Safe use and management of controlled drugs

Consultation on draft guideline
Stakeholder comments table

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Alderhey Children's NHS Foundation Trust	Full	26	8	Refers to "writing" prescriptions. There is a need to recognise that both primary and secondary care are moving towards electronic prescribing systems, to include CDs (ETP) and that the term "writing" may be taken literally and is therefore inappropriate.	Thank you for your comment. This wording has been amended to take into account electronic prescribing following further discussion by the Committee.
Alderhey Children's NHS Foundation Trust	Full	27	10	There is reference to prescribing enough of a controlled drug to meet the patient's clinical needs for no more than 30 days. Prescribers should also be asked to consider the pack size of an original pack of the product when prescribing. Frequently electronic prescribing systems in primary care default to 28days when pack sizes are 30 capsules (e.g. Equasym XL 30mg caps). This results in numbers of loose capsules, making stock checks difficult and eventually resulting I n patients receiving lots of small sections of foil packs.	Thank you for your comment. Prescribing in terms of pack sizes was not discussed by the Committee. Prescribers should prescribe an appropriate quantity of controlled drugs to meet the clinical needs of the person and this may be less or more than 30 days and the relevant information should be documented in the person's medical record. Prescribing controlled drugs using pack sizes to guide the quantity to prescribe may not meet the person clinical need.
Alderhey Children's NHS Foundation Trust	Full	27	5	Emphasise that the preference is to standardise dose conversion tables and use nationally approved tables rather than refer to locally produced tables. Perhaps this is something that could be considered by UKMI or the palliative care (pharmacists) groups.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.
Alderhey Children's	Full	30	19	The details listed in section 32 would typically be recorded on a traditional hospital drug chart or	Thank you for your comment. This wording has been amended to make it clear that this applies to all care settings following further

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NHS Foundation Trust				electronic medication administration record in a hospital setting. They forms part of the care record- this may need to be clearer. As it currently stands this statement would seem to apply to care home/primary care settings. The hospital situation also needs to be reflected.	discussion by the Committee. The recommendation intends to emphasise the importance of making a record of administration in the person's care record. The care record may vary depending on the arrangements of the care setting for recording administration, this may be in the form of a medicines administration record if the setting uses one or another type of record that is kept to log care provided. The term 'care record' has been added to the glossary section in the full guideline.
Alderhey Children's NHS Foundation Trust	Full	32	5	This depends on the area of the stock check. At ward level in our organisation we expect CD stock checks to be confirmed at each shift handover as the nurse in charge is transferring responsibility from herself to another nurse in charge and therefore they both need to agree the stocks for which that responsibility is being "transferred". A weekly stock check should be achievable and expected in a hospital pharmacy – at each dispensing staff are expected to confirm that the stock remaining in the cupboard matches the stock expected in the register.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.
Alderhey Children's NHS Foundation Trust	Full	36	10	The Local security management specialist should also be involved in ANY incident review involving controlled drugs, not just the CDAO	Thank you for your comment. Following further discussion by the Committee they agreed to include the responsible bodies listed in Regulation 13 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 to the relevant recommendation.
Alderhey Children's NHS	Full	49	?	Nationally approved dose conversion charts should be used in preference to locally approved dose conversion charts .	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid

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Foundation Trust					dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.
Alderhey Children's NHS Foundation Trust	Full	50	5	Again, change reference to "writing "prescriptions to reflect electronic prescribing	Thank you for your comment. This wording has been amended to take into account electronic prescribing following further discussion by the Committee.
Alderhey Children's NHS Foundation Trust	Full	116	?	Leave the term denatured in the glossary and add the term destroyed and its meaning.	Thank you for your comment. The definition of 'denatured' has been added to the glossary. The definition has been taken from the UK Environment Agency and takes into account destroying and disposal. .
Ambulance Pharmacists Network	Full	9	14-15	'Prescriber to dispenser to patient' describes only the standard model and doesn't represent the many models that exist including the ambulance sector.	Thank you for your comment. The text refers to background and policy context and the findings from the Shipman Inquiry which was based on the standard model.
Ambulance Pharmacists Network	Full	9	42-43	We are very keen that the correct balance is achieved between good governance requirements and operational necessity. Therefore we strongly agree with this statement.	Thank you for your comment.
Ambulance Pharmacists Network	Full	11	15-18	Include ambulance service in this long list of providers?	Thank you for your comment. The relevant text has been added to reflect your comment.
Ambulance Pharmacists Network	Full	27	1-6	This is important. Anticipatory prescribing (or lack of) causes many desperate situations during out of hours (OOHs) period which impacts on those charged with delivering OOHs	Thank you for your comment.

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				care which includes the ambulance service which is the default service when others fall short. Paramedics could provide more support to keep people at home if care plans and anticipatory prescribing was of a better quality and consistent in its layout etc. Thus training paramedics to support these patients would be possible. This should be given greater focus by commissioners.	
Ambulance Pharmacists Network	Full	27	25-27	A national opiate conversion document would be a useful development.	Thank you for your comment. Development of a national opiate conversion document is outside the scope of this guideline.
Ambulance Pharmacists Network	Full	29	3-5	We are not clear in what context our organisation would consider destroying patient own controlled drugs. This may apply to secondary care setting but it is not clear how it would apply in domiciliary or pre-hospital care. Ambulance policies require return of patients own drugs to community pharmacy for destruction. (page 27- line 34, page 29-31). Storing patient own drugs (PODs) awaiting destruction on an ambulance station or in an OOHs treatment centre could increase the risk of diversion or inadvertent re-administration. Patient's own drug 'green bags' are also a notable risk because ambulance staff will not necessarily recognise CDs and bags have on occasion ended up in mortuaries. Where green	Thank you for your comment. The recommendation you refer to is about organisations keeping records of destruction of patient's own controlled drugs and invoices for controlled drugs whey they are used or supplied. Where organisations encounter patient's own controlled drugs, a standard operating procedure should be in place to ensure they are handled safely and securely and the details of the procedure may vary according the care setting. Section 4 of the guideline has been restructured to reflect your comment about making the settings clear.

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				bags are used, we would recommend that a process is in place in the receiving unit to secure patients own drugs until they can be removed for destruction by an appropriate person.	
Ambulance Pharmacists Network	Full	26	30-32	Provision of advice about destruction of syringe drivers specifically would be helpful.	Thank you for your comment. Destruction and disposal of all controlled drugs is covered in section 8 of the guideline. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process such as destruction of syringe drivers are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for patients and local governance arrangements.
Ambulance Pharmacists Network	Full	31	8-9	It would be useful to define destruction as 'denaturing and rendering irretrievable'. The standard operating procedures (SOPs) required are the responsibility of the organisational CD Accountable Officer (CD AO).	Thank you for your comment. The guideline has a glossary section that covers the definition of 'denatured' that has been taken from the UK Environment Agency.
Ambulance Pharmacists Network	Full	31	23-33	SOPs should also take into account: • clear guidance on access by staff authorised to be in possession v's non-clinicians who are not; • role of non-clinicians in auditing, stock management and transportation; • role of the supervising clinician.	Thank you for your comment. The list in this recommendation is not exhaustive but includes the minimum dataset as agreed by the Committee. Additional factors can be taken into account depending on the health or social care setting, but this would be for the health or social care organisation to determine.
Ambulance Pharmacists Network	Full	32	10-17	It would be useful to include guidance about controlled drugs which have been supplied to a patient personally or to a third party. For	Thank you for your comment. The Committee concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination in line with

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				example, controlled drugs supplied to a patient are the property of the patient, and are in the patients' personal possession. For those supplied to a third party, then an SOP may be required. This is relevant to a number or providers including patient transport services. It would also be useful to include guidance about locked doctor's bags and the use of controlled drugs by British Association for Immediate Care (BASICs) doctors and ambulance staff responders, and requirements for overnight security in the HCP's home (as this is a rare event but a reality particularly in delivering a mobile service over a geographically wide area.	legislation and local governance arrangements.
Ambulance Pharmacists Network	Full	33	44-46	We would not want to do this. Our policies require staff to advise that drugs are returned to community pharmacy. We would suggest that allowing remote staff to 'destroy' PODs is not good practice and is a potential risk to the employing organisation.	Thank you for your comment. The recommendation you refer applies to organisations who handle patient's own controlled drugs for example in secondary care or a community pharmacy. If your standard operating procedures or policies require staff to advise that drugs are returned to community pharmacy then you would need to work in line with your policies. Section 4 of the guideline has been restructured to make the settings to which the recommendations are aimed at clearer.
Ambulance Pharmacists Network	Full	33	25-35	It would be helpful if advice about destruction of syringe drivers was included	Thank you for your comment. Destruction and disposal of all controlled drugs is covered in section 8 of the guideline. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process such as destruction of syringe drivers are for local consideration and determination as legitimate variation may occur across different health and care

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					settings, depending on the service provided for patients and local governance arrangements.
Ambulance Pharmacists Network	Full	35	1-3	Recommend that the commissioner require the provider organisations to provide the necessary assurance that good governance arrangements and clear lines of responsibility and accountability are in place, rather than these coming from commissioners.	Thank you for your comment. The relevant text has been added to reflect your comment.
Ambulance Pharmacists Network	Full	35	21-25	It would be useful to have some guidance for OOHs providers because it is much more difficult to look for and spot trends in OOHs service prescribing.	Thank you for your comment. Arrangements to access to prescribing data of controlled drugs are for local consideration and determination. Arrangements will vary depending on how services are commissioned and provided and what resources are available.
Ambulance Pharmacists Network	Full	35	29-32	It would be helpful to recommend that organisations support the AO and ensure that they have the capacity to deliver the role and its responsibilities. Importantly, this should include some definition of what needs to be reported as there seems to be a great deal of variation in what is reported. We are not sure that all AOs are clear about the reports and level of details that are needed.	Thank you for your comment. 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.
Ambulance Pharmacists Network	Full	53	21-25	The requisitions used in secondary care also now apply to ambulance services.	Thank you for your comment. Table 8 and 9 in section 6.1.1 in the full guideline summarises the different requisition requirements for primary and secondary care organisations.
Ambulance Pharmacists Network	Full	55	5-6	The 2008 group authority is not limited to NHS ambulance services; private providers are now contracted to provide significant care to NHS patients.	Thank you for your comment. The text you refer to is not specific to group authority.

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Ambulance Pharmacists Network	Full	61	general	It is a legal requirement for a hospital or ambulance requisition to be signed by a doctor or dentist.	Thank you for your comment. Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001. Regulation 14(6) of the Misuse of Drugs Regulations 2001 applies when obtaining stock controlled drugs from the organisations with an internal pharmacy.
Ambulance Pharmacists Network	Full	63	22	Include ambulance/ambulance station	Thank you for your comment. Following further discussion by the Committee, the term 'location' has been added to the recommendation to cover all parts of an organisation.
Ambulance Pharmacists Network	Full	66	Table 12	The summary table should include "ambulance paramedics"	Thank you for your comment. The relevant text has been added to reflect your comment.
Ambulance Pharmacists Network	Full	67	8-11	The Group Authority refers to "diazepam" and does not specify diazepam 5 mg/ml injection. *In pursuance of Regulations 8(3), 9(3) and 10(3) of the Misuse of Drugs Regulations 2001, the Secretary of State hereby authorises:* *1. ambulance paramedics, serving or employed at any approved ambulance station, to supply or offer to supply:* *diazepam and/or morphine sulphate injection (to a maximum of 20mg) and/or morphine sulphate*	Thank you for your comment. The relevant text has been amended to include only diazepam (and the other listed medicines). . .

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				oral *to any person who may lawfully have any of these drugs in their possession;* *and* *2. ambulance paramedics, serving or employed at any approved ambulance station to possess diazepam and/or morphine sulphate injection (to a maximum of 20mg) an/or morphine sulphate oral* *for the purposes of that service or employment, subject to and in accordance with the following terms……..* Private paramedic practice where a similar Group Authority describes CD use has been omitted but we would recommend that private providers be included in this guidance.	
Ambulance Pharmacists Network	Full	84	General	Suggest include "Security standards and guidance for the management and control of controlled drugs in the ambulance sector" http://www.nhsbsa.nhs.uk/Documents/SecurityManagement/Security_standards_for_the_management_and_control_of_CDs_in_ambulance_v2_-_April_2013.pdf	Thank you for your comment. The relevant text has been added to reflect your comment.
Ambulance Pharmacists Network	Full	88	General	There is no section addressing Ambulance Services. While many also deliver OOHs and Urgent Care services it would have been good to have the needs of such a mobile service	Thank you for your comment. The relevant text has been added to reflect your comment.

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				addressed separately. The NHS Protect & Ambulance Pharmacists Network (APN) developed document "Security standards and guidance for the management and control of controlled drugs in the ambulance sector" could form the basis for this section.	
Ambulance Pharmacists Network	Full	90	General	An Emergency Care example would be useful	Thank you for your comment. Emergency care would come under a number of settings such as secondary care accident and emergency, out of hours and urgent care which have all been included in section 8.5.
Ambulance Pharmacists Network	Full	91	General	Stock Management: A national labelling system for opiates etc would help to ensure that these drugs could be identified and help to reduce selection errors. Re temperature – cost implications for providing temperature controlled environments for storage are significant. This aspect of storage presents particular problems for the ambulance sector. However, there needs to be clear evidence to suggest deterioration that causes harm or reduces effectiveness before temperature is included in guidance or recommendations that would impact the ambulance sector.	Thank you for your comment. The Committee did not discuss any national labelling system for opiates or the cost implications for providing temperature controlled environments and deterioration of controlled drugs and its effects . The interventions your comment refers to were not identified in the review of evidence to take back to the Committee to discuss. The Committee therefore were unable to develop recommendations about them
Ambulance Pharmacists Network	Full	91	General	It would be useful to have some definitive guidance on what locks are acceptable, the design of vehicle safes and whether or not the safe needs to be bolted in a vehicle. Guidance should:	Thank you for your comment. While the scope of the guideline covers systems and processes for ensuring security, storage and transportation, it's not in the scope of the guideline to provide detail about particular locks or vehicle safes. This would need to be considered locally in line with legislation and local governance

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				• balance risks of keys v's keypads v's proximity readers. • consider how this guidance would equate to any guidance requirements for locked doctor's bag. We would suggest that there should be equity for ambulance services with GPs who carry a wider range of potent drugs. • Personal issue v's vehicle issue • Provide clarity on when distribution is'distribution' (in the legal sense) and not supply.	arrangements.
Ambulance Pharmacists Network	Full	95	General	Ambulance Services Policies do not allow for removal of patient's own CDs on their death.	Thank you for your comment. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for patients and local governance arrangements.
Ambulance Pharmacists Network	Full	95	General	It would be helpful to have guidance on the requirements for overnight security in the HCP's home.	Thank you for your comment. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination. Health professionals have a professional duty to ensure safe practice and work in line with their regulatory standards and legislation.
Ambulance Pharmacists Network		99	4-6	Ambulance Services Policies do not allow for removal of patient's own CDs on their death. We advise that they are returned to community pharmacy for destruction.	Thank you for your comment. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination as legitimate variation may occur across different health and care

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					settings, depending on the service provided for patients and local governance arrangements.
Ambulance Pharmacists Network	Full	99	31-32	We would not recommend having paramedics remove a patient's own CDs from the home after death.	Thank you for your comment. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the process are for local consideration and determination as legitimate variation may occur across different health and care settings, depending on the service provided for patients and local governance arrangements. Rec
Ambulance Pharmacists Network	Full	101	18-19	Ambulance Services have internal governance arrangements and oversight. Monitoring is done by a group within the trust with working knowledge of the sector but remote from site and with no attachment to it in daily working.	Thank you for your comment.
Ambulance Pharmacists Network	Full	101	43-44	We recommend that external monitoring should be done by professionals with a sound understanding of that sector, and sector specific legislation, and operational and governance requirements.	Thank you for your comment. The section your comment refers to is the introduction to the section which summaries legislation and outlines national policy. Recommendations would not fit within this section. The section has linked to the single operating model 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.
Birmingham St Mary's Hospice	Short	6	17	We have concerns about use of a conversion table as have seen cases in the past where people have read wrong part of conversion chart and had near misses for drug doses e.g.24 hour dose instead of the 4 hour dose, or wrong line	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.

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				on chart read. We do not endorse use of conversion charts in our organisation, instead support calculations with checks from other prescribers in practice or community team.	
Birmingham St Mary's Hospice	Short	6	2	Sometimes for palliative care patients, more than 30 days dosing is appropriate.	Thank you for your comment. 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.
Birmingham St Mary's Hospice	Short	5	25	Sometimes for palliative care patients, a maximum daily dose is inappropriate , particularly in specialist areas	Thank you for your comment. This wording has been amended to include frequency of doses to take into account that in some cases the maximum doses may not be appropriate following further discussion by the Committee.
Birmingham St Mary's Hospice	Short	7	26	Please could you add that requisition can be signed by doctor or nurse. Often nursing staff more aware of need for medications in a specialist unit (they monitor supplies and stock levels) so are more appropriate than doctors to sign, and adding necessity for doctor signature increases inefficiency	Thank you for your comment. The recommendation is aimed at health professionals who obtain stock controlled drugs from an external pharmacy (a pharmacy that is not part of the organisation that it supplies medicines to, for example a community pharmacy supplying medicines to a hospital) in which case Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001. Regulation 14(6) of the Misuse of Drugs Regulations 2001 applies when obtaining stock controlled

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					drugs from the organisations with an internal 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)..
British Pain Society	Full and short	general	general	The British Pain Society has considered the documents and welcomes the recommendations, which will help to tighten up procedures in all settings and will make for safer prescribing and handling of controlled drugs.	Thank you for your comment.
British Pain Society	Short Full	6 27	8-19 16-27	<u>The British Pain Society feels that there is a lack of guidance regarding 'total opioid load'</u> The recommendation to refer to local (where available) or national guidelines for doses generally or conversion of equivalent opioid doses is unhelpful. There is no logical reason for doses or conversion ratios to vary within the UK and differences between local guidelines are likely to cause confusion, uncertainty and potentially error. Page 49 of the full guideline acknowledges the uncertainty and inadequacy of the currently available guidance referencing palliative care guidelines in the BNF and noting that use of these may cause concern to patients. The BPS recommends that the guidelines provide more comprehensive advice on this important area of controlled drug prescribing in	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee. The Committee agreed that a recognised opioid dose conversion guide would take into account clinical setting of use and any national or local prescribing guides that may be used when prescribing, reviewing or changing opioid prescriptions.

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				order to reduce uncertainty and improve patient treatment including safety.	
Cambridgeshire and Peterborough Clinical Commissioning Group	Full	General	General	Question 3: what would help users overcome any challenges? The guidance contains no practical advice on how to actually achieve the safe use and management of controlled drugs. Some examples of what good / best practice looks like would be very helpful. Summarising all the legislation etc. rather than providing links to external sources would be beneficial. Many people especially time poor clinicians will not look further than one click for help or advice. Before I sat down to read your draft guidance (all three documents provided) I made a list of all the things that the excellent National Prescribing	Thank you for your comment. The aim of NICE guidelines is to develop recommendations from available evidence. NICE's remit for this guideline was to provide good practice recommendations for using controlled drugs. The rationale for the recommendations can be found in the 'linking evidence to recommendation' table that captures Committee discussions about what best practice looks like with some examples of how challenges have been overcome. Where the Committee felt that clarification about some controlled drug legislation was needed to ensure safe practice this was sought and included. The National Prescribing Centre's (NPC) document was primarily aimed at developing good practice for the management of controlled drugs in primary care, The NICE guideline is aimed developing recommendations based on legislation, evidence and expert consensus for all healthcare settings. During the scoping phase of guideline development, the areas to be considered in the draft scope went out for public consultation for 4 weeks. The comments received were taken into consideration and amendments made to the scope which then led to the development of the review protocols with the expert knowledge from the Committee.

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				Centre (NPC) "A guide to good practice in the management of controlled drugs in primary care (England) Third edition December 2009" hadn't been quite expansive enough on – prisons, paramedics, schools, out of hours, ambulance, substance misuse, home carers, armed forces. The NPC document was the go to document for primary care (the department of health wrote something similar for secondary care). For just about every scenario, the answer was in the NPC guide. I was so disappointed when I read your draft guidance. I don't believe it adds anything to the agenda. I don't believe it will help anyone to better use or manage controlled drugs.	
Cambridgeshire and Peterborough Clinical Commissioning Group	Full	General	General	Question 3: It would be helpful to add information and guidance about the plethora of different health care professionals who can now prescribe controlled drugs.	Thank you for your comment. The aim of the introductory text for this NICE guideline is to introduce what controlled drugs are and highlight areas where work has been carried out for the topic. To future proof the guideline, specific details on health professionals who can prescribe drugs has not been included the event of there being a change in legislation. The relevant legislation has been hyperlinked in the document for information and further information can be found on the Pharmaceutical Services Negotiating Committee website on which health professionals can prescribe controlled drugs and this has been added to the relevant text.
Cambridgeshire and	Short	7	25 - 28	1.1.15 Additional comment about only requisitioning whole packs only (rather than one	Thank you for your comment. The recommendation you refer to is a high level recommendation. Further details to include on a

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Peterborough Clinical Commissioning Group				or two dose units) would be helpful here.	requisition would need to be determined locally and may be part of a standard operating procedure for the organisation.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	8	1 - 3	1.1.16 Some additional guidance would be appreciated on how organisation can keep a requisition for two years and submit them to the NHS Business Services Authority Prescription Pricing Division every month.	Thank you for your comment. The aim of the short version of the guideline is to summarise all the recommendations. Section 6,1in the full version of the guideline provides details and a link to the NHS Business Services Authority website for further information on requisitions and submissions.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	8	9 - 12	1.1.19 Confirmation of who is not required to use a requisition form would be helpful at this point.	Thank you for your comment. Persons who can requisition controlled drugs in Schedule 2 and 3 are defined legislation and this should be part of the organisation's standard operating procedure. Persons who can requisition controlled drugs in legislation have not been detailed in the recommendation to future proof the guideline in the event of a change in the legislation. Section 6.1 in the full guideline provides a hyperlink to the relevant regulation for further information.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	9	5 – 17 13	1.1.22 to 1.1.23 jumped from supplying against a requisition to supplying against a prescription, the document may read better if these were under two different main headings as the change between subjects was not obvious and at first it seemed like a typing error on line 13.	Thank you for your comment. The structure and order of the recommendations in the short version of the guideline has been amended to reflect your comment.
Cambridgeshire and Peterborough Clinical	Short	10	6 - 8	1.1.28 more information on when to ask for identification e.g. what to do if a health care professional would be helpful.	Thank you for your comment. The circumstance may indicate to the health professional when to ask for identification, for example, if the person is a regular customer at a pharmacy then the health professional may not need to ask for identification. This would be

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Commissioning Group					down to the health professional's discretion and the circumstance. The recommendation is high level to account for the different care settings and circumstances.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	11	4 -13	1.1.32 guidance on use and availability of witness to administration would be helpful here.	Thank you for your comment. The Committee developed recommendations based on key principles of the intervention from the evidence found. The use and availability of witness to administration was not covered by the review question.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	13	12 - 14	*For recommendation 1.1.42, please provide comments on the feasibility of carrying out stock checks with a minimum frequency of once a week*. The Royal Pharmaceutical Society of Great Britain used to say stock checks should be done weekly OR MORE FREQUENTLY. This is advice that the CCG (and predecessor PCT used to advocate). In community pharmacy it can be argued that if a new responsible pharmacist is in charge and balance check should be undertaken, so this might be every day. It should be stressed that the inconvenience of undertaking weekly stock checks far outweighs the inconvenience of wading through months of prescriptions and invoices to identify whether a discrepancy is an administrative error or a	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.

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				dispensing error or a theft. Identifying a dispensing error weeks after the event is not helpful to the patient who may have been adversely affected (including hospitalisation). Identifying theft weeks after the event is not helpful to catching the culprit.	
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	14	2 – 6	1.1.44 Guidance on how to complete the controlled drug register if a delivery of a dispensed item has to be undertaken would be helpful. Many community pharmacies and dispensing practices routinely use a delivery driver (employee usually) to transport controlled drugs to older people who are house bound, to branches of the surgery or pharmacy.	Thank you for your comment. The Committee did not discuss how best to complete the controlled drug register when delivering a dispensed controlled drug. The local controlled drugs accountable officer would be able to provide further guidance on how this should be best managed depending on the care setting and incorporated into the local standard operating procedure. There needs to be an audit trail of movement of controlled drugs from on location to another.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	16	8	Further detail on what the coroner requirements are would be helpful at this point	Thank you for your comment. This would be down to local consideration depending on the investigation into the death. Details have not been added as this may vary and make the recommendation hard to implement.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	16	13	Regarding destruction of date expired schedule 3 and 4 part 1 controlled drugs, the word must is applied to making records of the destruction. Please clarify the use of must. I was not aware records for destruction of 3 and 4 part 1 controlled drugs was a legal requirement. Where would this information be recorded as there is no	Thank you for your comment. This wording has been amended following further discussion by the Committee to reflect your comment. The standard operating procedure should specify where records of destruction should be made for Schedule 3 and 4 (part 1) and this would need to be determined locally.

