Managing medicines in care homes

NICE good practice guidance

Draft for consultation, November 2013

Contents

1 Introduction

1.1 Purpose of this guidance

The purpose of this good practice guidance is to provide recommendations for good practice on the systems and processes for managing medicines in care homes.

1.2 Audience for this guidance

This guidance is for people and organisations involved with managing medicines in care homes, including:

- those who live in a care home
- care home providers
- commissioners
- providers of services to care homes and their residents
- those with an interest in how care in care homes is provided.

This guidance is written in the context of health and social care services in England, including independent organisations or contractors commissioned to provide such services. It will also be applicable as NICE guidance, as appropriate, to some of the devolved administrations (Wales and Northern Ireland).

1.3 Scope

The guidance is for all people who have a collective responsibility for residents' care, ensuring safe and effective use of medicines in care homes. This includes:

- residents living in care homes and their family members or carers (as appropriate)
- people who provide care in care homes (for example, care home staff and nurses employed by the home, GPs, community nursing teams and specialist nurses)

- people who provide services to care homes (for example, community pharmacists, GPs, dispensing doctors and appliance contractors)
- people who commission or monitor how care is provided in care homes (for example, local authorities, the Care Quality Commission (CQC) and the Office for Standards in Education, Children's Services and Skills (Ofsted)).

This guidance considers prescribing, handling and administering medicines to residents living in care homes and the provision of care or services relating to medicine services in care homes. In this guidance, the term 'medicine' includes all healthcare treatments that may be considered in care homes. Examples include continence products, appliances and enteral feeds.

This guidance does not provide recommendations for named medicines or for specific conditions or types of illness. The guidance also does not include managing medicines in the domiciliary care setting.

The good practice guidance and recommendations are written in the context of health and social care in England. The guidance is aimed at:

- NHS organisations
- local authorities (in England)
- independent organisations for example all types of independent care homes, voluntary and charitable agencies
- independent contractors, for example community pharmacies, GPs, appliance contractors, providers of care home staff.

All good practice guidance is developed in accordance with the NICE equality scheme.

1.4 Definitions used in the guidance

For the purposes of this guidance the term 'care home' covers the provision of 24 hour accommodation together with either non-nursing care (for example, residential home) or nursing care (for example, a care home with nursing). The care home can be of any size (number of residents) or have any type of resident (children, older people, people with cognitive impairment, young

disabled people, people with a learning disability), but should be a registered provider of care (for example, in England with either the CQC or Ofsted).

The term 'care home provider' is used for the registered provider of care. If regulation or practice differs for the type of care home (for example, a children's care home, an adults care home, a non-nursing care home or a nursing care home), then the type of care home is specified in the text.

For the purposes of this guidance, the term 'care home staff' includes registered nurses and social care practitioners working in a care home. When more specific information is required in the guidance, for example for training and competency (see section 3.17), this is specified in the text, for example 'registered nurse' or 'social care practitioner'.

When the term 'organisations' is used, this includes all providers (including care home providers) and commissioners, unless specified in the text.

Other definitions used for the purpose of this guidance are given in appendix A.

1.5 Person-centred care

This guidance offers recommendations for good practice on the management of medicines in care homes.

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

health professionals should follow advice on consent from the Welsh Government.

NICE has produced guidance on the components of good patient experience in adult NHS services. All health professionals should follow the recommendations in Patient experience in adult NHS services.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care. Families and carers should also be given the information and support they need.

Involving others

The views of residents living in care homes about who should and should not be involved in their care are important and should be respected. With the permission of the resident, family members or carers (as appropriate) should normally have the opportunity to be involved in decisions about care and treatment. If the resident lacks the capacity to decide who should and should not be involved, health and social care practitioners must act in the resident's best interests, bearing in mind the provisions of the Mental Capacity Act 2005.

Health and social care practitioners should take account of the views of family members or carers (as appropriate) when they describe the usual behaviour of the resident. This information, in conjunction with an assessment of the resident concerned, will help with decisions about care. It will also help to estimate the person's capacity to make decisions. Residents with reduced mental capacity should continue to have the opportunity to make informed decisions about those aspects of their care and personal lives for which they maintain capacity.

Good communication between health and social care practitioners and residents, their family members or carers (as appropriate) is essential for residents to receive the information and support they need. Evidence-based information should be offered in a form that is tailored to the needs of the person. The treatment, care and information provided should be culturally appropriate and in a form that is accessible to people who have additional

needs, such as physical, cognitive or sensory disabilities, or who do not speak or read English.

Family members or carers (as appropriate) should also be provided with the information and support that they need, and carers should be offered an assessment of their own needs.

1.6 Legal framework for managing medicines in care homes

The management of medicines in care homes is governed by legislation, regulation and professional standards, which are monitored and enforced by different regulatory organisations across England, Wales and Northern Ireland.

Legislation gives protection to all patients. The Medicines Act 1968 established a comprehensive licensing system for medicines in the UK, according to the MHRA, who also state that 'the Human Medicines Regulations 2012 set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance'.

This guidance is written in the context of the NHS and social care in England. The principles of this guidance may apply to Wales and Northern Ireland, but the legislation may differ. An overview of the legislation applicable to Wales and Northern Ireland is given in appendix B.

Adult care homes

In England the regulation of adult care homes is subject to the Health and Social Care Act 2008 and the associated regulations, in particular the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which sets out which health and social care activities a registered provider can carry out.

Care homes are subject to different regulations and regulators, depending on their location. The regulations that apply are:

England:

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Wales:

- The Care Homes (Wales) Regulations 2002

Northern Ireland:

- The Residential Care Homes Regulations (Northern Ireland) 2005
- The Nursing Homes Regulations (Northern Ireland) 2005

The Health and Social Care Act 2008 established the Care Quality Commission (CQC), the regulator of health and adult social care in England. The CQC 'ensures hospitals, care homes, dental and GP surgeries, and all other care services in England provide people with safe, effective, compassionate and high-quality care, and encourages them to make improvements'.

Children's care homes

The powers to regulate and inspect children's social care services, including children's homes, were transferred to the Office for Standards in Education, Children's Services and Skills (Ofsted) under section 148 of the Education and Inspections Act 2006.

Different regulators undertake the monitoring in Wales and Northern Ireland (see appendix B).

England:

- The Children's Homes Regulations 2001

Wales:

- The Children's Homes (Wales) Regulations 2002

Northern Ireland:

- The Children's Homes Regulations (Northern Ireland) 2005

Essential standards

Essential standards are the minimum standards required for providers to comply with legislation in respect of quality and safety.

Essential standards in adult care homes

Essential standards of quality and safety was published by the CQC (2010) to provide additional guidance for providers of adult care homes to aid compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009 in England. These essential standards have been developed to ensure people who use health and adult social care services know what to expect.

Outcome 9 of the Essential standards of quality and safety relates to management of medicines, supporting implementation of Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

Regulation 13 states: 'The registered person must protect services users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity'.

Outcome 9: Management of medicines states: 'People who use services:

- Will have their medicines at the times they need them, and in a safe way.
- Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

This is because providers who comply with the regulations will:

- Handle medicines safely, securely and appropriately.
- Ensure that medicines are prescribed and given by people safely.

- Follow published guidance about how to use medicines safely.'

Essential standards in children's homes

Children's homes: national minimum standards (Department for Education 2011) gives additional guidance for providers of children's care homes to aid compliance with the Children Act 1989: Guidance and Regulations Volume 5: Children's Homes in England, which also takes into account the requirements under the Care Standards Act 2000, in particular the Children's Homes Regulations 2001 (as amended).

Regulation 21: 'Medicines' states: 'The registered person shall make suitable arrangements for the recording, handling, safekeeping, safe administration and disposal of any medicines received into the children's home.'

Standard 6: 'Promoting good health and wellbeing' states: 'Children live in a healthy environment where their physical, emotional and psychological health is promoted and where they are able to access the services to meet their health needs.'

Similar minimum standards have been published in Wales and Northern Ireland (see appendix B).

Safeguarding

In England and Wales the Safeguarding Vulnerable Groups Act 2006 (with similar legislation applying in Northern Ireland) established the legal basis for an independent safeguarding authority now known as the Disclosure & Barring Service.

This service manages 2 lists of people barred from working with children and/or vulnerable adults. The Act places certain legal duties on local authorities and providers of regulated activity, including the reporting of individuals and the circumstances when reporting should happen. The service can also provide information about certain people on request.

2 Recommendations

This section will be completed when the final version of the guidance is published. Please see sections 3.1 – 3.17 for recommendations.

This good practice guidance has been developed for people and organisations involved with managing medicines in care homes, including people who live in a care home, the providers of care in care homes, providers of services to care homes and their residents, and those with an interest in how care in care homes is provided.

The recommendations for good practice have been developed by the Guidance Development Group (GDG), using relevant legislation, guidance and policy as the foundation for good practice. See appendix C for a list of key resources used in developing this guidance.

When a recommendation is aimed specifically at a person or organisation, this is clearly stated. In most cases the GDG was able to identify which person or organisation was responsible; if this is not specified it will be for organisations to consider and determine locally. The GDG agreed that arrangements will vary depending on local organisational structures, how services are commissioned and provided, and what resources are available.

2.1 Care home medicines policy

Please see section 3.1 for relevant recommendations.

2.2 Involving residents

Please see section 3.2 for relevant recommendations

2.3 Communication

Please see section 3.3 for relevant recommendations

2.4 Records management

Please see section 3.4 for relevant recommendations

2.5 Medication errors

Please see section 3.5 for relevant recommendations

2.6 Safeguarding

Please see section 3.6 for relevant recommendations

2.7 Medicines reconciliation

Please see section 3.7 for relevant recommendations

2.8 Medication review

Please see section 3.8 for relevant recommendations

2.9 Prescribing medicines

Please see section 3.9 for relevant recommendations

2.10 Ordering medicines

Please see section 3.10 for relevant recommendations

2.11 Dispensing and supplying medicines

Please see section 3.11 for relevant recommendations

2.12 Receiving, storing and disposing of medicines

Please see section 3.12 for relevant recommendations

2.13 Self-administration

Please see section 3.13 for relevant recommendations

2.14 Administration of medicines by care home staff

Please see section 3.14 for relevant recommendations

2.15 Covert administration of medicines

Please see section 3.15 for relevant recommendations

2.16 Homely remedies

Please see section 3.16 for relevant recommendations

2.17 Training and competency

Please see section 3.17 for relevant recommendations

3 Evidence and recommendations

When reviewing the evidence gathered for this guidance, the Guidance Development Group (GDG) concluded that the key principles in each of the following areas needed careful consideration:

- Care home medicines policy
- Involving residents
- Communication
- Records management
- Medication errors
- Safeguarding
- Medicines reconciliation
- Medication review
- Prescribing medicines
- Ordering medicines
- Dispensing and supplying medicines
- Receiving, storing and disposing of medicines
- Self-administration
- Administration of medicines by care home staff
- Covert administration of medicines
- Homely remedies
- Training and competency

Although this guidance is written in the context of the NHS in England, it also applies in Wales and Northern Ireland.

3.1 Care home medicines policy

Social care governance: a practice workbook (NI) (Social Care Institute of Excellence (SCIE) 2013) defined governance in social care as 'the process by which organisations ensure good service delivery and promote good outcomes for people who use services'.

This good practice guidance provides an opportunity for commissioners of services (local authorities and clinical commissioning groups), providers of

care home services and providers of services to care homes (GPs and community pharmacists for example) to review their policies, procedures and governance arrangements to support the safe and effective use of medicines in care homes. The GDG agreed that commissioners should ensure that arrangements are consistent, regardless of the level of care the provider is to deliver.

During its deliberations, the GDG recognised the importance of local commissioners, providers of care home services and providers of services to care homes working closely from an early stage to incorporate the necessary governance arrangements covering each step of the managing medicines in care homes process.

The GDG agreed that these local governance arrangements should establish clear lines of accountability and responsibility between commissioners, providers of care homes and the providers of services to care homes.

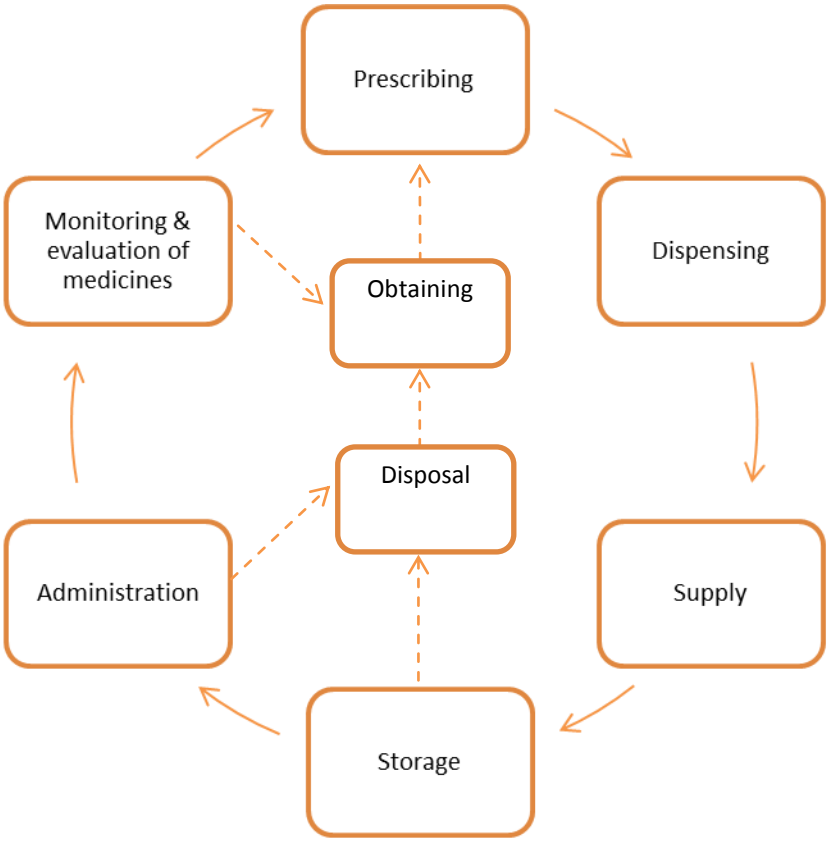
The GDG agreed that responsibilities and reporting arrangements should be stated in service level agreements or contract specifications. Key performance indicators or quality metrics may be included. Arrangements should ensure that providers comply with the Care Quality Commission's (CQC's) Essential standards of quality and safety (2010) or the Department for Education's Children's homes: national minimum standards (2011).

The GDG was aware that the CQC and the Ofsted do not specifically require a written medicines policy as part of the standards for adult and children's care homes. However, outcome 9A of the Essential standards of quality and safety (2010) requires that 'people who use services receive care, treatment and support that … follows clear procedures in practice, which are monitored and reviewed, which explain how up-to-date medicines information and clinical reference sources for staff are made available'.

The National Care Forum have resources available for supporting the safe use of medicines in care facilities.

Medicines management systems are developing and new models are emerging that have electronic systems in place. The system used for some of these components may be paper-based, electronic or a combination of both. Figure 1 summarises the key components of the managing medicines system that will be further discussed in the guidance.

Figure 1 Overview of the medicines management system



The GDG was aware of the legislation and regulation (see section 1.6) with regard to managing medicines in care homes and concluded that care home providers must have a care home medicines policy that includes written processes for the following:

- communication including transfer of residents to and from care homes (see section 3.3)
- records management (see section 3.4)
- medication errors (see section 3.5)
- safeguarding (see section 3.6)

- medicines reconciliation (see section 3.7)
- medication review (see section 3.8)
- ordering medicines (see section 3.10)
- receiving, storing and disposing of medicines (see section 3.12)
- self-administration (see section 3.13)
- administration of medicines by care home staff (see section 3.14)
- covert administration of medicines (see section 3.15)
- homely remedies, if appropriate (see section 3.16).

Recommendations

Recommendation 2.1.1

Care home providers must have a care home medicines policy that includes written processes for the following:

- communication including transfer of residents to and from care homes (see section 3.3)
- records management (see section 3.4)
- medication errors (see section 3.5)
- safeguarding (see section 3.6)
- medicines reconciliation (see section 3.7)
- medication review (see section 3.8)
- ordering medicines (see section 3.10)
- receiving, storing and disposing of medicines (see section 3.12)
- self-administration (see section 3.13)
- administration of medicines by care home staff (see section 3.14)
- covert administration of medicines (see section 3.15)
- homely remedies, if appropriate (see section 3.16).

See also recommendations: 2.5.1, 2.7.1, 2.8.1, 2.12.1, 2.13.6, 2.15.2

3.2 Involving residents

Safety of medicines in the care home (National Care Forum 2013) identified that 'when a person enters a home, staff often automatically assume

responsibility for managing medicines. This can lead to a loss of independence and control for the resident'. The report states that 'the starting point for medicines management should be for the person to be enabled to retain control of their own medicines, or as a minimum be involved in managing their medicines (in accordance with their ability and wishes)'.

The GDG agreed that where possible residents should be enabled and assisted to retain control of their medicines or as a minimum be involved in managing their medicines through shared decision-making processes. Shared decision-making has been defined by the King's Fund as 'a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient's informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences'.

This is also the definition used by the UK government in its policy document Liberating the NHS: No decision about me, without me, which restates the UK government's aim of giving people 'more say over their care and treatment with more opportunity to make informed choices, as a means of securing better care and better outcomes'.

In addition, the GDG was aware of a high-quality systematic review (Dwamena et al. 2012) that found that interventions such as clarifying patients' concerns and beliefs, communicating treatment options, using differing levels of empathy, and the patients' perception of providers' attentiveness to them and their concerns as well as their diseases, all had benefits when adopting a patient-centred approach.

The Essential standards of quality and safety (CQC 2010) requires that people who use services benefit from a service that ensures, whenever possible, information is available about the medicines they are taking, including the risks, and about medicines advisable for them to take for their health and wellbeing and also to prevent ill health.

The GDG were aware that there can be a number of barriers to involving residents in decisions about medicines, not least the issues of competence and mental capacity, valid and informed consent and health literacy. These issues are relevant to both children and adult living in care homes.

The GDG concluded that residency in a care home should not be a barrier to a resident's involvement in their care, being involved in decision-making about their care and treatment as for those people who are not resident in care homes. Residents living in care homes also have the right to access the same services and support as for those people not resident in care homes.

Informed consent to care and treatment

Consent will be considered within this guidance only in the context of managing medicines. Other guidance from NICE considers consent more widely (see Patient experience in adult NHS services: improving the experience of care for people using adult NHS services, NICE clinical guideline 138).

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (part 4, regulation 18) relating to adult services states: 'The registered person must have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them'.

The Children's Homes Regulations 2001 (part 4, regulation 20, [2] d) relating to children's services states: 'The registered person shall promote and protect the health of the children accommodated in a children's home. In particular the registered person shall ensure that … each child is provided with guidance, support and advice on health and personal care issues appropriate to his needs and wishes'.

The Reference guide to consent for examination or treatment (Department of Health 2009) states that 'It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person. This principle reflects the right of

patients to determine what happens to their own bodies, and is a fundamental part of good practice'.

The care of residents should take into account patients' needs and preferences. Residents in care homes should have the opportunity to make informed decisions about their care and treatment, in partnership with their health professionals and family members or carers (as appropriate). If residents do not have the capacity to make decisions, health professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. Guidance on consent is available in Wales, from the Welsh Government, and in Northern Ireland from the Department of Health, Social Services and Public Safety.

The Department of Health's advice on consent also covers the wide range of issues from voluntary informed consent to examination and treatment, the Mental Capacity Act 2005, the Mental Health Act 1983 and the circumstances in which decisions may be made for children lacking capacity (Gillick competence).

The GDG concluded that when a resident gives or refuses consent, and the resident's decision is valid and informed, this should be recorded in the care plan. The GDG also concluded that if a resident is giving valid and informed refusal for a medication, then the care home staff should detail the circumstances and reasons for refusal on the appropriate medication administration record and in the individual care plan and notify the prescriber (if the resident agrees) in line with the resident's care plan.

The World Health Organization (WHO) defines health literacy as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health'.

The GDG noted that evidence suggests that low health literacy is a significant barrier to preventative and therapeutic care.

The GDG was aware that there are additional factors that can be potential barriers for residents in relation to accessing, understanding and using information about medicines. These factors include language, hearing and culture, particularly for people from minority ethnic groups and those for whom English is a second language. Before having discussions with a resident, their hearing aids may need to be checked to ensure they are working properly, or if a resident is more alert in the morning it might be appropriate to plan discussions with the resident for these times.

The GDG agreed that health and social care practitioners should take account of a resident's individual needs and if appropriate use support materials, including large print leaflets, translated versions of texts, or offer access to additional resources such as nurse advisors or pharmacists to aid the resident's understanding.

The GDG concluded that a number of factors may affect a care home resident's ability to give informed consent, including their mental health, mental capacity, health literacy, vision, hearing, language and culture. Health and social care practitioners need to ensure that these factors are examined for each resident, with any barriers to informed consent identified and taken into account in the resident's individual care plan.

Mental capacity

The GDG recognised that in line with legislation every care home resident must be assumed to have the capacity to make decisions themselves regarding their medication. This includes consenting to take prescribed medication, refusing to take medication and being involved in decision-making about their plan of care, unless otherwise demonstrated under the Mental Capacity Act 2005 that they lack capacity. If health and social care practitioners have concerns about an individual resident's capacity, this should be assessed in line with the requirements of the Mental Capacity Act 2005, referring to the processes laid out in the Mental Capacity Act Code of Practice 2007.

The SCIE prevention of maladministration of medication checklist states that 'all residents should be supported to manage their own medicines unless they are assessed as lacking mental capacity to do so'.

The GDG was aware that the Mental Capacity Act 2005 sets out the following principles:

- 'A person must be assumed to have capacity unless it is established that he lacks capacity.
- A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
- A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
- An act done, or decision made, under the Mental Capacity Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests (known as a "best interests decision").
- Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.'

As set out in the Mental Capacity Act Code of Practice 2007, most of the Mental Capacity Act 2005 only applies to those aged 16 years or over and there is an overlap of legislation with the Children's Act 1989.

For residents who are assessed and found to lack capacity to make decisions and who have no-one else (other than paid staff) to support or represent them or be consulted, then it may be necessary, following the guidance laid out in the Mental Capacity Act Code of Practice 2007 to appoint an Independent Mental Capacity Advocate. An Independent Mental Capacity Advocate may be appointed for those residents who have particularly complex needs requiring decisions to be made about their medicines, including an assessment of the risks and benefits. Evidence states that care home residents are predominantly older. In addition to this, evidence suggests that the prevalence of dementia in care settings stands at around 70% (Matthews et al. 2013). Furthermore, care home residents may have conditions such as

learning disability or acquired brain injury. These residents may lack mental capacity or have cognitive impairment that would preclude them from being involved with decisions about their medications.

However, from additional evidence identified, the GDG agreed with the view that care home residents are not a homogenous group and it should not be presumed that individual residents are incapable of being involved with decisions about and the administration of their own medicines.

The GDG was aware that the Mental Capacity Act Code of Practice 2007 is clear that 'if a doctor or health professional proposes treatment or an examination, they must assess the person's capacity to consent'. In such cases the code of practice suggests that the involvement of a multidisciplinary team might be appropriate 'but ultimately, it is up to the professional responsible for the person's treatment to make sure that capacity has been assessed'.

The GDG was aware that the Mental Capacity Act Code of Practice 2007 recommends that 'the preparation of a care plan should always include an assessment of the person's capacity to consent to the actions covered by the care plan, and confirm that those actions are agreed to be in the person's best interests'.

When recording a best interest decision the Mental Capacity Act Code of Practice 2007 states that the record should set out:

- 'how the decision about the person's best interests was reached
- what the reasons for reaching the decision were
- who was consulted to help work out best interests, and
- what particular factors were taken into account.'

