed that organisations should have their own arrangements for disposal and destroying of controlled drugs in line with legislation regardless of the source of supply.

Disposal of remaining small amounts of controlled drugs after administration

The Committee discussed the disposal of remaining small amounts of controlled drugs after administration, particularly with liquid preparations in settings where they are used frequently, for example on wards and theatres and agreed that there was variation in practice. The Committee was concerned that there is a risk of diversion and misuse when disposal of these amounts cannot be audited. The Committee discussed further how this can be best managed and agreed that the amount of controlled drug administered and the amount of controlled drugs that remains after administration should be recorded in the controlled drugs register, and their disposal or destruction should be witnessed ideally by a second health professional. Both the witness and the person disposing of or destroying the controlled drugs should sign the controlled drugs register. The Committee also highlighted uncertainty with disposal of amounts that are too small to measure, for example in methadone bottles or remnants after the administered dose. The Committee discussed that some pharmacies dispose of these small amounts of controlled drugs remaining in their bottles into pharmaceutical waste bins and this may increase the amount of pharmaceutical waste produced, which has financial implications. The Committee also discussed what would be considered a 'small amount' and advised that it is an irretrievable amount left in the controlled drugs container. The Environment Agency was contacted to clarify the requirements for safe disposal of empty containers that contained controlled drugs. The Environment Agency referred to Water UK's guidance that addresses discharges of medicines to foul sewer from medical practices and indicates that discharge of medicines containing active ingredients is prohibited. If containers are rinsed, then the rinsings should not be discharged to foul sewer and rinsing is generally discouraged because there is natural tendency to use the foul sewer. The Safe Management of Healthcare (HTM 07 01) adopts the same position. The Environment Agency

confirmed that when medicines containers are thoroughly rinsed out and the rinsings are disposed of as waste medicines, then the clean containers are classed as packaging waste. When disposing of emptied and cleaned bottles of controlled drugs, the Environment Agency have advised that:

- the labels and identifiers should be removed from the container to prevent their presence causing concern in the waste chain
- the container should be placed in the relevant recycling stream for example for glass or plastic
- the container should not be placed in the mixed municipal waste.

Witnesses for controlled drug destruction

The Committee was aware of the legislation that requires destruction of stock controlled drugs to be witnessed by an authorised person. The Committee discussed the requirements of having an authorised person to witness the destruction of stock controlled drugs and agreed that organisations must have arrangements for witnessing the disposal of stock controlled drugs in Schedule 2, 3 and 4 of 2001 Regulations. The Committee discussed that it would be good practice to have a witness (another member of staff) to observe the destruction of controlled drugs in Schedule 3, 4 (part I) and 5.

Records

The Committee discussed the record keeping requirements when destroying and disposing of stock controlled drugs in Schedule 2, 3, 4 (part I) of 2001 Regulations. The Committee agreed that when destroying and disposing of stock controlled drugs in Schedule 2, 3, 4 (part I) of 2001 Regulations, health professionals must record the following in line with Regulation 27 of 2001 Regulations.

Disposal of patients' controlled drugs

The Committee discussed the disposal of patients' own controlled drugs that are no longer needed that have been brought with them into a hospital or a similar setting. The Committee was aware that some organisations have processes in place to dispose of them on the ward while others send them to their pharmacy for disposal. The Committee heard that in some hospices people are asked to bring in all their medicines, including controlled drugs, to improve medicines reconciliation, reduce waste and provide consistency. The medicines are screened for suitability of use and the person is asked to sign a form giving permission for the hospice to dispose of any medicines including controlled drugs that they no longer require (for example if the controlled drug has been stopped or changed). The Committee discussed that this may be safer for people who are prescribed controlled drugs, who are often dealing with many medicines, to go home with only medicines they currently require for the management of their symptoms. The Committee agreed that organisations should determine locally how best to handle patients' own controlled drugs as consent would be required.

Removal of controlled drugs from a person's home

The Committee discussed removing of controlled drugs from the homes of patients who are deceased to ensure that they will not lead to harm for other individuals. The Committee was not aware of any national guidance around this, but aware of the legislation on the possession of controlled drugs. Disposal would be to a place that can accept them for destruction, for example a pharmacy. Ideally the prescriber or the supplier of the controlled drug should be responsible for the removal of controlled drugs to be disposed of, however the Committee discussed that this process would often be unmanageable as controlled drugs are often supplied by different services. The Committee highlighted a number of factors that may affect how these controlled drugs are disposed of including:

- the service that supplied the controlled drug, for example palliative care (some

may have their own arrangements with an audit trail or similar paperwork)

- access to family members or carers who wish to take responsibility for returning controlled drugs to a pharmacy for disposal
- access to health or social care practitioners
- access to patient records to make a record
- access to the patient's controlled drugs within normal working hours or out of hours
- access to a pharmacy to deliver the controlled drug for destruction
- no audit trail and unreliable stock count once the controlled drugs has been supplied to the person
- controlled drugs (and other medicines) should not be removed or destroyed within 7 days of death in case there are any coroner's investigations into the death.

The Committee discussed that some organisations have local arrangements for removing controlled drugs that belonged to people who died. The Committee considered this as good practice and agreed that standard operating procedures could be developed based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died.

The Committee heard that in some organisations, health professionals have been advised not to transport controlled drugs from people's homes to a pharmacy for disposal as a result of the Shipman Inquiry. The Committee considered that there may be some circumstances where there is a greater risk if the controlled drug(s) are left in the person's home. On the recommendation of the Committee, the Home Office were contacted to seek advice on whether or not health professionals could take controlled drugs for safe disposal from a person who has died. Information from the Home Office states that health professionals can take controlled drugs under 2001 Regulations to a person who may lawfully possess in these situations, for example to a pharmacist. There are no time limits specified for when the controlled drugs must be delivered to the pharmacist but it is expected that this would be done at the earliest opportunity. For example, if the controlled drugs are picked up late at night when the local pharmacy is shut it will be reasonable in those circumstances for the health professional to temporarily store the drugs overnight and deliver them to the pharmacy at the earliest opportunity the next day. The legislation does not list specific professionals and can therefore be used by anyone provided they are taking the controlled drug to a person who can lawfully possess them. In addition, the Home Office have advised that when possible this activity should be witnessed by another professional and records kept to provide an audit trail.