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				legal requirement to keep a register?	
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	16	20 – 29	1.1.58/59 These are weak recommendations and should be strengthened. It is best practice for a second person to witness the destruction and disposal of patient returned controlled drugs. There is a general consensus that this is the weakest part of the controlled drug legislation and anything that can be done to minimise the risk of diversion at this point in the supply chain is welcome.	Thank you for your comment. The recommendation you refer to is a 'consider' recommendation as the evidence was limited and so the Committee based it on consensus taking into consideration good practice principles and resource implications depending on the care setting. See section 8.5 in the full guideline for the rationale.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	18	17 - 20	1.1.67 This is a weak recommendation. Either organisation should report to controlled drug accountable office or they shouldn't. Putting a time frame on the requirement is very helpful. Please be aware that getting general practice to report errors to an external person, either to the clinical commissioning group or to the controlled drugs accountable office, is very difficult and a forceful recommendation would be helpful.	Thank you for your comment. The recommendation has been reworded following further discussion and with reference to the Controlled Drugs (Supervision of Management and Use) Regulations 2013 by the Committee to reflect your comment.
Cambridgeshire and Peterborough Clinical Commissioning Group	Short	18	21 - 27	1.1.68 Does the guidance use different definitions for auditing controlled drug register and cabinets and reconciling stock and conducting a regular balance check. Please use language that people are familiar with in this context.	Thank you for your comment. The term 'audit' refers to systematic review of a practice, process or performance to establish how well it meets predetermined criteria. The procedure includes identifying problems, developing solutions, making changes to practice, and then reviewing the whole operation or service again. For example, an audit may be carried out on a register, cabinet and stock. The term 'audit trail' used in the guideline refers to records of action to assess practice against standards.
Cambridgeshir	Short	21	16 & 18	Please refer to community pharmacy not retail	Thank you for your comment. The relevant text has been amended

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e and Peterborough Clinical Commissioning Group				pharmacy.	to community pharmacy to reflect your comment.
Camden Clinical Commissioning Group	Full	14	41	Would be useful to add anyone handling CDs; delivery drivers (from wholesalers to pharmacies or from community pharmacies to patients) as historically many 'incidents' and breeches have arisen from CDs being left unattended at pharmacy locations or at patient's homes.	Thank you for your comment. The purpose and the audience of the guideline were agreed during the scoping phase of the guideline and it is not intended to be an exhaustive list**.** The guideline applies to anyone who uses or manages controlled drugs in their organisation or as part of their professional practice
Camden Clinical Commissioning Group	Short	4	12-13	*"Develop processes that support prescribers who have been assessed as competent "*– assessed by whom? This assessment should be done nationally. The recommendation is for 'organisations'. Does this include individual contractors in e.g. in GP practices / community pharmacy? How does NICE anticipate this will be delivered/implemented by individual contractors?	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
Camden Clinical Commissioning Group	Short	9	12-17	Add: "Full balance must be supplied within 28 days of the date on the prescription" as likely that this is sometimes carers who would be collecting the balance rather than patient.	Thank you for your comment. Recommendation 1.1.27 in the consultation version of the short guideline takes into account informing the person to pick up the remaining balance within 28 days of the prescription date.
Camden Clinical Commissionin	Short	10	4	"Ask them", implies it is optional; we suggest it should be changed to "inform patient that balance must be supplied within 28 days of the	Thank you for your comment. Following further discussion by the Committee, it was agreed that the term 'ask' would remain in the recommendation in line with NICE style.

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g Group				date on the prescription, or prescription will no longer be valid."	
Camden Clinical Commissioning Group	Short	11	14-15	*"Ensure the record is kept with the person"* → How will this be managed between care settings? E.g. How about a patient with dementia being discharged from hospital or outpatients' back into a care home? How will this communication be assured and whose responsibility will it be that this communication takes place?	Thank you for your comment. The term 'kept with the person' has been removed and the recommendation has been reworded to include the terms 'readily accessible'. The recommendation is about records of administration being readily accessible to the health professional(s) to ensure continuity of care and to avoid errors whilst they are under the care of the provider, for example an administration record being sent to pharmacy within a hospital for medicines to be dispensed for the person. When transferring to another care provider, organisations should have systems in place to provide a summary of care the person has received to the next care provider the person is transferred to.
Camden Clinical Commissioning Group	Short	11	26-27	*"When prescribing controlled drugs, involve the person's GP and any lead health professionals"* add: "Involving unnecessary delay"	Thank you for your comment. The Committee agreed that the wording was appropriate and no change was made.
Camden Clinical Commissioning Group	Short	15	20-22	*"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"* → how? Home visits? Might be fine for a DN? How is this practicable for a GP or community pharmacists if this recommendation applies to all 'health professionals'? And how about a patient discharged from A&E with a take-home dose of controlled drugs? This could lead to an	Thank you for your comment. This recommendation has been reworded and added to another recommendation following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment.

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				unnecessary delay in discharges, and without any further detail, variation in practice. It would be useful to have a national template with prompts to use when assessing patients' facilities for storing controlled drugs in their homes for health professionals to use when they are having conversations with the patient whilst not in the patient's home. A copy of this assessment could be also given to the patient to remind them of dangers of not securely storing CDs.	
Camden Clinical Commissioning Group	Short	16	19	Currently only need authorised person for witnessing destruction of schedule 2. Is a change in legislation proposed/anticipated that this requirement will be expanded to cover schedules 3 and 4 also?	Thank you for your comment. The relevant text about an authorised person for witnessing destruction of Schedule 2 controlled drugs has been amended to reflect your comment.
Care Quality Commission	Full	General	General	The guideline does not fully cover what to do when a service user brings in illicit drugs to an organisation. It would be helpful if the guideline provided some advice (if deemed appropriate) to bring clarity in this area.	Thank you for your comment. Schedule 1 controlled drugs are outside of scope.
Care Quality Commission	Short	1	5	Could you please include `destruction' within the paragraph of what the guideline covers.	Thank you for your comment. Handling is used as a broad term in the guideline and takes into account destruction. This is mentioned in the scope see section 8.1 in the full version of the guideline.
Care Quality Commission	Short	5	8	Prescribers should also take into account the 'quantity' that they prescribe.	Thank you for your comment. Quantity to prescribe is covered in recommendation 1.1.6 of the guideline.
Care Quality	Short	5	14	Perhaps include instructions on what the patient	Thank you for your comment. Unwanted or unused controlled

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Commission				should do with any unwanted/unused controlled drugs.	drugs.is covered in recommendation 1.1.11 of the guideline.
Care Quality Commission	Short	7	1	It would be helpful if the opening paragraph first mentioned seeking the individual's agreement to share confidential information with their GP (they cannot object if they are unaware confidential information may be shared).	Thank you for your comment. The list in this recommendation is not exhaustive but includes the minimum dataset as agreed by the Committee and 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].
Care Quality Commission	Short	12	18	Please replace the word 'premise' to 'premises'.	Thank you for your comment. The relevant text has been amended to 'premises' to reflect your comment.
Care Quality Commission	Short	12	17	Please consider including a bullet point that covers likelihood of diversion.	Thank you for your comment. The bulleted list is not intended to be exhaustive. The likelihood of diversion would be considered under 'whether the security setting is low, medium or high risk' in the third bullet point of the recommendation.
Care Quality Commission	Short	13	21 - 23	It would be helpful if you could remove `in the controlled drugs register' as the check does not have to be recorded here i.e. so that the bullet point reads `recording stock checks along with the date and signature of the health professional carrying out the check'.	Thank you for your comment. The text 'in the controlled drugs register' has been removed to reflect your comment.
Care Quality Commission	Short	14	20	Recommendation 1.1.48 may need clarification as might also apply to GP dispensing practices which do not have an internal pharmacy department.	Thank you for your comment. The recommendation has been amended to take into account GP dispensing practices following further discussion by the Committee.
Care Quality Commission	Short	15	6	It is a requirement that records are kept, please replace `Consider' to Records must be kept to provide etc.	Thank you for your comment. The term 'consider' has been removed following further discussion by the Committee to reflect your comment and taking into consideration legislation for record keeping in the Misuse of Drugs Regulation 2001.
Care Quality	Short	21	general	It might be useful to include what is a Lead	Thank you for your comment. The definition for lead controlled

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Commission				Controlled Drugs Accountable Officer between lines 4 and 5. These officers are specific to NHS England and have extra responsibilities over the controlled drugs accountable officer as set out in the 2013 Regulations.	drugs accountable officer is included in the glossary.
Care Quality Commission	Full	9	14	Please amend 'prescribing' to 'governance' plus it would be helpful here to mention the legislative framework i.e. the 2006 and 2013 regulations.	Thank you for your comment. The relevant text has been amended to governance to reflect your comment. See appendix F for legislative framework.
Care Quality Commission	Full	9	24	Reg 11 of the 2013 regs does not specify 'stocks' so need to amend to holding controlled drugs as otherwise could be misleading.	Thank you for your comment. The relevant text has been amended to 'holding' to reflect your comment.
Care Quality Commission	Full	9	27	May be helpful here to clarify that Department of Health have asked Care Quality Commission to oversee implementation of the regulations.	Thank you for your comment. This is standard text that was taken from the document Safer Management of Controlled Drugs to ensure wording is consistent.
Care Quality Commission	Full	9	44	Please remove 'should'	Thank you for your comment. The text 'should' has been removed to reflect your comment.
Care Quality Commission	Full	10	12 to 19	We consider that this paragraph is muddled, confusing and inaccurate: Re. the statement that Home Office leads on policy with regard to controlled drugs, is this correct? The 2013 regs are from Department of Health not Home Office?	Thank you for your comment. The text you refer to has been checked and clarified. The Home Office website specifies 'drugs policy', for the purpose of the guideline we have added in 'controlled' to drugs.
Care Quality Commission	Full	11	21	May be useful to specifically name care home providers/managers/care workers in examples of Social Care Practitioners – it's a large group of people who regularly handle and administer controlled drugs.	Thank you for your comment. The text you refer to is the standard definition used by NICE it is not intended to be an exhaustive list. Care homes were out of scope for this guideline. See Managing medicines in care homes (2014) NICE guideline SC1 for further information about managing controlled drugs in this setting.
Care Quality	Full	15	9 to 20	Is it possible to include that the guideline may be	Thank you for your comment. This is covered in section 2.4 as

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Commission				applicable to private providers?	'individual people and organisations delivering non-publicly funded services'.
Care Quality Commission	Full	27	36 to 37	It would be helpful if a statement or bullet point be added stating you should first obtain the patient's consent to share their confidential information with their GP.	Thank you for your comment. The aim of the recommendation is to set out key principles with regards to information sharing in line with A guide to confidentiality in health and social care (2013) by the Health and Social Care Information Centre (HSCIC). The patient has the right to refuse sharing their information and the HSCIC have further information about this on their website. Section 1.4 in the full guideline refers to the Department of Health's advice on consent guidance.
Care Quality Commission	Full	28	19	Please consider replacing `should' with `must'. It is a legal requirement in the MDR 2001 to have the requisition signed by a doctor	Thank you for your comment. The text in this section has been revised and amended in line with legislation.
Care Quality Commission	Full	29	4 - 5	Within the section of `Obtaining and supplying controlled drugs', the bullet point refers to destruction of patient's own controlled drugs. Would you consider moving this bullet point to a more relevant section? Suggestion would be for an additional bullet point on page 34 under paragraph 59.	Thank you for your comment. We are aware that there is an overlap in sections due to the broad nature of this topic. The recommendation you refer to is about **how long** to keep records and invoices for, whereas recommendation 59 is about **what** to record when destroying controlled drugs that have been returned by people.
Care Quality Commission	Full	29	40	Under section `Administering controlled drugs', it would be helpful to include social care professionals e.g. in Care Homes and Domiciliary care, or Schools. Consider including reference to Social Care and or making reference to NICE SC1.	Thank you for your comment. Section 7.1 in the guideline provides more detail about who can administer controlled drugs. The section your comment refers to is a brief summary to introduce the recommendations relating to administration. Reference to Managing medicines in care homes (NICE guideline SC1) (2014) has been made in section 2.6 and 7.1 of the guideline.
Care Quality	Full	31	10	Under paragraph 28 it might be helpful if there	Thank you for your comment. The bulleted list is not intended to be

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Commission				was a bullet point covering risk of diversion.	exhaustive. The likelihood of diversion would be considered under 'whether the security setting is low, medium or high risk' in the third bullet point of the recommendation.
Care Quality Commission	Full	31	2 to 5	Safe management and use of controlled drugs i.e. 2013 regs should be referenced in this para i.e. SOPs are in reg 11	Thank you for your comment. The relevant text has been added to reflect your comment.
Care Quality Commission	Full	34	20	This is the first mention of the 2013 regs - they need introducing and putting into context earlier in the guideline.	Thank you for your comment. Due to there being many Acts and regulations related to the use of controlled drugs, the Committee agreed that a summary of relevant legislation would be helpful and this is summarised briefly in Appendix F of the full guideline that has been cross referenced in section 1.2 of the introduction. The section you refer to is a summary of all the recommendations with a brief introduction paragraph. Further details of the 2013 Regulations can be found in section 9.1.
Care Quality Commission	Full	35	27	Would you include `NHS England' before the term 'lead' e.g. NHS England `Lead'.	Thank you for your comment. The recommendation has been amended to say 'NHS England lead CDAO' .
Care Quality Commission	Full	54	5 to 8	Please reword section on standard requisition as they will be downloadable from NHS BSA website from 30th November 2015.	Thank you for your comment. The relevant text about the approved mandatory requisition form for ordering Schedule 2 and 3 controlled drugs being available on the NHS Business Services Authority website has been added to reflect your comment.
Care Quality Commission	Full	55	7 to 19	Please amend in line with requisition legislation changes – new form must be submitted to NHS BSA.	Thank you for your comment. The relevant text about the mandatory requisition forms being sent to the NHSBSA Prescription Services. has been added to reflect your comment.
Care Quality Commission	Full	67	6 to 7	Please clarify position re. midwives in line with Midwives supply order and recent change in legislation.	Thank you for your comment. The section that your comment is referring to is about administration of controlled drugs. Midwives supply order amendments relate to supply and this is mentioned in section 6.1 of the guideline.
Care Quality	Full	67	8 to 11	The Group Authority wording does not specify	Thank you for your comment. The relevant text has been amended

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Commission				injection for diazepam and can be interpreted in a number of ways with many ambulance trust paramedics also administering rectal diazepam.	to be consistent with the wording the Home Office use for Group Authority.
Care Quality Commission	Full	96	general	Evidence to recommendations – Stock Balances – Weekly liquid balance checks will lead to people pouring out, measuring and returning liquid CD's to the bottle. Need to balance risk of loss/spillage etc. with visual check and final/empty tally.	Thank you for your comment. In the guideline recommendation 42 states to measure liquids on finishing a bottle to take into consideration loss of stock, and this would be part of the organisation's standard operating procedure for carrying out stock balance checks.
Care Quality Commission	Full	101	43	We monitor compliance against the Department of Health's `The Controlled Drugs (Supervision of Management and Use) Regulations 2013' the statement implies we monitor compliance against all controlled drugs regulations. We would be grateful if you could refer to the 2013 regs.	Thank you for your comment. The relevant text about monitoring compliance against the 2013 regulations has been added to reflect your comment.
Care Quality Commission	Full	102	6 (figure 1)	In the Care Quality Commission box, would you please amend to include; National oversight on the implementation of the 2013 Regulations, provide an annual controlled drugs report to Government on how organisations are implementing the 2013 regulations, maintain and publish a national register of controlled drugs accountable officers, lead a national group on controlled drugs and as a responsible body are required to attend CDLINs.	Thank you for your comment. The relevant text has been amended in Figure 1 to reflect your comment about the role and functions of the CQC.
Chelsea and Westminster	Short	5	4	If the indication is written in the patient notes, this is not easily searchable. The indication field	Thank you for your comment. Examples of local good practice that are not based on NICE guidance can be developed as Quality and

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NHS Foundation Trust				is available to be used on all prescribing screens on the Trust's electronic prescribing system; however this field is not mandatory at present but it could be made mandatory. Our trust has had experience of implementing this approach for antibiotics and would be willing to submit its experiences to the NICE shared learning database. Contact:	Productivity case studies and they need to highlight that the local project is cost-neutral or cost-saving in order to be considered.. See the NICE website for more details.
Chelsea and Westminster NHS Foundation Trust	Short	11	14	We are concerned that this recommendation might preclude the use of electronic prescribing systems. Administration of individual doses is recorded on the Trust's electronic prescribing system, which moves administered doses from the administration chart to the administered doses record. It is not feasible to keep the electronic record with the patient; however the system is accessible from portable devices that can be accessed near patient.	Thank you for your comment. This wording has been amended following further discussion by the Committee.
Chelsea and Westminster NHS Foundation Trust	Short	18	28	Our trust has had experience of implementing this approach for antibiotics and would be willing to submit its experiences to the NICE shared learning database. Prescribing trend data is available from the Trust's electronic prescribing system though the Data Warehouse; however this data needs to be interpreted manually linked to prescribing indications as any change to a prescription creates a new order which could lead to confusion when interpreting trends.	Thank you for your comment. You can submit your example on the NICE website.

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Chelsea and Westminster NHS Foundation Trust	Full Short	28 7	7 20	We have received strong feedback from the consultant for the End of Life Care Team that that this recommendation might impact negatively on patient care at the end of life. Multi-route prescriptions and protocol orders for the same drug are frequently prescribed through our Trust electronic prescribing system, in end of life care and surgical settings. The system set up differentiates between the different doses and routes ensuring that the health care professional has flexibility to administer by the most suitable route whilst minimising the need to repetitively enter data on the part of the prescriber. If multi-route prescriptions or protocol orders were not allowed, the tendency might be for prescribers to enter a prescription for a single route only, meaning that alternative routes are not available for administration when required.	Thank you for your comment. The recommendation is referring to situations when more than one controlled drug (which each have different routes of administration) is being prescribed, in which case they need to be prescribed separately on a medicines or inpatient record. It does not state that multi-route prescriptions should not be prescribed. Following further discussion by the Committee they agreed that the recommendation should also clearly state when each should be used to avoid administration errors.
Chelsea and Westminster NHS Foundation Trust	Short	5	14	There are concerns about how easy it will be implement this recommendation in practice. It will be very time consuming for the prescriber to transcribe all of the information to be given to the patient or carer at the point of counselling. However, electronic systems can assist by including mandatory information on indication and duration. More detailed documentation of instructions as to how long the drug will take to work and how to use controlled drugs prescribed	Thank you for your comment. Following further discussion by the Committee they agreed that this would constitute good practice given the risks associated with controlled drugs and so no change was made. Section 5.5 in the full guideline provides further detail on the rationale behind the recommendation.

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				in both sustained release and immediate release formulations may not be the most appropriate use of prescriber resource.	
Chelsea and Westminster NHS Foundation Trust	Short	5	21	There are concerns about how easy it will be implement this recommendation in practice for 'when required' controlled drugs. It will be very time consuming for the prescriber to transcribe all of the information to be given to the patient or carer at the point of counselling. However, electronic systems can assist by including mandatory information on indication and duration. More detailed documentation of instructions as to how long the drug will take to work and how to use controlled drugs prescribed in both sustained release and immediate release formulations may not be the most appropriate use of prescriber resource. Pharmacy labelling systems have limited space for dosing instructions and cautionary labels. If it is made mandatory to add further dosage instructions around the maximum daily dosage (possible) and duration (in end of life care describing duration might be distressing) on the label, might require up to 3 dispensing labels to be attached.	Thank you for your comment. Following further discussion by the Committee they agreed that this would constitute good practice given the risks associated with controlled drugs and so no change was made. Section 5.5 in the full guideline provides further detail on the rationale behind the recommendation.
Chelsea and Westminster NHS	Short	5	28	We have received feedback from the consultant for the End of Life Care Team that it is difficult to have any insight into patient supplies of strong	Thank you for your comment. Existing supplies of controlled drugs that a person has should be taken into account when the prescriber can do so. The Committee agreed that this constitutes good

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Foundation Trust				opioids at home, except when there is a Healthcare professionals involved in the patient's care at home, otherwise there is likely to be a vague estimate of the patient's own supplies.	practice. Section 5.5 in the full guideline provides further detail on the rationale behind the recommendation.
Chelsea and Westminster NHS Foundation Trust	Short	6	17	We are concerned that this recommendation requires individual organisations to develop their own opioid conversion table, which could lead to variations in dosing and duplication of effort. Could NICE refer to national validated opioid conversion tables, such as the Palliative Care Formulary, which has an online opioid conversion table?	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.
Chelsea and Westminster NHS Foundation Trust	Short	10	11	We are concerned that standard operating procedures around controlled drug administration are not intended for the purpose of assessing skills and competence, they describe the step by step process by which individuals already assessed as competent administer controlled drugs to a patient ,subject to a second check by a competent individual.	Thank you for your comment. The recommendation has been reworded for clarity and the wording about 'assessing skills and competence' has been removed following further discussion by the Committee.
Chelsea and Westminster NHS Foundation Trust	Short	13	19	Currently, standard operating procedures around controlled drug dispensing for our hospital require that Pharmacy stock levels are double checked after every dispensing and any discrepancies are investigated and rectified immediately. We are concerned that conducting a comprehensive weekly stock	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be

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				check, in addition to the comprehensive quarterly stock check, would take up to 1 day per week of a pharmacist/technician time (0.2 WTE) which would likely be taken away from other patient facing activities.	carried out more or less often depending on the setting.

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Cheshire & Wirral partnership NHS Foundation Trust	Short Full	7 53-61	16-18 24-28 General	Definition of an external pharmacy is very specific. There are many NHS hospitals/organisations today that have sub-contracted supply of medicines to an external pharmacy that provides a regular supply of medicines to the NHS organisation under a specific contract and in doing so operate a "closed pharmacy" arrangement such that they only supply medicines for that organisation from the said premises. In terms of requisitions for supply of stock medicines does the NHS organisation need to complete the new requisition paperwork that comes into effect from 30/11/15 to have a supply of stock medicines made from the external pharmacy that provides the service to the NHS organisation? This is not clear from the guideline nor the legislation around this. The evidence documented in full guideline on whether the hospital setting should use the new requisition paperwork or their own internal organisation wide one is not clear in terms of what the legal requirement is from the legislation. Can this be made clearer.	Thank you for your comment. The approved mandatory requisition form is used only when stocks of the controlled drugs are to be obtained in the community, including from wholesalers but outside settings such as hospitals where supply to wards are governed by different provisions. The information is in section 6.1.1 of the full guideline.
Cheshire & Wirral partnership NHS	full	28	18	Should non-medical prescriber be included in the prescriber list and not just doctor or dentist, as some do prescribe controlled drugs.	Thank you for your comment. Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in

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Foundation Trust					charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001.
Cheshire & Wirral partnership NHS Foundation Trust	full	30	28	The witness to the administration what standing does this individual have to be ie. Qualified health professional, unqualified care assistant – can this be clarified? Also for second signatures on administration of CDs can't find who it is that should be the witness is that a qualified health professional or not?	Thank you for your comment. 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. Second witness arrangements would need to be determined locally as arrangements will vary depending on how services are commissioned and provided and what resources are available. The second witness should be someone who is trained and competent in the area of administration of medicines.
Controlled Drugs Accountable Officers' Network (Scotland)	Full	28	25	Unclear as to why incorporating national medicines safety guidance about CDs into SOPs e.g. patient safety alerts should only be included in the *Obtaining & supplying controlled drugs* section as it is equally applicable to the *Prescribing* and *Administering* sections of the guideline. This statement would be challenging to implement as we don't feel that this is the purpose of SOPs as you cannot expect prescribers to check a SOP each and every time that they prescribe. For organisations it should be about ensuring that patient safety alerts are	Thank you for your comment. The Committee discussion about incorporating national medicines safety guidance about controlled drugs into standard operating procedures was carried out during the evidence review for the review question obtaining and supplying and so the recommendation has been included in the section so that the reader of the guideline can refer to the rationale behind the recommendation in the 'linking evidence to recommendation' section easily. However, as your comment suggests this applies to all areas. There is a short version of the guideline with only the recommendations structured differently to the full guideline to make it clear who the recommendations are aimed it. The comment relating to the recommendation itself, the Committee discussed the national safety alerts that have been issued as a result of reported

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				disseminated to prescribers in a timely manner.	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. They can be embedded with in standard operating procedures as a way of preventing incidents from recurring and as part of the wider medicines optimisation agenda..
Controlled Drugs Accountable Officers' Network (Scotland)	Full	29	4	We have previously provided feedback on the document *Recommendations for the Retention of Pharmacy Records 2015* to the East of England Senior Pharmacy Managers Network (EESPMN) and note that the recommendation about keeping records of the destruction of patients' own CDs for a minimum of 7 years refers to a 'broad consensus of best practice' from the EESPMN. The Controlled Drugs Accountable Officers' Network (Scotland) would like to highlight the odd situation whereby CD registers/record books containing records of CD destruction should be kept for longer than registers without. The legal requirement is that CD registers should be retained for 2 years although Dame Janet Smith, the Chair of the Shipman Inquiry recommended that this should be extended to at least 7 years. The RPSGB *Guidance for Pharmacists on the Safe Destruction of Controlled Drugs* in 2007 stated that records of	Thank you for your comment. The Committee highlighted that there was uncertainty on how long certain records relating to controlled drugs need to be kept for when there is no legislation. The recommendation you refer to was based on Committee consensus to provide organisations some guidance on record keeping of controlled drugs invoices and records of destruction unless legislation specifies otherwise. Section 6.5 in the guideline under 'record keeping relating to controlled drugs' provides the rationale for the consensus recommendation and links to the relevant guidance the Committee referred to during the discussions.

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				patient returned CDs should be retained for at least 7 years and this seems to have been translated into a general requirement to keep registers containing records of destruction for 7 years. However the current *Medicines Ethics and Practice* (*MEP*) states that registers must only be kept for 2 years after the date of the last entry. The current *MEP* makes no mention about the retention of records of patients' own CD destruction.	
Controlled Drugs Accountable Officers' Network (Scotland)	Full	37	30	More detail required about instalment dispensing prescriptions. The current *MEP* states that "The Home Office has confirmed that an instalment prescription must have both a dose and an instalment amount specified separately on the prescription" and in addition "The instalment direction is a legal requirement and needs to be complied with. However, because there are acknowledged practical difficulties with missed doses and dates when the pharmacy is closed (e.g. bank holidays), the Home Office has approved specific wording to be used that gives pharmacists a degree of flexibility when making a supply". This approved wording has been updated on 9 November 2015 in *Annex A* of *Circular 027/2015*: *Approved mandatory requisition form and Home Office approved wording* available via	Thank you for your comment. The relevant text about the Home Office Circular on approved wording for the instalment prescribing of controlled drugs has been added to reflect your comment.