The GDG concluded that assessment of a resident's mental capacity relating to medicines in care homes must be conducted in line with the Mental Capacity Act 2005 and should be assessed on an individual basis by the health professional proposing the treatment and recorded in the resident's

care plan. There should be an ongoing review, taking into account the cause of the individual resident's loss of capacity.

Factors that should be taken into account when making a decision

The Mental Capacity Act Code of Practice 2007 recommends that a 'best interests' decision about a care home resident's mental capacity should not be based on that person's age, appearance, condition or behaviour. A decision about what is in a resident's best interests should include consideration of all relevant circumstances, which may include:

- the resident's past and present wishes and feelings, beliefs and values
- the views of those close to the resident (such as friends, family members, carers and advocates)
- the views of those involved in caring for the person, any attorney appointed by the person under a Lasting Power of Attorney or deputy appointed for that person by the Court of Protection
- any advanced decision to decline treatment that is valid and applicable to current circumstances (SCIE state that an exception can be made regarding advance decisions if new treatments have come in that may have affected the person's decision had they known about them at the time).

The GDG was aware of guidance from SCIE on making decisions in a person's best interests. The GDG discussed and concluded that for care homes, the following good practice should apply to involving residents in best interest decisions:

- The resident should be involved in the decision as much as possible, with those involved in making the decision finding out about the resident's past and present views, wishes, feelings, beliefs and values.
- When possible, involve the resident in meetings in which decisions will be made about them.
- Talk to people who know the resident well. This could include the resident's family and friends, as well as the care home staff who have a good knowledge of the resident. Follow the legal requirements particularly of

those with lasting power of attorney as laid out in the Mental Capacity Act 2005.

- Try to limit any restrictions on the resident by delivering care and treatment in a manner that empowers residents.

1 Recommendations

Recommendation 2.2.1

Health and social care practitioners should ensure that residents have the same right to be involved in decisions about their care and treatment as people who do not live in care homes. Ensure residents have access to any support they need to enable them to take part in decision-making.

Recommendation 2.2.2

Care home staff should document a resident's valid consent, informed consent or refusal for a medicine in the resident's care plan. Record the circumstances and reasons for refusal in the medication administration record and the resident's care plan. Notify the prescriber (if the resident agrees) in line with the resident's care plan.

Recommendation 2.2.3

Health and social care practitioners should ensure that they:

- identify any barriers to the resident being able to give informed consent arising from a resident's mental health, mental capacity, health literacy, vision, hearing, language and culture
- record any identified barriers in the resident's care plan
- take account of any identified barriers when seeking the resident's informed consent for examination or treatment
- regularly review barriers to informed consent.

Recommendation 2.2.4

Health professionals prescribing a medicine should:

- assess a resident's mental capacity to give informed consent in line with the Mental Capacity Act 2005
- record the assessment in the resident's care plan
- undertake an ongoing review of mental capacity, taking account of the cause of the individual resident's loss of mental capacity.

Recommendation 2.2.5

Health and social care practitioners should ensure that residents are involved in best interest decisions, in line with the Mental Capacity Act Code of Practice (2007) and:

- explore their past and present views, wishes, feelings, beliefs and values
- involve them, if possible, in meetings at which decisions are made about their medicines
- talk to people who know them well, including family members or carers and friends, as well as care home staff
- deliver care and treatment in a way that empowers the resident and limits restrictions to their care.

3.3 Communication

The National Patient Safety Agency (NPSA) key functions and expertise for patient safety transferred to NHS England in April 2012. The NPSA stated that 'communication is a key factor in preventing patient safety incidents' (including medication errors) 'and also in learning from them afterwards. Communication includes the mechanics of communication as well as actually talking to one another'

The Care Home Use of Medicines Study (CHUMS) identified that, in relation to medicines errors such as administration, prescribing, monitoring and dispensing, communication problems between the care home provider, pharmacy and the GP practice were often unrecognised and not adequately addressed.

The Health Foundation's Making care safer (2011) details the thoughts and experiences of care home residents, carers and relatives in relation to medication safety. The report describes potential gaps in communication in relation to:

- communication during transfers of care
- a lack of communication between care home providers and GPs

- carers not being involved or updated in developments in resident care
- care plans either not being updated or not used in practice
- carers not being involved in care planning.

The GDG agreed that communication is important in managing medicines in care homes to ensure sufficient information is available at the right time for care home staff to safely manage residents' medication.

Processes should be recorded in the care home medicines policy (see recommendation 2.1.1) and should include:

- the transfer of residents to and from care home settings; this should cover the principles set out in Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) (staff responsibilities, the core content information that should accompany care home residents when they transfer providers and Medication Use Review (MUR) following transfer)
- residents visiting health professionals; care home staff should ensure that, in line with Health and Social Care Information Centre (HSCIC) rules on confidentiality (A guide to confidentiality in health and social care, 2013), information regarding residents' medication that is relevant, necessary and proportionate be shared to ensure safe care of the resident
- the recorded transfer of information during handover related to changes of a resident's medication.

Confidentiality

Confidentiality has been cited as a reason for not communicating information in relation to health and social care. In response to concerns over confidentiality the HSCIC produced A guide to confidentiality in health and social care (2013). It explains that residents should be told how confidential information about them will be used, who will see it and that this is central to processes for obtaining informed consent for care and treatment.

The HSCIC guidance was discussed by the GDG in relation to medicines in the care home. The HSCIC guidance discusses the importance of health and social care practitioners sharing information and when it is and is not

appropriate to do so. The guidance stresses that there is a risk of the loss of life when information is not shared when it should be. The HSCIC guidance sets out 5 rules for health and social care (see box 1).

Box 1 Health and social care information centre 5 rules on confidentiality (A guide to confidentiality in health and social care; HSCIC 2013)

- 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

In relation to medicines, confidential information should be shared with the health and social care practitioners who provide direct care to the resident (such as social care practitioners, doctors, nurses, those providing specialised care such as pharmacists, and administrative staff who support direct care) if it is expected to result in better or safer care. The information shared should only ever be relevant, necessary and proportionate.

Residents may express a wish for their information not to be shared. In some cases, the health and social care practitioners providing direct care to the resident may feel that this might compromise the safety of the resident's care. In these circumstances the team should inform the resident of this and document this in the resident's care plan.

The GDG agreed that organisations should also have processes in place to ensure the rules on confidentiality are followed, such as:

- a senior person taking responsibility for confidentiality within the care home
- the completion of an information governance toolkit by the care home

- ensuring that all organisations the care home deals with have a policy and commitment to confidentiality
- a reporting system in place in the care home to monitor that the rules are being followed.

The GDG was also aware of principle 7* of the Caldicott principles highlighting the duty to share information (see box 2).

Box 2 To share or not to share (A guide to confidentiality in health and social care**; HSCIC 2013)**

- Justify the purpose(s)
- Do not use personal confidential data unless it is absolutely necessary
- Use the minimum necessary personal confidential data
- Access to personal confidential data should be on a strict need-to-know basis
- Everyone with access to personal confidential data should be aware of their responsibilities
- Comply with the law
- The duty to share information can be as important as the duty to protect patient confidentiality

The GDG concluded that care home providers should have a policy for information governance covering the 5 rules set out in the HSCIC guidance, the Caldicott principles and the training of care home staff in relation to information governance. This should be recorded in the care home medicines policy (see recommendation 2.1.1).

Transfer of care

Transfers of care, the planned movement of a care home resident from one care setting to another, have been categorised into a number of different types including:

- admission to secondary care from the resident's usual residence
- transitioning between levels of care in the same hospital (for example, from intensive care to a regular hospital ward)

- discharge or transfer from one hospital to another place of care (for example, from hospital to intermediate care or a care home)
- discharge from hospital or intermediate care to home
- transitioning from one ambulatory care setting to another (for example, changing GP).

Evidence suggests that significant problems for patients arise from miscommunication and unintended changes relating to medicines when they transfer from one care setting to another. Published literature estimates up to 60% of medication errors occur during transfers of care.

Evidence from a UK study involving 8600 admissions to hospital from the general population demonstrated that when medicines were checked after admission most patients had at least one omitted drug or wrong dose. Evidence suggests that care home residents are at high risk of medicine error during transfers of care and the CHUMS identified that reducing errors during transfers of care and particularly those errors associated with admission to care homes is a priority.

In a review of the evidence, the GDG found that sufficient information about care home residents' care needs and medicines does not always go with a resident when they are admitted to hospital. Similarly information regarding medicines does not always get communicated to the care home when residents are discharged. This insufficient sharing of information has the potential to lead to conflicts in prescribing between, for example, primary and secondary care prescribers. It has been noted that verbal and written transfers of information regarding the details of residents' medicines on admission to care homes is often inadequate.

The GDG concluded that because of the increased likelihood of medication errors during transfers of care, care home providers should have processes in place for transfer of residents to and from care home settings. This should cover the principles set out in Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) (staff responsibilities, the core content information that should accompany care home residents when they

transfer providers and Medication Use Review (MUR) following transfer). The process should be recorded in the care home medicines policy (see recommendation 2.1.1).

Improving transfers of care (health and social care practitioners)

Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) developed 4 core responsibilities in relation to transfers of care for health professionals. Health professionals should:

- 'ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for on-going prescribing is clear'
- when taking over the care of a patient, 'check that information about the patient's medicine has been accurately received, recorded and acted upon'
- encourage patients (or their parents, carers or advocates) 'to be active partners in managing their medicines when they move', and be aware of 'why, when and what medicines they are taking'
- ensure that information about patients' medicines is communicated in a 'timely, clear; unambiguous and legible way'; ideally information should be generated and transferred electronically.

Evidence from the USA suggests that while a consultant pharmacist is the key person to perform medicines reconciliation on frail, medically complex, older adults being transferred to long-term care, the community pharmacists' primary responsibility is to clarify potential discrepancies between new medicines after transfer and the patient's home medicines regimen. This, the authors state, requires the community pharmacist to liaise with the primary care provider or other pharmacies as required.

The GDG agreed that community or care home pharmacists with the appropriate skills, knowledge and competencies could undertake this role in the UK setting. However, the GDG acknowledged that in many parts of the UK communication between pharmacists in different settings is variable. Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) stated that all community pharmacists should have an NHS.net web

address, which would facilitate secure communication between primary and secondary care.

The NHS Constitution (2013) states 'Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment'. The GDG was aware that evidence from the Health Foundation report Making care safer (2011) suggests that health and social care practitioners should empower care home residents and their family members or carers (as appropriate) to be involved in the transfer of medicines information when they are moving between care settings. If this is what the resident wants, then the information-sharing should be in line with the HSCIC guidance on sharing confidential information (see box 2).

The GDG concluded that health and social care practitioners should ensure that all necessary information regarding medication, including who will be responsible for ongoing prescribing, should be accurately recorded and transferred with care home residents in a timely manner.

The GDG further concluded that health and social care practitioners should check that information regarding a resident's medicine has been accurately received, recorded and acted on following transfer.

Improving transfers of care (organisations providing care)

Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) also stated 3 key responsibilities for organisations providing care. Organisations should:

- 'ensure that they have safe systems that define roles and responsibilities within the organisation, and ensure that health professionals are supported to transfer information about medicines accurately'
- ensure systems 'focus on improving patient safety and patient outcomes' and 'consistently monitor and audit how effectively they transfer information about medicines'
- share 'good and poor practice in the transfer of medicines … to improve systems and encourage a safety culture'.

The GDG therefore agreed that organisations transferring care home residents to and from different care settings (such as hospitals) should have processes in place that cover these transfers of care.

The GDG was aware of evidence suggesting that electronic discharge summaries may improve the quality and timeliness of discharge summaries. However, evidence also showed no effect on readmissions, emergency department visits, or adverse effects after discharge.

The GDG found that care home providers should consider having a process for ensuring residents are never sent into hospital without an accurate medication record and this should be recorded in the care home medicines policy (see recommendation 2.1.1). Evidence also states that when a resident changes GP on entering a care home, a handover of relevant, necessary and proportionate information needs to take place to ensure resident safety.

The GDG discussed the issue that hospitals often communicate electronically with general practice but not necessarily the care home or the community pharmacist with whom it may also be necessary to share relevant, necessary and proportionate medicines information as part of the wider care team to ensure resident safety.

The GDG concluded that organisations such as hospitals providing care should consider the use of electronic discharge summaries to improve the quality and timeliness of discharge summaries. The content of the summary should be in line with the Royal Pharmaceutical Society recommendations for core content of records for medicines when residents transfer to and from care providers (see also section 3.5).

Improving transfers of care (commissioners)

Keeping patients safe – getting the medicines right (Royal Pharmaceutical Society 2012) states that the core principles and responsibilities along with recommended core information for medicines transfer records would enable commissioners to open discussions with providers around the quality of information transfer regarding patients' medicines. In their next steps for

commissioners the Royal Pharmaceutical Society suggested that commissioners:

- review how effectively providers currently transfer information about patients' medicines
- review existing contracts, service level agreements, quality contracts and incentive schemes with providers to incorporate the principles and responsibilities, and recommended core information requirements, when appropriate
- work with provider services to agree robust, patient-focused outcome measures, which can then be incorporated into commissioning arrangements
- monitor provider services against agreed outcomes and if necessary agree improvement measures.

The CQC has developed a self-assessment tool for commissioners to identify how to commission safer services for patients after discharge. The tool recommends commissioners consider the use of standard, electronic discharge forms to help prevent GPs prescribing incompatible medication. The CQC also recommend increased sharing of discharge information with patients and pharmacists, which they state can provide an additional check that subsequent prescribing is safe.

Evidence suggests that pharmacy-led review of medicine lists may help identify omitted or indicated medicines on transfer.

The GDG concluded that commissioners should review their commissioning arrangements with their provider organisations to ensure the transfer of information about residents' medicines contains core information requirements and monitor this through their contracting arrangements.

Residents visiting health professionals

The GDG found examples from practice of how, when a care home resident requires an appointment outside of the care home with a health professional (for example, with a GP or other health professional), information about the

resident's medications should be available during the consultation (where this is in accordance with the resident's ability and wishes). The nature of the appointment and any outcomes (for example, altered medications) should be recorded in the resident's care plan, any prescribing changes should be amended on the resident's medicines administration record (see section 3.11) and the relevant medication ordering and disposal processes undertaken (see section 3.10 and section 3.12).

The GDG concluded that with regard to residents visiting health professionals, care home staff should ensure that, in line with the HSCIC rules on confidentiality, information regarding resident's medication that is relevant, necessary and proportionate be shared to ensure safe care of the resident.

Communication between care home staff

The GDG was aware of evidence advocating better information-sharing during shift handovers between care home staff. The evidence recommended increased robustness and recording, and that important information is read by staff coming on duty. The evidence also recommended that it should be clear what information is accessible to the residents, family members or carers (as appropriate), enabling them to stay up to date (if this is in accordance with the resident's ability and wishes).

The GDG discussed the need for care home staff, residents, carers and relatives to be aware of the unintended side effects of any medicines and any ongoing monitoring requirements that may be required.

The GDG concluded that care homes should have a clear process in place within the medicines policy for the recorded transfer of information during handover related to changes to resident medication and this should be recorded in the care home medicines policy (see recommendation 2.1.1).

1 Recommendations

Recommendation 2.3.1

Care home providers should have a policy on information governance covering the 5 rules set out in the Health and Social Care Information Centre's A guide to confidentiality in health and social care (2013), the Caldicott principles and the training of care home staff relating to information governance.

Recommendation 2.3.2

Health and social care practitioners should ensure that all information about a resident's medicines, including who will be responsible for ongoing prescribing, is accurately recorded and transferred with care home residents when they move from one care setting to another.

Recommendation 2.3.3

Health and social care practitioners should check that accurate information about a resident's medicines has been received and recorded, and is acted on after a resident's care is transferred from one care setting to another.

Recommendation 2.3.4

Organisations should have processes in place to ensure that accurate information about a resident's medicines of when a resident's care is transferred from one care setting to another (including hospital).

Recommendation 2.3.5

Organisations should consider using electronic discharge summaries, in line with the Royal Pharmaceutical Society recommendations for core content of records for medicines when a resident's care is transferred from one care setting to another.

Recommendation 2.3.6

Commissioners should review their commissioning arrangements with their provider organisations to ensure the transfer of information about residents' medicines contains core information requirements in line with the Royal Pharmaceutical Society recommendations. Commissioners should monitor

this through their contracting arrangements.

3.4 Records management

The underpinning legislation for records management principles is the Data Protection Act 1998. The Act sets out a framework of general standards that must be met and considered (in conjunction with other legal obligations) and regulates the processing of personal data (either in paper or electronic form). It applies to all personal information generally and not just to health records.

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which applies to care homes, states that: 'the registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity'.

Additionally regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 states that:

'(1) the registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of:

(a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and

(b) such other records as are appropriate in relation to:

(i) persons employed for the purposes of carrying on the regulated activity, and

(ii) the management of the regulated activity.

(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are:

(a) kept securely and can be located promptly when required;

(b) retained for an appropriate period of time; and

(c) securely destroyed when it is appropriate to do so.'

The CQC's Essential standards of quality and safety (outcome 9B) requires that when people who use services receive care, treatment and support that involves medicines, the provider has:

- 'the arrangements for recording when it is not possible for a person to be able to self-administer their medicines
- the recording of when medicines are given to the person.'

Outcome 21 of the CQC's Essential standards of quality and safety relates to record-keeping more generally and links to regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (as above), but includes the requirements that 'People who use services can be confident that their personal records for their care, treatment and support are properly managed because:

- the service has clear procedures that are followed in practice, monitored and reviewed, to ensure personalised records and medical records are kept and maintained for each person who uses the service
- records about the care, treatment and support of people who use services are updated as soon as practical
- verbal communications about care, treatment and support are recorded within personal records as soon as is practical
- records about care, treatment and support are clear, factual and accurate and maintain the dignity and confidentiality of the people who use services
- records are securely stored and transferred internally between departments and externally to other organisations, when required
- protocols exist with other organisations for secure information-sharing

- records about people who use services are used to plan appropriate care, treatment and support to ensure their rights and best interests are protected and their needs are met
- the record of the current interaction is linked with any previous records that exist for that person, whenever the service is able to reliably identify the person.'

The GDG acknowledged the requirements of the CQC in relation to record-keeping and managing medicines in care homes. The GDG agreed that a set of general principles would complement the CQC requirements such as those from Record keeping: guidance for nurses and midwives (Nursing & Midwifery Council (NMC) 2009), which the GDG agreed should be adapted to reflect the needs of care homes.

The SCIE states that 'poor record-keeping is essentially poor communication and can put both staff and residents at risk' (see also sections 3.3 and 3.5). The GDG acknowledged the legal requirements and importance of maintaining, storing and archiving appropriate organisational records.

The NMC's Record keeping: guidance for nurses and midwives (2009) states that 'good record keeping, whether at an individual, team or organisational level, has many important functions'. These functions of good record-keeping can be of benefit to residents, care home providers and commissioners in a number of ways including:

Clinical

- Supporting patient care and communications.
- Helping to identify risks, and enabling early detection of complications.
- Making continuity of care easier.
- Showing how decisions related to patient care were made.
- Supporting effective clinical judgements and decisions.
- Promoting better communication and sharing of information between members of the multi-professional healthcare team.

Administrative

- Helping to improve accountability.
- Supporting the delivery of services.
- Providing documentary evidence of services delivered.
- Helping to address complaints or legal processes.

Educational

- Supporting clinical audit, research, allocation of resources and performance planning.

The Department of Health's Records management: NHS code of practice 2006 covers NHS records of all types (including records of NHS patients treated on behalf of the NHS in the private healthcare sector, for example those residents of care homes who are eligible for NHS continuing care) regardless of the media on which they are held. The GDG discussed this in the context of social care and agreed that for residents living care homes these may consist of:

- patient health records (electronic or paper-based, including those concerning all specialties, and GP medical records)
- accident & emergency, birth, and all other registers
- administrative records (including, for example, personnel, estates, financial and accounting records; notes associated with complaint handling)
- emails
- computerised records
- scanned records
- text messages (for example, texts between a GP and a care home).

The GDG agreed that accurate and up-to-date record-keeping processes should be recorded in the care home medicines policy (see recommendation 2.1.1), which should detail the records to be maintained in relation to managing medicines in care homes. This should include:

- the resident's care plan
- the resident's medication administration record

- correspondence and messages (email, letters, text messages, transcribed phone messages) regarding medication
- transfer of care letters, temporary absence information
- copies of prescriptions, order notes for residents.

The GDG concluded that all care home providers must ensure appropriate records relating to medicines are kept secure, for an appropriate period of time, and destroyed securely when appropriate to do so.

Records of medicines administration

Care homes have a legal duty under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (regulations 13 and 20) to maintain accurate records of care given to residents, and a further requirement from the CQC under the Essential standards of quality and safety (outcome 9B) to keep records related to the administration and non-administration of residents' medicines.

As the SCIE stated, 'poor record-keeping is essentially poor communication', which was one of the causes of medication error identified by the CHUMS (see sections 3.5 and 3.14).

The NMC's Standards for medicines management (2010) sets out a number of standards for nursing registrants. Standard 8 (administration) states that: 'as a registrant, in exercising your professional accountability in the best interests of your patients: you must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible…'. Additionally, 'where medication is not given, the reason for not doing so must be recorded'.

The GDG agreed that evidence from legislation, regulation (both of care homes and of health professionals) and practice demonstrated that care home staff have a responsibility to make records of residents' medications that have been administered, refused, disposed of or returned to a pharmacy.

The GDG concluded that in line with the general principles for individual responsibility, paper-based or electronic records should be:

- legible
- signed
- have the correct date and time
- clear and accurate
- factual
- completed as soon as possible after administration
- avoid jargon or abbreviations
- easily understood by the resident, their family member or carer.

Record-keeping and the use of medicines administration records

Medicines administration records are for recording the administration and non-administration of medicines in care homes (see also sections 3.11 and 3.14).

Improving pharmaceutical care in care homes (Royal Pharmaceutical Society 2012) states that 'consent is required if pharmacists are providing services that involve accessing the following data protected information … Medicines Administration Recording (MAR) Charts – even if they are supplied by the community pharmacy, when they are used by the care home to record information the MAR becomes a confidential document'.

Medication administration records are used as a record of medicines administration. When care home staff complete hand-written medication administration records charts, there must be a process in place to double check that the details are correct, such as all entries on the medication administration record being checked for accuracy and signed by a second person before use. For records of disposal see section 3.12.

The GDG concluded that it would be good practice for hand-written medication administration records to only be completed by a trained and competent member of care home staff with designated responsibility for medicines in the care home. This record should be checked by another trained and competent member of staff who also has designated responsibility for medicines in the care home (see section 3.11).

Use of text messages

The NMC's Standards for medicines management (2010) discusses the handling of text messages, which are classed as legal documents when pertaining to residents. The NMC (standard 12) states that 'as a registrant, you must ensure that there are protocols in place to ensure patient confidentiality and documentation of any text received include: complete text message, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant. An order to administer medication by text messaging is an increasing possibility. A second signature – normally another registrant but where this is not possible another person – should sign to confirm the documentation agrees with the text message. It must be regarded as a patient contact and all documentation should be in keeping with the NMC's Record keeping: Guidance for nurses and midwives (2009). All received messages should be deleted from the receiving handset after documentation to maintain high standards of confidentiality'.

The GDG acknowledge that for nurses working in care homes this standard is expected of those registrants. For those social care practitioners working in care homes the GDG concluded that while text messaging should be used in exceptional circumstances only to convey details relating to care home residents, when this does take place the NMC standard should be adhered to in that:

- The care home medicines policy (see recommendation 2.1.1) should have a clear process in place in relation to text messages to ensure patient confidentiality and documentation of any text received including:
  - recording the complete text message, the telephone number (it was sent from), the time the text was sent, any response given, and the signature and date when received by the registrant to be recorded in the care plan
  - when orders to administer a medicine are received via a text message, the care home staff should seek assurance that that the sender of the text is a prescriber for the resident concerned (confirming that the

number of the phone is an agreed contact number for the prescriber recorded in the resident's care plan).