The Committee agreed that if a health or social care practitioner considers removing controlled drugs from a deceased person for safe disposal, then it should be discussed with their family member or carer if possible, and a record of the action taken, along with the amount of controlled drug(s) removed, should be made in the patient's medical record or notes (as an audit trail). The health professional should also consider any requirements of the coroner to keep any medicines in the person's own home for a period of time. The Committee also agreed that when controlled drugs are removed by the health professional it is preferable for this to be witnessed by another person and taking to a health professional such as a community pharmacist who is legally allowed to possess.

The Committee discussed that all health professionals in legal possession of a controlled drug have a professional duty of care to take all reasonable steps to maintain safe custody of that controlled drug at all times.

Witnesses for controlled drug destruction

When patients' own controlled drugs are destroyed, it is not a legal requirement to have a second person to witness this however the Committee discussed and agreed that it would be good practice to have a second person (preferably a registered health professional) to witness destruction. Some controlled drugs are supplied on a named patient basis, where it is not considered as stock, but belongs to the patient, and the Committee agreed that in these circumstances these would be disposed of in the same way as patients' own controlled drugs.

Records

The Committee discussed the records to keep when destroying and disposing patient's own controlled drugs and referred to the legal requirements for disposing stock controlled drugs. The Committee agreed that the same principles could apply to controlled drugs that have been returned by people. This would include:

- the date of receipt of the controlled drugs
- the date of destruction
- the signatures of the person destroying the controlled drugs and a witness.

Location of disposal

The Committee was aware that the destruction and disposal of controlled drugs is subject to Waste Management Licensing Regulations 1994 and the Hazardous Waste Regulations 2005. In addition, the Committee highlighted guidance for the denaturing of controlled drugs at a place other than a place of production from the Environment Agency. The Committee discussed whether destruction in hospitals or similar settings should take place on the wards or at the supplying pharmacy to minimise risk. The Committee heard that destruction should be carried out close to the place where the controlled drugs are being stored. A risk assessment could be carried out to determine locally the most appropriate place for destruction of controlled drugs where they have an internal pharmacy (for example, close to the place of use to minimise risks of controlled drug-related incidents and patient safety incidents). The Committee discussed how different formulations of controlled drugs are denatured and referred to the guidance from NHS England on methods used to destroy controlled drugs.

Stock balances

Evidence presented to the Committee included professional guidance from the Royal Pharmaceutical Society on managing controlled drug stock balances. The Committee discussed that this is an important part of handling controlled drugs because it is a good way of monitoring and highlighting any discrepancies early. The Committee reviewed the good practice points and discussed, the settings, amount of stock controlled drugs, frequency of use, frequency of controlled drugs stock balance checks, practicalities of checks, resources involved in carrying this out without affecting delivery of care and potential consequences of actions such as holding reduced stocks of controlled drugs in specific settings. The Committee also discussed the outcomes that can result from carrying out stock balance checks. These include reducing risks of diversion and identifying and resolving discrepancies or trends early.

The Committee discussed the process of stock balance checks and when they should be carried out. It heard that there is variation in practice in different settings. The Committee was concerned about checking balances of a liquid controlled drug as frequently as other formulations such as tablets, capsules or patches due to the loss of liquid each time it is measured. The Committee heard that some health professionals check liquid volumes by visual inspection to avoid loss, although this is not accurate. The Committee discussed the frequency of stock balance checks, and was aware that this also varied in practice depending on use. It considered the

	practicalities of weekly checks, which would not be appropriate in settings where controlled drugs are used infrequently. However, the Committee discussed the risk of missing or expired controlled drug stock going unnoticed for a long time, which would delay any investigation. During its deliberations, the committee recognised that the frequency of such checks could be determined locally after a risk assessment has been carried out, and that intervals of one week or less between checking would be the minimum given the risks associated with controlled drugs.

8.6 Recommendations & research recommendations

There are a number of regulations that apply to the handling of controlled drugs, including the Misuse of Drugs (Safe Custody) Regulations 1973, and the 2001 Regulations. Controlled drugs in Schedule 2 and 3 have additional restrictions placed on them and they are handled to allow their use to be monitored.

Organisations

37. **Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs.**

38. **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 of use
    - storage facilities needed
    - whether the security setting is low, medium or high risk
    - quantities of controlled drugs expected to be used
    - checking for discrepancies in stock balances at shift handover
    - frequency of staff turnover
    - accessibility for use by staff.

39. **A separate controlled drugs register must be kept for each premise of an organisation where controlled drugs in Schedule 2 are stored, in line with Regulation 20 of 2001 Regulations.**

40. **When developing standard operating procedures for storing controlled drugs, ensure that they meet the needs of their service and take into account:**
    - whether the security setting is low, medium or high risk
    - staff access to controlled drugs
    - the storage environment, including temperature and space in the controlled drugs cabinet
    - storage of stock and patients' own controlled drugs
    - any additional storage needs for controlled drugs with similar or 'lookalike' packaging and different strengths
    - the setting for use.

41. Consider developing standard operating procedures for risk assessing the use of controlled drugs in organisations where patients' own controlled drugs may be used and handled. The risk assessment may include:

- self-administration or self-possession
- storage requirements
- record keeping
- disposal.

42. Consider developing a standard operating procedure for carrying out stock checks of all controlled drugs entered into the controlled drugs register. The procedure should include:

- checking the balance in the controlled drugs register against current stock
- measurements of liquid balances and checks of remaining liquid stock when finishing a bottle
- the frequency of stock checks, which should be determined using a risk assessment and should be at least once a week
- recording stock checks in the controlled drugs register along with the date and signature of the health professional carrying out the check.

43. When developing standard operating procedures for transporting controlled drugs, take into account:

- storage while in transit
- security (for example, use of locked doctor's bags and ambulances)
- record keeping, such as the movement of controlled drugs supplied for use at different locations
- the supply process.

44. Do not routinely use couriers, taxis or equivalent services to transport controlled drugs or prescriptions for controlled drugs. If there are exceptional circumstances of urgent clinical need, use a delivery service that needs a signature on delivery to ensure that there is an audit trail.

45. Arrangements for destroying and disposing of controlled drugs must be in place and in line with the 2001 Regulations and the Controlled Waste (England and Wales) Regulations 2012, regardless of the source of supply.