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				https://www.gov.uk/government/publications/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording/circular-0272015-approved-mandatory-requisition-form-and-home-office-approved-wording	
Controlled Drugs Accountable Officers' Network (Scotland)	Short	4	12	This statement would be challenging to implement because it is unclear as to what it means in practice. What are the processes?	Thank you for your comment. The term 'processes' in the text refers to organisational policies or pathways used to deliver care. The recommendation has been amended to make this clear.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	5	24	This statement would be challenging to implement particularly with regard to convincing prescribers to include how long a when required CD should be used for.	Thank you for your comment. Following further discussion by the Committee, they agreed that this constitutes good practice given the risks associated with controlled drugs. Section 5.5 in the full guideline provides the rationale behind the recommendation under 'providing information about controlled drugs'.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	4 - 5	general	The statements about prescribing and the detail about documenting in patient's records would be challenging to implement and extremely difficult if not impossible to assess. We are unsure as to how compliance could be encouraged as this would create additional work for prescribers which is likely to be considered as additional work with no benefit to the patient or prescriber.	Thank you for your comment. 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. The Committee agreed that a recommendation about prescribing and the detail about documenting in patient's records would be good practice and enable continuity of safe care when patients see different prescribers or move from one care setting to another. See section

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					5.5 for the rationale for the recommendation.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	15	10	This statement would be challenging to implement as the person supplying the CDs will not necessarily be familiar with the location or arrangements of the custody location.	Thank you for your comment. The health professional could ask the custody officer about how they will be stored and advise on safe storage of the controlled drugs.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	15	15	This statement would be challenging to implement as discussing the person's preference for a lockable or non-lockable storage box would suggest that the organisation supplying controlled drugs would have to supply a box which isn't an appropriate recommendation.	Thank you for your comment. Following further discussion by the Committee, they agreed that the recommendation focusses on the health professionals to consider discussing with the person the options for storing their prescribed controlled drugs. The options may include taking into account person's preference for lockable or non-lockable storage. There is no explicit requirement to provide storage in the recommendation.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	15	20	This statement would be challenging to implement as the only real way to assess a person's method of storing their CDs in their home would require a domiciliary visit which is impractical given the number of persons who are prescribed and supplied with CDs.	Thank you for your comment. This recommendation has been reworded and added to another recommendation following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment.
Controlled Drugs Accountable Officers' Network (Scotland)	Full/Short	general	general	The recommendations should probably be arranged under recommendations for organisations, healthcare professionals, Accountable Officers etc rather than under prescribing etc as these groups need to be easily able to access the information that is	Thank you for your comment. The recommendations in the full guideline are grouped by review question and have been restructured to make them flow better. The short version of the guideline with all the recommendations has also been restructured to reflect your comment.

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				relevant to them.	
Controlled Drugs Accountable Officers' Network (Scotland)	Short	13	12	1.1.42 – We feel that this is mostly already happening in most areas so it wouldn't be difficult to implement a SOP. Weekly would be fine for most areas but we feel it would be challenging to get most GPs to do this particularly as the majority of them rarely need to access their own stocks unless they are dispensing practices. We consider that allowing wards to do weekly checks rather than daily would free up nursing time to the benefit of patients but this needs to be balanced against the security risks and the extra time required to investigate if CDs were misappropriated.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.
Controlled Drugs Accountable Officers' Network (Scotland)	Short	18	21	1.168 – Audit tools are already available so it would be relatively easy to produce a SOP for auditing CD registers and cabinets.	Thank you for your comment. You can submit audit tools to NICE for it to be considered for the endorsement programme.
Department of Health	Full	9	7	Add "diverted" after misused	Thank you for your comment. The relevant text has been amended to reflect your comment.
Department of Health	Full	9	15	I think it should say, "should" instead of could	Thank you for your comment. The relevant text has been amended to reflect your comment.
Department of Health	Full	9	30	add "supplying", after, "dispensing"	Thank you for your comment. The relevant text has been added to reflect your comment.
Department of	Full	9	Last line	Should "supply" be added?	Thank you for your comment. The relevant text has been added to

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Health					reflect your comment.
Department of Health	Full	10	Section 1.2, para 4	add, "diversion" after "potential for abuse"	Thank you for your comment. The relevant text has been added to reflect your comment.
Department of Health	Full	14	Section 2.4 bullet 3	add NHS England as one of the commissioners	Thank you for your comment. The relevant text has been added to reflect your comment.
Department of Health	Full	14	Section 2.4 bullet 5	Add "hospices"	Thank you for your comment. The list in the paragraph is not meant to be exhaustive. The guideline is also relevant for individual people and organisations delivering non-publicly funded services such as hospices.
Department of Health	Full	15	section 2.5 Bullet 2	Add "NHS England"	Thank you for your comment. The relevant text has been added to reflect your comment.
Department of Health	Full	17	Table 1	What is meant by "secure prescribing"?	Thank you for your comment. 'Secure prescribing' is ensuring safety and reducing risk when prescribing to a person.
Department of Health	Full	17	Table 1	add , "safe" before effective	Thank you for your comment. The review questions cannot be amended once they have been agreed during the scoping phase of guideline development. Therefore the term 'safe' has not been added to the review question.
Department of Health	Full	General		Suggest that, wherever the guidance refers to "handling" controlled drugs, it should talk about "managing" controlled drugs	Thank you for your comment. Handling is a term agreed by the Committee and takes into account possessing, storing, recording, transporting, disposing and destroying of controlled drugs. The term 'handling' is part of the management of controlled drugs as there are other elements involved within the management of controlled drugs. The title of the guideline captures the term 'management' that takes everything into account such as prescribing, obtaining and supplying, handling and monitoring. No amendment made.

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Department of Health	Full	General		Suggest using the term "safe disposal" instead of "disposing"	Thank you for your comment. Following further discussion the wording was agreed by the Committee. The term 'safe' has been added to the recommendations where this is relevant.
Department of Health	Full	26	Section 4.1, bullet 1	Talks about organisations develop processes that support prescribers who have been assessed as competent to prescribe CDs- is this do-able? Who will Asses them as being competent. Professionals act within their scope of practice and take clinical and professional responsibility for their actions and are regulated by their regulators.	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
Department of Health	Full	26	Para 3, bullet 3	Suggest adding "or increase" after "dose reduction", as some patients may have their does increased.	Thank you for your comment. This wording has been amended to 'adjust' following further discussion by the Committee to take into account an increase or decrease in dose.
Department of Health	Full	27	Para 9	Talks about a locally agreed opioid dose conversion – Why should there be a local decision about this? The BNF has recommendations for opioid equivalence	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.
Department of Health	Full	27	Para 11	Where it talks about advising people how to safely dispose – People won't dispose, it should say, "should advise people to take unwanted controlled drugs to a community pharmacy for safe disposal"	Thank you for your comment. The recommendation aims to ensure health professionals advise people on how to dispose used controlled drugs such patches or lozenges. Used controlled drugs may be disposed of at home providing the right advice has been given to the person who may not be able to get to a community pharmacy each time they have a used controlled drug to dispose of.
Department of Health	Full	28	Para 19, bullet 2	should it say name of the care setting ordering the controlled drugs	Thank you for your comment. Following further discussion by the Committee, they agreed to add the term 'location' in to

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					recommendation to take into account different area's within the organisation.
Department of Health	Full	28	Para 20	what about community pharmacies?	Thank you for your comment. The recommendation is specifically for organisations with internal pharmacies such as a prison or hospital.
Department of Health	Full	29		same as for para 11 on page 27 i.e. advising people to take unwanted CDs to a pharmacy for safe disposal	Thank you for your comment. The recommendation aims to ensure health professionals advice people on how to dispose used controlled drugs such patches or lozenges. Used controlled drugs may be disposed of at home providing the right advice has been given to the person who may not be able to get to a community pharmacy each time they have a used controlled drug to dispose of.
Department of Health	Full	30	Bullet 3	As per comment 13	Thank you for your comment. This wording has been amended following further discussion by the Committee.
Department of Health	Full	30	Para 30	should it not also say, "compliance with Misuse of Drugs Regulations"	Thank you for your comment. Following further discussion by the Committee, they found no specific regulation that covers the process of administration in the Misuse of Drugs Regulations 2001, therefore the amendment was not made.
Department of Health	Full	30	Para 33	record the administration of the CD- where should this be recorded?	Thank you for your comment. Records of administration can be made in the person's care record, this may be a medicines or inpatient chart or another type of record depending on the care setting. See also recommendation 32 in the guideline
Department of Health	Full	30	Para 35	complete relevant training and assessments to confirm competence in setting up devices ……." Who will assess competence?	Thank you for your comment. This recommendation has been amended following further discussion by the Committee The term 'assessment' has been removed from the recommendation.
Department of Health	Full	30	Para 38	Bullet 7- it would be better to specify, accessibility to the CDs	Thank you for your comment. The relevant text has been amended to specify staff access to controlled drugs to reflect your comment.
Department of Health	Full	31		it would be better to use the term, "Managing CDs" rather than "handling". Handling implies	Thank you for your comment. Handling is a term agreed by the Committee and takes into account possessing, storing, recording,

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				physical handling only	transporting, disposing and destroying of controlled drugs (see section 8.1). The term 'handling' is part of the management of controlled drugs as there are other elements involved within the management of controlled drugs. The title of the guideline captures the term 'management' that takes everything into account such as prescribing, obtaining and supplying, handling and monitoring. No amendment made.
Department of Health	Full	31	Para 40	Should it also say to comply with safe storage regulations?	Thank you for your comment. This wording has been amended to include the Misuse of Drugs (Safe Custody) Regulations 1973 following further discussion by the Committee.
Department of Health	Full	32	Bullet 2	Suggest redrafting. I know what is being implied but the way it has been drafted here is confusing – This is what has been used in the past – "Discrepancies can arise with liquids CDs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals."	Thank you for your comment. This wording has been amended to include visual inspection of liquid balances, periodic volume checks and checks to confirm the balance on completion of a bottle following further discussion by the Committee.
Department of Health	Full	33	Para 56, bullet 5	please add, "for safe disposal" after controlled drugs	Thank you for your comment. The relevant text has been added to reflect your comment.

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Department of Health	Full	34	Para 60, bullet 3	There may still be some residue left in the bottle. I think the advice from the Environment Agency may be that the container should be put into pharmaceutical waste	Thank you for your comment. Section 8.5 of the guideline includes the detailed advice provided by the Environment Agency. 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.
Earl of Mountbatten Hospice	Short	7	1	It's not necessary/sensible to inform the GP of every CD prescription when the patient is in a hospital inpatient setting. Suggest adding "for outpatients and patients at home"	Thank you for your comment. 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 should be recorded in their care record. In the case of a person being in hospital, this information would be provide to the GP on a discharge letter that would include the list of medicines the person is taking.
Earl of Mountbatten Hospice	Short	10	1	consider specifically mentioning folding transdermal patches in on themselves given some of the NLRS incidents with accidental exposure to transdermal patches	Thank you for your comment. The recommendation aims to capture all preparations of controlled drugs including transdermal patches. In the guideline there is a recommendation to incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs (see obtaining and supplying section). This would also include incorporating the drug safety update about serious and fatal overdose of fentanyl patches into standard operating procedures.
Earl of	Short	11	4	Found "care record" quite ambiguous here.	Thank you for your comment. The recommendation intends to

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Mountbatten Hospice				Concluded it meant "medication administration record". Am concerned this could be read to mean that doses etc. should be duplicated in the clinical notes – that would be absurd, pointless and unworkable (in a hospice setting)	emphasise the importance of making a record of administration in the person's care record. The care record may vary depending on the arrangements of the care setting for recording administration, this may be in the form of a medicines administration record if the setting uses one or another type of record that is kept to log care provided. The recommendation does not specify for records to be duplicated.
Earl of Mountbatten Hospice	Short	11	26	Again, it's not necessary or sensible to inform the GP of every CD infusion when the patient is in a hospital inpatient setting. Suggest adding "for outpatients and patients at home"	Thank you for your comment. The recommendation is about the decision to use a continuous administration device and involving the relevant people including the person's GP when making the decision. In terms of informing the GP of every controlled drug infusion, for all care settings, health and social care practitioners should proactively share complete and accurate information about medicines as recommended in the Medicines optimisation (2015) NICE guideline NG5**.** This would include informing the person's GP about medicines that the person in hospital
Guild of Healthcare Pharmacists	Full	37	28	This statement is slightly misleading as it implies that the validity period is for 'all' prescriptions but it only applies to NHS prescriptions (e.g. FP10HNC) or hospital discharge prescriptions but it does apply to hospital inpatient prescription treatment charts.	Thank you for your comment. The relevant text has been amended to reflect your comment. The term 'NHS' has been added to 'prescription' for clarity.
Guild of Healthcare Pharmacists	Full	51	1	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" but in association with this Recommendation 5.6.1 states:	Thank you for your comment. The term 'assessment' has been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.

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				"Develop processes that support prescribers who have been assessed as competent to prescribe controlled drugs." How should prescribers be assessed, especially clinical and professional competency as these skills would be difficult to assess?	
Guild of Healthcare Pharmacists	Full	97	37	Page 93 discusses 'Disposal of remaining small amounts of controlled drugs after administration' in wards and theatres, particularly with liquid preparations, and mentions that the Committee considered a 'small' amount is an irretrievable amount, but none of the recommendations discuss what should happen when large (and therefore 'retrievable') amounts of liquid remain after administration from discontinued syringes, infusion bags, or unused portions in ampoules or vials. For example Critical care units and Theatres prepare and administer relatively large volumes of liquid controlled drugs but significant volumes often remain unused after the administration process and cannot be returned to Pharmacy for safe disposal. Staff either dispose of the contents into a sharps box or pour the liquid into a CD denaturing kit, but both of these methods give a security problem. Sharps containers are used over several days so the liquid accumulate and could potentially be retrievable. Similarly, the contents of denaturing	Thank you for your comment. The linking evidence to recommendations (LETR) table captures the guideline development group discussions. There is a recommendation that covers controlled drugs left over after administration in section 8.6 of the guideline. There is also a hyperlink in section 8.1 to the guidance from NHS England on methods of denaturing controlled drugs for the user to refer to for information on denaturing controlled drugs. Standard operating procedures can include this information provided by NHS England.

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				kits congeal in a few minutes so if more liquid CDs are added during the course of the day, as in the case of ITUs, the subsequent liquids simply float on top of the congealed mass i.e. they are not denatured or rendered irretrievable. The 'RPS Guidance for pharmacists on the safe destruction of CDs' provides an alternative method of destroying liquid CDs by adding and adsorbing the liquid into an appropriate amount of cat litter or similar product. The cat litter or similar product is then disposed of by incineration. However, there is lack of definitive national guidance to ensure complete destruction and suitable disposal to ensure controlled drugs are rendered irretrievable from containers. A standard operating procedure based on such guidance (when made available) should be developed by organisations.	
Guild of Healthcare Pharmacists	Full	80	32	The recommended list of details for recording in the person's care record does not apply in the hospital setting. These details are recorded on the inpatient administration chart but this is not mentioned within the recommendation. Wards and departments within NHS Trusts also record the 'balance' of remaining stock of the controlled drug in the register following the administration of the medicine to the patient.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to take into account the differences in care records used in different settings. Recommendation 55 is aimed at records to be made if there are controlled drugs left over after administration. There is a separate recommendation that is aimed at controlled drugs 'balance' checks in section 8.6 of the guideline. It is considered as good practice to record the 'balance' of remaining stock of the controlled drug in the register following the administration of the medicine to a patient.

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				Recommendation number 55 (page 99) discusses the details to be recorded but this is only in relation to controlled drugs left over after administration!	See section 8.5 of the guideline for the rationale for the recommendation.
Guild of Healthcare Pharmacists	Full	98	08	Weekly stock checks should be the standard to allow for error investigation in a timely manner	Thank you for your comment.
Guild of Healthcare Pharmacists	Full	98	25	Routine couriers are required to deliver controlled rugs in secure bags to off-site NHS hospital units, anything else would create patient safety issues. Such supplies are delivered inside a sealed bag with numbered tags. The courier does not know the contents of the sealed bag, but the 'bag' is signed for by the courier and then on receipt.	Thank you for your comment. Following further discussion by the Committee, they agreed to reword the recommendation to place emphasis on having governance arrangements and processes in place if using couriers, taxis or equivalent services to transport controlled drugs or prescriptions for controlled drugs.
Guild of Healthcare Pharmacists	Full	98	42	Spillage of liquid controlled drugs occurs occasionally in hospital wards and departments. Should there be a recommendation that covers spillages?	Thank you for your comment. Spillage of liquid controlled drugs was not discussed by the Committee. This would be down for local determination and in accordance with the organisations policy for handling any kind of spillages and also the standard operating procedure for controlled drugs. Guidance from Department of Health advises that 'when spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one'.
Guild of Healthcare Pharmacists	Full	116	4	The Glossary provides a definition of an 'Authorised Person' for witnessing the destruction of controlled drugs, and gives hyperlinks to Regulation 27 of the 2001	Thank you for your comment. In section 9.1.1 of the guideline there is a link to the single operating model that has been developed by NHS England in 2013 to introduce standardised processes and documentation to support its area teams. The document also has a

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				Regulations, but Regulation 27 does not specify ' who' can be an authorised person. Also, lines 9 and 10 of the Glossary state "The lead controlled drugs accountable officer of NHS England may also appoint people as authorised witnesses" but it does not reference the "2007 Pharmacy & Industry Group, Department of Health Guidance on the destruction of controlled drugs – a new role for Accountable Officers - Authorising people to witness the destruction of controlled drugs Medicine" (link). This amendment to the Misuse of Drugs Regulations 2001 permits an Accountable Officer (i.e. not just the lead controlled drugs accountable officer of NHS England) to authorise people or groups of people to witness the destruction of controlled drugs in compliance with the regulation. We propose that it would be useful to highlight this amendment for NHS Trusts and Foundation Trusts.	section on authorisation of witnesses to destroy controlled drugs. The Committee considered the single operating model and agreed that a more recent publication should be referenced in the guideline.
Home Office	Full	9	19	The word "reducing" at the beginning of the lines needs to be deleted	Thank you for your comment. The relevant text has been removed to reflect your comment.
Home Office	Full	26	8	Please insert "Schedule 2 and 3" between the words "for" and "controlled"	Thank you for your comment. The relevant text has been amended to reflect your comment.
Home Office	Full	29	10	Please insert "the approved" before the word "mandatory" and delete "a"	Thank you for your comment. The relevant text has been amended to reflect your comment.
Home Office	Full	37	16	Instead of the word s "defines the people" use "identifies the professionals"	Thank you for your comment. The relevant text has been amended to reflect your comment.

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Home Office	Full	37	18 -20	The half of the line starting with "The Misuse …." up to the end of line 20 needs to be deleted as it's a repetition.	Thank you for your comment. The relevant text has been amended to reflect your comment.
Home Office	Full	38	16-17	Sentence beginning with "For Schedule 2 and 3 controlled drugs…. …..requirements apply (see table5) As of 1 June 2015 Schedule 2 and 3 controlled drugs can be prescribed under the NHS EPS only. This position needs to be reflected here.	Thank you for your comment. This section has been amended to reflect the new regulation about Schedule 2 and 3 controlled drugs being prescribed under the NHS EPS only.
Home Office	Full	General	General – Part 6	This part is unhelpfully vague on the MHRA and Home Office licensing requirements that apply to a registered pharmacist or pharmacy that supplies stock medicines including controlled drugs, and on the Home Office licensing requirements that would apply to a provider of health care services that holds stocks of controlled drugs. Section 6.1.1 titled 'Legislation, regulation and policy' should set out the basic legal requirements more clearly. The draft guidance focuses on who may obtain controlled drugs for use in their practice, business or profession and the example of a 'doctor's bag' is given. The emphasis appears to be on controlled drugs held by a practitioner. However in the absence of any parameters on the quantities that may be held and their use the impression given is that	Thank you for your comment. The section you refer to has been checked and clarified. The guideline provides a summary of legislation but does not aim to clarify all legislation related to controlled drugs as this is not NICE's remit The aim of the guideline is to review the evidence and to develop recommendations in line with the methods in the Guidelines Manual (2014) The aim of the introduction in section 6.1.1 for this NICE guideline is to introduce what the guideline means by obtaining and supplying controlled drugs. The term 'stock' controlled drugs has been defined in the glossary to make the context of use clear in the guideline. A hyperlink has been provided in the text to the Home Office webpage on 'How to apply for licences to handle controlled drugs as a company or individual traveller, including import and export procedures and fees controlled drugs' for users of the guideline to refer to for more information.

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				practitioners and other healthcare professionals may lawfully obtain stocks of controlled drugs that are for use by their businesses as a whole. This is a common misconception amongst many companies and other organisations that provide ambulance services, out of hours GPs services, diagnostic clinics, slimming clinics etc. The guidance as currently drafted would do little to clarify the situation. Given that the target audience includes pharmacists, healthcare professionals, healthcare providers and healthcare commissioner the Home Office view is that the document should be as clear as possible on these points. In this respect a distinction should be made in the guidance between stocks held by a dispensing doctor or other practitioners and those held by company or organisation.	
Home Office	Full	53	21-25	This paragraph is a bit unclear. Prisons and hospices are now exempted from using the new mandatory requisition form for schedule 2 and 3 controlled drugs. This position must be clearly stated here as the current drafting seem to imply that the form applies to these organisations.	Thank you for your comment. The relevant text has been added to section 6 to reflect your comment.
Home Office	Full	54	6-8	The new FP10CDF is available online and not through the NHS England area teams. Please replace "These forms can be obtained	Thank you for your comment. The relevant text about the approved mandatory form being available from the NHSBSA website has been added to reflect your comment along with a hyperlink to the

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				from the NHS England area teams who hold stocks of controlled drug requisitions" with "The new mandatory controlled drug requisition form is available online at the NHSBSA website http://www.nhsbsa.nhs.uk/PrescriptionServices/1120.aspx"	website.
Home Office	Full	60	General	**Heading: Requisitions for controlled drugs in Schedule 2 and 3** At lines 5 and 6 use of a mandatory requisition form has been referred to as being optional. This is certainly the case pre 30 November 2015 but form this date it is mandatory to use the form. The drafting needs to be clarified by including the relevant dates to avoid confusion.	Thank you for your comment. The relevant text has been amended to reflect the new regulation about the approved mandatory form being used in the community to requisition controlled drugs.
Home Office	Full	61	General	Third paragraph, under same heading as above. The last 5 lines of that paragraph states "*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."* In the Home Office's view, the statement above is incorrect and does not reflect the provisions of the 2001 Regulations. Regulation 14(5)(a) of the 2001 Regulations specifically requires a requisition **"furnished by the person in charge**	Thank you for your comment. The text has been removed and the relevant recommendation has been amended to reflect Home Office legislation.

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				or acting person in charge of a hospital or care home to be signed by a doctor or dentist employed or engaged in that hospital or care home. "	
Home Office	Full	67	8&9	Guidance currently states "*NHS employed ambulance paramedics serving at any approved ambulance station are able to administer diazepam 5mg/ml injection and/or morphine sulphate injection*…" The Home Office Group Authority for NHS paramedics does not impose a 5mg/ml limit on any drugs that are covered under the authority. The only limitation is the maximum 20mg. Unless this is a requirement in medicines legislation, this statement needs to be corrected.	Thank you for your comment. The relevant text has been amended to reflect your comment.
Inclusion London	General, full			All our comments involve the issue of 'over prescription' or inappropriate use of psychotropic drugs regarding Disabled people and older people: NHS England has promised 'rapid and sustained action to tackle the over-prescribing of psychotropic drugs to people with learning disabilities after three separate reports highlighted the need for change' see: https://www.england.nhs.uk/2015/07/14/urgent-pledge/ Therefore we request that a NICE guideline is	Thank you for your comment. The guideline covers the systems and processes for safe use and management of controlled drugs. It is not specific to any condition or class of controlled drugs, although certain conditions may be used to highlight a particular aspect of a system or process that needs explanation.