- A second signature from a senior colleague should be required to confirm the documentation agrees with the text message before administration.

The GDG concluded that processes for recording text messaging should be recorded in the care home medicines policy (see recommendation 2.1.1). Health and social care practitioners should only use text messaging to convey details of care home residents in exceptional circumstances.

Reporting adverse effects of medicines

The NMC's Standards for medicines management (2010), standard 25, discusses the reporting of adverse medication effects. It states: 'as a registrant, if a patient experiences an adverse drug reaction to a medication, you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately'.

The GDG agreed that residents can, and should be encouraged to, report any adverse effect from a medicine to the care home staff, their prescriber or directly to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. Any remedial action should be taken under the direction of a health professional.

The GDG concluded that care home staff should report all suspected adverse effects to medicines to the prescriber as soon as possible. Details of the effect on the patient should be recorded in the resident's care plan.

1 **Recommendations**

Recommendation 2.4.1

All care home providers must ensure that appropriate records of a resident's medicines are stored securely, for an appropriate period, and destroyed securely when appropriate.

Recommendation 2.4.2

Paper-based or electronic medicines administration records should:

- be legible
- be signed
- be clear and accurate
- be factual
- have the correct date and time
- be completed as soon as possible after administration
- avoid jargon and abbreviations
- be easily understood by the resident, their family member or carer.

Recommendation 2.4.3

Care home providers should ensure that hand-written medication administration records should only be completed by a trained and competent member of care home staff with designated responsibility for medicines in the care home. Ensure this record is checked for accuracy and signed by a second trained and competent person before use.

Recommendation 2.4.4

Health and social care practitioners should use text messaging to convey details of care home residents only in exceptional circumstances.

Recommendation 2.4.5

Care home staff should report all suspected adverse effects to medicines to the prescriber as soon as possible. Record details of any adverse effects in the resident's care plan (see recommendation 2.6.1).

2

3.5 Medication errors

The Francis Report (2013) emphasised the need to put patients first at all times, and that they must be protected from avoidable harm. The Berwick report (2013) recommends 4 guiding principles for improving patient safety, 2 of which are:

- 'place the quality and safety of patient care above all other aims for the NHS
- engage, empower, and hear patients and carers throughout the entire system, and at all times' (see section 3.2).

The GDG agreed that these guiding principles are also relevant to care home residents and apply across health and social care.

The NHS outcomes framework for 2013 to 2014 requires commissioners and providers of NHS services to reduce the incidence of medication errors causing serious harm. The GDG agreed that although care homes are not NHS services, this would also be relevant to care homes.

For the purpose of this guidance, medication errors are:

- prescribing errors
- dispensing errors
- medication administration errors
- monitoring errors.

See appendix A for definitions.

From the evidence identified, older residents living in care homes are frequently prescribed multiple medicines. The GDG recognised that many other residents, such as those with physical disabilities, also frequently take multiple medicines.

Evidence suggests people taking multiple medicines for long-term conditions are most likely to have a medication error. Care home residents appear to be

at greater risk of a medication error than most other patient groups, because of their complex health and care needs.

There is a limited evidence base on medication errors in care homes. However, the CHUMS (2009) identified an 'unacceptable level' of medication errors in older residents living in care homes. On any one day, 7 out of 10 residents experienced errors with their medicines. Most errors had negligible consequences for residents and no cases of harm were observed. However, in some cases, medication errors may have serious, potentially life-threatening consequences.

Although the CHUMS was conducted in older residents living in care homes, the GDG agreed that the findings were likely to apply to all care home residents who are taking medicines, such as children and people with learning and physical disabilities.

Prevalence of medication errors in the CHUMS

The prevalence of medication errors observed in the CHUMS is shown in table 1. Errors occurred at all stages, although the prevalence of monitoring errors was higher than other medication errors. There was no statistically significant difference in medication administration errors according to the principal medicines delivery system used (see section 3.11).

The mean potential harm (and range) for each type of error was estimated using a 0-10 scale (see table 1).

Table 1 Prevalence of medication errors and level of potential harm associated with errors in the CHUMS

	Prevalence of errors (95% CI)	% residents with at least 1 error (95% CI)	Mean level of harm[1] (range)
Prescribing errors	8.3% (7.1% to 9.7%)	39.1% (33.0% to 45.3%)	2.6 (0.2–5.8)
Dispensing errors	9.8% (8.5% to11.2%)	36.7% (30.8% to 42.9%)	2.1 (0.1–5.8)
Medication administration errors	8.4% (7.0% to 10.0%)	22.3% (17.3% to 27.9%)	2.0 (0.2–6.6)
Monitoring errors[2]	14.7% (10.3% to 20.1%)	18.4% (CI not reported)	3.7 (2.8–5.2)

[1]1–10 scale: 1 least harmful, 10 most harmful. [2]Only includes residents prescribed a medicine that required monitoring. CI: confidence interval

The most common types of medication errors observed in the CHUMS are shown in table 2.

Table 2 Most common types of medication errors observed in the CHUMS

Type of error	Most common reasons for error
Prescribing errors	• Incomplete information (38%) • Unnecessary drug (24%) • Dose or strength error (14%) • Omission of a medicine that should have been prescribed (12%)
Dispensing errors	• Labelling errors (7.3%) • Errors with the content of the medicine dispensed, for example incorrect strength (2.3%) • Clinical errors, for example dispensing a medicine that could result in a serious drug interaction (0.21%)
Medication administration errors	• Omission errors (49.1%) • Incorrect dose given (21.4%)
Monitoring errors	• Failure to request monitoring for a medicine that required monitoring (91%)

Causes of medication errors in care homes

A wide range of causes of medication errors in care homes have been identified in the published evidence, including:

Involving residents (see section 3.2)

- Residents (and some of their carers and care home staff) who are unable to give an accurate medication history.
- Reluctance of residents to complain or raise medicines-related problems.

Resident safety

- Inadequate knowledge about a resident and their condition, for example:
  - prescribers not knowing, or being unfamiliar with the residents
  - prescribing without computerised notes or prescribing software
  - inadequate medicines information in the care home.
- Inadequate review of medicines (see section 3.8).
- High workload of care home staff – approximately 40–50% of their time is spent on medicines-related activities.

Communication (see section 3.3)

- Poor communication and lack of information-sharing about medicines across health and social care, including with the resident and/or their carer. For example:
  - when there are changes to the resident's medicines
  - when the resident's care is transferred between different care providers, for example from the hospital to the care home following hospital discharge.

Medicines management systems (see sections 3.9–3.12)

- Inadequate medicines management systems from prescribing through to the resident receiving their medicines. For example:
  - failure to deal with changes to medicines accurately, and in a timely manner
  - delays in obtaining new medicines
  - failure to identify residents who require monitoring
  - inefficient management of repeat prescriptions
  - inadequate labelling of medicines.
- Several GP practices providing care for a care home's residents, with different systems in place.

- Inaccurate medicines records and discrepancies between different sources of medicines information (see section 3.7). This may be because of, for example:
  - advice from secondary care not being integrated accurately into the medicines records
  - prescribers not updating computerised notes on returning to their practice.
- Repackaging medicines into monitored dosage systems.

Medicines administration (see sections 3.13–3.15)

- Frequent distractions and interruptions of care home staff undertaking the 'drug round'.
- Poor design of medicines trolleys that are not able to facilitate the efficient storage and administration of both monitored dosage systems and original packs.
- Medicines administration records not being accurately maintained to reflect changes to residents' medicines.
- Environmental factors, for example poor lighting, temperature, cluttered workspace and noise.

Training and competency (see section 3.17)

- Inadequate medicines knowledge and poor training of care home staff, for example:
  - about adverse effects and drug interactions
  - how and when medicines should be administered and monitored
  - confusion between the generic and trade names of medicines
  - confusion between similar shaped and coloured medicines
  - inaccurate ordering of medicines and not anticipating 'out of stock' situations.
- Frequent use of new or agency care home staff.

Organisational governance

- Lack of timely access to primary care providers, such as GPs.

- Inconsistency of GPs – many residents see a number of different GPs, with the frequent use of locums.
- Lack of ownership of the whole medicines system and leadership in reducing medication errors across general practice, pharmacy and the care home.

Reducing medication errors in care homes

From the evidence identified, there have been some suggestions for interventions to reduce medication errors in care homes, but there is no robust evidence to support any particular strategies over others. These strategies include:

- having a preferred GP provider, with the ability to electronically prescribe from the care home
- GPs reviewing their process for identifying residents to be monitored and ensure monitoring is carried out (see section 3.9)
- medication reviews conducted by a pharmacist for all residents at least every 6 months (see section 3.8).

The GDG was concerned at the high prevalence of medication errors in care homes across the whole medicines system. The GDG agreed with the conclusions of the CHUMS that the failure to identify residents who required monitoring was a particular concern (see section 3.14).

The GDG was aware of the wide range of causes of medication errors and recognised the need to improve systems and processes for managing medicines in care homes across the whole medicines system. For example, the need for improved medicines management systems, better communication and improved organisational ownership and responsibility. The GDG agreed that implementing recommendations in this guidance will help to address the causes of medication errors (see sections 3.1, 3.3, 3.4, 3.5, 3.6 and 3.7).

The GDG concluded that all people, care homes and organisations commissioning or providing care for residents should ensure robust processes

are in place for identifying, reporting, reviewing and learning from medication errors involving residents, in line with local and national governance arrangements (also see section 3.6). Care home providers should have the process recorded in the care home medicines policy (see recommendation 2.1.1).

The GDG concluded that commissioners and providers may want to consider collaborating with all relevant stakeholders to develop a locally agreed action plan to reduce medication errors in care homes, in line with other local and national strategies for improving resident safety.

Recommendations

Recommendation 2.5.1

Organisations should ensure that a robust process is in place for identifying, reporting, reviewing and learning from medication errors involving residents (see also recommendations 2.6.1 – 2.6.10).

Recommendation 2.5.2

Health and social care practitioners should consider collaborating with all relevant stakeholders to develop a locally agreed action plan in line with other local and national strategies for improving resident safety and reducing medication errors in care homes.

3.6 Safeguarding

Safeguarding in relation to adult care homes is defined by the Essential standards of quality and safety (CQC, 2010) as: 'Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights'.

In relation to children in care homes the Department for Education's Working together to safeguard children (2013) defines safeguarding and promoting the welfare as:

- 'protecting children from maltreatment;

- preventing impairment of children's health or development;
- ensuring children are growing up in circumstances consistent with the provision of safe and effective care; and
- taking action to enable all children to have the best outcomes.'

For both adult and children's care homes there is legislation for England, Wales and Northern Ireland that relates to safeguarding. It is outside the scope of this guidance to cover all safeguarding legislation for the regions and therefore care homes should make themselves aware of the safeguarding legislation that relates to their care home residents, depending on the age and location of the care home.

There are regulatory requirements for care homes in England, both for adults and children, to have safeguarding processes in place. For adults in care homes in England the CQC's Essential standards of quality and safety (outcome 7) states the requirement that 'residents are protected from abuse, or the risk of abuse, and their human rights are respected and upheld'.

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 requires that: 'the registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity'.

For children in care homes in England, the Department for Education's Children's homes: national minimum standards (2011) standard 4 states that: 'Children feel safe and are safe. Children understand how to protect themselves; and feel protected and are protected from significant harm including neglect, abuse and accident'.

Notification of safeguarding incidents

For children in care homes any concerns from any health and social care practitioner about maltreatment should be dealt with by a referral to the local

authority children's social care team, which must initiate enquiries to find out what is happening to the child and whether protective action is required.

Local safeguarding children's boards were established in law by The Local Safeguarding Children Boards Regulations 2006, led by local authorities and having representatives from relevant local bodies (including the NHS). One of their roles is to 'coordinate the work to safeguard children locally and monitor and challenge the effectiveness of local arrangements' (Working together to safeguard children 2013).

The Office for Standards in Education, Children's Services and Skills (Ofsted) assesses council children's services, and also inspects services for looked after children, safeguarding and child protection. Local safeguarding children's boards need to have in place processes for informing Ofsted of any child protection concerns arising in the children's care home setting.

For adults in care homes the statutory body to whom safeguarding incidents must be reported is the CQC. Additionally many local authority areas will have local safeguarding bodies such as local safeguarding boards that will require local notification of safeguarding concerns.

The Care Quality Commission (Registration) Regulations 2009 (provision 18) sets out the conditions when the 'registered person' for the care home must notify the CQC of safeguarding incidents. The CQC must be notified without delay about incidents where a resident has, in the opinion of a health professional, suffered:

- 'an impairment of the sensory, motor or intellectual functions of the service user that is not likely to be temporary,
- changes to the structure of a service user's body,
- the service user experiencing prolonged pain or prolonged psychological harm, or
- the shortening of the life expectancy of the service user;'.

The same regulation (provision 18) also requires that the registered person should report any incident in which a resident, in the opinion of a health

professional, requires treatment (by any appropriate health professional) in order to prevent:

- 'the death of the service user, or
- an injury to the resident which, if left untreated, would lead to' those injuries stated above.

Additionally the circumstances in which registered person must notify the CQC include:

- 'any application made to a court in relation to depriving a service user of their liberty'
- 'any abuse or any allegation of abuse in relation' to a resident (physical or psychological ill-treatment)
- 'theft, misuse or misappropriation' of residents' property (medication included)
- 'neglect and acts of omission that cause residents harm or place at them at risk of harm'
- 'any incident which is reported to, or investigated by, the police;'.

The GDG discussed the implications of provision 18 of the Care Quality Commission (Registration) Regulations 2009 and identified that the regulations do not explicitly state that a health professional will always be contacted in the case of a safeguarding incident related to medicines.

The GDG concluded that in the event of a suspected or confirmed safeguarding incident involving medicines, always contacting an appropriate health professional to ask for opinion on the care required in relation to the medication incident would be considered good practice. An appropriate person may include the prescriber of the medication, an out-of-hours service or supplying community pharmacist, or an urgent care provider.

The GDG was also aware from oral and written evidence presented to it that many care home staff may not have the necessary skills to determine when a health professional's advice may need to be sought, or to identify or investigate incidents (for example, root cause analysis skills). From evidence

presented to the GDG by care home providers this is a particular concern when incidents happen 'out-of-hours'. The process for reporting medication incidents to a health professional (both in normal office hours and out-of-hours) should be recorded in the care home medicine policy (see recommendation 2.1.1). The reporting process should be agreed with the appropriate health professionals and commissioners (when appropriate).

The GDG concluded that the examination of the root causes of medication related safety incidents was likely to be a prerequisite skill for fully investigating incidents and that care homes should consider this in their training needs and commissioners should address this through contracting mechanisms.

Processes for notifying safeguarding incidents

Children's care homes should follow their locally established procedures for notifying their local authority children's social care team of any safeguarding incident or concern.

Evidence presented to the GDG suggests that, in relation to adult care homes, the interpretation and understanding of the term 'safeguarding' is inconsistent, with care home providers and care home commissioners often having differing views on what incidents should be regarded and/or notified as safeguarding issues.

The GDG heard that there is variation in the requirements for notifying other agencies (such as local authorities, clinical commissioning groups or local safeguarding boards) of safeguarding incidents involving medicines, with some areas requiring all safeguarding issues to be notified while others require only issues involving actual loss of health, safety or welfare of a resident be reported.

The GDG was aware that the UK government has made a statement on safeguarding policy that 'in order to support those people most vulnerable to abuse and neglect it is vital that agencies agree collectively, those issues that require a safeguarding response as opposed to issues, which relate to standards and quality of care more widely'.

The GDG concluded that care home providers should have a process for reporting of incidents locally (for example, to a local safeguarding board) and to the CQC (or other appropriate regulator) and this should be recorded in the care home medicines policy (see recommendation 2.1.1). The process should clearly state in what circumstances the CQC should be notified and the agreed local criteria and process for reporting medicines safeguarding incidents. Reporting requirements should be included in commissioning and contracting arrangements.

The GDG further concluded that the details of which agency incidents should be notified locally should be for local consideration and determination, but the arrangements should be agreed locally with stakeholders and incorporated both within the care home medicines policy and a local notification policy.

The CQC require that care home providers reporting safeguarding incidents must not be individually identified and instead residents must be referred to using a code unique to them or a unique identifier. Care homes must keep a record of these codes and who they refer to, in case the CQC needs to make further enquiries. In all cases the notifications about an incident affecting a person must include those details listed in box 3. In Wales and Northern Ireland similar requirements are in place with the CSSIW and the RQIA.

Box 3 Information to be notified to the CQC when a safeguarding incident has occurred

- A unique identifier or code for the person
- The date they were or will be admitted to the service
- Their date of birth
- Their gender
- Their ethnicity
- Any disability
- Any religion or belief
- Their sexual orientation
- All relevant dates and circumstances
- Any action taken in response to the incident

The GDG agreed that notifications should, when acceptable, follow requirements similar to those of the CQC and as a minimum contain:

- a unique identifier or code for the resident
- the date the resident was admitted to the care home
- the resident's date of birth
- the resident's gender
- any disability
- any religion or belief (if pertinent to the incident)
- all relevant dates and circumstances
- any action taken in response to the incident.

The GDG concluded that it would be good practice for care home providers to maintain a copy of what has been reported and to whom (CQC or a local safeguarding board) in the resident's individual care plan and to document who else has been notified (for example, residents, carers or advocates).

Learning from safeguarding incidents

The report into the Winterbourne view care home abuse case highlighted a series of serious failures in safeguarding the rights of residents in that care home. The GDG was aware that in A promise to learn – a commitment to act (2013), part of the Berwick review into patient safety, it is stated that 'patient safety cannot be improved without active interrogation of information that is generated primarily for learning, not punishment, and is for use primarily at the front line'. The GDG agreed that the same principal applies to the reporting of safeguarding incidents involving medicines in care homes.

The GDG discussed the requirement that the registered person must protect residents against the risks associated with the unsafe use and management of medicines, and the requirements to notify the CQC of safeguarding incidents that have occurred. The CQC's Essential standards of quality and safety (outcome 9B) require providers of care (care homes) to have 'arrangements for reporting adverse events, adverse drug reactions, incidents, errors and near misses. These should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety'.

Additionally, evidence suggests that local reporting may identify trends in medication errors caused by factors outside of the care home environment, such as in GP practices or community pharmacies, more quickly than if care homes dealt with issues internally.

From the oral and written evidence presented to it, the GDG identified some potential barriers to an open reporting culture. For example, diligent notification of incidents by some care homes might lead them to be seen as having difficulties managing medicines compared with other homes that did not notify incidents. In some instances, when care homes have reported safeguarding issues, they do not know what has been done with that information after it was submitted because little or no feedback has been given.

The GDG agreed that following a medication-related safeguarding incident the primary concern should be the welfare of the resident. It concluded that accurate records of the details of the incident should be made by care home staff as soon after the incident as is possible to help investigation and reporting of the incident.

From oral and written evidence presented to the GDG, a number of organisational outcomes from safeguarding notifications were identified:

- improved care
- improved management processes
  - policies
  - procedures
  - processes
  - defined roles and responsibilities
- learning opportunities (targeted areas of learning)
- improved opportunities for monitoring and error detection
- improved communication.

The GDG agreed that the benefits of local area notification of all incidents and the potential for shared learning were consistent with good practice.

The Royal Pharmaceutical Society's Improving pharmaceutical care in care homes (2012) has supported the introduction of error reporting by all service providers for all aspects of medicines use in care homes. This should be the basis of shared learning and improvements in care, safety and team work.

Evidence provided to the GDG suggests that services having a clear focus on involving residents and resident safety (see section 3.2) is paramount in improving safeguarding. The Department of Health, in Patients first and foremost (2013), has committed to a statutory duty of candour on health and social care providers to inform people who use the service and their family members or carers (as appropriate) about any problems that have affected the quality and safety of their care, and explain why they have happened.

From the oral and written evidence provided to the GDG, other factors that were identified as working well in learning from incidents that have occurred included:

- the involvement of the multidisciplinary team (GP, pharmacist, community matrons and specialist nurses, care home staff and management) in discussion of incidents and in supporting care homes when incidents have occurred with an emphasis on good communication (providing the resident agrees to the information-sharing, see section 3.3)
- using root cause analysis
- computerised incident reporting, which allows real-time analysis of incidents and opportunities for timely intervention
- shared learning from incidents (both within and, in anonymised formats, between care homes)
- local safeguarding teams providing feedback to care homes and staff on incidents they have looked at in a supportive, 'no-blame' manner to encourage further reporting
- regular staff training, including training for managers on incident investigation, medicines safety awareness-raising, reflective practice or clinical supervision (see section 3.17)
- monitoring of incident trends
- spot-checking of staff practice and competence (see section 3.17).

The GDG agreed that detecting problems quickly and investigating the root causes of problems were important first steps for any shared learning to take place, and that it is also necessary to explain any failings in care under a duty of candour. The GDG agreed that all members of the multidisciplinary team should be involved in shared learning following incidents.

The GDG concluded that open notification of all resident medication incidents would increase transparency and promote a learning culture. Whenever a local reporting system is in place (to a local safeguarding board, for example) there should be feedback about incidents to care homes to facilitate shared learning.

In review of the evidence presented, the GDG further concluded that if safeguarding reports are made to a local safeguarding body (such as a local safeguarding board) the reports should be monitored for trends as well as each report being investigated on its own.

Near misses

The NPSA defined a near miss as a prevented patient safety incident, however they go on to classify near misses and any other type of incident as patient safety incidents, which they define as: ‘A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care’.

Oral and written evidence provided to the GDG suggested that the term ‘near miss’ was often used in local policy documents, but was often poorly defined and could be interpreted to imply:

- incidents that reached the patient but that caused no harm or minimal harm (often these were seen as safeguarding incidents based on potential for harm)
- incidents that did not reach the patient, such as prevented patient safety incidents.

The oral and written evidence presented to the GDG suggests that some care home providers categorise near misses as either critical or non-critical, depending on whether they cause harm to a resident.

The GDG was aware from evidence presented to it that the most frequent reasons cited for escalating a medication incident from a near miss to a medicines related safeguarding issue were:

- actual harm
- CQC notification requirements
- as a result of an investigation/advice from a local safeguarding board
- when a breach of professional standards (such as record-keeping or the standards for medicines administration) has occurred.

The GDG agreed that if an incident has caused harm it should not be regarded as a 'near miss' even if harm was minimal, and that the incident should be notifiable locally (to a local safeguarding board for example) and to the CQC (if the incident met the CQC criteria for reporting).

The GDG agreed that resident medication safety incidents that are deemed to be 'near misses' should be reported locally if they could have caused harm to a resident. The same benefits of reporting medicines safeguarding incidents would likely also apply to near miss reporting (shared learning and encouraging an open reporting culture, for example).

The GDG concluded that all medication incidents, including all near misses, should be regarded and recorded as a resident safety incident, regardless of whether the incident caused harm and should be reported to regulators as appropriate.

Interventions that may help prevent safeguarding incidents

The NPSA's Seven steps to patient safety in general practice (2009) states that a strong safety culture requires a number of factors to be in place with regard to care homes. The GDG agreed that these were:

- ‘Leadership – the whole practice team to show that they believe in a good safety culture and are prepared to take ownership when things go wrong.
- Teamwork – the role of every practice member in promoting safety to be recognised and valued.
- Accountability – fair responsibility for your actions and accountability on four levels: professional, legal, ethical and contractual.
- Understanding – moving on from blaming the individual to recognising the role of system factors in patient safety.
- Communication – not assuming staff have understood the importance of patient safety and of recognising risks; remind them and applaud good practice. Make it commonplace and easy for all members of the team to speak up about concerns, taking care to reduce the impact of hierarchical relationships.
- Awareness of workload pressures – when times are busy, risks increase.
- Safety systems – robust systems to be put in place to prevent common errors’.

Oral and written evidence provided to the GDG showed that services should have a strong resident safety focus with good communication between health and social care practitioners, for example GPs, pharmacists, care home staff and residents (see sections 3.3 and 3.5). The GDG agreed that care home residents should receive the same level of care and support that would be received by a non-resident accessing care services.