46. When developing standard operating procedures for disposing of controlled drugs, including unwanted or expired stock and drugs returned by people, take into account:

- the place of destruction
- local agreement and records of authorised people to witness the destruction of controlled drugs.

47. Arrangements for witnessing the disposal of stock controlled drugs in Schedule 2, 3 and 4 must be in place and in line with Regulation 27 of the 2001 Regulations.

48. In organisations with internal pharmacies, use a risk assessment (see the Management of Health and Safety at Work Regulations 1999) to determine locally the

most appropriate place for destroying controlled drugs. This should consider how close the place of destruction should be to where the drugs are used to help minimise risks of controlled drug-related and patient safety incidents.

49. Consider developing standard operating procedures based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died.

50. Non-healthcare settings, such as schools, should have systems and processes in place for storing, recording and transporting controlled drugs that belong to a person who is under their supervision.

Organisations and health professionals

51. Consider keeping records to provide an audit trail for the supply, administration and disposal of controlled drugs and the movement of them from one location to another.

Health professionals

52. When supplying dispensed controlled drugs to a person in police custody, check whether the custody staff have adequate arrangements and handling facilities for controlled drugs.

53. Provide advice and information to people who are prescribed controlled drugs about how to store controlled drugs safely. Discuss storage options taking into account:

- the person's preference for a lockable or non-lockable storage box
- whether they are accessible to people who should and should not have access to them.

54. Assess if a person's method of storing their controlled drugs in their home could lead to an increased risk of controlled drug-related incidents, including patient safety incidents.

55. 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.

56. When a person has died in their home and controlled drugs need to be removed for destruction and disposal, 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.

57. When destroying and disposing of stock controlled drugs in Schedule 2, 3 and 4 (part I), health professionals must record the following, in line with Regulation 27 of 2001 Regulations:

- the name, strength and form of the controlled drug
- the quantity
- the date of destruction
- the signatures of the person destroying the controlled drugs and the authorised person witnessing the destruction.

58. Consider asking a second member of staff (preferably a registered health professional) to witness the destruction and disposal of a patient's returned controlled drugs.

59. 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 a witness.

60. When disposing of bottles of liquid controlled drugs containing irretrievable amounts:

- consider rinsing the bottle and disposing of the liquid into a pharmaceutical waste bin
- remove labels and other identifiers from the container
- dispose of the clean, empty container into the recycling waste.

Disposal of irretrievable amounts of controlled drugs does not need to be recorded.

9 Monitoring of controlled drugs (e)

9.1 Introduction

9.1.1 Legislation, regulation and policy guidance

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Regulations") came into force in April 2013 and apply in England and Scotland only. The 2013 Regulations carry forward the main provisions of the 2006 regulations and introduce new provisions to ensure consistency with the architecture in the NHS in England after the Health and Social Care Act 2012 was passed.

For the purpose of this guideline, the term monitoring includes, analysing, reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback relating to controlled drugs. NHS governance structures are in place to support the safe reporting of medicines-related patient safety incidents through the National Reporting and Learning System (NRLS) and the Medicines and Healthcare products Regulatory Agency (MHRA), including a national medication safety network of medication safety officers. This network discusses potential and recognised safety issues and identifies trends and actions to improve the safe use of medicines (see also the NICE guideline on Medicines optimisation [2015]).

The 2013 Regulations set out the governance arrangements required to ensure that systems are in place for the safe and effective management and use of controlled drugs. Controlled drugs accountable officers (CDAOs) and local intelligence networks form part of these arrangements.

A CDAO (also known as an accountable officer) is a 'fit, proper and suitably experienced person' who is appointed to ensure that systems for the safe management and use of controlled drugs are secure within their own organisation or at those they have a contract with. The requirements of a CDAO are specified in the 2013 regulations. In the 2013 Regulations, organisations are defined as 'designated bodies' and are responsible for appointing CDAOs.

Local intelligence networks (also known as LINs) provide an opportunity for organisations that have concerns about the activities relating to controlled drugs to share them as soon as possible with other local organisations who may also be affected or who may have related information. These networks bring together organisations from the NHS and independent health, and other responsible bodies, regulators and agencies including the General Pharmaceutical Council, NHS Protect and police services.