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				put in place that that would prevent the possibility that people with learning disabilities will continue to be 'over prescribed' with psychotropic drugs, until efficacy and safety' of psychotropic drugs has been researched further. The need for stronger NICE guidelines are indicated by the research which found that: "…changes are needed in the prescribing of psychotropics for people with intellectual disability. More evidence is needed of the efficacy and safety of psychotropic drugs in this group, particularly when they are used for challenging behaviour". http://www.bmj.com/content/351/bmj.h4326 https://www.improvinghealthandlives.org.uk/publications/1248/Prescribing_of_psychotropic_medication_for_people_with_learning_disabilities_and_autism There is also concerns raised regarding the use of antipsychotic medication for those with dementia, see: http://www.nhs.uk/news/2009/10October/Pages/Antipsychotic-use-in-dementia.aspx https://www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=389 As well as concerns regarding 'Overstated benefits and understated deaths' regarding psychotropic drugs prescribed, see article at:	

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				http://www.deadlymedicines.dk/wp-content/uploads/2014/10/G%C3%B8tzsche-Maudsley-slightly-corrected-version-bmj.h2435.full_.pdf We ask that there is a NICE guideline in place to ensure that clinicians are cautious when prescribing psychotropic drugs, particularly for people with dementia but also for people mental health support needs. We would like to suggest that NICE is cautious in continuing to sanction the use of psychotropic drugs for people with dementia and also people with mental health conditions until research clearly shows the efficacy and safety of this type of medication.	
Lancashire Care NHS Foundation Trust	Short	13	1.4.2	**Bullet point one:** The procedure should also include whose responsibility it is to complete the checks (i.e. Pharmacist or Nurse). If it is a Nurse then this should be consistent with the standards in their professional body **Bullet point three**: We agree the frequency of minimum once per week is appropriate as we have found this leads to issues being picked up in a timely way (from our experience of mental health wards). **Bullet point four:** If checks are made frequently (i.e. every day), the CD register may not be the	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment about making records in the controlled drugs register. It would be down to local determination to outline responsibilities in the standard operating procedure depending on the care setting

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				most appropriate place to record checks, a separate daily book may be more practical.	
Leeds Teaching Hospitals NHS Trust	Short	4	12	How will prescribers be assessed ?	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
Leeds Teaching Hospitals NHS Trust	Short	9	24	Could this increase the chance of error due to inadvertently omitting to do this?	Thank you for your comment. 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 is no legislation or national policy guidance found for this. The Committee found from discussions 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 therefore 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.
Leeds Teaching Hospitals NHS Trust	Short	13	19	Would this apply to pharmacy areas also?	Thank you for your comment. The recommendation your comment refers to applies to organisations that hold stock controlled drugs for supply and administration. This would also include pharmacies.
Leeds Teaching Hospitals NHS Trust	Short	16	1	Should it specify who's responsibility this should be?	Thank you for your comment. Organisational governance arrangements and responsibilities for controlled drugs are necessarily for local consideration and determination. Arrangements will vary depending on how services are

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					commissioned and provided and what resources are available.
Ministry of Defence	Short	14	1.1.46	More detailed guidance on who can be considered an "authorised" witness would be useful.	Thank you for your comment. The Misuse of Drugs Act 1971 designates certain people as authorised witnesses and detailed guidance is available in the single operating model developed by NHS England. As the information is available in the single operating model, the guideline includes the hyperlink to it to avoid duplication and to futureproof the guideline in the event of any changes.
Ministry of Defence	Short	Title Page	4	Destruction and disposal are not included as discrete areas. I accept this is covered under 'handling' but should they be specifically included instatement of scope of the document?	Thank you for your comment. The aim of the short guideline is to summarise all the recommendations. The section you refer to in your comment is the introductory text and it is the same text used in the scope of the guideline. The term 'handling' has been further defined to include destruction and disposal in the full guideline. The short guideline has been restructured to include a section on destruction and disposal of controlled drugs.
Ministry of Defence	Short	13	1.1.42	A weekly check is useful and advisable in a busy area – e.g. a hospital ward or very busy community Pharmacy where there is an infrastructure and process to conduct this frequency of checks. For other areas where CDs are not used as regularly but stored, and it is more difficult to conduct a meaningful check, perhaps this is too frequent. Therefore , should this statement be clarified: Suggestion: Facilities conducting daily CD transaction should conduct a check at least weekly. Facilities conducting less frequent CD transactions e.g. weekly should conduct a	Thank you for your comment. This recommendation has been reworded following further discussion by the Committee to take into account the frequency of use and controlled drug-related incidents.

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				monthly check.	
Ministry of Defence	Short	11	1.1.32	The recommendation to make an entry in the patient's record. Is this is addition to the medication chart – in patient prescription? Surely this is already carried out?	Thank you for your comment. The recommendation intends to emphasise the importance of making a record of administration in the person's care record. The care record may vary depending on the arrangements of the care setting for recording administration, this may be in the form of a medicines administration record if the setting uses one or another type of record that is kept to log care provided.
Ministry of Defence	Short	11	1.1.33	This is very important and often a problem as different hospital departments have their own administration forms which do not go with the patient. It is important to highlight this should NOT be a separate CD chart, as this would be an increase in risk to patient care.	Thank you for your comment. This recommendation has been reworded following further discussion by the Committee to make it clear that the record of administration should be readily accessible as this is the main focus of the recommendation and not about the use of separate controlled drug charts.
Napp Pharmaceuticals Limited	Full	General		We welcome the development of this guideline to support and improve the safe use and management of controlled drugs and thank you for the opportunity to comment on this draft.	Thank you for your comment.
Napp Pharmaceuticals Limited	Full	27 49	16 and 25	We agree that it is good clinical practice to consider the total opioid load when making adjustments to opioid dose and or changing the opioid. We do however have some concern about the concept of *local* conversion tables. We would suggest that the use of a nationally available conversion / equivalence chart should be encouraged which would avoid any potential loss of pain control or risk of side-effects	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.

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				particularly when patients are mobile across geographic areas. Equivalence charts are available in the BNF (this is recognised on page 49) and further information is available from the British Pain Society and The Faculty for Pain Medicine.	
Napp Pharmaceuticals Limited	Full	27 29	32 30	When discussing disposal we suggest that the term people could be replaced here with patients and their carers. We suggest that a more formal process should be in place to reconcile usage and to recover controlled drugs after a patient dies or completes his or her treatment. The process is still voluntary and possibly relies on HCPs, relatives or carers.	Thank you for your comment. The Committee agreed that the wording was appropriate and no change was made. For the purpose of this guideline, the term 'person' or 'patient' was used interchangeably depending on the context of use. The Committee was not aware of a formal process to reconcile usage and to recover controlled drugs after a patient has died. The process may vary depending on the resources available locally to do this. The Committee developed a high level recommendation based on consensus (recommendation 57) that considers: • discussing the removal of controlled drugs with a family member or carer recording the action taken and details of the controlled drugs listed in the person's medical record or notes • having a witness to the removal • any requirements of the coroner to keep medicines in the person's home for a period of time • taking the drugs to a health professional such as a community pharmacist who is legally allowed to possess controlled drugs for safe disposal.
Napp	Full	Gener		We suggest that it is important to ensure that all	Thank you for your comment. Education is outside the scope of this

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Pharmaceuticals Limited		al		people handling controlled drugs (health care professional, patients, carers, etc.) understand that supplying or selling controlled drugs is not only dangerous but is also a criminal offence. We believe that this opportunity for education should be included under the section Handling controlled drugs (d).	guideline.
Napp Pharmaceuticals Limited	Full	33	8-15	We suggest that it is important to stress the need for security to avoid any misappropriation of controlled medicines from the patient's home, hospice or hospital.	Thank you for your comment. This recommendation has been reworded and also includes wording to take into account storage methods at home and if they could lead to an increased risk of controlled drug-related incidents, including patient safety incidents.
Napp Pharmaceuticals Limited	Full	45	First paragraph Second sentence	Should this read: "The trade-off……" not as written: "The trade of…."	Thank you for your comment. The relevant text has been amended to 'trade off' to reflect your comment.
Napp Pharmaceuticals Limited	Full	46		When discussing good practice points did The Committee consider including in this guideline simple advice to avoid opioid induced side-effects such as the co-administration of anti-emetics for nausea in the opioid naive and laxatives to prevent and treat constipation?	Thank you for your comment. The guideline covers the systems and processes for safe use and management of controlled drugs. It is not specific to any condition, although certain conditions may be used to highlight a particular aspect of a system or process that needs explanation.
Napp Pharmaceuticals Limited	Full	52	9	Please include national here to reflect previous comments in the guideline, we suggest: "Use a locally or nationally agreed….." we believe that it would be ideal for NICE to standardise conversion rates to avoid confusion.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid

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					prescriptions. Standardising conversion rates for opioid controlled drugs is not within the scope of the guideline.
Napp Pharmaceuticals Limited	Full	91		We agree with The Committee that organisations should have procedures in place to manage controlled drug-related poisoning and overdose.	Thank you for your comment.
Napp Pharmaceuticals Limited	Full	General		What processes are available to prevent patients from stockpiling controlled medicines? What processes are available to monitor and prevent the sale of prescription medicines on the internet?	Thank you for your comment. Throughout the guideline recommendations have been made to ensure systems and processes are in place to prevent stockpiling of controlled drugs by patients such as reviewing controlled drugs prescribed using the repeat management systems. The sale of prescription medicines on line was outside the scope of this guideline.
Napp Pharmaceuticals Limited	Full	Specific question	1.1.42	Whilst there is a recommendation to carry out stock checks with a minimum frequency of once a week this is likely to cause additional work. There will need to be clarity on who carries out the stock checks, reporting processes for discrepancies, feedback for patients and HCPs. The main issue will be appropriate staffing levels and time for reporting back, this may be difficult for the NHS to implement when saving of £20bn are needed at present.	Thank you for your comment. The Committee agreed that in many cases a recommendation could not explicitly state which individual person or organisation was responsible for implementing the recommendation. Arrangements will vary depending on how services are commissioned and provided and what resources are available.
NHS Croydon Clinical Commissioning Group	Short	1	Who is this guideline for?	The first bullet point under the 'Who is the guideline for?' heading may want to list dentists in the examples of health care professionals. Whilst dentists can only prescribe a limited number of controlled drugs the guidance regarding appropriate prescribing would also	Thank you for your comment. The relevant text has been added to reflect your comment about the guidance also applying to dentists. The list of 'who the guideline is for' is not meant to be exhaustive and includes all organisations and health professionals who use controlled drugs.

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				apply to them. The third bullet point under the 'Who is the guideline for?' heading may want to again list dental practices (providing sedation services).	
NHS Croydon Clinical Commissioning Group	Short	5	25	It may be difficult for prescribers to establish how long a 'when required' controlled drug should be used for – especially when prescribed for break through pain in palliative care patients.	Thank you for your comment. A review date would be agreed between the prescriber and the patient depending on the patient's clinical need..
NHS Croydon Clinical Commissioning Group	Short	19	3	An additional bullet point could be added to state the frequency at which monitoring should be undertaken e.g. quarterly or more frequently if considered necessary.	Thank you for your comment. The Committee agreed that the purpose of the recommendations was to set out key principles. Details of the processes including the frequency at which monitoring should be undertaken are for local consideration.
NHS Dorset Clinical Commissioning Group	Full	28	13	First reference to SOPs, needs to be more specific about SOPs, what they are and why needed before this.	Thank you for your comment. The section you refer to is a summary of all the recommendations. The guideline has a glossary section that covers the definition you are referring to
NHS Dorset Clinical Commissioning Group	Full	28	18	Make clear the responsibility of dispensing doctors	Thank you for your comment. The aim of the recommendation your comment refers to is to provide good practice advice when requisitioning controlled drugs in Schedule 2 and 3 from an external pharmacy and not to define the responsibilities. The responsibility of the dispensing doctors is defined by their professional and regulatory body. The methods used to develop this guideline are included in the Guidelines Manual (2014).
NHS Dorset Clinical Commissionin	Full	28	11	Line 11 and onwards, what about orders from wholesalers. What setting are we in?	Thank you for your comment. The recommendations apply to all settings unless specified in the recommendation. The structure and order of the recommendations in the short and full version of the

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g Group					guideline has been amended to make the setting clear. Section 6.1.1 of the full guideline includes the use of the approved mandatory requisition form for ordering Schedule 2 and 3 controlled drugs in the community, including from wholesalers.
NHS Dorset Clinical Commissioning Group	Full	29	8	Line 8 and onwards, points 22 through 24. I feel you are confusing acts of procuring, supply, dispensing, obtaining by FP10/requisition etc. obtaining and supplying are very different functions depending on the settings. I think you need separation of the settings and the functions. Inside organisations with a pharmacy, inside organisations without a pharmacy, outside organisations getting stocks from pharmacies, community prescribing and dispensing to patients, getting stuff from wholesalers (pharmacies, disp practices). I feel this section has confused all of these very different functions.	Thank you for your comment. 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 and these have been defined in section 6.1 of the full guideline. The recommendations you refer to in your comment are in no specific order in the guideline due to the broad nature of the topic and the overlap, it has been difficult to group or theme the recommendations in each section. These recommendations specifically indicate what the supply or request is being made against such as a requisition or a prescription. Where there is a difference in supply requirements between care settings, this has been made clear in the recommendation to include the care setting for example the recommendation about the use of the approved mandatory form to obtain controlled drugs, the recommendation specifies 'in the community'.
NHS Dorset Clinical Commissioning Group	Full	30	33	Point 34. Who is providing the advice? Is this health professional to the patient or the organisation ensuring that health professionals have access to advice about this?	Thank you for your comment. The recommendation you refer to is the advice a health professional should give to the patient. The recommendation is under the sub heading 'health professionals'. To make this clearer, the recommendations in section 4 of the guideline has been restructured to reflect your comment.
NHS Dorset Clinical	Full	30	40	Point 36 here we are involving the persons GP. Prior to that I was not clear what setting we were	Thank you for your comment. The recommendation you refer to is for health professionals administering controlled drugs in primary

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Commissioning Group				in. are we in a patients home, hospital, hospice? I think we need to be clear where we are.	care. To make this clearer, the recommendations in section 4 of the full guideline has been restructured to reflect your comment.
NHS Dorset Clinical Commissioning Group	Full	30	44	What about informing and linking with out of hours services. Again not clear on the setting.	Thank you for your comment. The recommendation you refer to is for a health professional working in out of hours care setting to inform the patient's GP. To make this clearer, the recommendations in section 4 of the guideline has been restructured to reflect your comment.
NHS Dorset Clinical Commissioning Group	Full	31	41	Point 42. Surely that is a must do not a consider.	Thank you for your comment. 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. The recommendation that your comment is referring to is not supported by legislation and can therefore not be strengthened.
NHS Dorset Clinical Commissioning Group	Full	37	28	Whole paragraph. I think people get confused about length of validity of a prescription and the duration you can prescribe for. You mention the 30 days duration a few times throughout. I think it would be valuable to refer to both in one paragraph, to aid understanding.	Thank you for your comment. Section 5.1.1 of the guideline is the introduction to the section that summaries the legislation. The quantity of controlled drugs to prescribe is not in legislation and so has not been summarised in the section. Section 5.5 captures the discussion by the Committee about the quantity of controlled drugs to prescribe. 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

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					guidelines on clinical management'(2007, also known as the Clinical guidelines orange book).
NHS Dorset Clinical Commissioning Group	Full	all	all	The previous NPC publications on managing CDs in primary and secondary care, were excellent easy to follow and use guides and "go to" documents that covered all aspects of procurement, supply, dispensing etc etc. . Whilst I fully understand that the world has moved on, to replace those with this document is a retrograde step. There are far more complex care setting and responsibility arrangements now, but there are some key principles that are necessary in controlled drugs management, and I don't think this makes them clear. Whilst this is a draft, and I do not doubt the amount of work that has been put into it. We need something that one of our plurality of providers can pick up and use to formulate their SOPs and policies, and if this is not the document, what is? At this point I am not sure this can become that document.	Thank you for your comment. The aim of the guideline is to review the evidence and to develop recommendations in line with the methods in the Guidelines Manual (2014). The introduction sections in the guideline provide the key principles and relevant legislation for prescribing, obtaining and supplying, administration, handling and monitoring controlled drugs. The guideline has been developed using available evidence and Committee expertise. The recommendations developed are to ensure best practise in the areas where practice varied or the Committee highlighted that clarification was required. Both of the documents you refer to have been referenced in the guideline for the user to refer to when further information is required depending on the care setting. Covering every aspect controlled drug management would be difficult as the guideline covers all settings. Also, there are separate guidance documents available that cover the different aspects of the management of controlled drugs in different settings, and these have been hyperlinked in the guideline to avoid duplication of work that has already been done.
NHS Ealing Clinical Commissioning Group	Short	1	box	States the guidance is for use of providers where CDs are USED – this includes community pharmacy but CDs are not USED there.	Thank you for your comment. Community pharmacies stock controlled drugs for supply this includes providing supervised controlled drugs administration to people who self-administer controlled drugs in the pharmacy undergoing treatment for substance misuse. In this case, the controlled drug is being used in the community pharmacy for the purpose of supervised

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					self-administration.
NHS Ealing Clinical Commissioning Group	Short	4	13	Who assesses prescribers to determine if they are competent to prescribe CDs?	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
NHS Ealing Clinical Commissioning Group	Short	4	19	Why specify diversion just in the patient's home?	Thank you for your comment. The text 'patient's home' has been removed to reflect this comment.
NHS Ealing Clinical Commissioning Group	Short	6	27	Think there should be something specific around disposal of patches.	Thank you for your comment. The recommendation aims to capture all preparations of controlled drugs including transdermal patches. In the guideline there is a recommendation to incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs (see obtaining and supplying section). This would also include incorporating the drug safety update about serious and fatal overdose of fentanyl patches into standard operating procedures.
NHS Ealing Clinical Commissioning Group	Short	7	4	Need to mention Information Governance here	Thank you for your comment. The recommendation includes the 5 rules set out in A guide to confidentiality in health and social care (2013) by the Health and Social Care Information Centre. These 5 rules are part of the arrangements for information governance
NHS Ealing Clinical Commissioning Group	Short	7	11	What are the implications if patient refuses to share information	Thank you for your comment. The aim of the recommendation is to set out key principles with regards to information sharing in line with A guide to confidentiality in health and social care (2013) by the Health and Social Care Information Centre (HSCIC). The patient

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					has the right to refuse sharing their information and the HSCIC have further information about this on their website.
NHS Ealing Clinical Commissioning Group	Short	7	24	Are these recommendations or requirements? 'should' as against 'must'?	Thank you for your comment. This wording has been amended to 'must' following further discussion by the Committee.
NHS Ealing Clinical Commissioning Group	Short	10	18	The statement assessing the skills does not tally with the recommendation	Thank you for your comment. This recommendation has been reworded for clarity and the statement about assessing the skills has been removed following further discussion by the Committee.
NHS Ealing Clinical Commissioning Group	Short	15	18	Think it should state 'to ensure they are not accessible for people who should not have access to them'	Thank you for your comment following further discussion by the Committee they agreed that the recommendation clearly states that controlled drugs should not be accessed by those who are not authorised to have them and no change was made.
NHS Ealing Clinical Commissioning Group	Short	19	4	Should say NHS E lead CDAO I was unclear the difference between the lead CD AO and a CD AO	Thank you for your comment. The recommendation has been amended to say 'NHS England lead CDAO' .
NHS Ealing Clinical Commissioning Group	Short	22	5	Each medicine ENTRY….	Thank you for your comment. The term 'entry' has now been added to reflect your comment.
NHS England	Full	14	36-37	Could this also include NHS England as an example of a commissioner (of primary care contractors)	Thank you for your comment. The relevant text has been added to reflect your comment.
NHS England	Full	General	General	Concerned that there are no recommendations around the reporting of controlled drug incidents or concerns to the controlled accountable officer	Thank you for your comment. This has been captured in recommendation 1.1.67 of the guideline.

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NHS England	Full	27	36-47	There are exceptions to when confidential information about a patient between prescribers and non-prescribers. Much of the work of the Controlled Drug Accountable Officer is around the sharing of often highly confidential information between relevant parties including GP. By failing to mention this, it could be perceived that 'sharing information around individual of concern' is not allowed	Thank you for your comment The recommendation you refer to is aimed at prescribers who have started, changed or stopped controlled drugs for a person under their care and the clinical treatment provided to be shared with the persons GP to ensure continuity of care and prevent controlled drugs related incidents. This information would not routinely be needed by the controlled drug accountable officer unless there was an incident, in which case recommendation 1.1.67 would apply and information sharing would be part of the local process in line with information governance,
NHS England	Full	28	17-19	Pharmacists can also sign requisition forms, this is not explicit in the document	Thank you for your comment. Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001.
NHS England	Full	28	20	Can this please be specified as 'requisition forms' rather than requisitions in order to distinguish between the form and the stock obtained?	Thank you for your comment. The guideline has used the same terminology as in the Misuse of Drugs 2001 Regulations.
NHS England	Full	29	3-5	Records of destruction has little to do with obtaining and supplying controlled drugs and should not be in this section.	Thank you for your comment. The Committee agreed that records applied throughout the guideline and for this reason where there was the need to include relevant information about records such as invoices, it was added.

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NHS England	Full	29	6	Controlled drug legislation specifies that invoices need to be kept for 2 years. HMRC may have different requirements for tax purposes but that is irrelevant when this document is concerned with controlled drugs	Thank you for your comment. The requirements to keep controlled drugs requisition records for 2 years are placed on the "supplier" under Regulation 24 for Schedule 3 controlled drugs and under the combined effects of Regulations 19 and 21 for Schedule 2 controlled drugs. The Committee highlighted that there was uncertainty on how long certain records relating to controlled drugs that are not requisitions, for example a medicines chart containing a controlled drug prescribed on it, need to be kept for when there is no clear legislation (as there is for requisitions for controlled drugs in Schedule 2 and 3). The recommendation you refer to was based on Committee consensus to provide organisations some guidance on record keeping of controlled drugs invoices and records of destruction unless legislation specifies otherwise. See also section 6.5 in the full guideline for further details.
NHS England	Full	29	9-38	This section is particularly weak and does not make any recommendations around making dispensing decisions. There is nothing around checking that the drug, dose, route etc is suitable for the patient or that checks should be made with the prescriber if the quantity is for over 30 days or the request is too frequent. There is more information about these things in the section previously for prescribers and afterwards for administration. This seems a big omission for the 'supply' section especially as this is section that applies	Thank you for your comment. The Committee considered the importance of checking unusual or high doses of controlled drugs prescribed for a person. Following further discussion by the Committee, a new recommendation has been developed for health professionals to say that those who supply controlled drugs against prescriptions should follow the relevant standards set their professional regulator and check with the prescriber if there are concerns about whether the prescribed dose is safe for the person.

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				mostly to pharmacists, the 'medicines experts'. In relation to Q1. Which area will have the biggest impact…it is here that most NHS England Controlled Drug Accountable Officers would like to see pharmacists and dispensers being more proactive about checking that a prescription is safe/ suitable / effective/ reasonable and we need to be giving a consistent message about this	
NHS England	Full	29	35	Schedule 5 CDs can be dispensed for 6months from the appropriate date	Thank you for your comment. The recommendation has been reworded to only include controlled drugs in Schedule 2,3 and 4 following further discussion by the Committee to reflect your comment.
NHS England	Full	29	33-35	The term 'prescription date' is misleading and legislation around validity of prescriptions refers to the 'appropriate date'. For an NHS prescription, the appropriate date is the later of either the date on which the prescription was signed or a date indicated by the appropriate practitioner as the date before which it should not be dispensed. For private prescriptions, the appropriate date will always be the date on which it was signed. This issue already causes some confusion with pharmacists around whether a prescription is valid so NICE needs to make sure any guidance is perfectly clear to avoid the potential unnecessary refusal of a valid prescription.	Thank you for your comment. Following further discussion by the Committee, it was agreed to reword 'prescription date' to 'the date stated on the prescription' for clarity and to keep the recommendation wording in line with NICE style.

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NHS England	Full	31	10	We are concerned that this recommendation may imply that additional work is involved in the risk assessments for Schedule 3, 4 and 5 CDs. Please could the purpose and content of the risk assessment be clarified?	Thank you for your comment. The purpose of the risk assessment is to establish if 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 content of the assessment may include all the points stated in the recommendation; 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, accessibility for use and any data from relevant reported incidents.
NHS England	Full	32	41	Local arrangements for destroying and disposing of CDs after a patient has died – significant variability locally and we can ask AOs to share examples	Thank you for your comment. The accountable officers can submit and share these examples on the NICE website.
NHS England	Full	32	44	Non healthcare settings	Thank you for your comment. The intention of your comment is not clear.
NHS England	Full	33	11	Lockable storage boxes are not available from most organisations due to the costs involved	Thank you for your comment. Following further discussion by the Committee, they agreed that the recommendation focusses on the health professionals to consider discussing with the person the options for storing their prescribed controlled drugs. The options may include taking into account person's preference for lockable or non-lockable storage. There is no explicit requirement to provide storage in the recommendation.
NHS England	Full	38	1	Dental prescribing codes specific to dental	Thank you for your comment. However it is not clear where this

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				practitioners instead of one per area	comment relates to in the draft guideline.
NHS England	Full	38	24	Could this be explicit to also include Hospital doctors requesting private prescription	Thank you for your comment. The relevant text about hospital doctors requesting private prescription has been added to reflect your comment.
NHS England	Full	32	3-4	Measurements of liquid balances is part of 'checking the balances of controlled drugs' and should not be seen as separate.	Thank you for your comment. 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 and for this reason they agreed by consensus that standard operating procedures should include measurements of liquid controlled drug stock when finishing a bottle.
NHS England	Full	32	3-4	Q1 Checking the remaining stock when finishing a bottle is suggesting a much more than weekly check of some liquid CDs and will be a challenge to implement. In some cases this will mean balance checks regularly throughout the day and could result in an unnecessary drain on staffing resources for little gain. If there is a reported problem around stock levels (liquid or solid) then the SOP would be better to state that more regular reviews should be undertook	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The recommendation for standard operating procedure for stock checks now includes carrying out visual inspection of liquid balances, periodic volume checks and checks to confirm the balance on completion of a bottle. It also takes into account that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment.
NHS England	Full	32	3-4	Re recommendation 1.1.42 in short version or this section in the full version, weekly checks should be feasible and experience shows that most pharmacy contractors (external pharmacies) do this any way. When discrepancies arise, they are much harder to resolve or pinpoint the cause when more than a	Thank you for your comment.