The GDG found that it is often residents and their carers (family and friends) who are the first to notice any issues with their medication. Although often underestimated by staff providing direct care, evidence suggests that the perception of problems by residents is likely to be accurate. However, people will often choose not to report issues of concern if they are fearful of the reaction of care home staff or practitioners, or they think that their concerns will be dismissed (see section 3.2).

The GDG agreed that processes for informing residents how to raise concerns about their medicines should be a part of the care home medicines policy (see

recommendation 2.1.1) and also be part of the information given to residents on admission to the care home.

The GDG concluded that every care home resident and/or their family members or carers should know how to report medication incidents and concerns about medicines using the care home provider's complaints process, local authority (or local safeguarding board) process and/or the appropriate regulator's process.

Assessing and improving resident participation in safeguarding

The UK government policy on safeguarding recommends that the 6 principles should be used to identify the key outcomes of safeguarding for residents when assessing resident involvement in safeguarding processes.

The GDG noted evidence that suggests that one of the key interventions in order to ensure that the above outcomes can be achieved is advocacy, which has been defined as a principled activity encompassing 3 key principles:

- independence
- empowerment
- inclusion.

Advocacy has been found to be effective with diverse populations of older people in a range of settings. The Health Foundation and the SCIE have stated that all care home residents should have access to an independent advocate. The GDG found evidence of a range of proposed models of advocacy ranging from independent advocates for each home and local or national schemes, through to professional standards for advocacy (such as the NMC). Evidence suggests that advocates should be trained to recognise abuse and, in the context of inappropriate prescribing of medicines, should act as an advocate for the patient during medication review.

The CQC's Essential standards of quality and safety (outcome 1A) states: that to ensure 'personalised care, treatment and support through involvement… people who use services are involved in and receive care, treatment and support that respects their right to make or influence decisions because the

service…makes people who use services aware of independent advocacy services wherever they are available'.

Other interventions from the published literature, and written and oral evidence presented to the GDG, that were recognised to improve resident outcomes in relation to safeguarding include:

- all residents and carers having access to a formal complaints procedure that allows confidential complaints to be made to an independent body without fear of reprisal
- greater involvement of carers (resident's family and friends) in planning and reviewing care of the resident (with the resident's permission) (see section 3.3)
- an independent board of governors for care homes with a mandate for quality and safety that would be outside the normal management of the care home.

The GDG agreed that there was too little evidence of effectiveness to make a recommendation on the use of independent boards of governors for care homes.

The GDG concluded that all residents living in care homes should have access to advocacy and independent complaints services to address concerns relating to medicines.

1 Recommendations

Recommendation 2.6.1

Care home providers should report confirmed and suspected medication incidents to a health professional (both in normal office hours and out-of-hours).

Recommendation 2.6.2

Care home staff should contact an appropriate health professional to ask for advice on the care needed after a medication incident. An appropriate health professional may include the prescriber of the medicine, an out-of-hours service, the community pharmacist supplying the medicine or an urgent care provider.

Recommendation 2.6.3

Care home providers should consider using root cause analysis when investigating safety incidents related to medicines. They should also consider the training and competency needs of care home staff undertaking this role. Commissioners should consider addressing this through contracting mechanisms.

Recommendation 2.6.4

Care home providers should notify the appropriate regulators and the appropriate local safeguarding body (for example, a local safeguarding board or local safeguarding children's board) about any medicines safeguarding incident.

Recommendation 2.6.5

Care home providers should maintain a copy of the information reported about medicines safeguarding incidents and details of to whom it was reported (CQC or a local safeguarding [children's] board) in the resident's care plan and document who else has been notified (for example, residents, family members, carers or advocates).

Recommendation 2.6.6

Care home staff should record accurate details of any medication incident as

soon as possible to facilitate investigation and reporting of the incident.

Recommendation 2.6.7

Care home providers should promote an open culture for notifying all medication incidents to increase transparency and foster a learning culture.

Recommendation 2.6.8

Local safeguarding bodies (for example, local safeguarding [children's] boards) should investigate each individual medication incident report, monitor local trends and share information about medication incidents with care homes for facilitating shared-learning.

Recommendation 2.6.9

Health and social care practitioners should ensure that all medication incidents, including all near misses, are regarded and recorded as resident safety incidents, regardless of whether they caused harm, and should be reported to regulators, as appropriate.

Recommendation 2.6.10

Ensure that every care home resident and/or their family members or carers know how to report medication incidents and concerns about medicines using the care home provider's complaints process, local authority (or local safeguarding board) process and/or the appropriate regulator's process.

Recommendation 2.6.11

Ensure all residents have access to advocacy and independent complaints services to address concerns relating to medicines.

3.7 Medicines reconciliation

The CQC considers that managing medicines when a resident transfers from one setting to another is central to safe, high-quality care (see section 3.3).

Written evidence submissions considered by the GDG suggest that there are often no clear processes for communicating changes in medicines between providers in a timely manner, following a transfer of care (see section 3.3).

Residents who are transferred into a care home from other settings, such as after hospital discharge, often arrive with little information about their medicines.

When a resident is transferred into a care home, accurate and reliable information about their medication needs to be transferred at the same time. Medicines reconciliation enables this to occur and has been defined by the Institute for Healthcare Improvement as 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'.

The National Prescribing Centre (NPC)[1] publication Medicines reconciliation: a guide to implementation (2008) identified a number of benefits of medicines reconciliation, such as:

- increasing resident involvement (see section 3.2)
- improving communication between health professionals and other people involved in the transfer of resident's care, including residents and their carers (see section 3.3)
- improving multidisciplinary team working (see section 3.3)
- improving medicines record-keeping, with a minimum dataset of medicines information being recorded appropriately (see section 3.4)
- reducing the risk of medication errors and adverse effects of medicines (see section 3.6)
- reducing inefficiency and duplication of work.

NICE has also published guidance on Technical patient safety solutions for medicines reconciliation on admission of adults to hospital (2007). Although this guidance relates specifically to hospital admission, the GDG agreed that the principles may also apply in other care settings, such as care homes.

[1] The National Prescribing Centre (NPC) is now the NICE Medicines and Prescribing Centre.

The GDG concluded that medicines reconciliation in care homes has the potential to reduce medication errors and improve resident safety. The care home and other organisations commissioning or providing care for residents need to consider the resources that are necessary to ensure medicines reconciliation is carried out (see section 3.7).

The GDG further concluded that the process outlined in the NPC's Medicines reconciliation: a guide to implementation (2008) could be used as a guide to medicines reconciliation. A robust process for medicines reconciliation should be in place and should be recorded in the care home medicines policy (see recommendation 2.1.1).

Who should be involved in medicines reconciliation?

Evidence suggests that the following people may be involved in medicines reconciliation (NPC):

- the person responsible for the transfer of the resident's care
- the person receiving the resident into their care
- the resident and/or carer involved
- other people involved in managing medicines for the resident, such as pharmacists, prescribers, community matrons, care home staff, case managers, practice managers and ward clerks.

NICE guidance on medicines reconciliation recommends that pharmacists are involved in medicines reconciliation as soon as possible after hospital admission. The GDG agreed that medicines reconciliation in care homes should also involve a pharmacist.

The GDG also agreed that it would be beneficial to involve other health and social care practitioners who know the resident, such as the GP or a community matron. The patient and/or their carer should also be involved in the process, when possible.

Evidence also suggests that training and competency is an important area for local consideration (see section 3.17). People who are undertaking medicines reconciliation should be trained and competent in the following areas (NPC):

- effective communication skills
- technical knowledge of relevant medicines management systems (see figure 1 and section 3.1)
- evidence-based therapeutics.

The GDG agreed that medicines reconciliation has been difficult to address because of poor communication and a lack of ownership of the task. The GDG concluded that the person who is responsible for the resident's transfer into the care home, such as the care home manager, should be responsible for ensuring medicines reconciliation occurs, as part of the resident's care plan. Medicines reconciliation for residents in care homes should involve:

- the resident and/or their family members or carers
- a pharmacist
- other health and social care practitioners involved in managing medicines for the resident as agreed locally, such as the GP or community matron.

The roles and responsibilities of all people involved in medicines reconciliation, and how they work together, should be carefully considered and agreed locally. Training and competency needs should also be addressed (see section 3.17).

Information needed for medicines reconciliation

The CHUMS (2009) identified that 'incomplete information' was one of the commonest causes of prescribing errors. In order to complete the medicines reconciliation process effectively, evidence suggests that specific information about the medicines prescribed for a resident is needed.

The NPC guide on medicines reconciliation suggests a minimum dataset of information that should be available. The Royal Pharmaceutical Society transfer of care report includes core information that should be communicated when a resident moves between care providers. Information should be clear, unambiguous and legible and should be available as soon as possible.

The GDG recognised that medicines reconciliation in care homes should usually be between the care home medication administration record and the GP practice medication list.

The GDG concluded that all providers need to ensure that information about the resident and their medicines is available when a resident transfers into or from a care home, so that medicines reconciliation can be carried out. This information should be available on the day of the resident's transfer.

The GDG concluded that the core information included in the Royal Pharmaceutical Society transfer of care report could be considered the minimum information that is needed for medicines reconciliation, and this should be relevant to health and social care. The process for medicines reconciliation in care homes should be recorded in the care home medicines policy (see recommendation 2.1.1). All providers should ensure that the following information is available for medicines reconciliation on the day of the resident's transfer into or from a care home:

- resident details, including full name, date of birth, NHS number, address and weight if under 16 years
- GP details
- other relevant contacts defined by the resident and/or their carer, such as the consultant, usual community pharmacist, specialist nurse
- known allergies and adverse effects to medicines or excipients
- current medicines, including name, strength, form, dose, frequency, route of administration
- changes to medicines, including medicines started, stopped or dosage changed, and reason for change
- additional information and support, including review and monitoring requirements, adherence support
- information given to the resident and/or carer
- details of the person completing the record.

1 Recommendations

Recommendation 2.7.1

The person responsible for a resident's transfer into a care home, such as the care home manager, should ensure that medicines reconciliation occurs as part of a comprehensive needs assessment. Consider the resources needed to ensure that medicines reconciliation occurs in a timely manner (see recommendation 2.1.1).

Recommendation 2.7.2

Health and social care practitioners should ensure that the following people are involved in the medicines reconciliation process:

- the resident and/or their family members or carers
- a pharmacist
- other health and social care practitioners involved in managing medicines for the resident, as agreed locally.

Clearly define the roles and responsibilities of each person and how they work together and consider their training and competency needs.

Recommendation 2.7.3

All providers should ensure that the following information is available for medicines reconciliation on the day of a resident's transfer into or from a care home:

- resident's details, including full name, date of birth, NHS number, address and weight if under 16 years
- GP's details
- details of other relevant contacts defined by the resident and/or their family members or carers (for example, the consultant, usual community pharmacist, specialist nurse)
- known allergies and adverse effects to medicines or excipients
- current medicines, including name, strength, form, dose, frequency, route of administration
- changes to medicines, including medicines started, stopped or dosage

changed, and reason for change

- additional information, including review and monitoring requirements, adherence support
- information given to the resident and/or family members or carers
- details of the person completing the record.

3.8 Medication review

Evidence suggests that care home residents are frequently identified as a population that would potentially gain most benefit from medication reviews.

Medication review has been defined as (NPC) 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'.

Many care home residents have multiple and complex conditions. These conditions can change and the medicines residents receive to treat these conditions need to be reviewed on a regular basis, to ensure they remain safe and effective. In addition, age-related changes in pharmacokinetics and pharmacodynamics make children and older residents particularly susceptible to the adverse effects of medicines.

From the evidence identified, polypharmacy appears to be a particular issue in care homes. The CHUMS found that care home residents take an average of 8 different medicines each day. In addition, studies of prescribing in UK care homes suggest inappropriate prescribing may occur in 50–90% of residents.

A guide to medication review (NPC 2008) provides advice for commissioners and providers of medication reviews in a wide range of care settings. A number of potential benefits for medication review have been cited in the published evidence, such as:

- improving the current and future management of the resident's medical conditions
- greater resident involvement and support for shared decision-making
- reducing inappropriate polypharmacy and excessive prescribing
- reducing unwanted or unused medicines
- reducing adverse effects relating to medicines
- reducing costs.

Evidence suggests that medicines are often not adequately reviewed in care homes. The CHUMS highlighted medication review as one of the main areas where improvement was needed. A survey of UK care homes found that 44% of residents did not have a regular planned review of their medicines.

Evidence also suggests there is often no planned, structured approach to medication review and a more formal process for care planning and medication review would be beneficial. There also appears to be some uncertainty about who should undertake medication reviews, how often they should occur, and what standard criteria should be used. The GDG agreed that an optimal model for medication review in care homes has not been identified.

The GDG also highlighted the wide variation in the quality of medication reviews. This may mean that residents do not get the maximum benefit from their medicines and has the potential to lead to harmful adverse effects. They recognised that there are a number of reasons why medication reviews for care home residents do not appear to be adequate. These include:

- inadequate resources
- they are time-consuming and challenging to undertake, and there may be a lack of dedicated time
- lack of leadership and understanding of their importance
- not being considered a high priority
- inconsistency of primary care providers
- poor medicines management systems.

Although the GDG recognised that more high-quality studies are needed to determine the effect of medication review on outcomes for care home residents, they concluded that planned, structured medication reviews for residents represented good practice and may help to reduce the risk of medication errors and inappropriate or excessive prescribing. It should also be part of the resident's care plan as part of the care planning process.

The GDG concluded that there needs to be a clear, planned process in place for medication reviews for residents in care homes, and this should be recorded in the care home medicines policy (see recommendation 2.1.1). This should consider lines of responsibility and accountability between the care home, GP practice and community pharmacy.

Furthermore, given the lack of robust evidence to guide the optimal model for medication review, the GDG proposed that medication review for all people using medicines should be considered as a separate future topic for NICE good practice guidance.

Who should be involved in medication review?

A number of different health professionals can conduct medication reviews for care home residents. Evidence suggests that a pharmacist could potentially lead the process. The CHUMS recommends that pharmacists should regularly review residents and their medication and that they should also rationalise regimens to help care home staff work more safely. However, the available evidence appears to suggest that medication review should ideally involve a multidisciplinary group of key people, such as:

- the resident and/or their family members or carers (as appropriate)
- the GP
- a pharmacist
- care home staff.

The GDG acknowledged that the prescriber is ultimately responsible for ensuring medicines prescribed for residents are reviewed, but that the care

home also has ownership and responsibility to ensure that medication reviews occur.

The GDG discussed who should be involved in conducting medication reviews and who should lead the process. The GDG was aware that the pharmacist role may be undertaken by a care home pharmacist, a primary care pharmacist or the community pharmacist supplying the care home. The GDG agreed that the process should ideally be led by a dedicated care home pharmacist with appropriate clinical experience and training, such as a postgraduate clinical diploma and/or independent prescriber qualification. However, the GDG recognised that there are very few dedicated pharmacist roles specifically involved in providing services to care homes. The GDG agreed that experience and competence was important in determining who should lead the process, rather than which professional group they represented.

The GDG therefore concluded that the health and social care practitioners providing direct care to the resident should identify the named health professional responsible for undertaking medication reviews for each resident, taking into account their clinical experience and competency, their knowledge of the resident and their condition, and access to relevant information.

The GDG further concluded that the resident and their family members or carers (as appropriate) should be involved in their medication review and actively involved in decisions about their medicines (see section 3.2). Medication reviews should also involve a multidisciplinary team of locally determined practitioners. This may include a:

- GP
- care home pharmacist or primary care pharmacist
- community pharmacist
- practice nurse
- community matron or specialist nurse, such as a community psychiatric nurse
- care home staff

- social care practitioner.

The lead clinician responsible for undertaking the medication review should be determined locally for each resident. This decision should be based on their clinical experience and competence, knowledge of the patient and their condition and access to relevant information. The roles and responsibilities of each person and how they work together should be carefully considered and agreed locally. Training and competency needs should also be addressed (see section 3.17).

Frequency of medication review for care home residents

The National Service Framework (NSF) for older people (2001) recommends that 'all people over 75 years should normally have their medicines reviewed at least annually and those taking 4 or more medicines should have a review 6-monthly'. Evidence suggests this target may not be achieved in up to two-thirds of care home residents.

There is no robust evidence on the ideal frequency of medication reviews to improve outcomes for residents. It is generally accepted that residents should have a formal medication review at regular intervals of at least every 6 months. However, the GDG was aware that there may be resourcing implications to achieve this, particularly if this is undertaken by a locally determined multidisciplinary team.

In addition, it has also been suggested that a medication review should occur as soon as possible after a resident moves into a care home, for example after hospital discharge or as part of respite arrangements. There is also some evidence of specific residents being targeted for medication review, such as those taking a new medicine or high-risk medicines known to cause particular harm, such as anticoagulants, antipsychotics and non-steroidal anti-inflammatory drugs.

The GDG concluded that the frequency of medication reviews for care home residents should be determined on an individual case-by-case basis, depending on the health and care needs of the resident, with resident safety

paramount in decision-making. However, the GDG agreed that the frequency of multidisciplinary medication review should not exceed 1 year. More frequent medication reviews may be needed for some residents, for example:

- residents entering the end-of-life phase
- residents diagnosed with a new long-term condition
- residents who require frequent or complex monitoring
- residents who have been transferred to the care home, such as on hospital discharge.

The date of the next review should be established at the time of the medication review. The GDG agreed that the care home manager and the named, health and social care professional should ensure that all residents have multidisciplinary medication reviews within the agreed timeframe.

What should a medication review cover?

The NSF for older people (2001) and the NPC's Room for review (2002) highlight core areas that a detailed medication review should cover. Tools have also been developed to support medication review, such as the NO TEARS tool (Need/indication, Open questions, Tests, Evidence, Adverse effects, Risk reduction, Simplification/switches) and the STOPP and START criteria (Screening Tool of Older Person's potentially inappropriate Prescriptions and Screening Tool of Alert doctors to the Right Treatment).

Evidence suggests that developing standard criteria for medication review for may be beneficial. The GDG agreed that this could be addressed by future good practice guidance on medication review. However, the GDG recognised that based on the available evidence, some areas could be identified that should be covered in a medication review for care home residents.

The GDG concluded that a medication review for residents should discuss and review:

- the purpose of the medication review

- the resident's (and/or their family members' or carer's, as appropriate in line with the resident's wishes) perception and understanding of their medicines
- the resident's (and/or their family members' or carer's, as appropriate in line with the resident's wishes) concerns, questions or issues about their medicines
- compilation of all medicines (prescribed, over-the-counter and complementary medicines) being taken or used, and their indications
- the safety, effectiveness and appropriateness of all medicines, including compliance with national guidance
- any relevant monitoring tests
- any medicines-related problems experienced by the resident, such as adverse effects, difficulties with self-administration, difficulty swallowing
- medicines adherence
- further information or support needed by the resident and/or their family members or carers (as appropriate).

1 Recommendations

Recommendation 2.8.1

Health and social care practitioners should ensure the medication review process considers lines of responsibility and accountability between the care home, GP practice and community pharmacy. (See recommendations 2.1.1 and 2.8.4.)

Recommendation 2.8.2

Health and social care practitioners providing direct care to the resident should identify the named health professional responsible for undertaking medication reviews for each resident, taking into account their clinical experience and competency, their knowledge of the resident and their condition, and access to relevant information.

Recommendation 2.8.3

Health and social care practitioners should ensure that medication reviews involve the resident and/or their family members or carers and a local multidisciplinary team. This may include a:

- care home pharmacist or primary care pharmacist
- community matron or specialist nurse, such as a community psychiatric nurse
- community pharmacist
- GP
- member of the care home staff
- practice nurse
- social care practitioner.

The roles and responsibilities of each practitioner and how they work together should be carefully considered and agreed locally. Training and competency needs should also be addressed.

Recommendation 2.8.4

Health and social care practitioners should determine the frequency of multidisciplinary medication review for each resident on an individual, case-

by-case basis, depending on their health and care needs, with resident safety paramount in decision-making. Ensure that the interval between multidisciplinary medication reviews does not exceed 1 year.

Recommendation 2.8.5

The care home manager and the named, health and social care professional(s) for each resident should ensure that all residents have multidisciplinary medication reviews within the agreed timeframe.

Recommendation 2.8.6

Health and social care practitioners should discuss and review the following during a medication review:

- the purpose of the medication review
- the resident's (and/or their family members' or carer's, as appropriate in line with the resident's wishes) perception and understanding of the their medicines
- the resident's (and/or their family members' or carer's, as appropriate in line with the resident's wishes) concerns, questions or issues about their medicines
- all medicines (prescribed, over-the-counter and complementary medicines) being taken or used, and their indications
- the safety, effectiveness and appropriateness of all medicines, including compliance with national guidance
- any relevant monitoring tests
- any medicines-related problems experienced by the resident, such as adverse effects, difficulties with self-administration, difficulty swallowing
- medicines adherence
- further information or support needed by the resident and/or their family members or carers.

3.9 Prescribing medicines

The CHUMS found that the prevalence of prescribing errors for residents in adult care homes was 8.3% (95% CI 7.1–9.7), with 39.1% of residents having

at least 1 prescribing error (100/256) see tables 1 and 2. The most common errors included:

- incomplete information (38%)
- unnecessary drug (24%)
- dose/strength error (14%)
- omission of a medicine that should have been prescribed (12%).

Evidence suggests that the process of issuing prescriptions relies on the GP practice receptionist identifying each drug requested and having up-to-date patient records. The GDG found evidence that in some cases the doctor signing the prescription(s) does not always review the GP patient medical records when undertaking this task. In addition there are a lack of procedures for GP practice receptionists to generate prescriptions (for the GP to sign) when requested by care home staff during the ordering process (see section 3.10).

The GDG concluded that GP practices should ensure there is a clear written process for prescribing and issuing prescriptions for their residents living in care homes. The GDG recognised the importance of all prescribers and staff involved with prescribing and issuing prescriptions at the practice agreeing to this process. The process should consider the following:

- prescriptions to be issued in accordance with patient medical records
- records to be made in the GP patient medical record and resident care plan as soon as practically possible to update records with changes
- recording clear instructions on the use, duration and indication of the prescribed medicine
- monitoring requirements for relevant medicines
- prescribing quantities to fit within the 28-day supply cycle if appropriate, and necessary adjustments to be made for future supply (for example, if a new medicine is started on day 14 of the 28-day supply cycle, the quantity to prescribe will be 14 tablets, and the next prescription will need to be adjusted to 28 tablets if the medicine is to continue for the following month's supply)

- prescribing, monitoring and review of 'when required' and variable dose medicines
- generation of prescriptions when the care home sends the medicines order.

The GDG were presented with oral evidence describing reports of inadequate recording of prescriptions in the GP patient medical records when handwritten and issued in the care home.

The GDG discussed and agreed that, if possible, prescribers should have access to the GP patient medical records before issuing prescriptions. All medicines prescribed at the care home should be recorded in the GP patient medical record and the resident's care plan by the prescriber, updating any changes as soon as practically possible. This may include documenting instructions on the use (for example, where to apply a topical preparation and how much to use), expected duration and indication for the prescribed medicine. Instructions should also be provided and recorded for the resident (if self-administrating) and/or care home staff.

The GDG was aware that medicines are often prescribed on a monthly basis for care home residents with long-term conditions. In care homes, quantities of repeat prescribed medicines are issued on a 28-day supply cycle. Within this 28-day supply cycle, medicines are prescribed, ordered (see section 3.10) and supplied (see section 3.11). Evidence presented to the GDG suggests that quantities to prescribe for medicines that are new (repeat use) or have been changed should consider the point at which they are prescribed within the 28-day supply cycle, for example if a dose of a medicine has changed and a new prescription is required on day 21 of the 28-day supply cycle, then the quantity to prescribe would be 7 to synchronise the supply with other prescribed medicines for the remainder of the current cycle. In addition, where appropriate that the prescriber will need to consider prescribing for the next cycle.