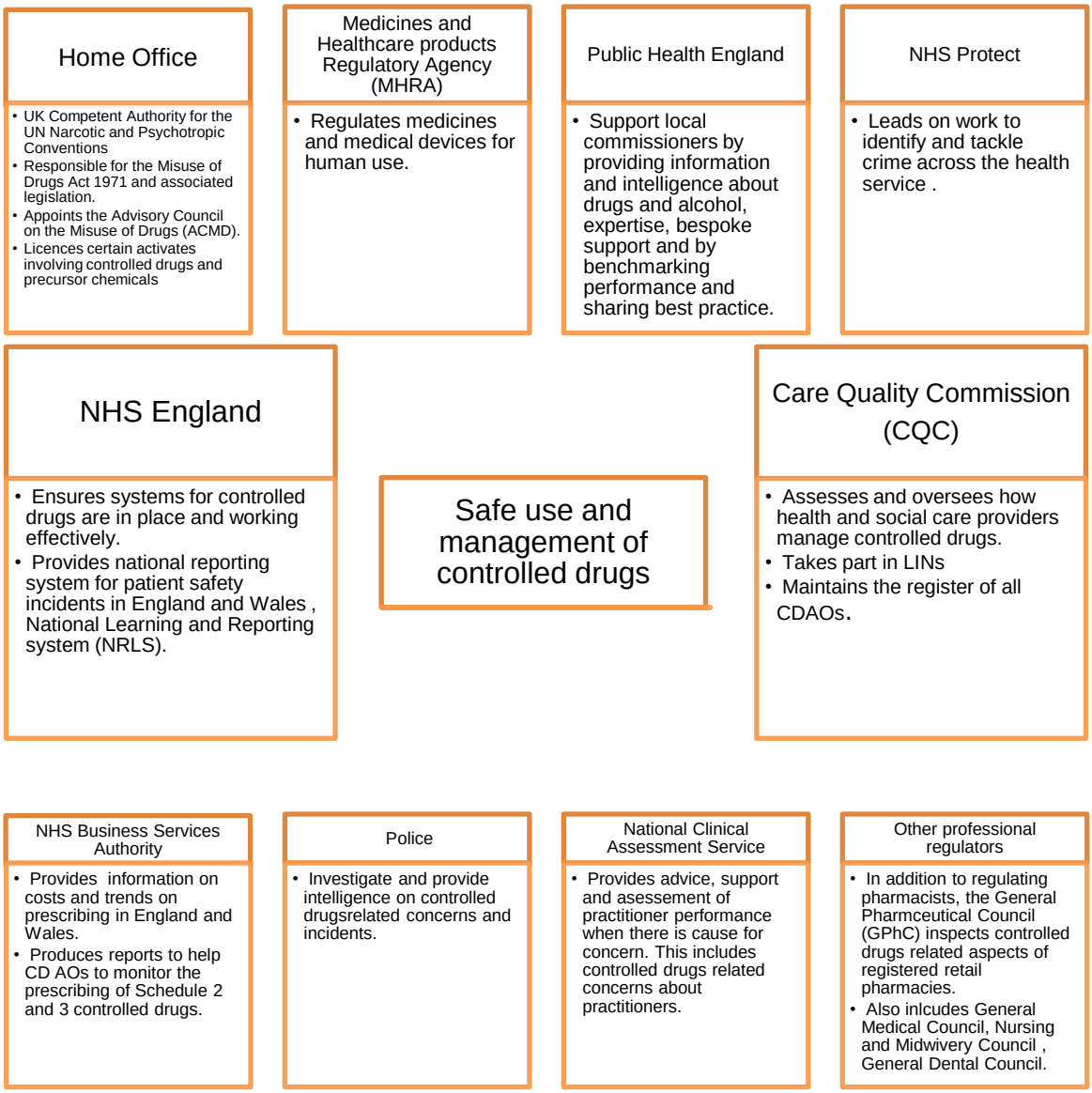
NHS England lead CDAOs are the assigned lead CDAOs for establishing LINs and the membership to the LIN in England. The lead CDAO is responsible for a designated geographical area and works with the organisations' appointed CDAOs. Organisations that are designated bodies but do not administer or hold controlled drugs are still required to appoint an accountable officer, although their responsibilities are reduced accordingly.

Responsible bodies are required to cooperate with other LIN members in relation to the handling of, and acting on, shared information including steps to protect the safety of patients and the general public. A duty of collaboration is placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces and the Care Quality Commission (CQC) to share intelligence on controlled drugs issues (see Figure 1). The CQC monitors progress on the implementation of the controlled drugs regulations and overall compliance with the requirements. Details of all the CDAOs within England are held in the Controlled Drugs Accountable Officer Register, which is published on

the CQC website. An annual report is published by the CQC summarising national trends and activities on the use of controlled drugs. The CQC lead the Controlled Drugs National Group that consists of regulators and key agencies who have areas of responsibility for controlled drugs within their remit.

The safe use and management of controlled drugs is governed and monitored and enforced by different regulatory organisations (see figure 1).

Figure 1: Summary of organisations involved in different aspects of the regulation and control of controlled drugs.



A single operating model has been developed by NHS England to introduce standardised processes and documentation to support its area teams. The single operating model outlines the lead CDAO responsibilities for establishing and managing arrangements for controlled drugs in line with the regulations.

9.2 Review question

In line with legislation and regulation for Schedule 2, 3, 4 and 5 controlled drugs of the Misuse of Drugs Regulations 2001, what interventions, systems and processes are effective and cost effective for **monitoring** use (including, analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback) of controlled drugs to **reduce controlled drugs-related incidents**, including **patient safety incidents**?

9.3 Evidence review

9.3.1 Evidence

The review protocols identified the same parameters for the review questions on obtaining and supplying, handling and monitoring of controlled drugs. Therefore a single systematic search was carried out (see appendix C.1.2) for these review questions. A total 17,542 references were identified from the search. After removing duplicates the references were screened on their titles and abstracts and each included study was identified as being relevant for inclusion for review. Two hundred and nine references were obtained and reviewed against the inclusion and exclusion criteria as described in the review protocol for monitoring of controlled drugs (appendix C.2.5). Of these, 208 references were excluded. A list of excluded references and reasons for their exclusion is provided in appendix C.5.5. Non-UK based national guidelines that were solely based on legislation were excluded on the basis that the UK have their own legislation and the guideline would not be applicable to the UK setting for the monitoring of controlled drugs.

In total, 2 qualitative studies were included for this review question. From the original search, 1 qualitative study was identified that involved interviewing and sending out questionnaires to general practices. An additional qualitative study was identified that evaluated the number of patient safety incidents pre- and post-implementation of the National Patient Safety Alert on preventing overdose with midazolam (see appendix D.1 evidence tables). There were no other studies identified that looked at interventions, systems or processes that could be effective for monitoring controlled drugs.

The qualitative studies were assessed using the NICE methodology checklist for qualitative studies.

In addition to the systematic search, national sources such as NHS England, the Medicines Healthcare products and Regulatory Agency (MHRA) and the Care Quality Commission (CQC) were searched to identify any safety information on practice relating to the monitoring of controlled drugs. There was no information relevant to this review question identified from these sources. No other information was found from other secondary sources that were listed to be searched in the review protocol. A citation search was also carried out using the references included for the review question to identify any additional papers. The citation search did not identify any relevant papers to include for the review.

1 **Table 20: Summary of included evidence**

Reference	Population	Aim of intervention, system or process	Findings
Investigation of systems to prevent drug diversion of opiate drugs in general practice in the UK. Barker R et al. (2004)	• General practitioners (GP)	• This study highlighted the systems used by GPs for handling and monitoring controlled drugs • N=142	• Internal monitoring of controlled drug registers and storage varied from daily to annually. • External monitoring of controlled drugs registers varied from 1-10 years.
Reducing risk of overdose with midazolam injection in adults: an evaluation of change in clinical practice to improve patient safety in England. Flood C et al. (2015)	• Health care trusts that provide acute care in England	• This study aimed to find out if the UK national patient safety alert 'reducing risk of overdose with midazolam injection in adults' resulted in a reduction in reports of severe harm and death caused by midazolam use and also to see if there was any change in practice for handling midazolam • N=333 health care trusts that provide acute care	• 498 incidents involving midazolam were received by the National Learning and Reporting System before the issue of the alert. Post-implementation of the alert, no incidents resulting in severe harm or deaths were received. • Purchase and use of high-strength midazolam by organisations decreased significantly as did the increased use of low-strength midazolam.