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				week has elapsed from last check. The time taken to resolve can then be considerable. Regular weekly checks help identify issues earlier and may be less time consuming in the long run	
NHS England	Full	32	18-19	There is no mention of posting prescriptions here which is routine practice for some GP practices and substance misuse services and sometimes results in missing prescriptions with either the patient or the pharmacy not receiving the forms.	Thank you for your comment. Following further discussion by the Committee, the recommendation is aimed at transporting controlled drugs. There is another recommendation that takes into account transporting prescriptions of controlled drugs in section 8.6 of the full guideline.
NHS England	Full	32	22-25	Reference could be made to the T28 exemption that is needed to enable denaturing of controlled drugs to take place.	Thank you for your comment. The linking evidence to recommendations (LETR) table captures the Committee discussions about the evidence presented. The T28 exemption was included as part of the discussion and can be found in section 8.5.
NHS England	Full	32	33	Only Schedule 2 controlled drugs need to be witnessed	Thank you for your comment. The relevant text about Schedule 2 controlled drugs needing to be witnessed has been amended to reflect your comment.
NHS England	Full	33	5-7	No advice here on what the pharmacy/dispenser should do if the custody staff say they do not have adequate arrangements	Thank you for your comment. The health professional would have to use their judgement depending on the circumstances and urgency of treatment. The health professional can provide advice on how to store the controlled drug safely.
NHS England	Full	33	18	Re CDs left over after administration- if they have been administered they are not left over. Could this be re-phrased to say 'remaining contents of a single dose unit' or similar	Thank you for your comment. The Committee agreed that the wording was appropriate and no change is needed. .
NHS England	Full	33	32-33	Consideration must be given to who is going to be in legal possession of the drugs They may	Thank you for your comment. The recommendation takes into account any requirements of the coroner to keep medicines in the

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				belong to a person's estate but other family members do not have legal possession under CD regs	person's home for a period of time.
NHS England	Full	33	36-38	Only schedule 2 CDs need to be witnessed	Thank you for your comment. The relevant text about controlled drugs in Schedule 2 has been amended to reflect your comment.
NHS England	Full	34	8-13	Whilst this is sensible and would be my preferred approach this is not the advice given previously by DH when we previously suggested such an approach: Waste medicines should not be discharged to foul sewer, so contaminated containers or their contents should not be rinsed out. Contaminated bottles, vials and ampoules should be disposed of as waste medicines. We were specifically advised that we could not advise people to rinse and dispose of the rinsing in the pharmaceutical waste despite the enormous cost and inconvenience the alternative caused. As such, this move is welcome.	Thank you for your comment. The recommendation was based on Committee consensus as there was no evidence or legislation around disposal of irretrievable amounts of liquid controlled drugs in large bottles. See section 8.5 of the full guideline for the rationale for the recommendation. The Environment Agency was also 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.
NHS England	Full	37	36	Please clarify the process for locum doctors who work privately, to obtain FP10PCDs (private CD prescriptions). There is variability around the country and loopholes. Should they register where they live or work? What about references?	Thank you for your comment. This is outside the scope of this guideline.
NHS England	Full	54	5-8	This section does not reflect the new arrangements coming into place from 30th November 2015	Thank you for your comment. The relevant text about the approved mandatory requisition form for ordering Schedule 2 and 3 controlled drugs being available has been amended reflect your comment.

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NHS England	Full	55	8-11	Community pharmacies do not need to use or submit requisition forms to NHSBSA for CD stock obtained	Thank you for your comment. The relevant text has been amended to make this clear to reflect your comment.
NHS England	Full	55	20	Review qu 6.2: it would be useful to include guidance for hospices for obtaining CDs. Some use private prescriptions and some use CD requisitions. In addition, it would make monitoring use using ePACT more robust.	Thank you for your comment. NICE develops recommendations for the NHS. The recommendations can be applied by non-NHS funded organisations.
NHS England	Full	61	31	Table 11 last paragraph- Schedule 5 CDs valid for 6m	Thank you for your comment. The relevant text has been amended to take into account the 6 month validity of prescriptions for controlled drugs in Schedule 5 to reflect your comment.
NHS England	Full	62		Record keeping- reference to HMRC guidance on keeping invoices- is it relevant to mix controlled drug regs with other regulations relating to tax. This document is about safe use and management 161of controlled drugs. CD regs states 2 years for Schedule 3 and 5	Thank you for your comment. The Committee highlighted that there was uncertainty on how long certain records relating to controlled drugs need to be kept for when there is no legislation. The recommendation you refer to was based on Committee consensus to provide organisations some guidance on record keeping of controlled drugs invoices and records of destruction unless legislation specifies otherwise. See section 6.5 of the full guideline for the rationale for the recommendation.
NHS England	Full	62		Supplying- no reference to the legal requirement around healthcare professionals acting in their professional capacity on behalf of the patient and collecting their CDs. Unless or ready known to the pharmacist the pharmacist must obtain name and address of healthcare professional, request evidence of identity and decide whether to supply if evidence not available	Thank you for your comment. This should be considered as part of the organisations standard operating procedure for transporting controlled drugs.
NHS England	Full	64	10-13	As before, legislation (CD) requires invoices to	Thank you for your comment. The Committee highlighted that there

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				be kept for 2 years for schedule 3 and 5. HMRC requirements should have no place in a clinical document	was uncertainty on how long certain records relating to controlled drugs need to be kept for when there is no legislation. The recommendation you refer to was based on Committee consensus to provide organisations some guidance on record keeping of controlled drugs invoices and records of destruction unless legislation specifies otherwise. See section 6.5 of the full guideline for the rationale for the recommendation.
NHS England	Full	82	Table 17	Destroying and disposing. As before, only Schedule 2 needs to be witnessed	Thank you for your comment. The relevant text about only Schedule 2 controlled drugs need to be witnessed for destruction has been amended to reflect your comment.
NHS England	Full	87	Table 19	Storage and possession. Schedule 3 CDs are subject to safe custody unless exempted –eg temazepam, buprenorphine require safe custody	Thank you for your comment. The relevant text about safe custody applying to controlled drugs in Schedule 3 with some controlled drugs being exempt from this requirement has been added to reflect your comment.
NHS England	Full	94	Table 19	Disposal of patient's controlled drugs: Re the comment about the prescriber (or supplier) ideally being responsible for removal of drugs to be 166disposed, please note that removal of 'excess' drugs after death was Dr Shipman's favourite way of obtaining his CD supplies. Because of this it is common practice for the patient's representative to arrange for the disposal with healthcare professionals only getting involved where there is an urgent safety risk or risk of diversion by household members.	Thank you for your comment. For reasons specified in your comment, there were discussions by the Committee that agreed 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.
NHS England	Full	95	Table 19	Not removing CDs for 7 days in case of coroner's investigation- same comments apply as before around legal possession. In addition,	Thank you for your comment. The text about not removing controlled drugs for 7 days after a person has died at home in section 8.5 has been amended to take into account the

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				where does this requirement come from?	requirements of the coroner. The coroner's requirements may depend on the local processes and resources.
NHS England	full	97		Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs. Consider including having a SOP for the prescribing of CDs.	Thank you for your comment. Section 9.6 has the recommendation for ' designated bodies putting 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.
NHS England	Full	98	38-39	Only schedule 2 need witnessed destruction	Thank you for your comment. The relevant text about controlled drugs in Schedule 2 only needing to be witnessed for destruction has been amended and made clear to reflect your comment.
NHS England	Full	102	6	We are concerned about the variability of the role of the Police CD Liaison Officers	Thank you for your comment. The guideline has been reviewed by a police controlled drugs liaison officer who was invited to be an expert reviewer.
NHS England	Full	100	3-10	Records only needed for schedule 2	Thank you for your comment. The relevant text about records only being required for controlled drugs in Schedule 2 has been amended to reflect your comment.
NHS England	Full	109	Table 21	Attendance at LIN meetings- there is NO legal requirement to attend a LIN meeting. Only the LIN is defined by legislation. Legislation does not define how the LIN operates as such- i.e. it is a network not a meeting. A member can be an active participant in a LIN but never attend. Conversely, someone could attend every meeting but not participate in discussion or share information effectively.	Thank you for your comment. The text about attendance has been removed and the section has been amended following further discussion by the Committee to reflect your comment. T
NHS England	Full	110		Engagement with attendance- as before, it is engagement with the LIN as a network that is	Thank you for your comment. This section has been reworded following further discussion by the Committee to reflect your

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				important rather than just attendance at a meeting. Unsure about reporting poor engagement to CQC. This has been discussed at length at previous LIN meetings and we need to understand what CQC is going to do with the information. Recent issues seen whereby CCGs have taken contractual action against organisation that have submitted occurrence reports to the LIN.	comment. The text about attendance and reporting poor engagement to CQC has been removed.
NHS England	Full	110		Reporting concerns or incidents- the regulations only specify that concerns are reported which is one of the reasons for variation in reporting. Some organisations report all incidents where as others only report a few issues where these are seen as a concern. This is where additional guidance would be useful for CDAOs	Thank you for your comment. The Committee found from discussions 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 developed a recommendation that takes into account reporting concerns and incidents.
NHS England	Full	112	38-39	As before, no one is legally required to attend a CD LIN meeting- what they must do is submit occurrence reports if requested, and co-operate with other members	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The text about notifying CQC of poor engagement by organisations that are legally required to attend CD LIN has been removed.
NHS England	full	97		Develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs. Consider including having a SOP for the prescribing of CDs.	Thank you for your comment. Section 9.6 has the recommendation for ' designated bodies putting 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.
NHS England	Short	14	17	Destruction – there is no mention of the role of	Thank you for your comment. The recommendation you refer to has

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				authorised witnesses in community pharmacy and GP practices. We are concerned about national variability and the cost implications for NHS England versus the risks involved when an authorised witness is not involved.	been amended to make it clear that the requirements for an authorised witness to be present for the destruction of controlled drugs in Schedule 2 and those in Schedule 3 and 4 are different. The recommendation has been kept high level to cover all care settings and this would include community pharmacies and GP practices.
NHS England	Short	6	2	This recommendation may be a challenging change because in practice there are instances when a consultant recommends prescribing for a longer period such as 3 months when they will see the patient again. Therefore they will prescribe for 3 months at a time if the GP involved will not participate in shared care of the patient. This is common in ADHD prescribing. It sounds as if this is still permitted as long as documented – is that correct?	Thank you for your comment. The Committee was aware that more than 30 day supply of controlled drugs may be necessary in some circumstances and that it would be considered good practice to document the reasons for this in the person's care record. See section 5.5 for the rationale for the recommendation.
NHS England	Short	7	27	A requisition is mandatory from November 30th, therefore line 27 should read MUST (rather than should)	Thank you for your comment. This had been amended to 'must' in the recommendation.
NHS England	Short	4	13	"…assessed as competent…"; who does this?	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
NHS England	Short	5	28	"Take into account any existing supplies the person has of 'when required' controlled drugs	Thank you for your comment. Following further discussion by the Committee, the wording was agreed to be appropriate and no

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				or other 'when required' analgesia.	change was made.
NHS England	Short	6	17	"Use a ***recognized*** **opioid**..."	Thank you for your comment. Following further discussion by the Committee, the wording was agreed to be appropriate and no change was made.
NHS England	Short	7	26	"…signed by a doctor**, *dentist or other health professional permitted in the Regulations***…"	Thank you for your comment. Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001.
NHS England	Short	12	18	"…each premise***s***"	Thank you for your comment. The relevant text has been amended to 'premises' to reflect your comment.
NHS England	Short	13	8	"self-adminstration ***and/***or self-possession"	Thank you for your comment. Following further discussion by the Committee, the wording was agreed to be appropriate and no change was made.
NHS England	Short	13	20	– Is stating "weekly" too prescriptive? Surely the frequency of stock checks is for the organisation to determine?	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.
NHS England	Short	1	Text box	– "…Recording information about ***the safe***	Thank you for your comment. Following further discussion by the

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				management and use of *controlled drugs…"*	Committee, the wording was agreed to be appropriate and no change was made.no change was made.
NHS England			1.1.2	When making decisions about prescribing controlled drugs: the list doesn't mention the risk of dependence to the CD. This is an important consideration when initiating opioids in a person who has a history of or is undergoing current treatment for substance misuse.	Thank you for your comment. Following further discussion by the Committee, the relevant wording about dependence to controlled drugs has been added to reflect your comment.
NHS England			1.1.4	Document and give clear instructions to the person taking or 14 administering the drug: The listed points don't mention the need to advise the patient about the risk of drowsiness that may impair driving and other tasks. I acknowledge this will be printed on the pharmacy/medicines label, but given there is now legislation about driving and the influence of medicines, I feel this should be included here.	Thank you for your comment. Following further discussion by the Committee, the relevant wording about the risk of drowsiness has been added to reflect your comment. A link to the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals has also been added.
NHS England			1.1.9	The use of a locally agreed opioid conversion table is reasonable, but this needs to be appropriate for the clinical setting. Secondary care led tables are complex and simpler versions are more suitable for primary care practitioners where the range of medicines used is smaller. Adding a phrase about the need for a conversion table that is suitable for the clinical environment in which the opioids are being prescribed would be helpful.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides and clinical settings that may be used when prescribing, reviewing or changing opioid prescriptions.
NHS England			1.1.10	The previous NPC CD 2009 guidance stated "It	Thank you for your comment. The Committee found from

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				is clear under the current legislation that repeat prescribing of CDs in Schedule 2 and 3 is not permitted. However, management systems which allow the patient to receive a prescription (hand signed by a practitioner) without a consultation is not subject to legislation, but is a clinical decision made on a case by case basis. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 CDs." The recommendation in NICE seems to imply that this legislation has changed and gives watered down advice. Given the known risk of addiction to opioids, this is a concern. Please can the GDG consider reviewing this to strengthen the need for careful clinical consideration if schedule 2 and 3 CDs are supplied on repeat prescriptions.	discussions 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 found from discussion 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.
NHS England			1.1.11	I do not believe prescribers will do this. More beneficial and practical for the dispensing pharmacist or supplying nurse (e.g. in community services and hospitals) to advise the patient about disposal arrangements.	Thank you for your comment. Section 5.5 of the guideline provides the rationale behind the recommendation. The Committee was aware that in many cases the health professional who supplies the controlled drug will advise people who are taking controlled drugs how to dispose of them safely, however, given the risks associated with controlled drugs, the Committee agreed that prescribers also have a responsibility to provide this advice to the person to prevent unauthorised access to unwanted controlled drugs.
NHS England			1.1.30	The recommendation also needs to include the	Thank you for your comment. The recommendation applies to all

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				standards set by the service commissioner as well as the regulator. This is because in specific services (such as supervised consumption of substance misuse medicines) additional requirements to support safe supervision are written into service specifications.	settings. While some settings or services may have a service specification, some settings or services may not. Following further discussion by the Committee, they agreed that this would depend on the setting or service and agreed to only include the professional regulator to take into account all settings.
NHS England			1.1.35	This recommendation deals with devices for continuous administration- there is an additional recommendation needed about training and competence in the use of **automated CD dispensing devices** used for liquid CDs such as methadone.	Thank you for your comment. Automated controlled drug dispensing devices was not discussed by the Committee as part of the review question looking at administration as these are not used to administer controlled drugs to a person. Areas related to training of health professionals was out of scope for the guideline and so a recommendation was not developed by the Committee.
NHS England			1.1.71	Please can providers for secure environments be explicitly included here. We have issues with engagement by CDAOs and providers with CD LINs and local oversight which this recommendation could help improve.	Thank you for your comment. The relevant text about secure environments has been added to reflect your comment.
NHS Protect	Full	63	19	We would suggest adding the word legible to the printed name e.g. printed name (legible) to aid later auditing or investigations where it may be necessary. We would also suggest that it states that the person ordering CDs is not the same person collecting or receiving CDs to promote transparency and reduce opportunities for diversion.	Thank you for your comment. Following further discussion by the Committee, no amendment was made to the recommendation as the term 'printed' would imply writing clearly without joining letters together. The Committee agreed that additional criteria can be added depending on the care setting.
NHS Protect	Full	63	6	Where organisations are obtaining their Schedule 2 and 3 CD stocks from an external	Thank you for your comment. The recommendation has been amended to a 'must' instead of 'should' following consultation.

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				pharmacy, the arrangement should be set out in a Standard Operating Procedure or Service Level Agreement between the two organisations. Suggest a line is added advising of this.	Following further discussion by the Committee, they agreed that legislation requires doctors or dentist to sign the requisition for stock controlled drugs and the organisation and external pharmacy supplying the controlled drugs need to ensure they are working within the legal framework.
NHS Protect	Full	64	40	We are concerned that this advice for professionals to 'use their professional judgement' is vague and may be open to interpretation, resulting in different levels of checks being carried out. Suggest rewording to: When supplying controlled drugs to a person or their representative professionals must take reasonable steps to confirm the identity of a representative before providing them with controlled drugs. A list of acceptable proof of identification documents is available from **https://www.gov.uk/government/publications/proof-of-identity-checklist/proof-of-identity-checklist**. Where identity cannot be confirmed no controlled drugs should be supplied.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. In addition, the list of acceptable proof of identification documents has been added to the linking evidence to recommendations table in the full guideline
NHS Protect	Full	79	General	This section looks at administration but does not address the issue of how the excess from a partial CD dose, is managed in terms of documentation, how it is discarded safely or whether it is witnessed. This is an area where	Thank you for your comment. Excess from partial controlled drugs dose after administration is covered in section 8.5 of the guideline under 'Disposal of remaining small amounts of controlled drugs after administration'. There is also a recommendation in this section that covers your point.

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				there is a history of abuse and there are documented cases where health professionals have used this for a recreational high leading to death in some cases. Unfortunately the varying practices and the ambiguity of how this is dealt with in practice remains an issue of concern.	
NHS Protect	Full	80	25	This may be addressed elsewhere in the document but as it is in the section on administration, where it makes reference to the setting up of devices, it should advise that consideration is given at an early planning stage about how CDs are managed when it is no longer needed such as if the patient is admitted to hospital, dies or it is no longer required. This particularly applies to when the patient is being nursed at home.	Thank you for your comment. Section 5.5 discusses anticipatory prescribing and a recommendation has been developed to follow local processes for reviewing anticipatory prescribing of controlled drugs and to 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.
NHS Protect	Full	97	8	Where reference is made to storage it should highlight that the storage needs to be secure. In our work with NHS trusts we continue to find issues around access to CD storage or the security of the storage itself. Although the opening paragraph makes the link about storage being in line with regulations, storage and the control of access is still an issue and therefore a direct reference should be made such as secure storage or securely storing.	Thank you for your comment. Following further discussion by the Committee, no amendment was made to the recommendation as it refers to standard operating procedures which would include in the procedure how to ensure secure storage.
NHS Protect	Full	97	12 & 23	The list doesn't reflect the use of existing data on reported incidents, where an actual theft or	Thank you for your comment. Following further discussion by the Committee, the recommendation now includes 'any data

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				unexplained loss may have occurred. Many organisations identify issues with particular CDs through monitoring/audit which can highlight unexplained irregular patterns of prescribing, requisitioning and use which can then provide direction and evidence to look into further. We have found that for different NHS organisations the CD being targeted varies. Added to the list should be - reported incidents involving CDs - an irregular pattern of requisitioning, prescribing and/or use of lower schedule CDs or a particular CD - if the environment where the CDs are stored is not staffed or overlooked - level of staff access - whether there is a high level of access to where the CDs are stored by unauthorised staff/public/patients - large quantities CDs being stored - unexplained discrepancies or losses.	from relevant reported incidents' to reflect your comment. Additional criteria to add could be determined locally.
NHS Protect	Full	97	23-32	Reference to storage should include secure storage of controlled drugs. The word secure or security doesn't just refer to a locked CD	Thank you for your comment. The term 'secure' has been added to the glossary section in the guideline to reflect your comment.

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				cupboard for schedule 2 CDs, it can also refer to the environment in which the cupboard or other lower schedule CDs are placed whether it is access controlled, has good key control and management, monitoring of who has access, has CCTV or has good natural surveillance from staff working in or overlooking the area. It is also necessary to remind people of this to encourage certain behaviours and an adherence to processes and procedures. Suggest adding means of access, lockable medicine storage systems that allows for key control/management.	
NHS Protect	Full	98	8-17	Need to include - Process in place for staff when unaccounted for losses/discrepancies are identified during the stock check, who they are escalated to - Independent audits of stock checks - Processes for when there is a short or long term closure of a ward/area/station hub with CD stock	Thank you for your comment. The recommendation you refer to aims to cover procedure used to check controlled drugs stock. The points you refer to may vary locally depending on the setting and resources available. This would need to be determined locally.
NHS Protect	Full	98	20	The first bullet is missing the word secure as CDs in transit are vulnerable and need to be securely stored, the second bullet is too vague and doesn't actually apply to this and integrity of	Thank you for your comment. The term 'secure' has not been added to the first bullet point as the second bullet point in the recommendation covers security. The Committee developed recommendations based on key principles of the process that could

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				the supply process is too vague and open to interpretation. There is also no mention of risk assessment. The risks associated to the transport of CDs are dependent on numerous factors and can include the local environment, local crime risks, distance to different delivery points etc. Suggest rewording to - Secure lockable storage while in transit - Security arrangements for staff and vehicles - Vehicles used for transport not bearing any physical indication they contain CDs - Record keeping…. - Actions if the CD order cannot be delivered - Identity checks of individuals CD order is handed over to e.g. wearing uniform, photographic ID - Audit of measures and procedures in place to ensure compliance - Risk assessment	be relevant to all settings. The detailed particulars may vary depending on the care setting and would need to be determined locally.
NHS Protect	Full	98	21	This could be dealt with as a separate issue, as it refers to staff who carry CDs on their person associated with their role such as paramedic. The security considerations for the person is to carry it out of sight, ideally stored in a pouch or belt to prevent breakages. For ambulances it should be in the organisation's approved vehicle in a secure lockable safe that is fixed to the	Thank you for your comment. The Committee developed recommendations based on key principles of the process that could be relevant to all settings. The detailed particulars may vary depending on the care setting and the health professional and their transport arrangements and would need to be determined locally.

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				vehicle.	
NHS Protect	Full	98	25-28	If a commercial courier is used, a signature alone is not sufficient, suggest adding that staff handing over the CDs should document information such as the vehicle registration, valid company ID or check that the courier is from the organisation's approved courier service and is wearing ID/uniform etc., before the CDs are handed over for delivery.	Thank you for your comment. The Committee developed recommendations based on key principles of the process that could be relevant to all settings. The particulars you refer to are all valid points and can be applicable to some care settings for example a retail pharmacy, however may be difficult to implement in others such as emergency care.
NHS Protect	Full	98	32-34	Unwanted, expired and returned CDs identified for disposal are at risk of theft and abuse. We have seen investigations at Trusts where poor record keeping of CDs returned for disposal were being abused by members of staff. Reference needs to be made to these CDs being securely stored. I would also add the management or documentation of CD stock for disposal as often the volumes can build up and if this isn't managed there is no way of knowing what's missing.	Thank you for your comment. The guideline has an overarching recommendation for organisations to develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing of controlled drugs. There is also another recommendation that takes into account storage requirements of controlled drugs in more detail in section 8.6. The term 'including or expired' has been added to the recommendation about storage to reflect your comment.
NHS Protect	Full	99	4-6	I made an earlier comment which concerned syringe pumps. Ideally this should be in a SOP for community staff and include points on record keeping and arrangements to have the CDs removed as soon as possible. A risk assessment would identify if there are any individuals within the home who may be at risk from CDs remaining in the home. This has been	Thank you for your comment. The Committee developed recommendations based on key principles of the intervention for all controlled drugs in a patient's home rather than specific administration devices. Recommendation in section 6.6 covers advising people how to safely dispose controlled drugs.

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				an issue before.	
NHS Protect	Full	99	31-38	This should be in a SOP for staff and include points on risk assessment to identify if there are any individuals within the home who may be at risk from CDs remaining in the home.	Thank you for your comment. Risk assessments may not be practical in every situation when a health professional is providing care out of hours or in an emergency. This would need to be determined by the health professional and their judgement as it would be difficult to define what this risk assessment would like.
NHS Protect	Full	100	9&10	Add printed and legible to signatures.	Thank you for your comment. This wording is consistent with Regulation 27(3) and so no change was made to be in line with the wording in the legislation.
NHS Protect	Full	112	15-17	Suggest adding that concerns can include items that provide access to CDs such as lost/stolen/missing CD keys, prescription forms/CD stationery. There also isn't any mention of addressing concerns about individuals, in terms of having a SOP of how to escalate concerns and to whom. In relation to this would be the appropriate pre-employment and ongoing professional registration checks that adhere to the NHS Employment Check standards, this would apply to employed, locum, agency, contract and bank staff.	Thank you for your comment. The recommendation aims to be concise and not an exhaustive list of examples of concerns, as these have been captured in section 9.5. There is a recommendation that covers having a robust system in place for raising and reporting concerns or incidents in section 9.6. This recommendation covers all types of concerns including with individuals. Checking employment status is not covered within the scope of the guideline.
NHS Protect	Short	Recommendation 1.1.68		NHS Protect has developed a medicine security self-assessment tool which was designed for use by providers of hospital based pharmacy services in the acute, mental health and	Thank you for your comment. You can submit your medicine security self-assessment tool to NICE for it to be considered for the endorsement programme.