The GDG discussed and agreed that good practice is represented by prescribers issuing 28-day prescriptions for residents on long-term medicines

when appropriate and to consider adjusting the quantity of newly prescribed or medicines that have changed to fit in with the 28-day supply cycle.

In addition, the GDG concluded that a collaborative approach is required between the prescriber, community pharmacy and care home to ensure effective communication when medicines have been started, stopped or changed, and that records used to record medicines administration are updated to accurately reflect the change to medicines.

From the evidence identified, the GDG found that clear instructions about 'when required' medicines should be taken provides clarity to care home staff when handling medicines for residents (see section 3.14). The GDG heard that the use of variable doses should be avoided whenever possible, unless care home staff are provided with criteria clarifying how much to give and under what circumstances. For example, when administering medicines for pain relief with a variable dose of 'take 1 or 2 tablets', the prescriber should provide a written instruction for circumstances to give 1 tablet and circumstances to give 2 tablets.

The GDG discussed and concluded that when prescribing variable doses and 'when required' medicines, it would be good practice for the prescriber to:

- document in the resident's care plan the instructions for:
  - circumstances for use
  - monitoring
  - expected outcomes
- include instructions on the prescription for community pharmacy to add to the label of the dispensed medicine
- specify the maximum daily dose and duration of use, when appropriate
- prescribe appropriate quantities, for example enough to last for 28 days or the expected duration of treatment
- liaise with care home staff in relation to the monitoring of efficacy and frequency of administration on an individual basis.

NICE quality standard for end of life care for adults covers all settings and services in which care is provided by health and social care practitioners to all adults approaching the end of life. Quality statement 11 states 'people in the last days of life are identified in a timely way and have their care coordinated and delivered in accordance with their personalised care plan, including rapid access to holistic support, equipment and administration of medication'. Anticipatory prescribing allows rapid access to those medicines required when providing palliative care in care homes. The GDG heard reports of local schemes for anticipatory medicines that are prescribed for use during end-of-life care.

The GDG discussed and agreed that the prescriber, care home provider and community pharmacist should be aware of local policies in place for anticipatory medicines. Residents in care homes should have the same access to anticipatory medicines as people who do not live in care homes.

1 Recommendations

Recommendation 2.9.1

GP practices should ensure that there is a clear written process for prescribing and issuing prescriptions for their care home residents. Agree the process with all prescribers and other staff involved with prescribing and issuing prescriptions. Include:

- issuing prescriptions in line with patient medical records
- recording changes to medicines in the GP patient medical record and in the resident's care plan as soon as possible
- documenting clear instructions on the use, duration and indication for the prescribed medicine
- monitoring requirements for relevant medicines
- ensuring prescribed quantities fit within the 28-day supply cycle as appropriate, and make adjustments for future supply. For example, if a new medicine is started on day 14 of the 28-day supply cycle, prescribe 14 tablets and adjust the next prescription to 28 tablets if the medicine is to be continued for the following month
- prescribing, monitoring and review of 'when required' and variable dose medicines
- issuing prescriptions when the medicines order is received from the care home.

Recommendation 2.9.2

The prescriber should record all medicines prescribed at the care home in the resident's care plan and update any changes in the GP patient medical record as soon as possible (see recommendation 2.3.6). This may include:

- documenting instructions on use, such as where to apply a topical preparation and how much to use
- expected duration of use
- indication
- additional instructions for use by the care home staff or resident (if self-administering).

Recommendation 2.9.3

Ensure effective communication and collaborative working between the GP practice, care home provider and the community pharmacy when medicines have been started, stopped or changed. Update records of medicines administration to accurately reflect the change to medicines.

Recommendation 2.9.4

When prescribing variable doses and 'when required' medicine(s) the prescriber should:

- document the following information in the resident's care plan:
  - circumstances for use
  - monitoring requirements
  - expected outcomes for the resident
- include dosage instructions on the prescription so this can be included on the label of the dispensed medicine, specifying the maximum daily dose and duration of use, as appropriate
- prescribe an appropriate quantity (for example, for 28 days or the expected duration of treatment)

When reviewing the medicine, the prescriber should liaise with care home staff to see how often the individual resident has received the medicine and review the efficacy.

Recommendation 2.9.5

The prescriber, care home provider and community pharmacist should follow local policies for anticipatory medicines. Ensure residents in care homes have the same access to anticipatory medicines as those people who do not live in care homes.

3.10 Ordering medicines

Care home providers are required to have clear processes in place that detail how medicines are ordered. Evidence suggests that this includes having a process in place for ordering repeat, acute and 'when required' medicines.

Verbal changes to medicines should only be considered under exceptional circumstances and this should also be included in the process.

The GDG was aware of evidence that where poor ordering systems are in place this can lead to medicines being lost, supplies running out or sharing and borrowing of medicines between residents.

The GDG was aware that legislation exists to ensure that prescribed medicines are only taken by the intended recipient. The GDG therefore concluded that medicines belonging to individual residents must not be borrowed or shared between residents.

Evidence suggests that care home providers often do not have contingency processes in place for obtaining medicines quickly, for example, during out-of-hours, and consequently residents may miss several days of their regular medicines.

Factors that can complicate the ordering process include:

- a lack of designated staff time to order
- limited number of staff designated to process the order
- multiple GP practices aligned to care home
- different types of prescription involved (such as for repeats, acute or 'when required' items)
- different floors or units within the same care home using different systems for obtaining medicines.

The GDG found evidence of over-ordering medicines by care home staff. They found that over-ordering and stockpiling of medicines and 'non-medicine' products are major issues that lead to medicine waste. Reasons for over-ordering include:

- tight deadlines for ordering
- lack of processes in place for ordering
- care home staff encouraging the continuation of medicines that are rarely used to ensure supply is available on the occasion it is needed.

The GDG discussed and agreed that the process for ordering medicines should follow the considerations outlined in box 4.

Box 4 Considerations for the care home medicines ordering process

Each home should have at least 2 competent members of staff who are able to undertake ordering of medicines (see section 3.17)
Use an up-to-date medication administration record or other accurate record of the resident's medication when ordering
Take into consideration ordering at different times – monthly basis and on an acute basis (for example, new prescription issued for a new or changed medicine)
Check and make appropriate records of quantities of repeat, acute and 'when required' medicines to avoid over-ordering and running out, according to a written process
Review expiry dates of medicines, consider medicines close to expiry (for example, the medicine at the point of checking may still be in-date, however it may expire by the time it's needed)
Synchronise medicines if changes have occurred during the middle of the 28-day supply cycle to regular medicines
Review previous usage of medicines before ordering and checking stock (stock reconciliation)
Protected time for ordering medicines, in particular for the monthly order
Maintain an audit trail of records kept

In light of the evidence the GDG discussed and concluded that care home providers must have processes in place for ordering medicines and this should be recorded in the care home medicines policy (see recommendation 2.1.1). The ordering process should ensure at least 2 competent members of staff are able to undertake ordering of medicines, although the ordering at any given time can be carried out by one member of

staff. The GDG also agreed that protected time should be allocated to carry out ordering of medicines to ensure residents receive all their medicines on time.

Methods of ordering

Evidence suggests that medicines can be ordered by the care home provider in a number of ways:

- directly from the GP practice using the repeat prescription ordering form (may use the right-hand side (FP10) of the prescription form)
- directly from the GP practice using the medication administration record
- via the community pharmacy supplying the care home, ordering prescriptions after visiting and/or consulting with the care home
- via the community pharmacy supplying the care homes, ordering prescriptions directly from the GP practice without contacting the care home.

The GDG was aware that some care homes may have an electronic system in place for ordering medicines.

From the evidence provided, the GDG recognised the importance of collaborative working and good communication between the GP practice, the community pharmacy supplying the medicines and the care home provider when ordering medicines.

The GDG found examples of collaborative working:

- managing repeat prescriptions by using electronic prescriptions between the GP practice, community pharmacy and care home
- having a joint approach with the clinical commissioning groups, councils, CQC, community pharmacy and care homes in developing a robust protocol for ordering medicines.

The GDG concluded that care home providers should maintain the responsibility for ordering medicines from the GP practice. This should not be delegated to the community pharmacy supplying the medicines to the care

home provider. However collaboration between the care home provider, GP practice and community pharmacy is essential.

The GDG was aware that, during the ordering process, care home providers may not have direct access to a prescription once a request for medicines has been made to the GP practice.

The GDG concluded that it would be good practice for care home staff to make appropriate records when ordering medicines, allowing care home staff to check that all medicines requested have been prescribed and supplied when receiving the order into the care home.

Evidence provided to the GDG suggests that the medication administration record should be used when communicating changes of medicines and discontinued medicines to the community pharmacy at the point of ordering.

The GDG discussed and agreed that good practice is represented by the care home provider informing the community pharmacy supplying medicines of any changes to medicines (including discontinuation of medicines) so that all records can be kept up-to-date.

Recommendations

Recommendation 2.10.1

Care home providers should ensure that medicines for individual residents must not be borrowed from, or shared with other residents.

Recommendation 2.10.2

Care home providers should ensure that care home staff have protected time to order medicines. Ensure at least 2 competent members of staff are able to undertake ordering of medicines, although the ordering at any given time can be carried out by one member of staff.

Recommendation 2.10.3

Care home providers should retain responsibility for ordering medicines from the GP practice. Do not delegate this responsibility to the community pharmacy supplying the medicines.

Recommendation 2.10.4

Care home providers should ensure appropriate records are maintained for ordering medicines. Check the medicines received against the original request to ensure that all medicines requested have been prescribed and supplied appropriately.

3.11 Dispensing and supplying medicines

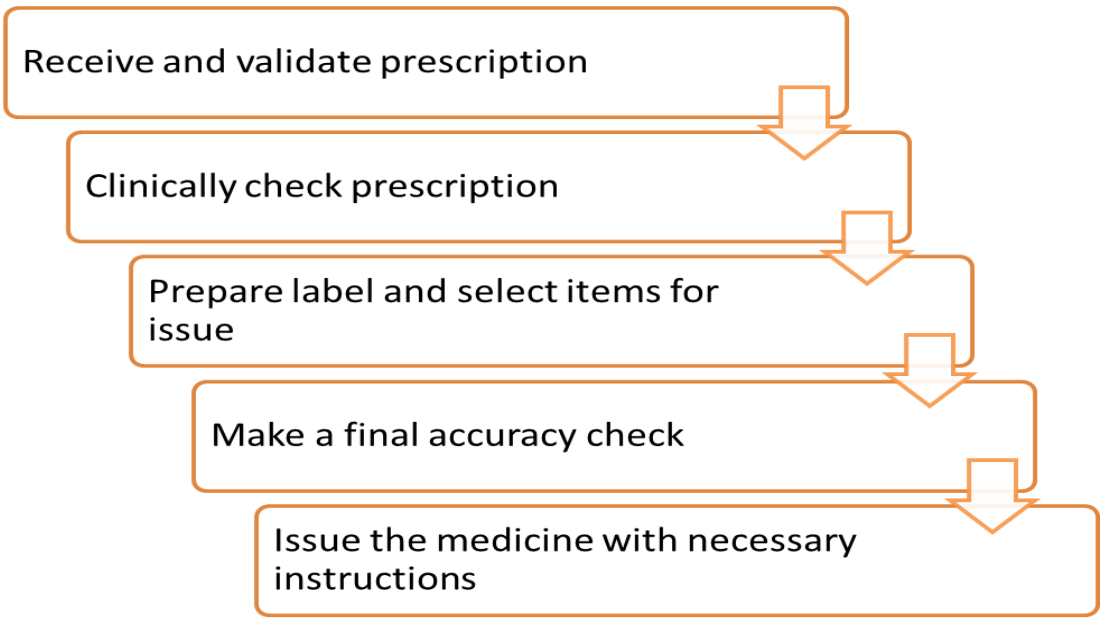
Medicines are mostly supplied by community pharmacies to care homes, however some care home providers obtain supplies of medicines from dispensing doctors. Dispensing doctors should follow guidance set out by the General Medical Council on delegating responsibility to dispense medicines within the practice.

This section focuses on the processes involved in the dispensing and supply of medicines by community pharmacies.

Dispensing

The dispensing process covers all activities involved from receiving the prescription to issuing the prescribed medicine to the patient (see figure 2).

Figure 2 Overview of the dispensing process, adapted from the WHO dispensing cycle



Evidence suggests that a pharmacist's clinical check of prescriptions before dispensing should include a review of both the prescription and the medicines administration record for errors, if the pharmacist is producing and supplying the medication administration record. This allows for double checking of, for example, dose, dose changes, frequency and times, identification of duplicate entries, review of new medicines and possible interactions with existing medicines.

The CHUMS highlighted the following as contributing to labelling and dispensing errors:

- IT system and information such as warnings or formulation being omitted from the medicine label
- inaccurate descriptions of medicines on the labels of monitored dosage system
- filling of monitored dosage systems.

The GDG reviewed the evidence and agreed that community pharmacies that supply medicines to care home providers should ensure robust processes are in place when dispensing and accuracy checking for care home residents using monitored dosage systems. The process should be followed by all people involved with dispensing medicines into monitored dosage systems.

Supply systems

Evidence suggests there are 2 widely used systems available to supply medicines:

- original packs
- monitored dosage systems, which may be single-dose or multi-dose.

The CHUMS highlighted that dispensing errors partly related to monitored dosage systems included:

- labelling found to be inadequate
- poor filling of compartments of the monitored dosage systems
- problems with identifying white tablets.

Improving patient outcomes through the better use of multi-compartment compliance aids (MCA) (Royal Pharmaceutical Society) suggests that monitored dosage systems should not automatically be the intervention of choice for all people and the use of monitored dosage systems should be considered following an individual assessment. An integrated approach between health and social care, between commissioners and care home providers, and among pharmacy bodies is suggested by the Royal Pharmaceutical Society on the continuing journey to improve patient outcomes. The GDG also heard that the community pharmacist could undertake an individual assessment of the resident's medicines needs before supplying medicines. See appendix D for comparison between each system.

The GDG was aware that the use of monitored dosage systems may often be driven by care home providers and patient demand. Also community pharmacy providers may suggest using a monitored dosage system as an 'added value' element of the supply of medicines.

The GDG discussed and concluded that care home providers should consider the most appropriate medicines supply system for the resident using a person-centred approach, seeking support from relevant health and social care practitioners. An assessment of the system needed for a resident should consider maintaining the resident's independence and their needs.

Medicines administration records

Care homes are required to keep appropriate records of all medicines and treatments given or administered to residents. A common type of medicines administration record used in care homes is the medication administration record, also known as 'MAR sheet' or 'MAR chart'. The GDG was aware that the responsibility of providing the medication administration record rests with the care home provider, who should produce an up-to-date list of medicines taken by residents when they first move into the care home, and is not the responsibility of the community pharmacy. However, the community pharmacy may provide them on request of the care home provider.

Evidence suggests that where the care home provider produces the medication administration records, there should be a process in place to check that the details are correct, such as all entries on the medication administration record being checked for accuracy and signed by a second person before use (see section 3.4). Community pharmacies producing medication administration records should also have a process in place and ensure that they are up-to-date and do not include any discontinued medicines on the medication administration record.

From the evidence identified, the GDG found that medicines administration records should include a resident's name and date of birth, allergies and intolerances, which medicines are prescribed with details and any special instructions.

In review of the evidence presented, the GDG found that the resident's GP, care home provider and community pharmacy have a joint responsibility to ensure this information is up-to-date and recorded accurately on the medication administration record.

The GDG discussed and agreed that a process should be in place for whoever is responsible for producing medication administration records. Medication administration records (paper-based or electronic) of individual residents should include the following details:

- the resident's name and date of birth
- which medicines are prescribed for the resident, including strength, route of administration and formulation, dose and frequency
- special instructions (such as before food, with food, after food)
- allergies or intolerances to medicines or excipients.

The prescriber, GP practice, community pharmacy and care home provider have a joint responsibility to ensure this information is up-to-date and recorded accurately on the medication administration record.

The GDG also agreed that, regardless of who is responsible for the production of medication administration records, good practice is represented by considering the following in the process for producing medication administration records:

- medication administration records should be accurate and up-to-date
- acute medicines should be taken off the medication administration record once treatment has finished
- changes to medicines should be updated on the medication administration record as soon as practically possible; this includes medicines that have been stopped, which should be removed from the medication administration record
- production of duplicated copies of medication administration records should be avoided
- liaising with key individuals such as the GP, to include allergies and intolerances to medicines (and excipients), on the medication administration records where known.

The GDG considered oral evidence suggesting that medication administration records vary in the information supplied for each medicine. The GDG was

aware that including as much supportive information as possible on the medication administration record, particularly in relation to medicines administration, represented good practice. See box 5 for examples of additional supportive information.

Box 5 Examples of additional supportive information to include on the medication administration record

- Administration of medicines at specific times of day, for example, for time-critical medicines
- Accurate description of medicines and whether they need to be taken with particular foods or drink (after discussion with the pharmacist if appropriate, and when required for the resident (see section 3.15)
- Maximum doses of medicines prescribed 'when required' or 'as directed', including indication for use
- Special handling requirements of medicines, for example, cytotoxic medicines
- Duration of treatment, if appropriate

The GDG concluded that the prescriber, community pharmacy and care home provider have a joint responsibility to ensure that information on the medication administration record is up-to-date and recorded accurately, including any supporting information that may be required.

The GDG found evidence of variation in the documentation of allergies and intolerances to medicines on the medication administration records. The GDG discussed and agreed that the prescriber, community pharmacy and care home provider have a joint responsibility to ensure allergies and any intolerances to medicines are accurately recorded on the medication administration record. This may also include recording allergies or intolerance to excipients in medicines.

1 Recommendations

Recommendation 2.11.1

Pharmacists supplying medicines to care home providers should ensure that robust processes are in place for dispensing and accuracy checking medicines for care home residents using monitored dosage systems. The process should be followed by all staff involved with dispensing medicines into monitored dosage systems.

Recommendation 2.11.2

Care home providers should determine the most appropriate system for supplying medicines for each resident on an individual, case-by-case basis, depending on their health and care needs. Maintain the resident's independence wherever possible and seek support of relevant health and social care practitioners as appropriate.

Recommendation 2.11.3

Ensure production of medication administration records (paper-based or electronic) includes the following:

- resident's details, including full name, date of birth and weight if under 16 years
- current medicines, including name, strength, form, dose, frequency, route of administration
- additional information, including review and monitoring requirements, adherence support, special instructions about how the medicine should be taken (such as before food, with food, after food)
- known allergies or intolerances to medicines or excipients

Recommendation 2.11.4

The prescriber, GP practice, community pharmacy and care home provider should ensure that information included on the medication administration record is up-to-date and recorded accurately, including any additional information that may be required.

Recommendation 2.11.5

The prescriber, GP practice, community pharmacy and care home provider should ensure allergies and any intolerances to medicines are accurately recorded on the medication administration record. This may also include recording allergies or intolerance to excipients in medicines.

3.12 Receiving, storing and disposing of medicines

Receiving medicines

The GDG recognised the importance of care homes having a process in place for receiving medicines into the care home once they have been ordered. Evidence suggests that on receipt of the medicines, the care home staff should check the dispensed medicines against their records of ordering. This would ensure that all medicines requested have been supplied and any discrepancies can be resolved, without delaying treatment to the resident.

Storing medicines

The CQC and the Children's homes: national minimum standards require providers to have clear processes in place for safe storage of medicines. For the storage of controlled drugs, care home providers must comply with the requirements of the Misuse of Drugs Act 1971 and their associated regulations, and the Safer Management of Controlled Drugs Regulations 2006. This includes appropriate storage of all controlled drugs administered to residents by care home staff (see section 3.14) and for controlled drugs supplied to residents to self-administer (see section 3.13). Specifications of cabinets and safes set out in Schedule 2 of the Safe Custody Regulations should be regarded as a minimum standard for the storage of controlled drugs.

In review of the evidence the GDG found variation in the way medicines are stored in care homes. Inefficient systems and processes for storing and managing stocks of medicines are widely reported as a cause of errors, wastage and delay. Evidence presented to the GDG suggests a lack of

processes in place or, where there are processes, a lack of awareness and training in how to follow them.

From the evidence provided, the GDG agreed that the following should be considered in a medicines storage process for care home staff to follow:

- where medicines are stored
- storage of medicines supplied in monitored dosage systems (these need much more storage space to cover the change-over period each month)
- storage requirements for specific medicines, such as controlled drugs, refrigerated items, external topical preparations, oral nutritional supplements, dressings and appliances
- secure access by authorised care home staff only
- storage temperatures and monitoring (fridge 2–8°C, room usually no more than 25°C)
- storage of medicines for self-administration (see recommendations 2.13.2, 2.13.5).

The GDG concluded that care home providers must have processes in place for safe storage of medicines, in accordance with legislation and regulations, and this should be recorded in the care home medicines policy (see recommendation 2.1.1).

In the review of its evidence, the GDG acknowledged the need to move to personalised care with residents having the option to keep their medicines in lockable cabinets in their room. This would ensure all medicines that belong to the resident are kept together and not transported around the care home, and also self-administration and/or administration by care home staff in their rooms can give them privacy.

The GDG concluded that storage requirements of residents' medicines should be assessed by the care home provider using a person-centred approach and provisions should be made based on the resident's needs, choices and risk assessment.

Disposing of medicines

The disposal of medicines is regulated by The Controlled Waste (England and Wales) Regulations 2012. Medicines fall under the category of 'clinical waste' under these regulations. Table 3 summarises the disposal requirements for the type of care home.

Table 3 Disposal requirements for the type of care home

Non-nursing care homes	• Clinical waste is treated as household waste • Medicines that are no longer required should be returned to the community pharmacy for disposal
Nursing care homes	• Clinical waste is treated as industrial waste and is subject to the Special Waste Regulations 1996 (as amended 2001). • The waste must be consigned to a suitably authorised waste management facility (this may be the community pharmacy that supplies the medicines; however, nursing care homes need to check if the community pharmacy agrees to disposing of the medicines)

A guide to the Disposal of medicines in nursing homes has been written for Northern Ireland by the Regulation and Quality Improvement Authority (2011). This covers the key legislation and regulation for the disposal of medicines in the region, including the Waste Management Licensing Regulations (Northern Ireland) 2003 and the Controlled Waste Regulations (Northern Ireland) 2002.

The CQC's Essential standards of quality and safety and regulation 21 of the Children Act 1989: Guidance and regulations volume 5: children's homes require care home providers to have a procedure in place for the safe disposal of medicines.

From the evidence provided, the GDG found that where poor practice has been highlighted, procedures are not clear for:

- disposal of medicines (including those in a monitored dosage system)
- recording of medicines that have been disposed of
- managing medicine supplies when no longer required by the resident.

The GDG acknowledged that for a resident who has passed away, their medicines should be retained under lock and key, segregated from other

medicines and kept within the service for at least 7 days in case there are any coroner's investigations into the death. Once the death certificate has been signed the medicines can be destroyed.

The GDG discussed and concluded that care homes must make arrangements to remove clinical waste and have a process in place to ensure the safe disposal of medicines, which should be recorded in the care home medicines policy (see recommendation 2.1.1). The process should consider the resident's consent and also how and when to promptly dispose of surplus, unwanted and expired medicines (including controlled drugs). The process should also include disposing of medicines for a resident who has passed away.

The Department of Health's report and action plan on 'Improving the use of medicines (for better outcomes and reduced waste)' recognises the specific needs and circumstances required for the care of older people, and that the care home providers and health professionals may have adopted a number of system approaches to the management of medicines that may in themselves create waste. For example, care home staff returning tubs of topical preparations back to the community pharmacy every month and ordering new ones.

The GDG discussed and agreed that as long as the medicine is still needed, is still within its expiry date and that the manufacturer's literature does not specify a short shelf-life when the product is opened, there is no requirement for the medicine to be disposed of early.

Records for disposing of medicines

Evidence suggests that when a medicine is being disposed of, specific records should be made as soon as possible on an appropriate electronic or paper-based record.