Analysis of the evidence

There were no RCTs or other types of studies included for this review question and so data was not analysed using GRADE or Review Manager to calculate statistical significance. The evidence has been summarised in table x summary of included evidence as a narrative under 'findings'.

9.3.2 Health economic evidence

A systematic literature search (appendix C.1.3) was undertaken to identify cost effectiveness studies evaluating the systems, interventions and processes for monitoring use (including, analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns, feedback) to reduce controlled drugs-related incidents, including patient safety incidents.

This search identified 2250 records, of which 2236 were excluded based upon their title and abstract. The full papers of 14 records were assessed and all were excluded at this stage. The excluded studies and the reason for their exclusion are provided in appendix C.7.5.

9.4 Evidence statements

9.4.1 Evidence

One very low quality study found that there is variation in the frequency of monitoring controlled drugs registers and storage in general practices that stock controlled drugs.

One low quality study found that a system used for reporting patient safety incidents and learning from trends in incidents received (through the use of alerts) reduces patient safety incidents and improves organisational systems or processes to ensure compliance with the alert to avoid future patient safety incidents.

9.4.2 Economic evidence

No relevant economic analyses were identified in relation for monitoring use (including, analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns, feedback) to reduce controlled drugs-related incidents, including patient safety incidents.

9.5 Evidence to recommendations

Table 21: Linking evidence to recommendations (LETR)

Relative values of different outcomes	The Committee discussed the relative importance of the outcomes and agreed that identifying and reporting of incidents (or potential incidents), diversion, monitoring use, misuse, potentially avoidable adverse events, health and social care practitioner reported outcomes and process measures were all critical and important when reviewing systems, processes or interventions for effective monitoring the use of controlled drugs . The Committee was aware of legislation, the 2013 Regulations, being in place to ensure organisations have the necessary arrangements in place to govern the use of controlled drugs. The Committee was presented with 2 studies for this review question. Only 1 of

	the studies (Flood C et al.) that looked at the effectiveness of rapid response reports (RRRs), reported outcomes that were relevant to this review question. The Committee found that resources such as RRRs, developed to disseminate actionable learning from patient safety incident reports, can reduce the number of severe harms and support organisations to put processes in place to prevent similar incidents from happening again. The Committee was aware that healthcare organisations report patient safety incidents (including controlled drug-related patient safety incidents) to the National Reporting and Learning System. The Committee was also aware of the NICE guideline on Medicines optimisation (2015), which provides recommendations on improving learning from medicines-related patient safety incidents to guide practice and minimise harm to people, and that this would also apply to controlled drugs. The Committee was aware of the gaps in the evidence and the lack of data for outcomes they agreed to include for assessing the effectiveness of systems, processes and interventions for monitoring the use of controlled drugs. However, the Committee recognised and discussed the complexities involved in arranging systems and processes for monitoring controlled drugs in various different settings and these discussions have been captured below.
Trade-off between benefits and harms	The Committee considered a number of interventions, systems, processes and policies that could be used to monitor the use of controlled drugs in practice. The Committee was aware that some are already in place such as the, national controlled drug prescribing reports, standard operating procedures relating to prescribing, supplying and administering controlled drugs, appointment of controlled drugs accountable officers (CDAOs) and the use of multiple incident reporting systems such as the National Reporting and Learning System and or other organisational incident reporting system. The costs of having these would be accounted for as they are already in place. The Committee highlighted that there is variation in how some activities are carried out due to resources. The Committee discussed that having systems and processes in place for monitoring controlled drugs can benefit and support organisations and health and social care practitioners to prevent controlled drug-related incidents, including patient safety incidents. The Committee agreed that where there is variation of processes used in practice to monitor controlled drugs, clarifying some of these processes and providing good practice recommendations will help organisations and health and social care practitioners to improve the care they give to people and prevent harm.
Economic considerations	No economic evidence was identified for this review question.
Quality of evidence	The Committee was aware that monitoring of controlled drugs is underpinned by legislation and national policy guidance from NHS England and the Care Quality Commission (CQC). The Committee was also aware that the evidence presented to them varied from very low to low quality. For this review question the recommendations were based on legislation, good practice advice from national policy documents and informal consensus by the Committee.
Other considerations: legislation, policy and practice	The Committee was aware of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 which lays out the legal framework for strengthening governance and monitoring arrangements for organisations that use controlled drugs to prevent controlled drug-related safety incidents, including patient safety incidents. **Establishing standard operating procedures** The Committee recognised that organisations may have different activities involving controlled drugs use and was aware that developing standard operating procedures relating to an organisation's controlled drugs activities is left to the judgement of the organisation's CDAO or other appropriate person if no CDAO is needed or appointed. The Committee was aware that the duties of the CDAO are defined in Regulation 11 of the 2013 Regulations who reviews

these arrangements. In addition, the Committee also discussed the importance of ensuring that standard operating procedures are reviewed regularly, staff are aware of the procedures and comply with them and the procedure is updated and risks are assessed with use.

Auditing and risk assessments

The Committee was aware that there is no legislation relating to the auditing of controlled drugs registers. However, premises that are registered with the General Pharmaceutical Council (GPhC) for example, pharmacies, are externally inspected by the GPhC, and this includes inspection of the controlled drugs registers and storage of controlled drugs. The Committee heard that the GPhC inspect registered pharmacies on a 3 year cycle.

The Committee was aware of the Care Quality Commission (CQC) and its remit in relation to controlled drugs safe use and management, and found that it does not routinely carry out inspections of controlled drugs registers. The Committee discussed who would be responsible externally for carrying out audits of controlled drugs registers and cabinets. The Committee also discussed the value of having audits of controlled drugs registers and cabinets. The Committee heard that controlled drugs registers may include false records that may not be picked up during an audit of the register and there could be a risk of diversion and misuse. The Committee discussed that if a discrepancy is identified, who would this be reported to, in addition to notifying the person responsible for ensuring that the controlled drugs register is maintained. The Committee recognised the variation in resources that may be available for carrying out these audits and agreed that this may be determined locally. The Committee recognised that there is no formal process to report these types of issues and discussed how ongoing trends could be identified if there was no process for reporting minor discrepancies (see also below under 'considerations for reporting and learning from controlled drug-related incidents').