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				community settings, the tool focuses on the security and governance arrangements of all medicines within the organisation. The tool has been developed by NHS Protect with the support of the Chief Pharmaceutical Officer at the Department of Health and in consultation with the Care Quality Commission, Royal Pharmaceutical Society, pharmacy leads and security specialists at NHS organisations. http://www.nhsbsa.nhs.uk/4430.aspx	
NHS Sheffield CCG	Short	1	Box	Does not make any specific reference to applicability to hospitals or secondary care	Thank you for your comment. The relevant text has been added to reflect your comment.
NHS Sheffield CCG	Short	6	24 -27	!.1.11 This would be better done by dispenser not prescriber – as per 1.1.26	Thank you for your comment. The recommendation your comment is referring to is for prescribers. Health professionals such as dispensers or pharmacists also should provide advice on how to dispose controlled drugs as in 1.1.26.
NHS Sheffield CCG	Short	7	25	This also needs to refer to the use of controlled stationery	Thank you for your comment. The recommendation your comment refers to is specifically about requisitions and who can sign them. The Security of prescription forms guidance produced by NHS Protect is available and hyperlinked in the guideline that can be used as an aid in helping to develop and implement local procedures and systems for the promotion of security of prescription forms.
NHS Sheffield CCG	Short	9	18	1.1.24 replicates 1.1.4 – may there be occasions when different advice is given. How would this be managed?	Thank you for your comment. Recommendation 1.1.4 is about providing the advice when prescribing the controlled drug to the person taking the controlled drug or the carer administering it. Recommendation 1.1.24 is about providing advice when supplying the controlled drug. The health professional would need to identify

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					what information has already been given to the person or the carer. .
NHS Sheffield CCG	Short	9	24	This is not applicable in all scenarios. E.g. hospital pharmacies routinely sign CDs at the point of dispensing not on collection by the ward. Similarly in community pharmacies where running balance checks are used to ensure dispensing accuracy prior to collection or delivery.	Thank you for your comment. Following further discussion by the Committee, they agreed that the recommendation is for health professionals in primary care and the recommendation has been reworded to reflect this.
NHS Sheffield CCG	Short	10	21	Not all persons administering controlled drugs will be subject to professional regulation. This guidance would benefit from a definition of the term 'Health Professional' which is used widely in the document	Thank you for your comment. Section 1.4 in the guideline provides a definition for 'health and social care practitioners' that is used to define the wider care team, including but not limited to, home care workers, personal assistants, case managers, care coordinators, social workers, doctors, pharmacists, dentists and nurses. When specific recommendations are made for a particular professional or practitioner group, this is specified in the recommendation. The recommendation you refer to is aimed at health professionals ad indicated by the subheading the recommendation is under.
NHS Sheffield CCG	Short	10	26	To what does the term 'other formulations' refer?	Thank you for your comment. 'other formulations' include liquids, patches, parenteral or tablets. For example if a parenteral dose of morphine had been prescribed, then the person administering the dose should check if the patient has had an oral dose of the same drug prescribed to avoid overdose of the drug in question.
NHS Sheffield CCG	Short	11	6	Is it necessary for the name of the person to be recorded in their own record?	Thank you for your comment. This is in line with the Department of Health guidance Safer management of controlled drugs and the Committee agreed that this information could be adapted and used in other care settings as well as in secondary care as good practice.
NHS Sheffield	Short	11	11-13	The guidance needs to take into account the	Thank you for your comment. This would need to be part of a

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CCG				records that need to be kept in any electronic system, e.g. where the administering person can be identified through their log-on.	standard operating procedure where the use of electronic systems would need to be taken into account as part of the process and other governance arrangements.
NHS Sheffield CCG	Short	11	14	This needs to be rewritten as "Ensure the record is kept with the person to ensure continuity of care and to prevent:…" since recording the administration of the CD is covered in 1.1.32	Thank you for your comment. This wording has been amended to make the recommendation clear that it refers to making the records accessible following further discussion by the Committee.
NHS Sheffield CCG	Short	11	19	Who is to provide this advice and to whom. Query - should this sit within the dispensing section	Thank you for your comment. The advice is to be provided by the health professional to the person who will be administering the controlled drug who may be the person self-administering or a carer who will be administering the controlled drug.
NHS Sheffield CCG	Short	11	26	Should this sit within the prescribing section?	Thank you for your comment. The structure and order of the recommendations in the short version of the guideline has been amended to reflect your comment.
NHS Sheffield CCG	Short	12	4	This should specify "Provider" organisations.	Thank you for your comment. Section 1.3 in the guideline defines the term 'organisation' in the guideline. The term 'organisations' is used to include all commissioners and providers, unless specified otherwise in the text. The structure and order of the recommendations in the short version of the guideline has been amended to reflect your comment.
NHS Sheffield CCG	Short	13	20	1.1.42 – weekly stock checks of doctors bags is not considered feasible in primary care	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee about the feasibility of carrying out stock checks with a minimum frequency of once a week. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations

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					stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.
NHS Sheffield CCG	Short	15	10	How could this be done?	Thank you for your comment. The health professional can ask the police officer about the arrangements that they have to ensure safe storage of controlled drugs and advise on how they should be stored safely.
NHS Sheffield CCG	Short	23	15	Should this sit within the administration section?	Thank you for your comment. The section your comment refers to is the glossary section. Each section in the guideline does not have a separate glossary section for the term to be added to the relevant section. The term your comments relates to has been kept in the final glossary section.
NHS Sheffield CCG	Short	General	General	The numbering system used does not enable easy navigation of the document. As indicated in comments above, some of the recommendations appear to be in the wrong section, which makes it confusing.	Thank you for your comment. The structure and order of the recommendations in the short and full version of the guideline has been amended to reflect your comment.
NHS Tees, Esk and Wear Valleys Foundation Trust	Short	7	1.1.15	External pharmacy and associated description is not clear whether this includes a contracted pharmacy. Our organisation is supplied by a contracted onsite pharmacy run by an external company. Is there a reason why the orders couldn't be signed by an independent prescriber from any profession including pharmacy?	Thank you for your comment. The guideline has a glossary section that covers the definition you are referring to. Regulation 14(5)(a) of the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015 specifically requires a requisition "where furnished by the person in charge or acting person in charge of a hospital, organisation providing ambulance services or care home, be signed by a doctor or dentist employed or engaged in that hospital, organisation or care home" when the requisition is furnished for the purposes as set out in Regulation 14(2) of the Misuse of Drugs Regulations 2001.
Norfolk and	Short	Gener	General	The guidance looks like a very useful practical	Thank you for your comment.

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Suffolk NHS Foundation Trust		al		summary of controlled drug legislation and how it can be applied in different healthcare settings	
Norfolk and Suffolk NHS Foundation Trust	Short	14	2	This recommendation will be a challenging change in practice because of the large geographical area of a mental health trust and when CDs are required outside of normal working hours and supplied by the on call pharmacy service delivery services are not available	Thank you for your comment.. The Committee agreed that the recommendation should be reworded to reflect that where delivery services are used then, organisations should ensure governance arrangements and processes are in place to ensure that this happens safely and securely.
Norfolk and Suffolk NHS Foundation Trust	Short	13	17	The guidance could be a bit clearer on whether the liquid stock check is by visual inspection and reconciling when a bottle is finished or measuring at each stock check which if at each shift change will result in losses each time it is measured	Thank you for your comment. The Committee discussed that some health professionals check liquid volumes by visual inspection to avoid loss, although this is not accurate. The Committee also discussed the frequency of stock balance checks particularly for liquids, and was aware that frequent checking of liquids would result in losses. The Committee therefore agreed that reconciliation of liquid stock when finishing a bottle would avoid loss as this would be checked only when the remaining amount in the bottle is finished. This has been outlined in the recommendation.
Norfolk and Suffolk NHS Foundation Trust	Short	13	20	In mental health we don't use many CDs so are able to check daily and often at each shift change where risk assessed as required. We have a CD stock check booklet we would be willing to share	Thank you for your comment. You can submit your example on the NICE website.
Norfolk Medicines Support Service	Short	General	General	Question 1: The front pages makes reference to this document applying to Social Care practitioners e.g. home care workers, however, throughout the remainder of the document, it is	Thank you for your comment. The sections with the recommendations have a subheading that states who the recommendation is aimed at for example organisations, health and social care practitioners or health professionals. Overall the

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				unclear whether the recommendations apply to home care or domiciliary home care workers. This sector would not have access to secure storage of medication, or access to witness for administration.	guideline applies to everybody who use or manage controlled drugs in their organisation or professional practice.
Norfolk Medicines Support Service	Short	12-14	P12, line 14 to p14 line 16	Question 2: Unclear if these recommendations apply to home care. The majority of these recommendations would be unworkable in this sector, due to working within a person's own home and working alone.	Thank you for your comment. Controlled drugs once dispensed to a person, becomes the person's property and so they should be advised on safe storage at home. The recommendations on the pages you refer to are all aimed at organisations which have been included as a subheading to make this clear. The short guideline has been restructured to make this clearer.
Norfolk Medicines Support Service	Short	General	General	Comment 1: Our local authority would not commission a double-up call for home care for witnessing of controlled drugs administration due to the additional costs involved.	Thank you for your comment. The recommendation you comment refers to specifies in the bullet list 'name and signature or initials of any witness to administration', the term 'any' in the sentence indicates that where there are 2 health professionals, then this would be considered as good practice. The Committee w\as 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.
Norfolk Medicines Support Service	Short	General	General	Question 3: Unclear how this might affect continuing health care provision if looking after a person in their own home – is storage, recording, counting etc. required?	Thank you for your comment. Once controlled drugs have been issued to a person for treatment it becomes their property and so there is no legislation on how they should be stored or recorded by the person. Organisations providing continuing health care should have standard operating procedures in place to ensure health and social care practitioners provide advice and information to people taking controlled drugs on how to store them securely and to

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					dispose them safely.
Norfolk Medicines Support Service	Short	13	12	Comment 2: It is felt that a weekly stock check would be achievable in home care, although practically this would need to be for all medication, as workers may not have access to the latest list of controlled drugs. It is also felt that in this setting, highlighting which medicines are controlled drugs, and handling these differently, may actually highlight that these medications may be valuable and actually encourage diversion in some cases.	Thank you for your comment. The recommendation your comment refers to is aimed at health professionals who work in organisations where controlled drugs are kept as stock and an entry in the controlled drugs register is required to record receipt and supply. The recommendation does not include checking controlled drugs in a person home as they are not classed as 'stock' and would not be required to have a controlled drugs register. Checking controlled drugs in people's own home where a home care service is provided would be down to local determination and the persons circumstances, for example if history of previous abuse or risk of diversion. A standard operating procedure for this could be determined locally.
North Bristol NHS Trust				**1.1.25 when dispensing CDs in Schedule 2 in advance of collection.** As our electronic CD register is linked to the Pharmacy system, we would no longer be able to dispense Schedule 2 CDs for Out-Patients in advance. They could only be dispensed if the patient was waiting – this will delay patient supply processes	Thank you for your comment. Patient supply process would not be delayed if records of the controlled drug supply are written up once the controlled drugs have been handed to the patient.
North Bristol NHS Trust				**1.26 When supplying CDs, advise people how to safely dispose of unwanted CDs and used CDs.** **1.53 Provide advice and information to people who are prescribed CDs about how to store CDs safely. Discuss storage options.** **1.1.54 Assess if a person's method of storing**	Thank you for your comment. Patient information leaflets are produced by the manufacturer of the medicines and do not fall within the remit of NICE. To help with implementation we ask stakeholders to share examples of good practice on the NICE website and/or if any tools have been developed by organisations to help with the implementation of the guideline and they can be considered for the endorsement programme.

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				their CDs in their home could lead to an increased risk of CD related incidents, including patient safety incidents. All of these could be easily implemented nationally by NICE producing a generic patient information leaflet which provides advice to the patient on how to dispose and store CDs safely which could be used in all organisations.	
North Bristol NHS Trust				**1.1.47 Arrangements for witnessing the disposal of stock CDs in Schedule 2, 3 and 4 must be in place.** The Medicines, Ethics and Practice (MEP), the professional guide for pharmacists, Edition 39 July 2015 (p.108) states; Is an authorised witness required? For expired/obsolete/unwanted stock -Yes, if Schedule 2. For Schedule 3 medicines it would be good practice to have another member of staff witness the denaturing. (NB: If a pharmacy is engaged in manufacturing, compounding, importing or exporting Schedule 3 or 4 Controlled Drugs then record keeping arrangements apply. Therefore, destruction of these requires an authorised witness.) Currently our trust follows the MEP guidance and so have arrangements in place for witnessing the disposal of stock CDs in	Thank you for your comment. The recommendation has changed and reworded to take into account that the witnesses arrangements differ for controlled drugs in Schedule 2 and those in Schedule 3 and 4 following further discussion by the Committee to reflect your comment. The Committee agreed to develop 2 separate recommendations to take into account the different destruction and disposal requirements for Schedule 2, 3 and 4 controlled drugs.

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				Schedule 2 and 3. As we are not engaged in manufacturing, compounding, importing or exporting Schedule 3 or 4 Controlled Drugs we see no reason why this extra burden needs to be imposed.	
North Bristol NHS Trust				***1.1.57 when destroying and disposing of stock CDs in Schedule 2, 3 and 4 Part 1, and health care professionals must record…….*** The Medicines, Ethics and Practice (MEP), the professional guide for pharmacists, Edition 39 July 2015 (p.108) states; Record keeping -an entry should be made in the CD register for Schedule 2 CDs. (NB: If a pharmacy is engaged in manufacturing, compounding, importing or exporting Schedule 3 or 4 Controlled Drugs then record keeping arrangements apply. Therefore, destruction of these requires an authorised witness.) Currently our trust follows the MEP guidance and so have arrangements in place for recording the disposal of stock CDs in Schedule 2. As we are not engaged in manufacturing, compounding, importing or exporting Schedule 3 or 4 Controlled Drugs we see no reason why this extra burden needs to be imposed.	Thank you for your comment. The recommendation has changed and reworded to take into account that the witnesses arrangements differ for controlled drugs in Schedule 2 and those in Schedule 3 and 4 following further discussion by the Committee to reflect your comment. The Committee agreed to develop 2 separate recommendations to take into account the different records requirements for Schedule 2, 3 and 4 controlled drugs.
North Bristol NHS Trust				**For recommendation 1.1.42 Recording stock checks in the CD register along with the date and signature of the health professional**	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment about records being made in the controlled drugs

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				carrying out the check. Our trust has had experience implementing this approach. The majority of our wards/departments that hold CDs are stock checked once a day by two suitably trained staff. Other areas that have been risk assessed are checked less frequently (but with a minimum frequency of once a week). For wards, a record of the stock check is made in a designated check book (not the CD register) and signed and dated by two suitably trained staff. We are concerned that this recommendation may imply that these records can only be made in the CD register. We have developed a SOP for the recording of stock checks and would be willing to share this information with NICE as an example of best practice.	register. Organisations can share examples of good practice on the NICE website and/or if any tools have been developed by organisations to help with the implementation of the guideline they can be considered for the endorsement programme.
North Bristol NHS Trust				**For recommendation 1.1.68 Consider developing standard operating procedures for audits of controlled drugs registers and cabinets.** Our trust has had experience implementing this approach. All areas that hold CDs are audited every 3 months by a Pharmacist. This audit includes a storage review as well as a stock balance check. We have developed a SOP for this and would be willing to share this information with NICE as an example of best	Thank you for your comment. You can submit your audit example on the NICE website. The status of automated cabinets was not covered by the review question as it was not considered a priority during the scoping phase of the guideline.

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				practice As a concern we would raise the status of automated cabinets – the security of these devices is in question – especially research from the USA identifying Infosec (information security) issues (REPORT http://www.bloomberg.com/features/2015-hospital-hack/) especially around "jackpotting" cd's out of such devices using hard coded passwords and system vulnerabilities	
North of England Commissioning support unit	Full	92	General	Regarding deliveries of CD's from pharmacy to patients at home. We have dealt with a number of incidents of losses whilst the CD's were with a driver for delivery. This is an excellent opportunity to issue detailed guidance as there is little or no official guidance out there at the minute. Consider providing greater guidance than currently included, e.g. an example of an auditable delivery system, for example: •A register should be kept in pharmacy 'CD Delivery Book' This should show details of the CD being delivered (extra printed label). •The delivery driver should check the CD's being received by him/her then sign time/date to show receipt.	Thank you for your comment. The list is not exhaustive but includes the minimum dataset as agreed by the Committee. Additional information may be needed depending on the health or social care setting, but this would be for the health or social care organisation to determine.

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				•There should be an extra signature space provided for the possible return of undelivered CD's. (return signed timed /dated by the responsible pharmacist) •A number of deliveries for that day could be shown on one page. •Removing the prescription from the pharmacy for the purpose of delivery should be avoided. •The delivery driver should carry a 'CD delivery sheet' again multiple deliveries could be shown on one page or a single page for individual patients. •A printed label showing the CD's could be appended to the sheet identifying what is to be delivered. The patient/representative should be asked to check the medication and sign time/date the receipt. •The driver should where possible prioritise the delivery of CD's and consideration should be given to security whilst delivering. Remain vigilant, consider the location the delivery vehicle is parked during deliveries and do not leave medication on show in the vehicle. These suggestions are not too onerous it is clear that they will allow for a robust system which is auditable in the unlikely event of problems arising.	

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North of England Commissioning support unit	Full	26	14	"Assessed as competent" needs clarification, as there is an implication that the undergraduate qualification from Universities which allows professional registration, and so allows practitioners to legally prescribe is not suitable for the task of competency?	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
North of England Commissioning Support Unit	Full	27	10	"no more than 30 days" presumably applies only to primary care, as most hospital prescriptions will be for no more than 7 or 14 days.	Thank you for your comment. Following further discussion by the Committee, they agreed that 'no more than 30 days' in the recommendation takes into account prescribing for a shorter duration, therefore no amendment was made to the recommendation.
North of England Commissioning Support Unit	Full	27	25	Tighten the wording for "locally agreed opioid dose conversion table" change to a "nationally recognised opioid dose conversation table, which has been adopted locally" Otherwise you will get postcode conversions.	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.
North of England Commissioning Support Unit	Full	29	45	Re-word this to determine that if the SOPs don't already have this wording, then risk assess their absence	Thank you for your comment. Risk assessment of their absence could be determined locally depending on the care setting.
North of England Commissioning Support Unit	Full	31	8	Develop a policy that includes these issues, otherwise you are mandating a separate policy and organisations may wish to have the choice of a separate policy or incorporating into an overarching policy.	Thank you for your comment. Following further discussion by the Committee, they agreed that if there is already an overarching policy in place then standard operating procedures for storing, transporting, destroying and disposing of controlled drugs can be incorporated into the overarching policy.
North of	Full	31	34 & 41	Do you mean (a) develop an SOP on how to do	Thank you for your comment. The recommendation you refer to is

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England Commissioning Support Unit				a Risk Assessment, or (b) do a Risk Assessment or (c) develop an SOP or (d) carry out a risk assessment as to whether as SOP is needed which incorporates etc. or even (e) make sure these factors are included in your SOP	about developing a standard operating procedure on how to carry out a risk assessment for using and handling patient's own controlled drugs. The risk assessment may include looking at self-administration or self-possession, storage requirements, record keeping and disposal.
North of England Commissioning Support Unit	Full	General	General	There is no mention in your document about the use of new technology to support safe storage (e.g. Omnicell cabinets), or electronic registers for record keeping or electronic prescribing systems. This is an omission and at least needs to be mentioned.	Thank you for your comment. Section 5.1 in the guideline mentions the use of electronic prescribing systems for controlled drugs. Section 8.1 in the guideline mentions the use of electronic controlled drug registers. Storage requirements for controlled drugs must be in line with the Misuse of Drugs (Safe Custody) Regulations 1973. Apart from the Committee being aware of electronic systems being used for some controlled drug activities and including these in the introductory sections of the guideline, the Committee did not specifically discuss the use of new technology to support safe storage, use of electronic registers or electronic prescribing for recommendations to be developed.
North of England Commissioning Support Unit	full	general	general	Generally disappointed with the document. I don't think this NICE guidance gives us anything new or clarity on issues that have been previously considered grey areas. Still lots of mentions of local guidance or locally approved etc. Lots of examples where it says 'consider doing' – would it not be better to provide guidance of what should/must be done? Leaves it open to interpretation.	Thank you for your comment. The strength of recommendations are based on the quality of evidence, clinical and cost effectiveness of the intervention and clinical experience; a strong recommendation can only be made where evidence is identified or where there is legislation. Although there was some legislation, there was limited evidence found for the Committee to make strong recommendations where legislation was not available. The guideline is very broad and covered different care settings for which there is variation in how controlled drugs are manged. Many of the recommendations were based on Committee consensus. The

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					Committee agreed that the purpose of the recommendations was to set out key principles and that the detail of the process was for local consideration as legitimate variation may occur across different health and care settings, depending on the service provided for patients and local governance arrangements.
North of England Commissioning Support Unit	Full	90	general	Discuss a person's preference for locked or non-locked storage – does this mean organisations should provide storage? (substance misuse services do, but not current practice in palliative care)	Thank you for your comment. Following further discussion by the Committee, they agreed that the recommendation focusses on the health professionals to consider discussing with the person the options for storing their prescribed controlled drugs. The options may include taking into account person's preference for lockable or non-lockable storage. There is no explicit requirement to provide storage in the recommendation.
North of England Commissioning Support Unit	Full	94 to 96	general	When a patient has died in their own home there is no mention of nurses destroying the controlled drugs using a DOOP kit – this was one of the recommendations of the CD pilot a few years ago which many organisations still recommend	Thank you for your comment. There is a recommendation in the guideline that takes into account having standard operating procedures in primary care organisations based on local arrangements for destroying and disposing of controlled drugs that belonged to a person who has died, this may include the use of a DOOP kit if one is being used locally. The Committee did not discuss the use of a DOOP kit for nurses to destroy controlled drugs in a patient's home where they have died. The preliminary searches did not identify this practice.
North of England Commissioning Support Unit	Full	33	25, 36, 44	Some of the document doesn't flow very well – for example point 56 refers to drugs in a patient's home, point 57 refers to stock drugs, point 58 refers to patient's own drugs	Thank you for your comment. The recommendations in the full guideline are grouped by review question and have been restructured to make them flow better. The short version of the guideline with all the recommendations has also been restructured to reflect your comment.
North of England	Full	34	10	Statement – "consider rinsing the bottle"… - should this not be a must do? (see 2 above)	Thank you for your comment. Recommendations that have a 'must' are based on legislation or strong evidence. For the

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Commissioning Support Unit					recommendation your comment refers to, there is not a legal requirement to do this and there was no evidence identified. The recommendation was based on Committee consensus as they highlighted that some pharmacies dispose of small amounts of controlled drugs remaining in their bottles into pharmaceutical waste bins and this may increase the amount of pharmaceutical waste produced, The Committee noted that the empty glass bottles could be recycled to reduce the amount of unnecessary waste. Water UK's guidance 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.
North of England Commissioning Support Unit	Full	88	general	CD stationery – prescribers to carry a small number of prescriptions – we have concerns about prescriptions being removed from the pad – much more likely to lose single sheets than a pad – would tear out single cheques and carry them about separate from the book (we have challenged this NHS Protect recently and they still advocate separating prescriptions from the pad as best practice)	Thank you for your comment. The linking evidence to recommendations (LETR) table captures the Committee's discussions about the evidence presented. The number of prescriptions that prescribers should carry was not discussed by the Committee and therefore cannot be added to the LETR table. The Committee was aware of 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.
North of England Commissioning Support Unit	Full	General	General	Examples of Good practice/best practice and standard operating procedures would be very useful to improve safety and standards for patients, providing consistency in practice.	Thank you for your comment. Any accepted shared examples and tools that have been endorsed can be found on the home page of the guideline on the NICE website once published.

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Nottingham University Hospitals NHS Trust	Short	4	12-14	We are concerned that this recommendation may imply that there should be a formal process in place for assessing competency to prescribe controlled drugs in the Trust. Is this the case and would this include all newly qualified doctors and existing prescribers before they can prescribe? Will non-medical prescribers also require assessment? This would be a large burden for the Trust. Currently F1 doctors have a prescribing skills assessment at undergraduate level. This is generic and may or may not include CDs as all universities have different tests. There is a 'mop-up' for F1s if they have had nothing, but it does not include F2 or above doctors starting, or any existing drs/prescribers.	Thank you for your comment. This recommendation has been reworded to make the intention of the recommendation clear following further discussion by the Committee. The term 'assessment' has also been removed to reflect your comment. It would be down to local determination to assess competence of health professionals.
Nottingham University Hospitals NHS Trust	Short	5	14-20	This will be challenging in practice. The patient may not have capacity at that time and their carer may not be present at the time of prescribing.	Thank you for your comment. The recommendation is to support good practice. 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.
Nottingham University Hospitals NHS Trust	Short	5	28-29	This will be challenging in practice because it is not always possible to find out what 'when required' CDs the patient has in their possession and they do not always know. If prescribing 'when required' CDs on admission to hospital, there is already so much information to find out that it is possible that the dr will not ask about 'when require' CDs if the patient has not brought	Thank you for your comment. Following further discussion by the Committee, they agreed that it would be good practice to ask about and take into account any existing supplies the person has of 'when required' controlled drugs given the risks associated with them and so no change was made to the recommendation.

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				them with them.	
Nottingham University Hospitals NHS Trust	Short	5	25-26	This will be challenging in practice to have this information available when dispensing. Pharmacists already screen the discharge TTOs for legality We already request that the prescriber puts in a minimum interval already (e.g. minimum 2 hourly) if requesting additional information on the prescription i.e. how long it should be used for, this may slow down the processing of the prescriptions.	Thank you for your comment. The Committee discussed good practice in prescribing 'when required' medicines. The Committee found from discussions 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 and therefore agreed that it would be good practice to 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.
Nottingham University Hospitals NHS Trust	Short	7	1-15	We are concerned that there is already so much to document (in these recommendations) that documenting this in every patient record will be very time consuming and may not be needed: Most organisations (including NUH) are already bound by strict information governance rules- staff must annually undertake updates and there are ongoing spot checks performed by the IT department on all aspects of information governance. Does this recommendation add additional assurance to existing measures that are in place? And would this be at the expense	Thank you for your comment. The recommendation you refer to is to ensure information about controlled drugs prescribed for a person is communicated to the person's GP to prevent controlled drugs related patient incidents. The Committee discussed the 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 bullets in the recommendation should already be carried out in line with 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]). Particular emphasis

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				of documenting something else e.g. dosing schedules, telling the patient how to use the CDs, how to use SR and IR preps , why it is being prescribed etc. It will be challenging to implement putting all this into an individual's care record for every patient where CDs are prescribed in hospital. Perhaps this could become a policy statement i.e. lines 12 and 13 of this section still stand, and Trust policies could ensure that staff follow confidentiality arrangements without recording it patient by patient. The NICE guidelines already request a lot of additional information that needs to be recorded in the patient's care record.	has been placed on controlled drugs because of their harmful properties and risks with misuse and diversion.
Nottingham University Hospitals NHS Trust	Short	7	18-19	This will be challenging in practice because how will the prescriber know of the expiry dates of the Controlled drugs held by the patient- these may be at home, or in hospital they would certainly be in a locked cupboard that is probably in a different room to the patient. Should the prescriber leave the patient to go and look in the cupboard? Probably not a good use of their time, and key access is restricted in hospital. Doctor would not normally be permitted lone access to the CD cupboard therefore a nurse would need to come with them removing them both from direct patient care.	Thank you for your comment. The term 'where practicable' has been added to the recommendation to take into account the practical difficulties with checking the expiry dates of drugs stored by the person, particularly at home.
Nottingham	Short	11	4-13	It is not possible (without electronic prescribing	Thank you for your comment. The recommendation had been

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University Hospitals NHS Trust				and administration systems and maybe not even then) to record the signature of the nurse administering and witnessing the administration in the patient record- there is just not the space on the drug chart. If they had to record it elsewhere e.g. in the notes, this would be likely to not happen and would take the nurse away from the patient. These 2 signatures are already recorded in the CD register therefore perhaps it should be sufficient to record the information here (where there is space) rather than in the patient record.	reworded following further discussion by the Committee to take into account that there may be more than one place to record witness to administration. It would be down to local determination where the signature of the nurse administering and witnessing the administration would be recorded depending on the care record and setting.
Nottingham University Hospitals NHS Trust	Short	11	23-25	It would prove a challenge in practice to ensure that all staff had completed competency assessment for setting up devices for continuous infusion. If e.g. PCA/epidural -there are competencies in place which nursing staff must pass. For SC infusion the Trust has a generic SC infusion competency (not just CD pumps). If a SC competency for CDs was in place, ward staff could complete but may not have enough appropriate patients on which to maintain competence and they would still need to seek specialist advice.	Thank you for your comment. 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 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. This also includes seeking specialist advice when needed.
Nottingham University Hospitals NHS Trust	Short	12	26	We are not sure how the temperature in the CD cupboard will be monitored in practice. Currently it is proving a challenge to implement room temperature monitoring across the Trust to	Thank you for your comment. The recommendation refers to taking temperature into account when storing controlled drugs and not monitoring the temperature as you would for medicines that are stored in the fridge. The same temperature considerations would

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				ensure compliance with CQC regulations. Perhaps CD cupboard temp monitoring could be covered by room temp monitoring processes, rather than having an extra thing to monitor which may then not happen.	apply to controlled drugs as other medicines that are stored at room temperature.
Nottingham University Hospitals NHS Trust	Short	12	21-28 general	We believe that SOPs should not be developed by first looking at what space is available in the cupboard but should be the other way round, i.e. risk assessments should assess: compliance with national guidelines, local incidents, best practice etc. These should determine what needs to be kept in the CD cupboard, and then wards should purchase appropriately sized cupboards. Being realistic there may not be the money to replace all CD cupboards, but throughout the hospital we should aim to have the same processes in place (underpinned by a generic risk assessment completed by the Trust rather than by each area), otherwise different wards will be doing different things just because they have different size CD lockers. Policy becomes hard to understand and enforce when different processes in place. Wards who are unable to comply with the requirements due to restricted space should do an individual risk assessment- they may be permitted a variation of the policy if they were deemed low risk but this should be a minority of areas.	Thank you for your comment. The recommendation you refer to provides a list of points to take into account when developing a standard operating procedure for storing controlled drugs in all care settings. There is no reference to the standard operating procedure being solely based on what space is available as this would vary on care settings and volumes of controlled drugs kept. The first bullet point in the recommendation covers security of storage and risk assessment. Particulars to include in the standard operating procedure would need to be determined locally to take into account the care setting.