In review of the evidence, the GDG found that specific records should include as a minimum: the date, the medicine, the quantity being disposed of, the reason for disposal and the name of the care home staff making the record. In addition to this, the name, strength and form of the medicine will need to be

recorded in the resident's record when medicines are disposed of by care home staff on behalf of the residents. When the medicines are consigned for disposal on behalf of the resident, the waste transfer note would only need to include the quantity, name, strength and form and not the resident's name. The GDG discussed and agreed that when disposing of medicines, the care home provider could consider the good practice points outlined in box 6.

Box 6 Good practice points to consider when disposing of medicines

- Use the medication administration record to record the quantity of any remaining items at the end of the 28-day cycle that can be carried forward for use in the next month if it is still prescribed
- Medicines waiting to be disposed of should be recorded and stored securely in a tamper-proof container in a locked cupboard until they are collected or taken to the pharmacy
- Medicines that have been discontinued or items no longer used should be highlighted to the supplying community pharmacy so that the item is not printed on the next 28-day medicines administration record and the remaining quantity should be disposed of according to the disposal procedure

Controlled drugs

The GDG discussed and agreed that the NPC's A guide to good practice in the management of controlled drugs in primary care (England) can be used to highlight key points to consider when disposing of controlled drugs in care homes. These have been summarised in table 4:

Table 4 Disposal requirements for controlled drugs in care homes

	Non-nursing care home	Nursing care home
Arrangements	• Controlled drugs should be returned to the relevant pharmacist or dispensing doctor at the earliest opportunity for appropriate destruction	• The care home will need to make arrangements for the collection of waste medication with a Waste Management Regulations licensed waste disposal company • Controlled drugs must be denatured before being handed to the waste disposal company, for example in specially designed denaturing kits
Records	• Care homes should record the forms and quantities of controlled drugs they are returning, and the pharmacist/dispensing doctor should sign for them on receipt. If pharmacy staff collect the controlled drugs, they should sign for them in the controlled drugs register at the time of collection • Relevant details of any such transfer for disposal should be entered into the controlled drugs register and signed by a trained and competent member of staff, returning the drug	• For 'stock' controlled drugs, a registered nurse and an authorised witness for destruction should sign the controlled drugs register • For controlled drugs supplied to individual residents, a registered nurse and a suitably trained witness should sign the controlled drugs register • A record of the waste transfer note needs to be made by the appropriate nursing care home staff

The GDG agreed that good practice is represented by having specific records for medicines (including controlled drugs) that have been disposed of and by considering additional good practice points (see box 6) during the process.

1 Recommendations

Recommendation 2.12.1

Care home providers must comply with the Misuse of Drugs Act 1971 and their associated regulations, and the Safer Management of Controlled Drugs Regulations 2006, when storing controlled drugs.

Recommendation 2.12.2

Care home providers should consider including the following information in their process for the safe storage of medicines:

- where medicines are stored
- storage of medicines supplied in monitored dosage systems
- storage requirements for specific medicines, such as, controlled drugs, refrigerated items, external topical preparations, oral nutritional supplements, dressings and appliances
- secure access by authorised care home staff only
- storage temperatures and monitoring (fridge 2–8°C, room usually no more than 25°C)
- storage of medicines for self-administration (see recommendations 2.13.2, 2.13.5).

Recommendation 2.12.3

Care home providers should assess a resident's individual requirements for storing their medicines and should provide storage facilities based on individual needs, choices, risk assessment and type of medicines system the resident is using.

Recommendation 2.12.4

Before disposing of a medicine, care home staff should find out:

- if the medicine is still needed
- if the medicine is still within its expiry date
- if the medicine has a short shelf-life once opened

Recommendation 2.12.5

Care home providers should consider the following when safely disposing of medicines and removing clinical waste:

- resident's consent to dispose of the medicines
- how and when to dispose of surplus, unwanted and expired medicines (including controlled drugs)
- disposing of medicines of a resident who has passed away.

(See also recommendation 2.1.1)

Recommendation 2.12.6

Care home providers should maintain records of medicines (including controlled drugs) that have been disposed of, or are awaiting disposal. Store medicines awaiting disposal in a secure, tamper proof container in a secure cupboard until they are collected or taken to the pharmacy.

3.13 Self-administration

Self-administration of medicines is when a resident stores and administers medicines for their own use.

The CQC gives guidance for care home providers to consider in relation to self-administration and 'supporting and reminding residents to self-administer their medicines independently where they are able to do so by minimising the risk of incorrect administration'. The Children's Homes Regulations 2001 require the care home provider to make suitable arrangements for safe administration.

The GDG was aware of evidence that in relation to care homes control of medicines was a key theme with care home staff and health professionals. They cited concerns over safety, quality and continuity of care for their need to maintain control of prescribing and/or administration of medicines. Evidence demonstrates that this is very rarely challenged by residents and that residents reported that they had little involvement in prescribing decisions or self-administration of their medicines, often just taking what they were given. While it was recognised by health professionals that self-administration might

return independence and personal control to residents (if they were able to self-administer) and there was general support for them to do so, care home staff felt that difficulties would arise in medication recording, polypharmacy and medication review. Further, it was felt that running 2 systems (self-administration and supervised administration) would prove difficult in practice.

From the evidence provided, the GDG concluded that care home staff should presume that a resident is able to self-administer their medicines when they first move into a care home.

The GDG found evidence of variation in criteria for risk assessment used across care homes. Some evidence suggests validated self-administration tools used in hospitals could be adapted for use in care homes supporting self-administration. The risk assessment should consider the differing levels of administration support a resident may require. For example, the resident may be able to self-administer their oral medicines, but not any creams or ointment, or they may be able to use their inhalers, but may require assistance with oral medicines. Care home providers have a duty of care to support and remind residents to self-administer and this must be taken into consideration when assessing the competency of a resident.

The GDG discussed and agreed that risk assessment should use a person-centred approach to determine the level of support needed to self-administer. The following may be considered during the risk assessment:

- if self-administration will be a risk to the resident or to other residents
- risk management
- competency of the resident
- storage of medicines for self-administration
- responsibility of the care home staff, which should be written in the care plan for each resident.

Evidence outlining the most appropriate person to undertake the risk assessment for self-administration is mixed. The GDG discussed and agreed that when assessing whether a resident can safely self-administer, a

collaborative approach may be required depending on the needs of the resident. This should involve the resident (and family members or carers, if the resident wishes) and care home staff and may involve any other key people such as the GP, pharmacist or other allied health professional or social care practitioner as appropriate. The people who should be involved in the risk assessment should be determined on an individual case-by-case basis and they should identify whether an adjustment to medication will enable the resident to self-administer. The process for assessing whether as resident can self-administer some or all of their medicines should be recorded in the care home medicines policy (see recommendation 2.1.1).

During its deliberations, the GDG recognised that records required for self-administration depend on the support the resident needs to self-administer. The CQC's Essential standards of quality and safety outlines what care home providers should do to comply with regulation 13 and 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2012 in relation to self-administration of medicines and records. The care home provider should ensure records are made of any medication taken or reminded by the resident where this is part of the plan of care. The Children's Home Regulations 2001, Regulation 21 requires the children's care home provider to ensure a written record is kept of the administration of medicine to any child. However, if safely self-administered by the child, then a written record is not required (registered nurses providing care should also refer to the NMC's Standards for medicines management (2010) for any additional information regarding records for self-administration for children).

The GDG discussed and concluded that adult care home providers must ensure records are made for residents when they have been supplied the medicines for self-administration or when they are prompted to self-administer.

The GDG discussed this in the context of children's care homes and concluded that the children's care home provider must ensure records are made for residents living in children's homes who are able to self-administer

their medicines. The medication administration record should be used for recording:

- that the resident is self-administering
- whether they require monitoring (for assessment of ability or compliance with therapy)
- that medicine has been taken as prescribed (either by direct observation or by questioning the resident)
- who has recorded this.

Evidence gathered suggests that care home providers should make provisions for their residents who wish to self-administer and keep their medicines in their room. The GDG discussed that the designated place for the storage of medicines should be secure (in a locked cupboard or drawer) and that the resident understands the requirement for the medicines to be kept safely and out of reach from other residents.

The GDG concluded that the storage of medicines for self-administration should be based on an individual risk assessment and, if considered appropriate, medicines may be stored in the resident's room in a lockable cupboard or drawer. Appropriate access provided for those medicines with special storage requirements (see section 3.12).

Controlled drugs

Residents can administer their own controlled drugs, if they are self-administering their medicines. Evidence suggests that residents who self-administer controlled drugs do not need to use a controlled drugs cabinet to store them in, but should store them in their personal lockable non-portable cupboard or drawer in the care home. Some care homes may have a policy that controlled drugs may only be administered by trained care home staff, and case safe custody regulations will apply when the care home look after controlled drugs.

A guide to good practice in the management of controlled drugs in primary care (England) (NPC 2010) suggests a record of a resident's own controlled

drugs should be kept, in addition to the records maintained on the medication administration record. There is no need to keep a record in the controlled drug register when the resident is wholly independent and is responsible for requesting a prescription and collecting the controlled drugs personally from the community pharmacy. If the resident does not arrange the supply and collection of controlled drugs but relies on the care home staff to do so, there should be clear records made in the controlled drugs register, including:

- receipt from the community pharmacy
- supply to the person
- any subsequent disposal of unwanted controlled drugs.

The controlled drugs register should contain separate pages for each resident's medicines and should have a column for recording running balances in order to maintain effective control and identify any discrepancies. If residents are self-administering, each individual dose taken does not need to be recorded.

The GDG concluded that processes for how the self-administration of controlled drugs are managed should be recorded in the care home medicines policy (see recommendation 2.1.1) and should clearly state:

- risk assessment
- obtaining or ordering
- supply
- storage
- records if prompted, supplied or when residents give the care home unwanted controlled drugs
- disposal.

1 Recommendations

Recommendation 2.13.1

Care home staff should presume that a resident is able to self-administer their medicines unless indicated otherwise following an individual risk assessment. Identify whether an adjustment to the medication regime for example, will enable to resident to self-administer.

Recommendation 2.13.2

Health and social care practitioners should undertake an individual risk assessment to determine the level of support a resident will need to self-administer their medicines. Risk assessment should consider:

- if self-administration will be a risk to the resident or to other residents
- the competency of the resident, such as whether the resident has mental capacity and dexterity to administer their medicines appropriately
- storage requirements for medicines
- the responsibilities of the care home staff, which should be written in the resident's care plan.

Recommendation 2.13.3

Collaboration between health and social care practitioners is required when undertaking an individual risk assessment to determine whether a resident can safely self-administer their medicines. Determine who should be involved in the risk assessment on a case-by-case basis involving the resident (and their family members or carers if the resident wishes) and care home staff. Consider involving additional key practitioners such as the GP, pharmacist, and/or other health and social care practitioners as appropriate.

Recommendation 2.13.4

Care home providers must ensure that records are maintained when adult residents are supplied medicines for self-administration, or when residents are prompted to self-administer.

Recommendation 2.13.5

Care home providers should ensure that medicines for self-administration

should be stored as identified in the individual risk assessment, such as in a lockable cupboard or drawer in a resident's room. Ensure that residents have appropriate access to medicines that have special storage requirements (see recommendations 2.12.1, 2.12.2, 2.12.3).

Recommendation 2.13.6

Care home providers should ensure that the process for self-administration of controlled drugs includes:

- individual risk assessment
- obtaining or ordering controlled drugs
- supplying controlled drugs
- storing controlled drugs
- recording supply of controlled drugs to residents
- prompting residents to take controlled drugs
- disposal of unwanted controlled drugs.

See recommendation 2.1.1.

3.14 Administration of medicines by care home staff

The administration of medicines is a fundamental task in care homes and widely undertaken by nurses and trained care home staff. The CHUMS (2009) found that care home staff may spend as much as 40–50% of their time on medicine-related activities, with errors occurring on 8.4% of observed medicine administration events (see section 3.5). The study highlights the importance of ensuring robust processes are in place for medicines administration in care homes.

For the purpose of this guidance, the GDG agreed to use the Medicines Act 1968 (section 130) definition of medicines administration: 'To give a medicine either by introduction into the body, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not'.

Evidence suggests that medicines administration processes should adopt a person-centred approach by engaging the resident or their advocate in decisions about their medicines. When this happens, medicines may be more likely to be taken as prescribed. The GDG was aware that residents may be prompted or given medicines to take by care home staff, which does not fall into the above definition of administration but supports the residents in taking their medicines (see section 3.13).

Legislation for medicines administration is included in regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 for care homes and regulation 21 of The Children's Homes Regulations 2001 for children's homes (see appendix B). The care home provider is responsible for ensuring adequate systems for medicines administration are in place.

In addition, the NMC and the Royal Pharmaceutical Society have produced standards and guidance on the use of medicines in care homes, for nurses and pharmacists respectively, to support adherence to legislation.

The GDG agreed that care home providers must ensure processes are in place for medicines administration and this should recorded in the care home medicines policy (see recommendation 2.1.1).

Evidence identified suggests medicines administration is predominantly undertaken by registered nurses and trained care home staff. Care home staff should be competent in administering medicines to residents (see section 3.17).

Registered nurses are health professionals who have legal and professional accountability. When registered nurses delegate medicines administration to care home staff, the registered nurse remains responsible and accountable for the appropriateness of the delegation. The nurse must ensure the competence of the care home staff and that delegation does not compromise existing resident care (see section 3.17).

Evidence suggests current policies for administration of medicines are not person-centred and are based on tasks, schedules and systems. The GDG

found evidence that where protocols are in place this has led to good practice in the administration of medicines, and where no written procedures or protocols were in place care homes failed to meet medicines management standards. The GDG discussed and agreed that medicines administration protocols should include systems and processes, but should be focused on the individual needs of residents. Good medicines administration protocols support achievement of meeting medicines management standards.

The GDG therefore concluded that the following should be considered in a medicines administration process:

- medicines that require specific administration techniques, such as patches, creams, inhalers, eye drops
- details of timely documentation to be made once administration of each medicine is complete
- process of administration, 6 R's of administration:
  - right resident (use of a photo and personal details with the medication administration record)
  - right medicine
  - right route
  - right dose
  - right time
  - residents' right to refuse
- take into consideration administration during meal times and if the resident is asleep
- use of the correct equipment to administer medicines (depending on the formulation, for example use of oral syringes for small doses of liquid medicines)
- how to record and report administration errors and adverse drug effects
- how medicines that are prescribed 'when required' are handled and used
- how to manage medicines when the resident takes temporary absence
- monitoring (for example, side effects) and evaluation of medicines administered.

Administration of 'when required' medicines

Care home providers should have procedures in place that include how medicines that are prescribed 'when required' are handled and administered. In review of its evidence, the GDG discussed and agreed that processes for administering 'when required' medicines include the following:

- identified reasons for giving the 'when required' medicine
- how much to give if variable dose has been prescribed
- the minimum time between doses if the required outcome did not occur
- eventual outcome
- if there is any confusion or ambiguity about what medicines or doses are to be given, the provider should make every effort to clarify the details with the prescriber
- 'when required' medicines should be detailed in the resident's personal care plan.

Evidence gathered suggests that 'when required' medicines should only be issued in their original packs to allow for date checking. The GDG concluded that 'when required' medicines should be kept within their original packaging and requests should not be made to be supply them in a monitored dosage system.

Timings for administering medicines

Evidence suggests that medication errors are more prevalent during the morning administration rounds. The GDG agreed that for those medicines that do not need to be administered in the morning, the resident, care home staff, prescriber and pharmacist can agree to administer these medicines at a time appropriate to the resident.

The GDG was aware that care home staff must not prepare medicines in advance for administration. This is known as 'potting up' which is illegal and does not follow good practice.

Medicines supply systems used for administration (see section 3.11)

Evidence suggests that the use of monitored dosage systems is seen as an automated process with little consideration about what the medicines are prescribed for and makes administration easier. The CHUMS highlighted that within the care homes using monitored dosage systems that were part of the study, 40% of doses for residents could not be handled using monitored dosage systems.

Evidence suggests that care homes having more than one system in place to administer medicines can contribute to administration errors because of lack of training and procedures and poor storage facilities when using monitored dosage system and original pack medicines (see appendix D).

The GDG was aware that regulation 22 of the Health and Social Care Act 2008 requires that care home staff must be trained and competent to use systems adopted in the care home for administering medicines. Regulation 26 of the Children's Homes Regulations 2001 requires that the care home staff must have the qualifications, skills and experience necessary to carry out their duties.

Documentation and recording

Evidence reviewed suggests that the care home provider needs to decide on the way in which records are kept. The records must be complete, legible, up to date, indelible, dated and signed to show who has made the record. The medication administration record is the most common record used in care homes. This record contains a list of the medicines administered to residents, which identifies the appropriate medicines for the person giving them and allows them to record that administration.

Evidence reviewed suggests that care homes do not record administration at the time of resident taking the medicine, and some rely on memory to record administration. The GDG agreed that appropriate records must be made as soon as practically possible, when the care home staff have administered the medicine, supplied the medicine or prompted the resident to self-administer

(see section 3.13). The GDG discussed and agreed a list of good practice points to consider when making records for medicines administration (box 7).

Box 7 Good practice points to consider for recording medicines administration

- Record administration once the care home staff have confirmed that the resident has taken their prescribed medicine
- Care home staff should record on the medication administration record, the date and the most appropriate time as specified on the relevant medicines administration record where the resident has more than one record
- Single person administration recording is less error prone than double recording on medication administration records
- Record 'when required' medicines only when they have been actually administered, noting the dose administered and the quantity left to ensure adequate supply and reduce waste
- Records to be kept and reasons why medicines have not been given
- Appropriate records may be required to record the full details of related information that may be useful for medicines administration (special diets, vegetarian)

Evidence demonstrates that there may be more than one record of administration of medicines, particularly when external health professionals such as district nurses come into the care home to administer medicines. The GDG concluded that external health professionals administering medicines to residents in the care home must make a record of administration on the appropriate care home medication administration record and in their own records. They should also consider undertaking the visit jointly with the care home staff responsible for administering medicines to the resident.

There is evidence suggesting that recording administration of some medicines on the medication administration record may not be considered appropriate. For example warfarin, variable insulin, oral nutritional supplements, dressings, depot injections or emollients (skin moisturisers), for which separate recording sheets may be used.

The GDG concluded that it would be good practice to make an entry on the relevant medication administration record when a medicine has a separate record for recording administration (for example, 'see warfarin administration record').

Controlled drugs

In accordance with CQC regulation, systems should be in place to ensure providers comply with the requirements of the Misuse of Drugs Act 1971, and their associated regulations and the Safer Management of Controlled Drugs Regulations 2006 when handling controlled drugs in care homes.

Evidence gathered suggests that if residents are not able to self-administer in a nursing care home, a medical practitioner or a registered nurse should administer the controlled drugs. In non-nursing care homes, controlled drugs should be administered by appropriately trained and competent care home staff and this should be witnessed by another appropriately trained care home staff member. The administration process should be fully completed for each resident, before moving on to the next resident.

The GDG agreed that good practice is represented by recording the care home staff administration of controlled drugs on the medication administration record and the controlled drug register. The care home staff administering the controlled drug and the appropriately trained witness should record their signatures in the controlled drugs register and the administering care home staff should record on the medication administration record (no signature is required by the appropriately trained witness on the medication administration record).

Disruption of medicines administration

From the evidence provided, the GDG found disruptions during administration of medicines to residents contributes to administration errors, and this was found to be most common during the morning medicines administration round with a few members of care home staff responsible for administering. Consequences of disruptions include:

- medicines trolleys being left unattended and unlocked
- some residents not receiving medicines that day
- mistakes with administration
- medicines being misplaced or lost
- delay in medicines administration round prevent residents receiving medicine on time
- no check that administration has been completed for each resident.

The GDG discussed and agreed possible interventions that could be used to avoid disruptions during the medicines administration round. These interventions are listed in box 8. The GDG was aware that avoiding disruption in the medicines administration round requires a team approach and a culture change. No single intervention will be suitable for all care homes and an individual approach will be required to establish what works for the care home in reducing interruptions.

Box 8 Possible interventions to avoid disruption to medicines administration rounds

- Address staff deployment and engage more trained care home staff during key times of drug rounds to ensure the administering care home staff have time to engage with the resident and check the medicine has been taken correctly
- Change administration times (for example from the morning to the lunchtime medicines administration round)
- Avoid planned breaks during the medicines administration round
- Work to make fewer distractions for the administering care home staff (having strategies in place to manage interruptions, such as returning non-urgent phone calls received after the medicines administration round)

Temporary absence from the care home

Residents may be absent from the care home for a period of time (for example when staying with relatives or friends). The GDG found examples from practice of how a resident's temporary absence from the care home could take account of the need for the administration of medication and a record of the resident's temporary absence. The GDG concluded that when a

resident leaves a care home temporarily, the care home provider should have a process in place to ensure relevant resident's medicines are sent with them, including a list of the current medicines and a copy of the medication administration record; this should be recorded in the care home medicines policy (see recommendation 2.1.1).

The GDG recognised the importance of care home staff ensuring that the resident, or the person who will be caring for the resident during their absence, understands what medicines they are currently taking.

The care home staff should give the resident or carer clear directions and advice on the administration of the resident's medication (when this is in accordance with the resident's ability and wishes). This should include the time of the last and next dose of each medicine to be administered.

Some evidence suggests that the care home provider should liaise with their community pharmacist supplying medicines for help and advice on managing residents' medicines during temporary absence. A separate container of medicines specific to the time of day might be needed if a resident takes regular leave, for example lunchtime medicines for a resident attending an adult training centre, or a separate supply of medicines for the full period of a holiday. If the resident regularly goes to spend weekends with family, there is no reason why their medicines should not go with them because the medicines are the resident's property.

The GDG discussed and agreed that the care home staff must ensure appropriate records are made and should ensure relevant information is provided to the resident and their family members or carers (as appropriate) when taking temporary absence from the care home. This may include:

- the medicines taken for leave
- clear directions and advice on administration of medicines
- time of the last and next dose of each medicine to be administered.

Information about medicines

In review of the information presented, the GDG found that care home staff may use a variety of resources to find information on medicines. The GDG discussed and agreed that care home staff should have access to appropriate medicines information and resources such as up-to-date patient information leaflets and the British National Formulary (BNF). The GDG was aware that there would be a small cost implication to care homes (for example purchasing copies of the BNF), but acknowledged that free access to up-to-date BNF and BNF for children (BNFC) via the NICE evidence portal.

Reliable and up-to-date resources and websites that may be used to find information on medicines are listed in box 9.

Box 9 UK-based websites and resources for information on medicines

Health professionals could use the following:

- British National Formulary (BNF)
- British National Formulary for Children (BNFC)
- Electronic Medicines Compendium

Health and social care practitioners could use the following:

- Patient.co.uk
- NHS choices website
- NICE Evidence
- Medicines and Healthcare Products Regulatory Agency (MHRA)

The GDG discussed and agreed that care home staff should only use UK-based websites that are reliable such as those outlined in box 9.

1 Recommendations

Recommendation 2.14.1

Care home providers should ensure that a medicines administration process, recorded in the care home medicines policy, includes the following:

- techniques for administration of medicines such as, patches, creams, inhaler or eye drops
- recording as soon as possible after administration of each medicine is complete
- administration of medicines using the 6R's of administration:
  - right resident (use of a photo and personal details with a medication administration record)
  - right medicine
  - right route
  - right dose
  - right time
  - resident's right to refuse a medicine
- administering medicines during meal times
- administering medicines if the resident is asleep
- using the correct equipment to administer medicines using the correct equipment (depending on the formulation, such as the use of oral syringes for small doses of liquid medicines)
- recording and reporting administration errors and adverse drug effects
- administering medicines when the resident is temporarily absent from the care home
- monitoring (for example, side-effects) and evaluating medicines administered.

(See recommendation 2.1.1).