The Committee heard that licensing decisions made by the Home Office for organisations are made on a risk-assessed basis irrespective of the activity, for example supply or possession. These risk assessments are carried out annually when they are renewed. As part of the renewal process, there are a number of 'self-check' questions and declarations that have to be made by the organisation to indicate compliance with regulations and legislation. The licences also include reporting of incidents such as losses or thefts. In addition the Home Office also use other regulatory bodies' information for example CQC reports about organisations to inform that risk assessment for the years that have not been visited. The Home Office visit the organisations they have issued a licence to approximately every 3 to 5 years depending on a risk assessment to check compliance with controlled drugs regulations and legislation.

The Committee noted the findings from the qualitative study, Barker et al., which suggested that there is a variation in the frequency of internal and external monitoring of controlled drugs registers and in the way that controlled drugs are stored within general practices. The Committee discussed that depending on the care setting there is variation in the frequency of audits that are carried out on controlled drugs registers and cabinets: from having no audit to having frequent audits. The Committee heard that controlled drugs registers and cabinets may be audited internally or externally depending on the care setting and local arrangements.

The Committee heard that in some care settings, for example ambulance services, internal audits of controlled drugs registers and cabinets are carried out frequently, however, there are no external audits (where someone external to the service comes to carry out the audit). In hospital settings, the Committee

found that the pharmacy team that supplies the wards with controlled drugs often carries out a quarterly audit of the controlled drugs register and cabinet to monitor compliance with controlled drugs regulations. The Committee also heard that sometimes audits of the controlled drugs register and cabinet may be carried out by the ward staff or pharmacy teams that work within the ward. The Committee discussed that it may be more appropriate for someone external to the ward to carry out this audit.

Controlled drugs accountable officers and the nominated persons

The Committee was aware that the 2013 Regulations requires 'designated bodies' to appoint a CDAO for their organisation to assure the quality of the processes in place to manage controlled drugs. The Committee discussed that some clinical commissioning groups and smaller healthcare providers for example, private healthcare facilities, are exempt from appointing a CDAO. The Committee discussed the risks of controlled drug-related safety incidents and also the process of governance and sharing local intelligence about controlled drug-related activities with healthcare providers that do not have a CDAO. The Committee was aware that regulations require CDAOs to be responsible for ensuring that standard operating procedures are in place for managing controlled drugs in their organisation. For organisations that nominate a person to oversee its arrangements for controlled drugs use, the Committee discussed that it would be good practice for the nominated person to ensure that there are processes in place for safe use of controlled drugs including standard operating procedures for managing controlled drugs in the organisation. The committee further discussed and agreed that it would be good practice for organisations that are not required by legislation to appoint a CDAO should consider appointing a nominated person to:

- work in accordance with appropriate governance arrangements for the safe use and management of controlled drugs
- make sure processes are in place for safe management and use of controlled drugs and the reporting and investigating of concerns
- liaise with the local NHS England lead controlled drugs accountable officer and local intelligence network members.

The Committee was aware of the NHS England guidance: the single operating model that supports NHS England area teams in establishing its statutory responsibility in relation to the 2013 Regulations. The Committee highlighted that CDAOs should work in accordance with this single operating model.

Governance arrangements in provider organisations

The Committee was concerned about governance arrangements (including responsibilities and accountability) for managing controlled drugs in provider organisations that do not need to appoint a CDAO. The Committee heard that where the provider organisations are subject to registration with the CQC, then the CQC can request periodic declarations and self-assessments from these organisations about how they meet their controlled drugs governance arrangements. The Committee discussed that commissioners can also ensure that governance arrangements with clear lines of responsibility and accountability for managing controlled drugs in the services they commission are in place when developing contractual arrangements.

Local intelligence networks and their membership

The Committee was aware of the importance and benefits of local intelligence networks (LINs) that enable organisations that are concerned about activities associated with controlled drug-related incidents, including patient safety incidents to share their concerns with other local organisations that may be affected or that may have complementary information. The Committee also

discussed the benefits of LINs providing opportunities for sharing learning and expertise among local organisations.

The Committee heard that there is variation in the membership of LINs across England and that, although there is a requirement for CDAOs and nominated people from responsible bodies to attend LIN meetings, there can be poor attendance from some members. The Committee discussed that the lead CDAO should monitor attendance of those individuals who are legally required to attend LIN meetings and should inform the CQC of poor attendance. The Committee agreed that the lead CDAO should notify the CQC of poor attendance by those individuals who are legally required to attend LIN meetings. The Committee discussed that in some cases there may be a need to share local intelligence across local area teams, for example, if there is a concern about a prescriber who works across geographical boundaries. The Committee heard that some LINs that have extended their membership to other relevant organisations for example, substance misuse, palliative care and out of hours services. The Committee discussed the importance of having LINs in place to share any concerns and learn from controlled drugs activities that may affect other organisations locally and nationally. The Committee heard that the Care Quality Commission should be notified by the lead CDAOs of poor engagement by those individuals who are legally required to attend local intelligent network meetings.

Monitoring and analysing prescribing data relating to controlled drugs

The Committee was aware of Regulation 13 of the 2013 Regulations. This regulation stipulates that analysis tools need to be made available to the CDAO's designated body to look at prescribing of controlled drugs by individuals.

The Committee discussed the Shipman Inquiry's Fourth Report that made a number of recommendations to strengthen the prescribing of controlled drugs and for monitoring their movement from prescriber to dispenser to patient. The Committee further discussed about monitoring of prescribing trends. The Committee was aware that the NHS Business Services Authority (NHS BSA) produces a suite of reports to highlight potential causes for concern within the prescribing of controlled drugs. The Committee was aware of the following BSA reports:

- Controlled drugs analysis reports which provide an analysis of unusual behaviour in controlled drugs prescribing at prescriber and practice level;
- Controlled drugs comparator reports which provide a high level view of controlled drugs prescribing at Regional Office, Area Team and Primary Care Organisation level;
- Controlled drugs Requisitions reports which provide information on all requisitions within NHS England Regional Teams and can be filtered on NHS or private requisitions;
- Private controlled drugs analysis reports which provide data on the private prescribing of controlled drugs.