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Nottingham University Hospitals NHS Trust	short	18	28-29 general	It is not possible to look at prescribing data at NUH as there is no electronic prescribing in place. Other data is available (but is less specific)- such as dispensing data and issue of medicines. This has been used in the past to monitor usage of e.g. codeine pre-packs, to identify when usage has been excessive. Perhaps the guideline could refer not only to prescribing data but other data too-prescribing data only tells you what the prescriber Is doing, but by looking at issues you can identify when drugs are being misappropriated.	Thank you for your comment. The Committee was aware that the data contained within the NHS Business Services Authority reports relates to prescriptions dispensed in primary care in England and does not hold any secondary care information. Registered users of the portal can access all of these reports but if organisations are using the guest log in they will only have access to controlled drugs comparator reports. The recommendation relates to looking at prescribing trends which can only be carried by looking at prescribing data. Prescribing data can be in the form of NHS Business Services Authority reports or other types of reports if there are other mechanisms to gather prescribing data, for example audits in secondary care.
Nottingham University Hospitals NHS Trust	Short/ long	General	General	There is no mention of the CQC self-assessment document which has proved extremely useful for providing guidance to the Trust on CDs- we were able to complete a self-assessment against specific criteria and generate an action plan based on a gap analysis. We will continue to use this document as the basis for the monitoring/security/procedural aspects of our policies and procedures (i.e. but not for clinical usage of CDs, prescribing etc.)	Thank you for your comment. The Committee was aware 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. This is included in section 9.5 of the guideline.
Nottingham University Hospitals NHS Trust	Short	General 1.1.42	General	At NUH it would be feasible to carry out weekly stock checks of stock CDs (i.e. those CDs supplied by Pharmacy)- in fact ward staff do them daily and our audit data shows us that this is generally being adhered to. Where this is	Thank you for your comment

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				more difficult is stock checking of patient's own CDs which may also be in the CD cupboard (but not the register as there is separate documentation)- it is not feasible to check these daily. We are looking at ways of checking them once and then 'quarantining' them during the admission until the patient takes them home.	
Nottingham University Hospitals NHS Trust	Short	General 1.1.68	General	Types of audit to audit cabinets- this could be done relatively less frequently and could include- are there just CDs and or medicines keys in the locker (as per NUH policy), is it big enough to be able to adhere to policy, does it meet the British standards for security purposes (although not sure how the auditor would assess this), is the key to the CD cupboard at the time of the audit in the possession of an authorised key holder? Audit of actual balances (stock drugs matched against the register entries) should take place very frequently (e.g. daily at NUH) and audits are done by the ward manager or a nominated deputy Pharmacy should perform an independent check of these -it would be helpful to have a recommendation from NICE e.g. quarterly- this would not only audit stock CDs against the register but also POD CDs, it also identifies any CD stock that is	Thank you for your comment. The Committee developed the recommendation based on key principles that could be applied to all care settings and not a particular one. The Committee agreed that the frequency of checks would depend on the frequency of use and controlled drug-related incidents, and risk assessment which would vary depending on care settings and resource and the recommendation has been reworded to reflect this. If you have an audit tool that can be used or adapted by other organisations then you can submit it to NICE for it to be considered for the endorsement programme.

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				present that is not in the register, and audits whether entries in the register have 2 signatures and that they are not crossing out entries, and whether discrepancies are being managed appropriately. The person responsible for auditing should usually be the person who is responsible for the security of the CDs e.g. at NUH this would be the ward manager or their nominated deputy, but Pharmacy would perform a second independent check periodically.	
Nottinghamshire Healthcare NHS Foundation Trust	Full	93-94	41-55 And 1-9	**Rinsing pharmaceutically contaminated items described as a potential cost saving.** With reference to "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" (Page 93). The committee ought to consider that their proposal to rinse containers will not typically be expected to deliver a financial saving as the rinsing's will require to be "disposed of as waste medicines" (Page 94). The large volume of water required which will then be disposed as pharmaceutical waste (I am unaware of any formal procedure or process that would be able to ensure complete removal of	Thank you for your comment. The intention of the recommendation was to enable health professionals to dispose of empty and clean bottles in a safe way when disposing of small volumes of irretrievable amounts of liquid controlled drugs into the pharmaceutical waste bin. The Committee was aware of Water UK's guidance, however, they agreed by consensus that the recommendation would provide guidance to health professionals who do rinse irretrievable amounts of liquid controlled drug into the pharmaceutical waste bin where a small rinsing volume is produced. This approach would not be suitable for large volumes of rinsings as your comments suggests, in which case the organisation should have arrangements in place to dispose of large volumes of irretrievable amounts of liquid controlled drugs. Water UK's guidance 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

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				contamination) combined with staff resources and specialised plumbing to capture this water would be equally as or potentially more expensive. It is worthwhile noting that most NHS Trusts appear to pay for clinical waste (including pharmaceutical waste) by weight not volume, and the rinsing's would be extremely heavy compared to empty bottle.	is generally discouraged because there is natural tendency to use the foul sewer. The Committee noted guidance from Water UK and agreed that small volumes of rinsings should be placed into the pharmaceutical waste bin to avoid contamination to the fowl sewer. The bottle can be placed into the recycling waste to avoid unnecessary pharmaceutical waste.
Nottinghamshire Healthcare NHS Foundation Trust	Full	93-94	41-55 And 1-9	**Discussion with waste management company (recycling)** Where an organisation chooses to recycle their pharmaceutical glass it should be made clear that the organisation must discuss this with their waste management company. Some organisations are more keen than others on this activity and may choose to refuse this waste, whether or not their concerns are founded.	Thank you for your comment. Details of the process are for local consideration and determination in line with legislation and local governance arrangements.
Nottinghamshire Healthcare NHS Foundation Trust	Full	93-94	41-55 And 1-9	**Discussion with waste management company (incineration)** The promotion of rinse and recycle could generation much larger volumes of pharmaceutical waste which obviously would have a high water volume. Whilst one or two such small containers might be acceptable, there may be implications for the incineration plant if large volumes of water are added to the incinerator at once. It may be worthwhile discussing this issue with incineration plant	Thank you for your comment. The Department of Health guidance on Safer management of controlled drugs: a guide to good practice in secondary care provides guidance on how best to manage large volumes of controlled drugs waste in health care organisations. Some health care organisations may provide denaturing kits for use on wards to destroy large volumes of controlled drugs that have been used for patients. This may also be appropriate where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on the wards. Where denaturing kits are provided, a standard operating

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				operators.	procedure should be developed for this practice.
Nottinghamshire Healthcare NHS Foundation Trust	Full	93-94	41-55 And 1-9	**Rinsed pharmaceutical items as suitable for recycling.** The option to rinse and recycle pharmaceutical containers is well presented (Page 93-94) however it should be made clearer whether it is preferred to rinse and recycle or dispose as pharmaceutical waste. From my perspective the rinsing of pharmaceuticals is fraught with complications (as is highlighted briefly in the draft) and should be avoided at all costs, and the option rinse and recycle should be offered as an unattractive alternative.	Thank you for your comment. Recommendation 60 in the guideline states that the clean and empty container can be placed into the recycling waste.
Nottinghamshire Healthcare NHS Foundation Trust	Full	93-94	41-55 And 1-9	**Consideration of location and organisation type** The organisation should also be instructed that larger organisations should consider this issue on a case by case basis. Our organisation has a number of pharmacies, as well dozens of locations only having small dispensaries and these actin different capacities. What is appropriate for one will not necessarily be appropriate for another, especially when we consider the difference between owned property compared to leased property, or in-house activity compared to community settings (which is highlighted by HTM07-01 page 130).	Thank you for your comment. The Committee agreed that the purpose of the recommendation was to set out key principles. Details of the process are for local consideration and determination in line with legislation and local governance arrangements.

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Nottinghamshire Healthcare NHS Foundation Trust	Full	32	5-6	We are concerned that this recommendation would cause a significant increase in workload for our pharmacy departments. Each pharmacy holds a large variety of controlled drugs in different strengths and preparations. It is our current practice within pharmacy to check the balances and stock are correct after each dispensing. Each pharmacy carries out a full stock check of all controlled drugs once a month. The total time it currently takes for all four of our pharmacies to undertake a full stock check is12 hours. This means it would take an additional 36 hours per month for us to comply with the once weekly stock checks. Our wards currently check the controlled drug stocks once or twice a day at shift changes, however they document this on a separate log, and not in the ward controlled drug register.	Thank you for your comment. Following further discussion by the Committee, the feasibility of carrying out stock checks with a minimum frequency of once a week was reconsidered and the recommendation has been reworded. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.
Nottinghamshire Healthcare NHS Foundation Trust	Full	80	14-17	(General information on page 78 also) This recommendation will be a challenging change in practice because 'the supply of Schedule 2 and 3 controlled drugs without possession of a lawful prescription could be prosecuted as a criminal offence' (Medicines, Ethics and Practice, Edition 39, Royal Pharmaceutical Society, page 40). Our Trust has wards spread over a large geographical area, which are not always near to the supplying pharmacy. Some of our wards	Thank you for your comment. The term 'kept with the person' has been removed and the recommendation has been reworded to include the terms 'readily accessible'. The recommendation is about records of administration being readily accessible to the health professional(s) to ensure continuity of care and to avoid errors whilst they are under the care of the provider,

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				prescribe leave or discharge medication on a specific section of the inpatient prescription /administration card. We would therefore not always be able to comply with this recommendation, and keep the administration record with the patient whilst dispensing leave or discharge controlled drugs, as this would necessitate dispensing from a fax, which is not classed as a legally valid prescription. It may be that other options could be suggested in the guidance to help compliance.	
Nottinghamshire Healthcare NHS Foundation Trust	Full	100	3-10	We are concerned that this recommendation may imply that destruction of stock controlled drugs in Schedule 3 and 4 (part1) requires an authorised witness. According to Medicines, Ethics and Practice, Edition 39, Royal Pharmaceutical society (page 108), only stock controlled drugs in schedule 2 require an authorised witness (unless a pharmacy is engaged in manufacturing, compounding, importing or exporting Schedule 3 or 4 controlled drugs, then record keeping arrangements apply and so destruction requires and authorised witness).	Thank you for your comment. The recommendation has been revised and 2 recommendations have been developed to reflect the differences in legislation for recording controlled drugs in Schedule 2 and those in Schedule 3 and 4 (part 1). A strong recommendation has been made for controlled drugs in Schedule 2 as there is a requirement in legislation to have an authorised person to witness the destruction. The Committee agreed to make a weak recommendation for controlled drugs in Schedule 3 and 4(part1) and considered it would be good practice to have another person (this can be a registered health professional for example a doctor, pharmacist, nurse or a pharmacy technician or another competent health or social care practitioner depending on the setting and local standard operating procedure) to witness the destruction.
Rowcroft Hospice	Full - Summary	27	4	'When required' CD's are reviewed daily in an inpatient hospice setting and the frequency of dose would therefore be more appropriate than a maximum daily dose.	Thank you for your comment. The frequency would be part of the dosage instructions (as stated in the recommendation), however the Committee agreed that maximum daily dose would provide the person taking the controlled drug extra information on the total

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					amount that can be taken.
Rowcroft Hospice	Full - Summary	30	30	We are concerned that 'ensuring the record is kept with the person' will increase risks in terms of patient safety and breaking confidentiality. There is a greater risk of administering the medication to the wrong patient, and that drug doses could be altered by relatives/patients, or patients/relatives could read each other's charts. Our drug charts are stored in a ward office or drug room to aid medical review and prompt access. With e-prescribing this would also not be possible to store with the person.	Thank you for your comment. The recommendation has been reworded to make it clear that the record is easily accessible following further discussion by the Committee to reflect your comment.
Royal College of General Practitioners	Full	General	General	It might be helpful to have a list of controlled drugs near the beginning of the guidance summary as well as the schedules in the definitions section. (IR)	Thank you for your comment. The guideline hyperlinks to the list of all the controlled drugs and their Schedules on the Misuse of Drugs Regulations 2001 webpage. It is not possible to list all the controlled drugs in the guideline due to updates in legislation. Section 1.2 in the full guideline provides an overview of the Schedules. The definitions section includes terms used in the guideline for clarity and is not intended to be an exhaustive list of all terms that are used commonly in practice.
Royal College of Nursing	General	General	General	The Royal College of Nursing (RCN) welcomes the opportunity to comment on the draft guideline for the safe use and management of controlled drugs. Members of the RCN with interest in this area were invited to review and comment on the draft guideline. The comments below reflect the views of our members.	Thank you for your comment.
Royal College	Gene	Gener	General	Our members would welcome guideline in this	Thank you for your comment. The Committee highlighted that there

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of Nursing	ral	al		area. They, however, have raised concerns at the lack of clarity of opioid conversions as the British National formulary (BNF) version is not widely supported. There is also a lack of evidence to help healthcare professionals to deal with this irregularity. There is a need for clear national guidance as there is a distinct variation in different practice settings for example between chronic pain services and palliative care.	is variation in different care settings on the opioid conversion charts used, Opioid conversion charts/tables were only discussed by the Committee as it was considered to be part of the prescribing process for the safe use of controlled drugs. The main purpose of the review question was to look at the clinical and economic evidence for systems and processes for prescribing, The review question did not specifically address different types of opioid conversion charts that are available and their variation in different practice settings to formulate a standard national one.
Royal College of Physicians	Full	general	general	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with experts in clinical pharmacology and therapeutics and palliative medicine and would like to make the following comments:	Thank you for your comment.
Royal College of Physicians	Full	general	general	Overall, our experts are concerned with the amount of evidence to support this review. They suggest that it would be beneficial for the advice to be distilled into a small number of key recommendations, with detail added for explanation. Our experts note that controlled drugs are prescribed in various circumstances including acute severe pain, malignant disease, addiction, and chronic non-cancer pain, for example. These are not clearly differentiated, although approaches to them may differ.	Thank you for your comment. There is a short guideline that just has the recommendations without all the detailed evidence. There will also be a NICE pathway for the guideline for the users to have easier access the recommendations. The guideline covers the systems and processes for safe use and management of controlled drugs. It is not specific to any condition, although certain conditions may be used to highlight a particular aspect of a system or process that needs explanation. The Committee agreed that the purpose of the recommendations was to set out key principles due to limited evidence available.

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Royal College of Physicians	Full	51	1 - 3	1. Develop processes that support prescribers who have been assessed as competent to prescribe controlled drugs. Our experts endorse this point strongly and note that this process should be applied to all prescribers of controlled drugs. Processes should not place unnecessary barriers on prescribers. Our experts agree on this point and note the example of mine overseers administering morphine to injured miners.	Thank you for your comment.
Royal College of Physicians	Full	51	4 - 11	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	Thank you for your comment. The list in this recommendation is not exhaustive but includes the minimum dataset as agreed by the Committee. Additional information may be needed depending on the health or social care setting, but this would be for the prescriber to determine.

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				person may be opioid naïve. • Evidence-based sources for prescribing decisions when possible. Our experts believe it is important to include a point on the problem of over-willingness to prescribe opioids long-term to those with chronic pain syndromes Also over-reluctance to prescribe them to those with life-shortening pain from cancer.	
Royal College of Physicians	Full	51	12 - 21	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. Our experts note that taking into account clinical factors should highlight caution in elderly, those	Thank you for your comment. Recommendation 2 takes into account clinical factors such as risks of prescribing for example in people who are elderly and also other medicines they may be on. The recommendation has been reworded and the term 'titrate' has be removed to reflect your comment. The advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals has also been added to the relevant recommendation.

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				with renal impairment, as well as history of opioid intolerance and concurrent prescription of sedative drugs. There is a need to include caution about driving and refer to 2015 Drug-driving legislation. Our experts reiterate that there is no warning that the indication should be for opioid-responsive pain that is not part of a chronic pain syndrome. They also note that the recommendation regarding titration implies that clinical effect is guaranteed, and note that 'Titrate up and down' by itself unhelpful. Increments of 30% of current dose are generally recommended in palliative care practice.	
Royal College of Physicians	Full	51	22 - 28	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. Our experts are concerned that these	Thank you for your comment. Following further discussion by the Committee, they agreed that this constitutes good practice given the risks associated with controlled drugs. The health professional would need to take into account the acute or long-term use when providing instructions to the person or carer tailor the advice where needed. Section 5.5 of the full guideline provides the rationale behind the recommendation.

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				recommendations do not differential between use of opioids in acute pain (eg myocardial infarction or serious trauma) and in more long-term use (eg in palliative care).	
Royal College of Physicians	Full	51	29 - 36	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. Our experts note that it is also beneficial to include data on dosage instructions to avoid unnecessarily long or high exposure to opioids. Our experts note that It is difficult to specify a maximum dose of prn medication, however, prescribers should ensure the patient and carer are given guidance on how frequently the	Thank you for your comment. The wording 'or frequency of doses' has been added following further discussion by the Committee to reflect your comment about it being difficult to specify a maximum dose of 'when required medicines' in some cases. There is a separate recommendation that applies to all controlled drugs about providing information and advice to people taking controlled drugs that takes into account your comment about prescribers should ensure the patient and carer are given guidance on how frequently the breakthrough medication can be used and to seek advice when required. Following further discussion by the Committee they took into account your comment about it being difficult to find out in some care settings the person's existing supplies of controlled drugs at home. The Committee agreed that the prescriber could ask the person or carer if they have any controlled drugs at home and therefore amended the recommendation to include asking about existing supplies of controlled drugs to take into account the practicalities in some care settings. . .

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				breakthrough medication can be used and to seek advice if needing for example more than does daily on a regular basis. Our experts believe it would be useful to include 'when possible' in the last line above on existing supplies. Prescribers in a hospital OP setting cannot know what amounts are in the house or prescribed by the GP. If there is concern about possible mis-use then a single prescriber (ie hospital clinician or GP) should be agreed.	
Royal College of Physicians	Full	51	37 - 40	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. Our experts believe this would read better as 'Only prescribe enough of a controlled drug to meet the person's clinical needs. Do not prescribe for longer than 30 days at one time. If, in exceptional circumstances, you must prescribe a larger quantity, you should document the reasons for this in the person's care record.'	Thank you for your comment. Wording was considered by the Committee and no change has been made.

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Royal College of Physicians	Full	51	41 - 42	7. Inform people who are starting controlled drugs that they or their representative may need to show identification when they collect the controlled drugs. Our experts note that does not apply to inpatients.	Thank you for your comment. The structure, settings and order of the recommendations in the guideline has been amended to reflect your comment.
Royal College of Physicians	Full	52	1 - 8	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. Our experts suggest the following amendments:	Thank you for your comment. Wording was considered the Committee and no change was made.

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				Line 5: Dose (especially important when dose conversions or dose equivalence is needed) Line 7-8: If you depart from guidance on prescribing, document the reasons why in the person's care record	
Royal College of Physicians	Full	52	9 - 10	9. Use a locally agreed opioid dose conversion table when prescribing, reviewing or 9 changing opioid prescriptions to ensure that the total opioid load is considered. Our experts note that this is discussed on page 49 and that the outcome of the discussion is unclear. Our experts suggest using the British National Formulary (BNF) conversion table which is nationally agreed. BNF recommends the below: Our experts in palliative medicine would like to note that this table does not include fentanyl transdermal patches which are in common use; Our experts also note that a dose conversion of oral morphine to oxycodone of 2:1 is usually used and 10: 6.6 is not practical. Our experts advise that it is best to refer the prescriber to	Thank you for your comment. The recommendation has been reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account national guides that may be used when prescribing, reviewing or changing opioid prescriptions.

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<tr><td></td><td></td><td></td><td></td><td>local pain/palliative care guidelines.

Equivalent doses of opioid analgesics
This is only an approximate guide (doses may not correspond with those given in clinical practice); patients should be carefully monitored after any change in medication and dose titration may be required
Analgesic | Route | Dose
Codeine | PO | 100 mg
Diamorphine | IM, IV, SC | 3 mg
Dihydrocodeine | PO | 100 mg
Hydromorphone | PO | 2 mg
Morphine | PO | 10 mg
Morphine | IM, IV, SC | 5 mg
Oxycodone | PO | 6.6 mg
Tramadol | PO | 100 mg
PO = by mouth; IM = intramuscular, IV = intravenous, SC = subcutaneous</td><td></td></tr>
<tr><td>Royal College of Physicians</td><td>Full</td><td>52</td><td>11 - 14</td><td>10. When prescribing a repeat prescription of a controlled drug for treating a long-11 term condition, take into account the controlled drug and the person's individual 12 circumstances to determine the frequency of review for</td><td>Thank you for your comment. The Committee heard that there is variation in practice when setting a review date for a consultation for prescriptions issued using repeat management systems. 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</td></tr>
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				further repeat 13 prescriptions. Our experts would like to reiterate the points made in response to recommendation 9.	setting a review period as a more frequent review may be needed.
Royal College of Physicians	Full	52	15 - 17	11. When prescribing controlled drugs, advise people how to safely dispose of: • unwanted controlled drugs at a community pharmacy • used controlled drugs. Our experts would like to highlight the inaccuracy of the term 'unwanted' as many people do want controlled drugs. They suggest 'no longer required' instead. Our experts also note the need to clarify what is meant by 'used controlled drugs', and state that if this is a reference to fentanyl patches, for example, it should be explained.	Thank you for your comment. Wording was considered by the Committee and no change was made.
Royal College of Physicians	Full	52	18 - 29	12. When prescribing controlled drugs outside of general practice, inform the person's GP of all prescribing decisions in line with the following rules **:**	Thank you for your comment. The recommendation includes the 5 rules set out in A guide to confidentiality in health and social care (2013) by the Health and Social Care Information Centre which is where the wording you comment refers to has been taken from. These 5 rules are part of the arrangements for information

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				• 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. Our experts wish to highlight that the sentence 'Confidential information about service users or patients should be treated confidentially and respectfully' is circular, and introduces the term service users. They suggest rephrasing to: 'Be	governance. No amendment made.

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				sure that confidential information remains confidential…' '…except when it is necessary to share it with others for the safe and effective care of an individual...' '…in which case, you should respect the individual's right to object to the confidential information being shared.' Our experts have concerns on the drafting on confidentiality and suggest specialist advice may be beneficial.	
Royal College of Physicians	Full	52	32 - 35	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. Our experts note that anticipatory prescribing is explained on page 50.	Thank you for your comment
Royal College of Physicians	Full	52	36 - 38	14. When prescribing controlled drugs (for example, on a medicines or inpatient	Thank you for your comment. Following further discussion by the Committee, this wording has been amended to include when each route should be used to avoid administration errors.

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				record) that are to be administered by different routes, prescribe each as a separate item. Our experts believe that this is potentially good advice (see page 48), but not entirely clear. In particular, the situation where 'morphine 5 mg IV/oral as required for pain up to 30 mg daily' might be written, the choice of route is left to the person administering the drug. If the prescription is written as two separate items: a. morphine 5 mg IV as required for pain up to 30 mg daily b. morphine 5 mg oral as required for pain up to 30 mg daily Our experts note there has to be some way of signalling to the person administering the medicine that it is either a. or b. Standard in-patient prescription charts do not allow this.	
Royal College of Physicians	Full	60	11 - 12	Our experts wish to highlight a typographic error here where it states 'The trade of' instead of 'The trade-off'.	Thank you for your comment. The relevant text has been amended to 'trade off' to reflect your comment.
Royal College of Physicians	Full	63	6 - 8	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	Thank you for your comment. This recommendation applies to organisations that have a contract with an external pharmacy to supply medicines for inpatient use, for example a hospital that has a contract with a retail pharmacy that supplies medicines to them.