Recommendation 2.14.2

Care home providers should ensure that a process for administering 'when required' medicines is recorded in the care home medicines policy, and

includes the following:

- the reasons for administering the 'when required' medicine
- how much to give if a variable dose has been prescribed
- the minimum time between doses if the required outcome has not occurred after the first dose
- the intended outcome
- details of when to clarify the details with the prescriber if there is any confusion or ambiguity about what medicines or doses are to be given
- recording 'when required' medicines in the resident's individual care plan.

Recommendation 2.14.3

Ensure 'when required' medicines are retained in their original packaging.

Recommendation 2.14.4

The resident, care home provider, prescriber and pharmacist should agree the appropriate time for administering medicines for each individual resident. Avoid busy times for medicines administration, such as a morning medicines round when possible.

Recommendation 2.14.5

Care home staff must be trained and competent to use system(s) adopted in the care home for administering medicines, including monitored dosage systems.

Recommendation 2.14.6

Care home staff must make appropriate records as soon as possible, when they have administered the medicine, supplied a medicine or prompted the resident to self-administer a medicines and ensure that they:

- record administration once it has been confirmed that the resident has taken their prescribed medicine(s)
- record the date and time taken as specified on the relevant medicines administration record
- record 'when required' medicines only when they have been administered, noting the dose administered and the quantity left, to ensure adequate

supply and reduce waste

- record when and why medicines have not been administered
- record any supporting information that may be useful for medicines administration, such as special dietary needs
- recognise that medication errors are less likely to occur if 1 member of staff records administration on medication administration records rather than 2 staff recording.

(See recommendation 2.14.1)

Recommendation 2.14.7

Health professionals administering medicines to residents in the care home must record the administration on the care home medication administration record and in their own records. Health professionals should consider seeing the resident with the care home staff responsible for administering medicines to the resident.

Recommendation 2.14.8

When a medicine has a separate administration record, such as warfarin, care home staff responsible for administering medicines should make an entry on the relevant medication administration record as cross-reference.

Recommendation 2.14.9

Care home staff should ensure that appropriate records are made of controlled drugs that have been administered to residents. The care home staff administering the controlled drug and an appropriately trained witness should sign the controlled drugs register and the medication administration record.

Recommendation 2.14.10

Care home providers should consider potential interventions to avoid or reduce disruptions during the medicines administration round, such as:

- ensuring that more trained care home staff are on duty during medicines administration
- reviewing the times for administering medicines (for example administering

once daily medicines at lunchtime rather than in the morning, if appropriate)

- avoiding planned breaks during the medicines administration round.

Recommendation 2.14.11

Care home staff must ensure that appropriate records are made and should ensure relevant information is provided to the resident and/or their family members or carers when the resident is temporarily absent from the care home. This should include:

- the medicines taken with the resident
- clear directions and advice on administering the medicines
- the time of the last and next dose of each medicine.

Consider liaising with the community pharmacy for advice on managing residents' medicines during temporary absence.

Recommendation 2.14.12

Health and social care practitioners should use reliable and up-to-date resources to find out information about medicines. These may include:

Health professionals using the following:

- British National Formulary (BNF)
- British National Formulary for Children (BNFC)
- Electronic Medicines Compendium

Health and social care practitioners using the following:

- Patient.co.uk
- NHS choices website
- NICE Evidence
- Medicines and Healthcare Products Regulatory Agency (MHRA)

3.15 Covert administration of medicines

'Covert' is the term used when medicines are administered in a disguised format without the knowledge or consent of the person receiving them, for example, in food or in a drink.

The care home provider should have procedures for arranging for covert administration of medicines only when it is needed, in accordance with the Mental Capacity Act 2005. When covert administration of medicines is being considered, there should be best interest meetings (see section 3.2) with people who know and understand the resident to decide whether it would be in the resident's best interest.

The GDG discussed and agreed that in some circumstances covert administration of medicines is necessary and justified, but that it should never be used for residents who have capacity to make decisions about their medical treatment. Covert administration of medicines should only be considered under exceptional circumstances.

The GDG discussed and concluded that care home providers should have a process in place for covert administration of medicines and this should be recorded in the care home medicines policy (see recommendation 2.1.1). Covert administration of medicines should only take place within the context of existing legal and best practice frameworks to protect the resident receiving the medicines and the care home staff involved in giving the medicines.

Evidence presented to the GDG suggests that commissioners and providers of care home services should consider having a wider policy on the covert administration of medicines, developed and agreed with relevant health and social care practitioners and organisations, as appropriate.

The GDG discussed and agreed that commissioners and providers of care home services across organisational boundaries may consider having a wider policy on the covert administration of medicines.

Evidence suggests that for residents who lack capacity, the decision for covert administration of medicines should not be undertaken without being discussed with care home staff, relevant health professionals (including the pharmacist) and the family members or carers of the resident.

In further review of this evidence the GDG discussed and agreed that the process for covert administration of medicines should include:

- assessment of capacity
- a best interest meeting to undertake assessment of mental capacity in line with the Mental Capacity Act and safeguarding and deprivation of liberties discussions if appropriate
- clear documentation to record the reasons for presuming mental incapacity, and the proposed treatment plan
- discussion of the reasons for the treatment plan with care home staff, relevant health professionals (including the pharmacist) and the family members or carers of the resident, or advocate (unless it is clear that the resident would not have wished this) and a record of the discussion made
- regular review of the need for continued covert administration of medicines.

1 **Recommendations**

Recommendation 2.15.1

Health and social care practitioners should consider covert administration of medicines only in exceptional circumstances.

Recommendation 2.15.2

Covert administration should only take place in the context of existing legal and good practice frameworks to protect the resident who is receiving the medicines and the care home staff involved in administering the medicines.

Recommendation 2.15.3

Health and social care practitioners should ensure that the process for covert administration of medicines includes:

- assessment of mental capacity
- a best interest meeting to undertake assessment of mental capacity in line with the Mental Capacity Act and safeguarding and deprivation of liberties discussions if appropriate
- clear records of the reasons for presuming mental incapacity and the proposed treatment plan
- discussing the treatment plan with care home staff, relevant health professionals (including a pharmacist) and the family members or carers of the resident, or advocate (nominated representative) , unless it is clear that the resident would not have wished this and a record of the discussion is made
- a regular reviews of the need for continued covert administration of medicines.

Recommendation 2.15.3

Commissioners and providers of care home services may want to consider establishing a wider policy on the covert administration of medicines across organisational boundaries.

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3.16 Homely remedies

Homely remedies are 'medicines that can be obtained without a prescription from a community pharmacy or supermarket'. Examples of homely remedies include: mild pain relief medicines, cough medicines, antihistamines, anti-diarrhoea preparations and laxatives. The homely remedy may be purchased by the resident or by the care home.

The NMC's Standards for medicines management state 'Homely remedy protocols are not prescriptions but protocols to enable administration of general sales list (GSL) and pharmacy only (P) listed medicines in settings, for example, care homes, children's homes and some educational institutions. Although they have no legal standing they are required for liability purposes'.

The GDG discussed and agreed that where a care home provider offers residents' treatment for minor ailments with homely remedies, a process for use should be in place and this should be recorded in the care home medicines policy (see recommendation 2.1.1). The process should be agreed in consultation with an appropriate health professional and care home provider and it should be reviewed regularly.

The GDG discussed the evidence and agreed that homely remedies protocols should include:

- which medicinal product may be administered and for what indication it may be administered
- which residents may be excluded from receiving specific homely remedies (for example, paracetamol could not be given to a resident who is already prescribed paracetamol)
- the dose and frequency
- maximum daily dose
- time limit before referral to a GP.

In review of its evidence the GDG agreed that it would be good practice for all care home staff using a homely remedies protocol to be named in it and that

they should sign to confirm they are competent to administer the medicinal product, acknowledging they will be accountable for their actions.

The GDG was aware of regulation in relation to record keeping in care homes (see section 3.4) and agreed that it would be good practice for care home staff to record homely remedies in the same way as recording prescribed medicines on the medication administration record and for this to be included in the process for using homely remedies.

Recommendations

Recommendation 2.16.1

Care home providers offering homely remedies for treating minor ailments should consider including the following in their homely remedies process:

- which medicines may be administered and for which indications
- which residents may be excluded from receiving specific homely remedies (for example, paracetamol could not be given to a resident who is already prescribed paracetamol)
- the dose and frequency
- maximum daily dose
- how long the medicine should be administered before referring the resident to a GP.

(See recommendation 2.1.1)

Recommendation 2.16.2

Care home staff following a homely remedies process should be named in the process and should sign to confirm that they are competent to administer the medicine and acknowledge that they will be accountable for their actions.

3.17 Training and competency

Care home providers (children's home or adult's care home) should comply with regulations appropriate to the type of care being provided in relation to training and staff support:

Health and Social Care Act 2008 (Regulated Activities) Regulations 2010:

- Regulation 21 – Requirements relating to workers
- Regulation 22 – Staffing
- Regulation 23 – Supporting workers

Children's Homes Regulations 2001:

- Regulation 25 – Staffing of children's homes
- Regulation 26 – Fitness of workers
- Regulation 27 – Employment of staff

Outcomes 12, 13 and 14 of the CQC's Essential standards of quality and safety and standards 17, 18 and 19 of the Department for Education's Children's homes: national minimum standards provide further guidance for care home providers to ensure care home staff have the right skills, qualifications, competence and knowledge to support residents.

Care home providers who provide nursing care employ registered nurses who must act according to guidance published by the NMC. Care home providers who provide non-nursing care employ care home staff to provide personal care. Training for care home staff in nursing and non-nursing care homes should be provided in accordance with the regulations of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 or Children's Homes Regulations 2001.

Care home staff education and training

The GDG found evidence of variation in training, qualifications, skills and responsibilities of staff working in care homes. Evidence suggests that some care home staff have inadequate knowledge and poor training on medicines use and handling. CHUMS (2009) states that 'staff numbers, skill sets, and

training may be important determinants in medicines administration errors'. A learning report 'Making care safer' by The Health Foundation using the thoughts and experiences from carers and relatives on improving medication safety for residents in care homes suggests that only qualified and designated care home staff should be tasked with administering medicines. The GDG discussed and agreed that the care home provider must designate only care home staff who have undertaken the necessary training and competency assessment to administer medicines.

The GDG was aware of evidence that identified significant deficiencies in care home providers' performance and practice and that spending more money on training did not always improve the quality of care. Evidence suggests that although care home providers often achieve the minimum standards for managing medicines, over time their standards can fall, resulting in failure to meet the minimum standards. Care home providers need to sustain good practice using the guidance and learning and development programmes available to them.

The GDG agreed that training and assessment of competency is essential to reduce variation in skills and to maintain good practice when handling and administering medicines in care homes. The GDG concluded that care home providers should ensure an internal and/or external learning and development programme is used to assess competencies for medicines administration. The programme used should meet the requirements of the regulators, the needs of the residents they care for and the training and competency needs of the care home staff they employ.

Training

Many 'learning providers' provide training on the safe handling and administration of medicines for care home staff. The GDG heard that care home providers may use an accredited learning provider, which can award a qualification, or a non-accredited learning provider. Training may be delivered by an external learning provider, in-house by the care home provider or by a community pharmacist supplying the medicines.

The CQC's Essential standards of quality and safety mentions Skills for Care's advice on the units and training and/or subsequent qualifications required to meet the learning outcomes relevant to the job role. 'Skills for Care ensure that England's adult social care workforce has the appropriately skilled people in the right places working to deliver high quality social care'. Skills for Care support employers with information, resources and tools to develop the skills of social care practitioners.

Standard 18.3 of the Department for Education's Children's homes: national minimum standards refer to the training needs for care home staff that are responsible for administering medicines in children's homes.

The CQC's Essential standards of quality and safety states that all care home staff should 'receive a comprehensive induction that takes account of recognised standards within the sector and is relevant to their workplace and their role'. The relevant induction in this context means the Common Induction Standards (CIS). Table 5 summarises the induction standards relevant to managing medicines, depending on the type of care setting.

Table 5 Induction standards relating to medicines

Care setting	Induction standard	Details and outcome(s)
Adult social care	Common Induction Standard 8 – Health and safety in an adult social care setting	'Agreed ways of working regarding medication and health care tasks • Understand the main points of agreed ways of working about: – medication agreed with your employer – healthcare tasks agreed with your employer • Be aware of tasks relating to medication and healthcare procedures that you are not allowed to carry out at the current stage of training'
Children's and young persons' social care	Induction Standard 3 for the children's workforce – Understand health and safety requirements	'Medication and healthcare procedures • Know what 'healthy care' means for your work with children and young people • Know about any infection control procedures • Know about any allergies, medical conditions of the children and young people you work with, and about any medication they are on • Know how to respond, or acquire first aid or medical treatment in an emergency • Know what you are not allowed to perform, in relation to medication and healthcare procedures, at this stage in your learning'

Completion of induction training is subject to a recorded assessment that identifies the areas of work that the care home staff are competent to undertake at that point in time.

Standard 18.5 of the Department for Education's Children's homes: national minimum standards (NMS) states:

- 'All new staff engaged from the commencement of the NMS (in April 2011) are to hold the level 3 Children & Young Peoples Workforce Diploma which must include mandatory social care units; or be working towards the Diploma within 6 months of confirmation of employment'
- 'All existing care staff have attained a minimum level 3 qualification'.

For adult social care, the CQC requires care home staff to have undertaken the following:

- 'training and qualifications that satisfy the learning outcomes as advised by Skills for Care
- units or qualifications relevant to the job role as advised by Skills for Care.'

The GDG found that some Qualifications & Credit Framework (QCF) units exist to support the obtaining of the Health and Social Care Diploma. The units required for handling and administering medicines include:

- Administer medication to individuals and monitor the effects (Level 3) (ASM 34) applying to health care settings
- Understand the administration of medication to individuals with dementia using a person-centred approach (Level 3) (DEM 305)
- Support use of medication in social care settings (Level 3) (F/601/4056) applying to health and social care settings

These units comply with outcome 9, management of medicines in the CQC's Essential standards of quality and safety.

The GDG also found that the unit 'support use of medication in social care settings (F/601/4056)' covered health and social care and the learning outcomes may be useful for identifying the training required for the role of handing and administering medicines. Box 10 summarises the learning outcomes in this unit.

Box 10 Learning outcomes in the unit F/601/4056 Support use of medication in social care settings

1. 'Understand the legislative framework for the use of medication in care settings
2. Know about common types of medication and their use
3. Understand roles and responsibilities in the use of medication in social care settings
4. Understand the techniques for administering medication

5. Be able to receive, store and dispose of medication supplies safely
6. Know how to promote the rights of the individual when managing medication
7. Be able to support use of medication
8. Be able to record and report on use of medication'

The GDG discussed that care home staff must undertake the necessary induction training relevant to the type of care setting they are working in. The GDG agreed that in addition to the required induction training, all care home staff (including nurses as part of their continual professional development) involved with the handling and administration of medicines to residents should successfully complete the necessary training units to fulfil the requirements of the identified learning and development needs required for this role.

Evidence presented to the GDG suggests that training may be required from more than one source. This may include training from:

- pharmacists on how to use monitored dosage systems
- the care home provider on how to use internal policies on handling medicines so that care home staff are aware of the internal procedures
- local health professionals who can deliver informal training in relation to medicines and health needs of individual residents.

The GDG found that additional training for administration of subcutaneous injection, rectal or vaginal preparations would be required for care home staff (excluding registered nurses) if medicines need to be administered by these routes for residents who are unable to self-administer.

The GDG discussed and agreed that the care home provider should identify additional training needs of the care home staff responsible for handling and administering medicines. For example, training on how to use monitored dosage systems may be provided by the community pharmacy or by local organisations, providing newsletters or guides to increase staff awareness in medicines handling and use.

Assessment of competency

The GDG found that for accredited learning providers, a competent assessor undertakes the assessment of knowledge, understanding and competency of the care home staff required to meet the learning outcomes specified in the unit undertaken. Non-accredited learning providers do not need to provide assessors to assess knowledge and competency, but if there is an assessor, then the standards of the assessor are determined by the learning provider. If non-accredited learning providers are used, the GDG agreed that the care provider should establish a formal way to assess whether the care home staff are sufficiently competent in handling and administering medicines before being allowed to administer medicines.

The GDG discussed and agreed that care home providers should consider using an accredited learning provider so that the care home staff who are responsible for the handling and administration of medicines can be assessed by a competent assessor.

In the review of evidence the GDG found that care home staff need to have the necessary competencies when taking responsibility for the handling and administration of medicines. The GDG was aware that completion of training does not necessarily mean that a person is competent to undertake the task. The GDG agreed that it is an unacceptable risk to allow care home staff who do not have the necessary skills and competencies to administer medicines. If the member of care home staff is not assessed as being competent despite completing the required training, they must not be allowed to administer medicines to residents (see section 3.14).

Review of skills and competencies

The CQC requires care home staff in adult social care to have their qualifications, knowledge and skills reviewed on a regular basis. For children's care homes, the Department for Education's Children's homes: national minimum standards states 'all staff have their performance individually and formally appraised at least annually and this appraisal takes into account any views of children the service is providing for'.

Therefore, the GDG agreed that good practice is represented by having an annual review of knowledge, skills and competencies relating to the handling and administration of medicines. In the event of a medication incident or error, this review may need to be sooner to identify support, learning and development needs.

Health professionals education and training

Standard 18 of the Department for Education's Children's homes: national minimum standards and outcome 14 of the CQC's Essential standards of quality and safety were discussed by the GDG. The GDG agreed that any health professional who provides care to residents in care homes will:

- be professionally qualified and, if applicable, registered by the appropriate professional body
- be able demonstrate to professional regulators that they continue to meet professional registration requirements, if applicable
- be appropriately trained to work with specific groups of residents (for example, children, adults or residents with dementia), and
- have a good understanding of care for specific groups of residents and the policies and purpose of the care home.

The GDG concluded that health professionals working in or providing services to care homes should work to standards set by their professional bodies and ensure that they have the appropriate skills, knowledge and expertise in managing the safe use medicines to residents living in care homes.

1 Recommendations

Recommendation 2.17.1

Care home providers must ensure that only designated staff who have undertaken the necessary training and competency assessment administer medicines.

Recommendations 2.17.2

Care home providers should establish an internal and/or external learning and development programme to assess competencies for medicines administration. The programme used should meet the requirements of the regulators, the needs of the residents and the training and competency needs of care home staff.

Recommendation 2.17.3

Care home providers should identify any additional training needs of care home staff responsible for handling and administering medicines.

Recommendation 2.17.4

Care home providers should consider using an accredited learning provider so that care home staff who are responsible for handling and administering medicines can be assessed by a competent assessor.

Recommendation 2.17.5

Care home staff must undertake the necessary induction training relevant to the type of care setting they are working in. All care home staff (including nurses as part of their continuing professional development) involved in administering medicines should also successfully complete the training units needed to fulfil the learning and development requirements for this role.

Recommendation 2.17.6

Care home staff who do not have the necessary skills and competencies to administer medicines despite completing the required training must not be allowed to administer medicines to residents.

Recommendation 2.17.7

Care home providers should ensure that all care home staff have an annual review of their knowledge, skills and competencies relating to handling and administering medicines. In the event of a medication safety incident, this review may need to be more frequent to identify support, learning and development needs.

Recommendation 2.17.8

Health professionals working in, or providing services to, care homes should work to standards set by their professional bodies and ensure that they have the appropriate skills, knowledge and expertise in managing the safe use medicines to residents living in care homes.

1

2

4 How this guidance has been developed

This good practice guidance was developed using the methodology described in the Integrated process statement – good practice guidance and the Interim methods guide for developing good practice guidance.

4.1 Scoping workshop

A scoping workshop was held to inform the scope of this guidance. It included representatives from NHS service providers and commissioners, regulators and social care. See appendix E for a list of attendees.

4.2 Guidance Development Group

A Guidance Development Group (GDG) was formed to work with the NICE project team. The recruitment process for both members and the group Chair and Deputy Chair followed the NICE recruitment processes for committees and groups. See appendix F for members of the GDG.

4.3 Literature search strategy

A literature search was undertaken based on the scope of the guidance (see appendix G for details of the literature search). The project team analysed the search results and sifted the results for relevance. Evidence was identified covering 7 main areas:

- involving residents
- resident safety
- communication
- medicines management systems
- medicines administration
- training and competence
- organisational governance.

4.4 Additional evidence

Additional evidence was also identified by the project team and GDG. Following appraisal of the relevant published literature, the project team

conducted a gap analysis. The GDG reviewed the evidence and the project team's gap analysis.

The GDG concluded that the most appropriate method to address the gap analysis was a call for evidence from care home service providers and commissioners.

The NICE project team sent an email request to its database of people with a significant role or interest in medicines and prescribing issues. Respondents submitted evidence by completing a web-based or Word version template, and were able to supply additional information to the project team by email.

There were 135 completed submissions received from organisations across England, Wales and Northern Ireland. See appendix H for organisations that submitted written evidence.

The GDG invited 11 organisations to give further evidence orally, of which 7 were able to attend. See appendix H for organisations that provided oral evidence.

Appendix A Glossary

Definitions for terms included in this glossary are for the purposes of this guidance only.

28-day supply cycle

28-day supply of medicines

Accredited learning provider

Learning providers who have been certified competent to provide validated education and training and issue credentials

Acute prescription

Prescriptions that are prescribed as a 'one-off' for a limited period of time to manage a condition that is short-lived

Administration

To give a medicine by either introduction into the body (for example, orally or by injection) **or** external application

Advance decision

A legally binding document that enables someone, aged 18 and over and while capable, to set out in advance the treatments and procedures that they do not consent to in the future when they may lack the capacity to consent to or refuse that treatment (previously called advance directive or 'living will')

Ambulatory care

Care delivered to patients when they are not resident in a healthcare institution (for example, at outpatient clinic, emergency department and in primary care)

Anti-diarrhoea medicines

Type of medicine used for treating diarrhoea

Anticipatory medicines

Medicines prescribed 'just in case' to a named person to ensure there is no delay in therapy, for example for use in palliative care

Antihistamines

Type of medicine that is used for treating reactions to allergies

Best interest decisions

If a resident lacks mental capacity to make a particular decision then whoever is making that decision or taking any action on that person's behalf must do this in the person's best interests.

Candour

Being honest and straightforward in attitude and speech

Capacity

The ability to make a decision (Mental Capacity Act 2005), including

- decisions that affect daily life (for example, when to get up, what to wear or whether to go to the doctor when feeling ill, and more serious or significant decisions)
- decisions that may have legal consequences, for them or others (for example, agreeing to have medical treatment, buying goods or making a will).