The Committee heard that the data contained within these reports relates to prescriptions dispensed in primary care in England as the BSA does not hold any secondary care information. Registered users of the portal can access all of these reports but if organisations, for example clinical commissioning groups (CCG's) are using the guest log in they will only have access to controlled drugs comparator reports. The Committee discussed that CDAOs have access to these reports to monitor prescribing of controlled drugs locally and nationally. The Committee heard that accountability of the CDAO lies with NHS England and that local prescribing data lies with CCGs as they are responsible for commissioning services. The lead CDAOs do not routinely have access to local prescribing data to undertake investigations relating to their CDAO work. The

Committee discussed that access to prescribing data for all controlled drugs would be useful to identify:

- prescribing trends and potential risks of unintended use
- the reasons for very high, increasing or very low volume prescribing.

Reporting and learning from controlled drug-related incidents.

Submissions of occurrence reports

The Committee was aware of Regulation 11 and 13 of the 2013 Regulations, for raising and reporting concerns or incidents about controlled drugs in a timely way and to start investigations if appropriate. Legislation requires lead CDAOs to ensure there are systems in place for incident reporting and recording concerns relating to the use of controlled drugs for their organisation. The Committee discussed the variation in the way incidents and concerns relating to controlled drugs are reported and recorded. The Committee heard that some organisations submit periodic declarations of incidents, some have local arrangements for reporting incidents through a local system and some organisations (that are designated bodies) submit quarterly occurrence reports. The Committee also heard that the submission of occurrence reports is variable in that they are submitted infrequently by designated bodies. The Committee discussed that LINs need to be more engaged with attendance (discussed above) and submissions of occurrence reports and agreed that the lead CDAO should report poor engagement to the CQC. The Committee heard that barriers to reporting incidents relating to controlled drugs should be identified so that solutions can be devised to increase reporting. The Committee also discussed that the lead CDAO should consider presenting incidents and identified themes including actions taken and harms prevented at the LIN meetings to share learning.

Incident reporting systems

The committee was aware that, although the National Reporting and Learning System is available for reporting all medicines-related incidents nationally, they felt that there needs to be a formal system for gathering national intelligence about all controlled drugs-related incidents including patient safety incidents. The Committee discussed that there are several processes in place for reporting controlled drugs-related incidents including patient safety incidents such as local, national and to the CDAO and this may depend on the type of organisation and the setting it is in. The Committee was aware of the role of Medication Safety Officers (MSOs) who can work with CDAOs to share and learn from controlled drugs-related incidents including patient safety incidents. There was no evidence to show which systems are the most effective for reporting controlled drug-related incidents including patient safety incidents. The Committee discussed what may be considered as good practice in local processes when multiple incident reporting systems are used. The Committee considered including the following in local processes:

- reviewing arrangements regularly to reflect local and national learning
- carrying out risk assessments of incidents
- sharing learning.

Types of incidents

The Committee discussed the types of incidents that may range from minor to serious. Minor incidents may include discrepancies involving controlled drug stock; a serious incident may include harm to a patient or misuse by a health professional. The Committee heard that NHS England has a serious incident framework that defines serious incidents and may be considered to form part of the system used when reporting incidents and concerns relating to controlled drugs. The Committee discussed the risks associated with controlled drugs and that in some cases low level information for example several similar incidents in

	other localities identified from the LIN about controlled drugs may be valuable in identifying a significant incident or patterns of use, and the CDAO should ensure that the processes are clear about the types of incidents to report and to record. The Committee also discussed that the setting in which the incident occurs may affect how and when the incident is reported. When and how to report an incident The committee highlighted the importance of people knowing how and when to report an incident. There was concern raised about the length of time it takes for some controlled drugs-related incidents to be reported to the CDAO. The Committee referred to the Medicines optimisation [NICE guideline NG5] and discussed the recommendation about reporting all identified medicines-related patient safety incidents consistently and in a timely manner, in line with local and national patient safety reporting systems, to ensure that patient safety is not compromised. The committee further discussed that incidents should be reported in a timely manner, ideally within 48 hours to their CDAO to allow them to carry out their legal duty. The Committee also discussed when necessary actions should be taken when reviewing incidents or concerns relating to controlled drugs. There was no evidence to inform this and the Committee discussed that it would depend on the nature of the incident. Any necessary action taken would be on a case-by-case basis and linking this to any other relevant intelligence.

9.6 Recommendations & research recommendations

Monitoring of controlled drugs includes analysing, identifying and reporting incidents, recording harms, sharing information, sharing learning, addressing concerns and feedback. The aim of the 2013 Regulations is to strengthen the governance arrangements for the use and management of controlled drugs in different care settings.

Organisations

61. Designated 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, as specified in Regulation 11 of the 2013 Regulations.

62. Designated bodies must appoint a controlled drugs accountable officer, who will quality assure processes for managing controlled drugs in their organisation, in line with Regulation 8 of the 2013 Regulations.

63. Organisations that are not required by legislation to appoint a controlled drugs accountable officer should consider appointing a nominated person. The nominated person should:

- work in accordance with appropriate governance arrangements for the safe use and management of controlled drugs
- make sure processes are in place for safe management and use of controlled drugs and the reporting and investigating of concerns
- liaise with the local lead controlled drugs accountable officer and local intelligence network members.

64. Establish processes for developing, reviewing, updating, sharing and complying with controlled drugs-related standard operating procedures in line with legislation and national guidance. A risk assessment may be used when establishing processes.

65. Commissioners of healthcare services should include governance arrangements with clear lines of responsibility and accountability for controlled drugs in their contracts with provider organisations.

66. When multiple systems are used for reporting controlled drug-related incidents (for example, 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.

67. Consider including in local processes how to inform the controlled drugs accountable officer or nominated person of controlled drug-related concerns or incidents in a timely way, ideally within 48 hours.

68. Consider developing standard operating procedures for audits of controlled drugs 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.

69. Consider putting processes in place to access prescribing data for all controlled drugs to identify:

- prescribing trends and potential risks of unintended use
- the reasons for very high, increasing or very low volume prescribing.