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				should be provided. Our experts agree that this is reasonable and note that it applies mainly to general practice.	Settings such as hospitals are governed by different provisions when requisitioning controlled drugs in Schedule 2 and 3 for use on the wards. The approved mandatory requisition form is used when stocks of the controlled drugs are to be obtained in the community, such as general practices or wholesalers. The requirement to use the mandatory form applies to the professionals listed at Regulation 14(4) of the 2001 Regulations,
Royal College of Physicians	Full	63	14 - 15	18. Incorporate national medicines safety guidance about controlled drugs, such as patient safety alerts, into standard operating procedures for controlled drugs. Our experts expressed concern as to whether this will have any impact without further measures. They note that those who read SOPs may only do so once, and may not read updates. Our experts believe a more effective way of transmitting safety data to those responsible for patient care (including patients themselves) is needed.	Thank you for your comment. Improving learning from medicines related patient safety incidents is important to guide practice and minimise patient harm. The Committee agreed that standard operating procedures should take into account national medicines safety guidance about controlled drugs to avoid incidents from reoccurring and this would constitute good practice. See section 6.5 of the full guideline for further details on the rationale. Details of how to transmit safety data to those responsible for patient care would need to be considered locally.
Royal College of Physicians	Full	64	25 - 29	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	Thank you for your comment

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				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. Our experts agree that this would be worthwhile.	
Royal College of Physicians	Full	64	33 - 35	26. When supplying controlled drugs, advise people how to safely dispose of: • unwanted controlled drugs at a community pharmacy • used controlled drugs. Our experts would like to reiterate the points made on recommendation 11.	Thank you for your comment. Wording was considered by the Committee and no change was made..
Royal College of Physicians	Full	79	5 - 12	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	Thank you for your comment.

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				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. Our experts agree that this is a reasonable recommendation given the lack of evidence.	
Royal College of Physicians	Full	79 - 80	14 - 3	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.	Thank you for your comment.

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				Our experts note it is good practice to establish from a doctor the prescribed dose and whether it is taken under supervision. If no dose has previously been prescribed, then the dosing schedule in *BNF* or *Summary of Product Charactersistics* should be followed.	
Royal College of Physicians	Full	80	4 - 23	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.	Thank you for your comment

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				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. Our experts agree that these recommendations are reasonable and note the shift in emphasis from drug addicts to the dying.	
Royal College of Physicians	Full	80	24 - 28	36. When prescribing controlled drugs,	Thank you for your comment. Recommendation 12 includes the 5 rules set out in A guide to confidentiality in health and social care

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				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. Our experts would like to reiterate the comments made in response to recommendation 12 with regard to confidentiality.	(2013) by the Health and Social Care Information Centre which is where the wording about confidentiality has been taken from. Recommendation 36 refers to ensuring the patient's GP is aware of any controlled drugs prescribed to them for example when visited during out of hours by a doctor and a syringe driver has been set up. By telling the patient's GP about this it would ensure continuity of safe care for the patient.
Royal College of Physicians	Full	99	14 - 16	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. Our experts note that this deals only with storage and may not be adequate for preventing deaths in custody. There needs to be both verification of the dose and observation of the effects of the dose. Our experts wish to highlight the comment on page 90:	Thank you for your comment. The recommendation you refer to is about having adequate arrangements in place to handle controlled drugs in a high risk environment. The review question did not specifically look into the evidence for interventions to prevent deaths, therefore no recommendation was developed for preventing deaths in custody. There is guidance from the Home Office for handling controlled drugs for people in police custody, this includes requirements for the detention, treatment and questioning of suspects.

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				'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.' However, the police are responsible for checking the status of persons in custody.	
Royal College of Physicians	Full	99 - 100	31 - 2	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	Thank you for your comment. The recommendation applies to all health care professionals who may encounter such a situation. Details of the process need to be determined locally.

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				drugs. Our experts note that this provision does apply to a doctor or nurse who attends after the patient has died. Our experts believe that it needs to be more directive to define good practice.	
Royal College of Physicians	Full	111	23 - 28	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. Our experts agree with this recommendation.	Thank you for your comment.
Royal Surrey County Hospital NHS Trust	Full	14 -15	29-8	The purpose and audience section of the guidance, whilst including GPs, pharmacists and nurses makes no specific reference to the role of secondary care organisations, for instance there is no mention of hospital medics as part of the audience whilst in the body of the document it is obvious they would be covered by the recommendations. A specific mention of secondary care organisations, and their role in the process, would resolve any confusion as to if the recommendations apply in this setting	Thank you for your comment. The relevant text about hospitals has been added to reflect your comment.
Royal Surrey	Full	Gener	General	The patients care record is mentioned	Thank you for your comment. The term 'care record' has been

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County Hospital NHS Trust		al		throughout the document but this is not defined anywhere. Can it be the patient's drug chart or notes in a secondary care setting?	added to the glossary section in the guideline to reflect your comment.
Royal Surrey County Hospital NHS Trust	Full	29	4-5	The Department of Health 'Safer management of Controlled Drugs A guide to good practice in secondary care (England) states in section 7.15.2.1: 'Although recording of patient returned CDs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2001 as amended, The Controlled Drugs (Supervision of Management and Use) Regulations 2006 require Standard Operating Procedures to be in place for maintaining a record of CDs specified in Schedule 2 that have been returned by patients. These Regulations came into force 1st January 2007 in England.' This implies there is no legal requirement relating to patient controlled drugs so the statement 'Unless legislation states otherwise' is misleading. Ideally this NICE guidance should give a definitive answer, preferably as a table of which requirements are legally binding, which are considered good practice and which are suggested as an option. This should cover both records required at each stage and denaturing	Thank you for your comment. The Committee highlighted that there was uncertainty on how long certain records relating to controlled drugs need to be kept for when there is no legislation. The recommendation you refer to was based on Committee consensus to provide organisations some guidance on record keeping of controlled drugs invoices and records of destruction unless legislation specifies otherwise. The recommendation you refer to has been checked and clarified. See section 6.5 of the guideline under 'record keeping' for the rationale. Section 6.5 of the guideline mentions 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, that can be referred to if a summary is required. Recommendations 45 and 46 of the guideline provides information on legal arrangements for destroying and disposing controlled drugs and what needs to be taken into account in standard operating procedures for destroying and disposing controlled drugs.

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				and disposal requirements.	
Royal Surrey County Hospital NHS Trust	Full	29 62	27-29	**This will cause the hospital pharmacy considerable difficulty to implement and will have a large impact on practice**. The evidence does state that there is no legislation or national guidance on this. If we have a number of prescriptions to dispense patients will often leave a controlled drugs outpatient prescription whilst they attend other departments. This way it can be ready for their collection when they return which means they do not have to wait as long and that the dispensary can manage its workflow better. At the point of collection the details of the person collecting the prescription are filled in the register. It should therefore be possible to pick up on audit if an outpatient has not returned for a prescription and if these items have been returned to stock, which is current practice. The prescription and dispensed items are held in the controlled drugs room until collection. If we don't enter the dispensing until collection there is a risk that the entry will not be made. With the constant flow of work the levels are cross checked regularly. If more than one	Thank you for your comment. Following further discussion by the Committee, they agreed that the recommendation is aimed for health professionals who supply controlled drugs in primary care. The recommendation has been reworded to make this clear.

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				prescription for the same drug is present at the time it will be impossible to check stock levels and easy to think items are missing that have been dispensed and are not entered into the register. This will then render these regular checks pointless but we rely on these checks to spot and rectify any errors quickly.	
Royal Surrey County Hospital NHS Trust	Full	31	10-19	If it states 'Carry out a risk assessment', does this mean a formal risk assessment must be done? Most of the document suggests considering a risk assessment. Currently the wards treat all schedule 2 and 3 controlled drugs (and a few locally agreed other items) to the same level as schedule 2. However there is no shift changeover check for discrepancies for any schedule of controlled drugs. This would be impossible from a staffing level. A once weekly check is required as a minimum, and this frequency is increased if problems occur.	Thank you for your comment. The Committee agreed that the purpose of the recommendation was to set out key principles. Details of the process are for local consideration and determination as variation may occur across different health and care settings, depending on the service provided for patients and local governance arrangements. The risk assessment could be formal or informal depending on what is in the standard operating procedure, the setting and the risk of diversion.
Royal Surrey County Hospital NHS Trust	Full	31	33	Please can you clarify what 'setting for use' refers to if the security of the setting has already been assessed.	Thank you for your comment. The 'setting for use' refers to any setting where controlled drugs are stored for the purpose of use or supply for example accident and emergency, operating theatres, pharmacies or urgent care.
Royal Surrey County Hospital NHS Trust	Full	31-32	41-9	Specific comment was requested for this section. Schedule 2 drugs require register entries whilst schedule 3 to 5 controlled drugs do not. It should	Thank you for your comment. Some organisations may treat controlled drugs in Schedule 3, 4 and 5 in the same way as Schedule 2. For this reason, the recommendation does not specify controlled drugs in Schedule 2, butt 'all controlled drugs entered into the controlled drugs register'. Following further discussion by

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				therefore be made clear that the checks are required for schedule 2 only. It closely mirrors our current practice outside pharmacy for schedule 2 and 3 drugs (because external to pharmacy these items are all treated to the same level as schedule 2 but this is local practice rather than a legal requirement) Stock balances in wards or departments are checked once a week or occasionally, in maternity and theatre areas, more frequently. At this point liquids are assessed visually however the volume at the bottle end should be confirmed and documented in the register. The controlled drugs stock checks are recorded in a separate locally printed controlled drug stock check book rather than the register. This book prompts them to sign that either everything is correct (two signatures as two people are required to do the check) or if there is a problem what it was and who it was reported to. The frequency of the check is increased if problems occur, initially to daily for a four week period and then if another problem occurs to shift change for four weeks. Thus the areas where there are problems have their monitoring increased. This book constitutes the separate bound record	the Committee, the feasibility of carrying out stock checks with a minimum frequency of once a week was reconsidered and the recommendation has been reworded. The Committee agreed that the frequency of stock checks should be based on the frequency of use and controlled drug-related incidents, and risk assessment. For most organisations stock checks should be at least once a week, but they may be carried out more or less often depending on the setting.

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				book which the Department of Health 'Safer management of Controlled Drugs A guide to good practice in secondary care (England) 2007 section 4.8.1.2 allows to be used to record these CD checks. A complete controlled drug audit in pharmacy is undertaken every 3 to 6 months. A weekly balance check would be impossible from a staffing perspective given the number of items involved. However members of staff are asked to check the computer, register and stock on the shelf all match at the time of dispensing each drug and initial the balance to confirm this is right.	
Royal Surrey County Hospital NHS Trust	Full	33	42-43	Authorised witnesses are required for the destruction of schedule 2 controlled drugs. The Medicines Ethics and Practice Guide for Pharmacists states that an authorised witness is only required for Schedule 2 destruction. It is good practice to have another appropriate member of staff to witness denaturing of schedule 3 items. Our current process is that all patients own controlled drugs in schedules 2 and 3 (as these	Thank you for your comment. The recommendation has been revised and 2 recommendations have been developed to reflect the differences in legislation for recording controlled drugs in Schedule 2 and those in Schedule 3 and 4 (part 1). A strong recommendation has been made for controlled drugs in Schedule 2 as there is a requirement in legislation to have an authorised person to witness the destruction. The Committee agreed to make a weak recommendation for controlled drugs in Schedule 3 and 4(part1) and considered it would be good practice to have another person (this can be a registered health professional for example a doctor, pharmacist, nurse or a pharmacy technician or another competent health or social care practitioner depending on the setting and local

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				are not covered by the same controls) are destroyed on the wards using a denaturing kit provided by the pharmacist who must do the disposal with a medicines assessed nurse or medicines management technician or another pharmacist. This is documented in the patients own controlled drug register on the ward. All other schedule 2 items that have been supplied to the ward or department by pharmacy for stock or for use for a particular patient during their inpatient stay and are no longer fit for use are returned to pharmacy for destruction with a pharmacist and an authorised witness as is the legal requirement. All schedule 3 items, which do not legally require an authorised witness to destroy them, are denatured at ward level in the same way as patients own controlled drugs with a pharmacist and another appropriate member of staff. Destruction is documented in the CD register (as all schedule 3 items are in a CD register in our trust although this is not a legal requirement). Schedule 4 (part 1) drugs are returned to pharmacy for denaturing but no records are kept.	standard operating procedure) to witness the destruction.

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				It is very difficult to keep on top of destroying the schedule 2 drugs within pharmacy as we need to use an authorised witness from outside the department. The definition of an authorised witness is a registered practitioner who is not involved in the day to day controlled drugs activities and we have interpreted this to rule out our regular pharmacists and ward staff, although other trusts have not so this could do with clarification. It is much better to denature any items not requiring an authorised witness at ward or department level, as close to the point of use as possible. This means the ward pharmacists are active in the management of stock in their area, items can be destroyed in a timely manner and the process is fitting for the level of security required. It is also more time efficient. The wording of this statement implies it is a legal requirement so that needs to be confirmed as it does not comply with the Royal Pharmaceutical Society Guidance, Medicines, Ethics and Practice, The professional guide for Pharmacists. The Department of Health 'Safer management of Controlled Drugs A guide to good practice in secondary care (England)' Oct 2007 also specifically discusses schedule 2 drugs. If this NICE guidance comes into practice	

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				all schedule 2, 3 and 4 (part1) drugs would have to be returned to pharmacy for destruction, causing a significant amount of expired drugs to be held which could otherwise have been destroyed. **This will have a significant impact on our practice and be challenging to manage.** Currently there can be significant amounts of fluid left in some of the theatre bins where part doses of items such as epidurals have been wasted. It would help significantly if there was something to add to the bins (similar to cat litter) to denature these items. Denaturing kits are one use only and so if they were used for this it would have a significant cost implication.	
Royal Surrey County Hospital NHS Trust	Full	35	15-20	Specific comment on this section requested. Currently audits of all Cd areas are undertaken between 3 and 6 monthly in accordance with The Department of Health 'Safer management of Controlled Drugs, A guide to good practice in secondary care (England) Oct 2007. The senior pharmacist in charge of an area is responsible for co-ordinating the audits but these can be done by a more junior pharmacist. The pharmacist must do it with a second member of staff, either a medicines assessed nurse, pharmacist or medicines management technician. Audit forms are available for each	Thank you for your comment. You can submit your audit tools to NICE for it to be considered for the endorsement programme.

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				area. On this form all their stock drugs are checked and there are separate sections for temporary stock and patients own drugs to confirm they have been checked. A second part to the form ensures documentation checks are completed in every area. This includes checking • For two signatures on entries for each drug • That the ward / department stock checks are done on a regular basis • The integrity and security of the controlled drug cupboard.	
Secure Environment Pharmacists Group	Full	4	16-23	When making decisions about prescribing controlled drugs: the list doesn't mention the risk of dependence to the CD. This is an important consideration when initiating opioids in a person who has a history of or is undergoing current treatment for substance misuse.	Thank you for your comment. Following further discussion by the Committee, the relevant text about controlled drug dependency has been added to reflect your comment.
Secure Environment Pharmacists Group	Full	5	14-20	Document and give clear instructions to the person taking or 14 administering the drug: The listed points doesn't mention the need to advise the patient about the risk of drowsiness that may impair driving and other tasks. I acknowledge this will be printed on the pharmacy/medicines label, but given there is now legislation about driving and the influence of medicines, I feel this should be included here.	Thank you for your comment. Following further discussion by the Committee, the relevant wording has been added to reflect your comment. A link to the advice from the Department of Transport on drug driving and medicine: advice for healthcare professionals has also been added.
Secure	Full	6	17-19	The use of a locally agreed opioid conversion	Thank you for your comment. The recommendation has been

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Environment Pharmacists Group				table is reasonable, but this needs to be appropriate for the clinical setting. Secondary care led tables are complex and simpler versions are more suitable for primary care practitioners where the range of medicines used is smaller. Adding a phrase about the need for a conversion table that is suitable for the clinical environment in which the opioids are being prescribed would be helpful.	reworded following further discussion by the Committee to reflect your comment. The Committee agreed that a recognised opioid dose conversion guide would take into account the clinical setting and the use of national guides when prescribing, reviewing or changing opioid prescriptions.
Secure Environment Pharmacists Group	Full	6	20-23	The previous NPC CD 2009 guidance stated "It is clear under the current legislation that repeat prescribing of CDs in Schedule 2 and 3 is not permitted. However, management systems which allow the patient to receive a prescription (hand signed by a practitioner) without a consultation is not subject to legislation, but is a clinical decision made on a case by case basis. It is good practice that patients should be reviewed before prescribing Schedule 2 and 3 CDs." The recommendation in NICE seems to imply that this legislation has changed and gives watered down advice. Given the known risk of addiction to opioids, this is a concern. Please can the GDG consider reviewing this to strengthen the need for careful clinical consideration if schedule 2 and 3 CDs are supplied on repeat prescriptions.	Thank you for your comment. The Committee found from discussions 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 found from discussion 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

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Secure Environment Pharmacists Group	Full	6	24-27	I do not believe prescribers will do this. More beneficial and practical for the dispensing pharmacist or supplying nurse (e.g. in community services and hospitals) to advise the patient about disposal arrangements.	Thank you for your comment. . Section 5.5 of the guideline provides the rationale behind the recommendation. The Committee was aware that in many cases the health professional who supplies the controlled drug will advise people who are taking controlled drugs how to dispose of them safely, however, given the risks associated with controlled drugs, the Committee agreed that prescribers also have a responsibility to provide this advice to the person to prevent unauthorised access to unwanted controlled drugs.
Secure Environment Pharmacists Group	Full	10	20-29	The recommendation also needs to include the standards set by the service commissioner as well as the regulator. This is because in specific services (such as supervised consumption of substance misuse medicines) additional requirements to support safe supervision are written into service specifications.	Thank you for your comment. The recommendation applies to all settings. While some settings or services may have a service specification, some settings or services may not. Following further discussion by the Committee, they agreed that this would depend on the setting or service and agreed to only include the professional regulator to take into account all settings.
Secure Environment Pharmacists Group	Full	11	23-25	This recommendation deals with devices for continuous administration- there is an additional recommendation needed about training and competence in the use of **automated CD dispensing devices** used for liquid CDs such as methadone.	Thank you for your comment. Automated controlled drug dispensing devices was not discussed by the Committee as part of the review question looking at administration as these devices are notused to administer controlled drugs to a person. Areas related to training of health professionals was out of scope for the guideline and so a recommendation was not developed by the Committee.
Secure Environment Pharmacists Group	Full	19	11-20	Please can providers for secure environments be explicitly included here. We have issues with engagement by CDAOs and providers with CD LINs and local oversight which this recommendation could help improve.	Thank you for your comment. Following further discussion by the Committee, the relevant text about secure environments has been added to reflect your comment.
South Central Ambulance	Full	32	10-17	It would be useful to include guidance about controlled drugs which have been supplied to a	Thank you for your comment. The linking evidence to recommendations (LETR) table captures the guideline development

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Service NHS Foundation Trust				patient personally or to a third party. For example, controlled drugs supplied to a patient are the property of the patient, and are in the patients' personal possession. For those supplied to a third party, then an SOP is required. This is relevant to a number or providers including patient transport services.	group discussions about controlled drugs being the property of the patient for example in school or day care settings. Recommendation 37, refers to having standard operating procedures in place for transporting controlled drugs, the particulars in the standard operating procedure would need to be determined locally.
South Central Ambulance Service NHS Foundation Trust	Full	53	21-25	The requisitions used in hospitals also now applies to NHS ambulance services	Thank you for your comment. The text in this section has been checked and clarified. The term 'organisation providing ambulance services' as in the Circular 019/2015: Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2015 (S.I. 2015/891) has been added to Regulation 14(4) and this has been included in table 8 in section 6.
South Central Ambulance Service NHS Foundation Trust	Full	55	5-6	The 2008 group authority is not limited to NHS ambulance services; private providers are now contracted to provide significant care to NHS patients, and inclusion of this guidance would be consistent with the aims of this document (page 10,line 1-5)	Thank you for your comment. Section 2.4 in the guideline sets out the purpose and the audience and this includes that the guideline may also be relevant to organisations delivering non-publically funded services. Legislation and good practice principles apply to all organisations using controlled drugs.
South Central Ambulance Service NHS Foundation Trust	Full	61	General	A hospital/ambulance requisition signed by a doctor or dentist is a legal requirement	Thank you for your comment. The text in this section has been revised following further discussion by the Committee to highlight the legal requirement.
South Central Ambulance Service NHS Foundation	Full	63	22	Include ambulance/ambulance station	Thank you for your comment. The bullet point you refer to in your comment has had the term 'location' added to it following further discussion by the Committee. This would take into account other similar services provided by an organisations.

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Trust					
South Central Ambulance Service NHS Foundation Trust	Full	66	Table 12	The summary table should include "ambulance paramedics"	Thank you for your comment. The relevant text 'Under Schedule 17 to the Human Medicines Regulations 2012 registered paramedics can administer certain named controlled drugs by injection without a prescription on their own initiative for the immediate, necessary treatment of sick or injured people (in emergency situations)' has been added to table 12 to reflect your comment.
South Central Ambulance Service NHS Foundation Trust	Full	67	8-11	The reference to diazepam 5 mg/ml injection is incorrect. The group authority refers to "diazepam" A group authority issued by the Home Office authorises registered paramedics to supply, offer to supply, and possess morphine sulphate (in the form of morphine sulphate injection to a maximum of 20mg and oral) and diazepam to administer for the immediate necessary treatment of sick or injured persons. However, the authority covers the individual paramedics and not the company or body corporate employing them. (CQC Annual Report 2009)	Thank you for your comment. The relevant text has been amended to 'Under Home Office Group Authorities registered paramedics working within the NHS and outside the NHS; can obtain, possess and administer diazepam and/or morphine sulphate injection (to a maximum of 20mg) and/or morphine sulphate oral' to reflect your comment.
South Central Ambulance Service NHS Foundation Trust	Full	84	General	Suggest include "Security standards and guidance for the management and control of controlled drugs in the ambulance sector" http://www.nhsbsa.nhs.uk/Documents/SecurityManagement/Security_standards_for_the_management_and_control_of_CDs_in_ambulance_v2_-_April_2013.pdf	Thank you for your comment. The relevant text 'there is also guidance and security standards for the management of controlled drugs in the ambulance sector' has been added to section 8.1 to reflect your comment.

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South Central Ambulance Service NHS Foundation Trust	Full	90	General	An Emergency Care example would be useful	Thank you for your comment. The linking evidence to recommendations (LETR) table captures the guideline development group discussions about the evidence presented. Out of hours and urgent care have been included as part of the discussion and the same good practice principles would apply when using controlled drugs in emergency care settings. The LETR table captures examples that have been discussed and is not intended to provide an exhaustive list of examples as there are many examples that could be included.
South Essex Partnership University NHS Foundation Trust	Full	32	18-19 (para 44)	It should be noted that many NHS organisations such as mental health and community health services trusts which are dispersed over a wide geographic area may contract their transport services, including the transportation of medicines, to a firm of couriers. Therefore the statement "Do not routinely use couriers, taxis or equivalent services to transport controlled drugs ….." needs to be qualified to make it clear that this should refer commercial couriers on an ad hoc basis.	Thank you for your comment. Following further discussion by the Committee, they agreed to reword the recommendation to place emphasis on having governance arrangements and processes in place if using couriers, taxis or equivalent services to transport controlled drugs or prescriptions for controlled drugs.
South Essex Partnership University NHS Foundation Trust	Full	33	15-17 (para 54)	It should be noted that whilst advise can be provided, medicines dispensed to an individual patient are their property and they cannot be forced to store them in any particular way	Thank you for your comment. The Committee was aware of this and developed the recommendation to ensure advice and information is provided to the person on safe storage of controlled drugs.

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South Essex Partnership University NHS Foundation Trust	Full	31-34	general	Handling controlled drugs (d) In places, this section seems to veer from a paragraph which is applicable in a primary care setting to one that is applicable in a secondary care setting and back again. For example paras 54 and 56 relate to use of CDs in a patient's own home, whilst para 55 talks about CD registers which would not be used in a patient's home but in other settings, and para 57 about destruction of stock CDs which again would not be relevant in a patient's home. Paragraphs need to be grouped together to flow more logically.	Thank you for your comment. The recommendations in the full guideline are grouped by review question and have been restructured to make them flow better. The short version of the guideline with all the recommendations has also been restructured to reflect your comment.
South Essex Partnership University NHS Foundation Trust	Full	33 95 (Table 19)	32-33 (para 56)	Recommendation 56 includes the statement "any requirements of the coroner to keep medicines in the person's home for a period of time" and Table 19 the statement that "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 Bedfordshire Coroner's Officer has responded that if the death is unexpected then the Coroner would seize any medicines via the Police. In Community Health Services deaths are invariably expected following incurable disease.	Thank you for your comment. This would be down to local consideration depending on the investigation into the death. Details have not been added as this may vary and make the recommendation hard to implement.

Safe use and management of controlled drugs

Consultation on draft guideline
Stakeholder comments table

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				Coronial law, policy and practice should be confirmed with the Ministry of Justice and there should be some qualification in the Guidance on the requirements. Otherwise there will unnecessary delays in disposal of CDs in the community, increasing the risk of theft or diversion.	
South Essex Partnership University NHS Foundation Trust		29 - 30	General	It should be recommended as good practice that a witness should be provided by care home managers when a healthcare professional visits a care home to prepare and administer controlled drugs to a resident under their care.	Thank you for your comment. Care homes were out of scope for this guideline. See Managing medicines in care homes (2014) NICE guideline SC1 for further information on witnesses for controlled drug administration.
St Raphael's Hospice	Full	1.1.21		Section on nausea from opioids: preferable to mention patients prone to migraine or vestibular disorders are more likely to experience nausea with initiation of opioids and hence a concurrent anti-emetic drug would be advisable.	Thank you for your comment. 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