(See also lack of mental capacity)

Care home

This term is used for 'adult and children's care homes' for the purpose of this guidance

Care home staff

Includes registered nurses and social care practitioners for the purpose of this guidance

Care plan

An agreement (usually a written document) between a resident and their health and social care practitioners to help them manage their daily health and care

Care Quality Commission (CQC)

The body established under the Health and Social Care Act 2008 whose job is to ensure hospitals, care homes, dental and GP surgeries and all other care services in England provide people with safe, effective, compassionate and high-quality care

Carer

An informal or an unpaid carer

Clinical check

Identifying pharmacotherapeutic problems by collecting and evaluating all relevant information, including patient characteristics, disease states, medication regimen and, when possible, laboratory results

Collaboration

Joint working between health and social care practitioners to achieve shared objectives in the care of residents

Commissioner

Those people from either health or social care who undertake commissioning

Commissioning

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

Confidence interval (CI)

The confidence interval (CI) is a way of expressing how certain we are about the findings from a study, using statistics

Competent assessor

People who have been trained to accredited standards to support and assess learners who are working towards qualifications

Court of protection

A specialist court, set up under the Mental Capacity Act 2005, to deal with decision-making for adults (and children in a few cases) who may lack capacity to make specific decisions for themselves

Covert administration

When medicines are administered in a disguised format without the knowledge or consent of the person receiving them, for example, in food or in a drink

Designated person

A person who has been identified as being suitable for, and therefore given responsibility for, a specific duty, by the person having overall responsibility for the system

Dispensing

Labelling from stock and/or supplying a clinically appropriate medicine to a patient, carer or client (usually against a written prescription) for self-administration or administration by another professional, and advising on safe and effective use

Dispensing doctors

Doctors who provide a dispensing service to some or all of their patients

Dispensing error

One or more deviations from an interpretable written prescription or medication order, including written modifications to the prescription made by a pharmacist following contact with the prescriber

Disposal

The safe removal and/or destruction (where legally permitted) of unwanted, damaged, out-of-date or part-used medicines from the care home

Emergency department

A department in a hospital where people who have severe injuries or sudden illness are taken for emergency treatment (also called ‘accident and emergency’)

Evidence-based

Evidence-based decisions or recommendations are based on research findings that have been systematically appraised – that is, the best available evidence

Excipient

Inactive substance included with the active ingredient of a medicine

Filling

Putting medicines into the compartments of a monitored dosage system

Gillick competence

An objective test of a child's competence to make decisions about their own medical treatment from a legal case (Gillick v West Norfolk & Wisbech AHA & DHSS [1983] 3 WLR (QBD))

Healthy care

What children and young people should expect and what they are entitled to in a healthy care environment

Homely remedies

Medicines for minor ailments that can be bought without prescription, such as paracetamol for headaches or remedies for indigestion

Independent Mental Capacity Advocate

Individuals who represent vulnerable people who lack capacity to make important decisions about serious medical treatment where they have no family and friends available for consultation about those decisions

Informed consent

A person's agreement to treatment after having received full information about what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead (see also valid consent)

Lack of mental capacity

The Mental Capacity Act 2005 defines a lack of mental capacity as when 'a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain'

Lasting power of attorney

The Mental Capacity Act Code of Practice 2007 defines a lasting power of attorney as when one person gives another person authority to make a decision on their behalf, through a power of attorney, which is a legal document. 'Under a power of attorney, the chosen person (the attorney or donee) can make decisions that are as valid as one made by the person (the donor)'

Laxatives

Type of medicines used for treating constipation

Learning provider

Education and training organisation

Local safeguarding board

In Department of Health (2000) guidance, safeguarding adults was stated to be a multiagency responsibility and local authorities were encouraged to consider structures for interagency collaboration: Safeguarding Adults Boards. Membership of the board includes statutory and independent agencies engaged in adult social care, community organisations and groups, including people who use services and carers. The draft Care and Support Bill states that 'Each local authority must establish a Safeguarding Adults Board (an "SAB") for its area' (Department of Health)

Medication administration error

Any deviation between the medication prescribed and that administered. This includes 'omission errors', when a dose of medication has not been administered by the time of the next scheduled dose

Medication administration record

A document on which details of all medicines given in a care setting are recorded, usually designed to show the dose given, the time when given and the identity of the person who gave it

Medication error

A prescribing error, dispensing error, administration error or a monitoring error

Medicines and Healthcare products Regulatory Agency (MHRA)

'The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.'

Medication review

A structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste

Medicinal product

Any substance or combination of substances created to treat or prevent disease

Medicines reconciliation

The process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route of administration – and comparing them to the current list in use, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated

Monitored dosage system

System for packing medicines to make their use easier, for example, by putting medicines for each time of day in separate blisters or compartments in a box

Monitoring error

When a prescribed medicine is not monitored in a way that would be considered acceptable in routine general practice. It includes tests not being carried out at the frequency required

Near miss

Prevented resident safety incidents

Obtaining or ordering

To request a prescription from the prescriber for a named person

Office for Standards in Education, Children's Services and Skills (Ofsted)

A non-ministerial government department of Her Majesty's Chief Inspector of Schools In England (HMCI) that inspects and regulates services which care for children and young people, and those providing education and skills for learners of all ages.

Organisation

Unless stated otherwise, use of the term 'organisation' in this guidance includes providers (both NHS and non-NHS), including care home providers and commissioners

Out-of-hours

The time period outside of normal GP surgery hours (normally the out-of-hours period is from 6.30 pm to 8.00 am on weekdays and all day at weekends and on bank holidays)

Over-the-counter medicines

Medicines that can be bought without a prescription

Patient

In this guidance when the text refers to patients in general (including care home residents) then NICE uses patient. However, when the guidance refers specifically to care home residents then NICE uses the term resident

Polypharmacy

When a person is prescribed 4 or more drugs.

Potting up

Medicines prepared in advance for administration

Prescribing

Authorising in writing the supply and administration of a medicine or other healthcare treatment for a named individual patient

Prescribing error

A prescribing decision or prescription-writing process that results in an unintentional, significant reduction in the probability of treatment being timely and effective, or an increase in the risk of harm

Primary care pharmacist

Pharmacists, mostly employed by primary care organisations, who are significant in the management of medicines. They focus on maximising benefit

and minimising risk related to medicines and help make decisions around the use of resources allocated for medicines

Provider

An organisation that directly provides health or social care services (such as a care home)

Receiving medicines

Accepting medicines that have been dispensed and supplied by the pharmacy or dispensing practice

Registered manager

A person registered with the Care Quality Commission under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as a manager

Registered person

A person who is the service provider or registered manager (Health and Social Care Act 2008 (Regulated Activities) Regulations 2010)

Regulators

Organisations set up to protect the public to ensure that health and social care practice and professionals meet the standards for care and/or practice set by the relevant regulator (for example the Care Quality Commission is the regulator for social care in England and publishes the Essential standards of quality and safety)

Repeat prescription

Prescriptions that are re-prescribed without a consultation between the doctor and patient

Repeat prescription ordering form

The right-hand side of the prescription (FP10) containing the list of repeat medicines the person can select to re-order, also known as the 'GP medication list'

Resident

Person living in a care home to receive personal care, who may or may not also be receiving nursing care

Resident safety incidents

Any unintended or unexpected incident that could have led to, or did lead to, harm

Risk assessment

Method used to determine a person's level of ability to manage their medicines and their suitability to self-medicate

Root cause analysis

A systematic investigation technique that seeks to understand the underlying causes and environmental context in which an incident happened

Safe custody of medicines

Medicines such as controlled drugs that are legally required to be locked up in a safe or cabinet or other locked container

Self-administration

When a person is responsible for storing and administering medicines for their own use

Shelf-life

The recommended maximum time that the medicine can be stored for as stated in the manufacturer's literature during which the defined quality of the medicine remains acceptable under expected (or specified) conditions of storage.

Stock medicine

Medicines that have been purchased by a care home registered to provide nursing care, for use in named residents against a written prescription that has been signed by the prescriber before the medicine is given

Storing (of medicines)

Safe keeping of medicines in a clean, lockable and secure facility

Supply

To provide a medicine to a patient or carer for administration

Supply system

The mechanism for delivering residents' medication (for example monitored dosage system or original pack)

Synchronise

A supply of medicines where all quantities have been adjusted to finish at the same time, intended to help people to avoid accumulating medicines

Temporary absence

Applies to residents who take planned or unplanned leave

Transfer of care

The planned movement of a care home resident from one care setting to another

Valid consent

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (see also informed consent)

Variable dose

Medicines for which the dose has been prescribed based on the outcome required. For example, 1 or 2 paracetamol 500 mg tablets depending on the severity of pain

Waste transfer note

A document that must be completed when waste is transferred from one party to another

When required medicine

A medicine to be given when required for a defined problem, for example pain, constipation

Appendix B Overview of legislation, regulators and minimum standards published for England, Wales and Northern Ireland

Country		Regulation	Regulators	Standards
England	Adults	Health and Social Care Act 2008 (Regulated Activities) Regulations 2010	Care Quality Commission (CQC)	Essential standards of quality and safety (CQC)
	Children	Care Standards Act 2000 Education and Inspections Act 2006 (section 148) Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 The Children's Homes Regulations 2001	Chief Inspector of Education, Children's Services and Skills ('CIECSS') (if not regulated by above then Care Quality Commission (CQC) regulate	Children's homes: national minimum standards (Department for Education) Children Act 1989: Guidance and Regulations Volume 5: Children's Homes
Wales	Adults	The Care Homes (Wales) Regulations 2002 Care Standards Act 2000	Care and Social Services Inspectorate Wales (CSSIW)	Care Homes
	Children	The Children's Homes (Wales) Regulations 2002	Care and Social Services Inspectorate Wales (CSSIW)	Children's Homes
Northern Ireland	Adults	Residential Care Homes Nursing Homes Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003	Regulation and Quality Improvement Authority (RQIA)	Nursing home minimum standards (RQIA) Residential care homes minimum standards (RQIA)
	Children	The Children's Homes Regulations (Northern Ireland) 2005		

Appendix C Key resources

This section will be completed when the final version of the guidance is published

Appendix D Comparison between monitored dosage systems and original packs

	Monitored dosage systems	Original packs
Advantages (Supply)	• 'Added value' element of supply by the pharmacy	• Better use of pharmacist's time • Re-packaging not required
Disadvantages (Supply)	• Not all medicines suitable • Re-packaging may often be unlicensed • Lack of evidence to support use • Pharmacies not reimbursed for use of monitored dosage systems • Robust filling and checking procedures required • Time consuming to fill and to check • Issues with variable doses, short courses, once-weekly medicines • Issues with medicines started mid-cycle or interim medicines • All labels may not fit on the monitored dosage system	• Packaging may be too bulky
Advantages (Administration)	• Provide a 'safety net' to care home staff compared to original packs, when they have been trained to use it correctly • Facilitate self-administration and compliance	• Maintains resident dignity and independence • The resident is taking the medicine as they would do in their own home • Not being re-dispensed (potentially then in an unlicensed form) • Take up less space compared with monitored dosage systems • Patient information leaflet enclosed in original pack supporting medicines

		information requirements/needs • Resident can see the original pack (identification purposes) • Less waste • May be beneficial for patients who go on short-term leave/utilise day services • Easier to amend medication following changes (for example, dose changes or if the medicine is stopped) • Lower risk of infection
Disadvantages (Administration)	• Opinion there is over reliance on monitored dosage systems – thoughts this may be de-skilling care home staff • High-risk medicines may be an issue • Difficulties if medicines are stopped, need to be omitted, or to identify if they are being given in an unlicensed way, if a monitored dosage system contains all medicines in single blister • Requires 2 systems to be used, monitored dosage system and original packs for acute and 'when required' medicines • Arrangements need to be made for those on short leave from care home • Over-reliance of the use of monitored dosage system: care home staff may fail to look at the label and description of medicine	

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Appendix E Scoping workshop attendees

David Alldred
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Helen Brewah
Community Matron, Southern Health NHS Foundation Trust

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National Pharmacy Manager, Care Quality Commission

Peter Budden
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Chief Pharmacist, Northumbria Healthcare NHS Foundation Trust

Angela Close
Staff Nurse, Doves Nest Nursing Home

Martyn Diaper
Clinical Lead for Primary Care Patient Safety, NHS Institute for Innovation and Improvement

Angela Duce
Director of Operations, Norwood

Mary Freeman
Director, Sunny Bank Psychiatric Rehabilitation Service

Vinod Gowda
Consultant Geriatrician-Community, St Helens and Knowsley Teaching Hospitals

Fazeela Hafajee
Project Manager Standards, Learning & Qualifications, Skills for Care

Jane Hinsley
Quality consultant/pharmacist, Bupa care services

Susan Hogston
Head of Clinical Quality and Nurse Lead, Sue Ryder

Susanna Jacks
General Practitioner, Aneurin Bevan Health Board

Yogini Jani
Lead Pharmacist Medication Safety & Honorary Associate Professor, University College London Hospitals NHS Foundation Trust & University College London School of Pharmacy

Sarah Jewitt
Specialist Nurse, Sheffield Children's NHS Foundation Trust

Nick Kaye
Community Pharmacist, S. Kaye & Son Ltd

Hayley Latchem
Community Pharmacist, Boots UK

Alison Marshall
Pharmacy Technician, Medicines Management Team East Lancashire Primary Care Trust

Juliette Millard
UK Nursing & Health Professions Advisor, Leonard Cheshire Disability

Sandra Sweeney
Senior Pharmacist Medicines Management Social Care Support Team, NHS North Yorkshire and York/North Yorkshire and Humber Commissioning Support Unit

Helen Whiteside
Care Home Pharmacist and Medication Review Pharmacist, Leeds South and East Clinical Commissioning Group

Appendix F The Guidance Development Group and NICE project team

Guidance Development Group

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Research & Development Pharmacist, Northumbria Healthcare NHS Foundation Trust

Gerry Bennison
Patient and Public Involvement representative

Brian Brown
National Pharmacy Manager, Care Quality Commission

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Advanced Nurse Practitioner, Central Nottinghamshire Clinical Services

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Lead Nurse/Care Homes, Shropshire Community Health NHS Trust

Kathryn Goodfellow
Care Homes Development Manager, Superdrug stores

Fazeela Hafajee
Standards and Qualifications Project Manager, Skills for Care

Daniel Harwood
Clinical Director for Community Health, Clinical Director for the Mental Health/Learning Disability Directorate and Consultant Old Age Psychiatrist, South London and Maudsley NHS Foundation Trust

Susanna Jacks
General Practitioner principal, Aneurin Bevan Health Board/Vauxhall Surgery Chepstow

Barbara Jesson
Principal Pharmacist, Croydon Clinical Commissioning Group

Susan Lee
Care Home Support Pharmacist, Biodose Services

Juliette Millard
UK Nursing & Health Professions Advisor, Leonard Cheshire Disability

Tariq Muhammad
Managing Director, Pharmacy Plus

Ivor Nathan
Patient and Public Involvement representative

Alaster Rutherford (Chair)
Independent healthcare consultant

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Medicines Standards Officer – Care Homes, NHS West and South Yorkshire and Bassetlaw Commissioning Support Unit

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Consultant Old Age Psychiatrist in specialist care, South London and Maudsley NHS Foundation Trust

Ian Turner
Chairman, Registered Nursing Home Association

Louise Winstanley
Head of Medicines Commissioning, Fylde & Wyre Clinical Commissioning Group

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Social Care Advisor, NICE

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Policy Officer, The Association of Directors of Children's Services Ltd

NICE project team

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Appendix G Literature search

Search strategy

Search question	See search questions below
Search date	Searches were conducted during April 2013
Search terms	See list of requested search terms below
Sources	See sources searched below
Publication period	Unlimited
Restrictions	None
Inclusion criteria	Any relevant publication or website
Publication	Website, peer-reviewed journal, guidance

Search questions

What is the evidence for:

- raising concerns and safeguarding
- ensuring resident safety (including reducing errors, incident reporting, near misses and yellow card reporting)
- ensuring residents' informed consent and the assessment of residents' mental capacity
- shared decision making?

What is the evidence for:

- managing medicines throughout transfers of care between care providers
- standards for records and record?

What is the evidence for:

- medicines reconciliation
- ordering and supply of medicines (including medication administration systems, acute and repeat medications)
- storage of medications
- disposal of medicines (including waste medicines)?

What is the evidence for:

- ensuring resident safety
- clinical and medication review (including polypharmacy)?

What is the evidence for:

- care home staff administering medicines to residents
- reducing disruption of medicine administration
- resident's self-administration of medicines
- covert administration of medicines
- use of over-the-counter (OTC, inclusive of homely remedies) medicines?

What is the evidence for:

- role of the GP (including named and non-named GPs for care homes)
- role of the community pharmacist
- role of care home staff
- role of commissioners?

What is the evidence for:

- education, training and assessment of competence of staff responsible for managing medicines?

Search terms

- Raising concerns and safeguarding
- Resident safety (including errors, incident reporting, near misses, yellow card reporting)
- Residents informed consent/mental capacity
- Shared decision making
- Resident transfers of care (between providers of care)
- Standards for records and record-keeping
- Medicines reconciliation
- Ordering and supply of medications (including medication administration systems, acute and repeat medications)
- Storing medications

- Disposal of medications (including medicines waste in the care home setting)
- Clinical and medication review (including polypharmacy)
- Care homes staff administering to residents
- Disruption of medicines administration
- Residents self-administration of medication
- Covert medication administration
- OTC medications (homely remedies)
- GPs (including named and non-named for care homes)
- Community pharmacists
- Care home staff
- Commissioners in managing medicines in care homes
- Staff education, training and competence

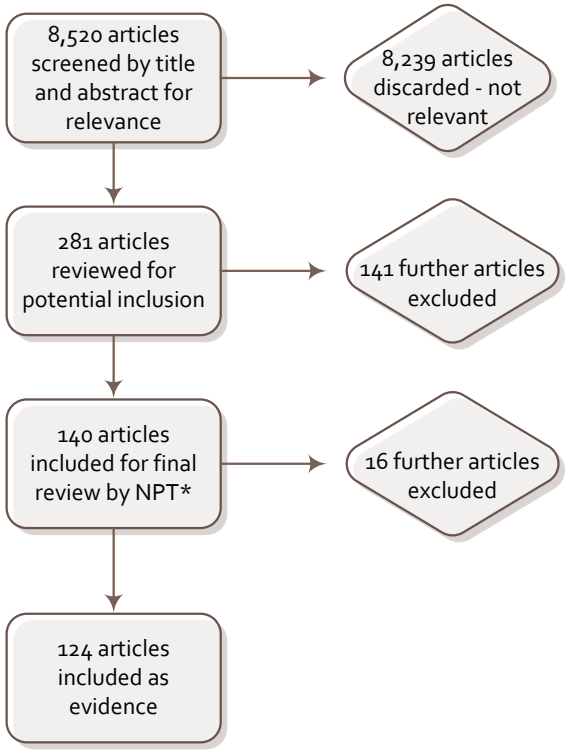
Sources searched

- PubMed
- EMBASE
- British Nursing Index
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Health Management Information Consortium (HMIC)
- Health Business Elite
- Department of Health
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS Evidence
- National Institute for Health and Care Excellence (NICE)
- Care Quality Commission (CQC)
- Social Care Institute for Excellence (SCIE)

Inclusion and exclusion of evidence

Evidence identified from the literature search was included or excluded as shown in figure 3.

Figure 3 Inclusion and exclusion of evidence identified from the literature search



* NPT: NICE project team

Appendix H Additional evidence

Organisations providing written evidence submissions

- A.G.E. Nursing Homes Ltd
- Abbeyfield Kent Society
- Abbeyfield Maidenhead Society
- Alpha Care Homes
- Anchor Trust
- Aneurin Bevan Health Board
- Armscare
- Ashmore Nursing Home Ltd, Bury St Edmunds
- Ashtons Hospital Pharmacy Services Ltd
- Askham Care Homes Ltd
- Bedfordshire Clinical Commissioning Group
- Birmingham Cross City Clinical Commissioning Group
- Blackpool Teaching Hospitals NHS Foundation Trust
- Bolton Clinical Commissioning Group
- Bromley Clinical Commissioning Group
- Bupa Care Homes
- Cambridge Nursing Home, London
- Camden Clinical Commissioning Group and Camden Local Authority
- Camphill Communities East Anglia, Thornage Hall
- Care UK
- CareTech Community Services Ltd
- Central Eastern Commissioning Support Unit
- Churchfields Nursing Home, London (Yewtree Care Ltd)
- Coppice Lea Care Home, Surrey (Caring Homes Group)
- Cornwall Partnership NHS Foundation Trust
- Derbyshire Community Health Services
- Dimensions UK
- Dorset Clinical Commissioning Group
- Eden Place Mental Health Nursing Home (Eden Place Ltd)

- Four Seasons Health Care
- Fourways Rest & Nursing Home, Peacehaven
- Fylde and Wyre Clinical Commissioning Group
- Garth House Nursing Home, Dorking (Caring Homes Group)
- Glan-Yr-Afon, Blackwood (Comfort Care Homes)
- Goatacre Manor Care Centre, Wiltshire
- Gorselands Nursing Home, Hampshire
- Gorsey Clough Nursing Home, Bury
- Gracewell Healthcare
- Guy's and St Thomas' NHS Foundation Trust
- Harewood Park, Moorlands Rehabilitation Ltd
- HC-One
- Healthcare Pharmacies Ltd
- Hillingdon Clinical Commissioning Group
- Holmeview Resource Centre, Bradford
- Holmwood House Nursing Home, Bristol
- Homerton University Hospital NHS Foundation Trust
- Hope Residential Care, Blackpool
- Horsham and Mid Sussex Clinical Commissioning Group
- Leeds Community Healthcare NHS Trust
- Leeds South and East Clinical Commissioning Group
- Leeds West Clinical Commissioning Group
- Leonard Cheshire Disability
- Liz Butterfield, self-employed
- Lloyds Pharmacy, Peninsula Community Healthcare and various surgeries
- Lotus Care Group
- Loxley Court Nursing Home, Sheffield (Exemplar Health Care)
- Luton Clinical Commissioning Group
- Maria Mallaband Care Group
- Marie Louise House Nursing Home, Romsey (The Healthcare Management Trust)
- Medvivo

- Mencap
- Methodist Homes Association
- Mid Yorkshire Hospitals NHS trust
- Midnight Pharmacy
- Milton Keynes Community NHS Trust
- Morton Grange Nursing Home, Inverhome Ltd
- Nene Clinical Commissioning Group
- NEW Devon Clinical Commissioning Group
- NHS Anglia
- NHS Great Yarmouth & Waveney Clinical Commissioning Group
- NHS North Yorkshire and Humber Commissioning Support Unit
- NHS Portsmouth Clinical Commissioning Group
- North Hill Care Home, Sheffield
- North of England Commissioning Support (NECS)
- North Yorkshire County Council
- Northfield Nursing Home, Sheffield (Palms Row Health Care Ltd)
- Northumbria Healthcare NHS Foundation Trust
- Nottingham Community Housing Association
- Nottingham West Clinical Commissioning Group
- Nottinghamshire Healthcare NHS Trust, Bassetlaw Health Partnership
- Optalis
- Park House Nursing Home, Peterborough
- Park Lodge, Leeds (Villa Care Ltd)
- Peverel Court Care
- PS4U Ltd
- Regency Healthcare
- Risby Hall Nursing Home, The Partnership in Care
- Rivermead Care Home, Norton Malton (Barchester Healthcare)
- Ruislip Nursing Home, Hillingdon
- Scio Healthcare Ltd
- Sense
- Solihull Community Services, Heart of England NHS Foundation Trust

- South West Yorkshire Partnership NHS Foundation Trust
- Southern Derbyshire Clinical Commissioning Group
- St Helens & Halton Primary Care Trust
- St. Martins, Abbeyfield Kent Society
- Staffordshire and Stoke on Trent Partnership NHS Trust
- Steve Turner Innovations CIC
- Stoke-on-Trent Clinical Commissioning Group
- Sue Ryder
- Sun Court Nursing Home, Sheringham
- Sunnyside Nursing Home, Bluebell Care Services Ltd
- Talbot Court Care Home, Port Talbot
- The Dynes, Abbeyfield Kent Society
- The Glen Nursing Home, Sheffield
- The Hope Residential & Nursing Care Home, Cambridge
- The Laurels Nursing Home, Hastings
- The Lodge Trust, Rutland
- The Manor House, Seaton, Devon
- The Old Vicarage Residential Care Home, Leigh
- The Partnership in Care
- The Royal Alfred Seafarers Society
- The Royal Care Home, St-Anne's-on-the-Sea
- Town Thorns Care Centre, Warwickshire (BEN – Motor and Allied Trades Benevolent Fund)
- Ubu
- University of Exeter
- University of Leeds
- Walsingham
- Wandsworth Clinical Commissioning Group
- Ward House Nursing Home Ltd, Isle of Wight
- Well Springs Nursing Home, Bradford
- Wells House Ltd, The Manor and The Lawns Nursing Home, Plymouth
- Wiltshire Clinical Commissioning Group

Organisations providing oral evidence

- Blackpool Teaching Hospitals NHS Foundation Trust
- Camden Clinical Commissioning Group and Camden Local Authority
- Dimensions UK
- Fylde and Wyre Clinical Commissioning Group
- Methodist Homes Association
- Midnight Pharmacy
- The Royal Care Home, St-Anne's-on-the-Sea