Lead controlled drug accountable officers, controlled drugs accountable officers and nominated persons

70. Controlled drugs accountable officers must ensure that robust systems are in place for raising and reporting concerns or incidents about controlled drugs in a timely way (including those for starting investigations) in line with Regulations 11 and 13 of the 2013 Regulations.

71. Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should:

- include other relevant local organisations, such as substance misuse, palliative care and out-of-hours services, in local intelligence networks
- work with local intelligence networks in other areas when needed
- notify the Care Quality Commission of poor engagement by those legally required to attend local intelligent network meetings.

72. Lead controlled drugs accountable officers with a responsibility for governance and safety in the use of controlled drugs should consider:

- identifying barriers to reporting
- identifying trends in incidents reported
- providing feedback of actions from controlled drugs-related incidents including patient safety incidents, and from occurrence reports to controlled drugs accountable officers
- sharing learning with their controlled drugs accountable officers, including trends or significant incidents, to support continuing professional development
- reporting organisations that submit occurrence reports infrequently or with insufficient detail to the Care Quality Commission.

73. An organisation's controlled drugs accountable officer or nominated person should review controlled drug-related concerns or incidents and take any action needed on a case-by-case basis.

10 References

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11 Glossary

This glossary provides brief definitions and explanations of terms used within this guideline. Further definitions and explanation of terms can be found on the NICE glossary page.

Authorised person

In Regulation 27 of the 2001 Regulations requires that controlled drugs that are held as stock by health professionals or organisations must only be destroyed in the presence of an authorised witness. The Act designates certain people as authorised witnesses. This includes any police constable and inspectors of the General Pharmaceutical Council.

The lead controlled drugs accountable officer of NHS England may also appoint people as authorised witnesses.

Authorised signatory

A nominated registered nurse, midwife or operating department practitioner eligible to sign hospital requisitions. Names should be detailed in local standard operating procedures.

Continuous administration devices

Controlled automatic device for administering medicines, including controlled drugs, at a set rate of dose per time. An example of this is a syringe pump.

Controlled drugs accountable officer

A 'fit, proper and suitably experienced person' who is appointed to ensure that systems for the safe management and use of controlled drugs are secure within their own organisation or in those they have a contract with.

Denatured

Text Do you think adding in this term here will confuse some readers? Perhaps we should add a glossary term explaining how this links with 'destroying'.

Designated body

Designated bodies in England are NHS foundation trusts, NHS trusts, English independent hospitals, the NHS Commissioning Board[c] and the headquarters in England of regular or reserve forces.

See Regulation 7 of the 2013 Regulations for more information.

Designated individuals

The person under whose supervision the licenced activity is authorised to be carried out.

Discharge prescription

Prescription for medicines that patients take with them at the time of discharge.

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

Diversion

Removal of controlled drugs for unauthorised use.

Doctor's bag

A lockable bag containing medicines and medical equipment, occasionally including controlled drugs that doctors use when outside, and sometimes inside, their surgeries.

External pharmacy

A pharmacy that is not part of the organisation that it supplies medicines to. For example a retail pharmacy supplying medicines to a hospital.

Group authority

Persons who are covered by an applicable Home Office licence group authority can possess and supply Controlled Drugs in accordance with the terms of the group authority.

Health prescription

This includes National Health Service (NHS) prescriptions issued by independent and supplementary prescribers.

Instalment dispensing

Dispensing against a prescription that contains a direction that specifies instalments of the total amount of controlled drug may be supplied at stated intervals.

Internal (inpatient) pharmacy

A pharmacy that is part of the organisation it supplies medicines to for example a hospital pharmacy or prison pharmacy that belongs to the organisation providing a service.

Irretrievable amounts

An immeasurable or residual amount of liquid remaining after use.

Mandatory form

In the context of the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015, this is the form approved by the Secretary of State, the Welsh Ministers or the Scottish Ministers, for the purposes of requisitioning Schedule 2 and 3 controlled drugs.

Medicines or inpatient record

A record of all the medicines the person is taking when in an inpatient setting. Each medicine has to be signed by a prescriber. The record forms the authority to administer the medicine.

Lead controlled drugs accountable officer

The lead controlled drugs accountable officer has the responsibility for the governance and safety in the use of controlled drugs. Regulation 8 of the 2013 Regulations places a requirement on NHS England to nominate or appoint a fit, proper and suitably experienced

person to be NHS England's lead controlled drugs accountable officer in respect of each of its local intelligent network (LIN) areas.

Nominated person

A person who is not involved in the day-to-day handling of controlled drugs who has been appointed to oversee the management and governance of activities related to controlled drugs.

Opioid naive

When a person has a low tolerance to doses of opioid medicines.

Part supplies of controlled drugs

An incomplete supply of a requested quantity of controlled drug. An example of a part supply would be when a pharmacy does not have the full quantity of the medicine to provide the quantity requested.

Practitioners

In the context of the Act, this is defined as a doctor, dentist, veterinary practitioner or veterinary surgeon.

Repeat management systems

A system to manage regular medicines that do not need consultation with the prescriber each time a prescription for that regular medicine is requested. The prescriber will set a number of repeat prescriptions to be issued for the regular medicine without consultation.

Repeat prescription

Prescription for a regular medicine on a repeat basis without the need for consultation with a prescriber. See also 'repeat management systems'.

Responsible body

Responsible bodies in England are regulatory bodies that include: designated bodies, clinical commissioning groups, NHS Protect, the Prescription Pricing Division of the NHS Business Services Authority, the Care Quality Commission, local authorities, and police forces.

See Regulation 6 of the 2013 Regulations for more information.

Reversal agents

Medicines used to reverse the harmful effects of other medicines such as opioid controlled drugs.

Rinsings

The removal of an irretrievable amount of liquid medicine with water in the final stage of emptying or washing the container before disposal. See also 'irretrievable amounts'.

Standard operating procedures

A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes. For example the management of controlled drugs.

Stock (controlled drug)

The term ‘stock’ refers to controlled drugs that have not been issued or dispensed to a patient but is for use by the healthcare provider for administration or supply.

Supervised consumption

Consumption of medicines such as controlled drugs that supervised by a health professional to ensure that the patient takes their medicine as prescribed.

Total opioid load

The total dose of opioid (often converted to morphine equivalent daily for comparison) that is taken in a 24-hour period.

When required

Medicines that are taken when they are needed to manage a symptom, for example a pain killer for short term pain.