NICE Medicines and technologies programme

Draft for consultation

Managing medicines for adults receiving social care in the community

NICE guideline

Methods, evidence and recommendations

October 2016

Draft for consultation

National Institute for Health and Care Excellence

Disclaimer

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1 Introduction

1.1 Background and policy context

The number of people in England who have health problems requiring both health and social care is increasing. It is estimated that the number of people over 85 will increase by 18% between 2015 and 2020 (UK Government 2015). An ageing population means there are likely to be more people living with complex health needs (more than one long-term health condition), who require support from a combination of health and social care services (UK Government 2013).

The Care and Support White Paper (HM Government 2012) sets out the government's vision for a reformed care and support system. It announced the transfer of funding from NHS England to local authorities in 2013/14. The Better Care Fund (2013) requires NHS commissioners and local authorities to pool budgets and shift resources into social care and community services for the benefit of the NHS and local authorities, to promote integration across health and social care.

Several services can be offered to people assessed as needing social care and support, such as home care, residential care, respite care, day care and intermediate care. These services can be funded by health or social care commissioners or the person using the services themselves. The range and type of social care and support provided in people's own homes varies, but usually includes support with activities of daily living (which may include help with taking medicines) and essential domestic tasks.

Home care is sometimes seen as a low-paid, low-expectation service, rather than a professional integrated service. There is variation in staff training and low pay, which leads to a high turnover of paid carers (32% leave within 12 months; 56% within 2 years) and can result in a lack of continuity of care and a lack of flexibility in changing care arrangements (Commissioning home care for older people; Social Care Institute for Excellence [SCIE] 2014).

In 2013/14, 470,000 people in England made use of home care support funded by their local authority in the form of non-direct payments. Of these people, almost 80% were aged 65 or older (Community care statistics, social services activity, England 2013-14; Health and Social Care Information Centre [HSCIC] 2014). Spending on home care provision for older people (65 and over) was £1.8 billion in 2013/14, approximately one-fifth of the total social care expenditure on older people (Personal social services: expenditure and unit costs, England 2013-14; HSCIC 2014). In addition, an increasing number of people receive direct payments from local authorities, which may be spent on home care or other care and support services (full data are not available). At any one point during 2013/14, 155,000 people received a direct payment as one of their community based services (Community care statistics, social services activity, England 2013-14; HSCIC 2014). Additionally, there is a lack of reliable data about those who fund their own care at home with estimates varying between 70,000 (Paying for social care. Beyond Dilnot; The King's Fund 2013) and 270,000 (figure for 2010) when activities such as shopping and housework are included (People who pay for care: An analysis of self-funders in the social care market; Institute of Public Care 2011).

See the NICE guideline on Home care for more information.

Managing medicines

Medicines are the most common intervention in healthcare. 1.08 billion prescription items were dispensed in the community in England in 2015, at a cost of £9.2 billion (Prescriptions Dispensed in the Community, England 2005-15; HSCIC 2016). As people live longer, the number of older people with complex needs who live at home is increasing (Commissioning

home care for older people; SCIE 2014). Consequently, more people are taking multiple medicines (polypharmacy) to manage their complex needs. The risk of people suffering harm from their multiple medicines, such as a medicines-related hospital admission, is increasing.

Up to half of all medicines prescribed for long-term conditions are not taken as recommended (Medicines adherence. NICE guideline CG76; NICE 2009) and older people living at home may not take their medicines as prescribed. This may be intentional or unintentional (Helping older people to take prescribed medication in their own home: what works?; SCIE 2005). Intentional reasons for non-adherence include concerns about the value or effectiveness of medicines, their side-effects, and the inconvenience of taking the medicines at the prescribed times and frequency. Unintentional reasons for non-adherence include a lack of easily understandable information, difficulty reading labels and opening containers, and the need to take many different medicines or many doses. Therefore it is important that older people and their carers receive the information they want and need about their medicines (Medicines and older people implementing medicines-related aspects of the NSF for older people; Department of Health 2001).

In the Health Survey for England (HSCIC 2014), almost all people aged 65 and over who needed help with activities of daily living (social care) were taking at least 1 prescribed medicine. These people were also most likely to report that they had taken multiple prescribed medicines in the last week: most were taking at least 3 medicines and a substantial number were taking at least 6.

The main responsibility for taking medicines among adults receiving social care in the community lies with the person themselves, or an informal carer or home care worker, rather than a health professional (see terms used in the guideline). The Health Survey for England (HSCIC 2014) found that around 7% of men and women aged 65 and over needed help with taking their medicines. This percentage increased with age in both sexes (12% of men and 19% of women aged 85 and over) suggesting that people's ability to take medicines is associated with age. The survey also suggested that a gap exists between the number of people who need help taking their medicines and those who receive help.

The Care Certificate is a recognised set of standards for non-regulated health and social care practitioners (i.e. not doctors, nurses or other regulated health professionals). This has been developed jointly by Skills for Care, Health Education England and Skills for Health. It is designed to ensure that this workforce have a core set of skills, knowledge and behaviours to provide compassionate, safe and high-quality care and support, within an introductory period of their employment. The Care Certificate contains 2 standards in relation to medicines (standards 13.5a and 13.5c).

Medicines use can be complex, and ensuring people can take their medicines safely and effectively continues to be a challenge for health and social care services. See the NICE guideline on Medicines optimisation for more information. The Care Quality Commission (CQC) use NICE guidelines and NICE quality standards to inform the inspection process.

1.2 Legal framework

This guideline has been developed in the context of a complex and rapidly evolving landscape of guidance and legislation, most notably The Care Act (2014). This introduced new responsibilities for local authorities, including those to act on behalf of people who self-fund their own care. It also has major implications for adult care and support providers, people who use services, carers and advocates. The majority of the Care Act took effect from April 2015, with specific financial provisions coming into force from April 2016. The Department of Health has published statutory guidance to support implementation of part 1 of the Care Act by local authorities.

The Care Act places a duty on local authorities to promote wellbeing (a positive state of mind and body, feeling safe and able to cope, with a sense of connection with people, communities and the wider environment) and meet needs (rather than requiring them simply to provide services). It also requires local authorities to assess and offer support to address the needs of carers, independently of the person they care for. This is aligned with a range of other carer-specific policies, for example NHS England's Commitment to Carers. Local authorities also have a duty to prevent, delay or reduce the development of people's social care needs, so far as possible, and to work in an integrated, person-centred way, with all other support agencies including those in the third sector. They must provide information and advice for the whole population, including people who self-fund their own home care and support. Furthermore, the Care Act requires local authorities to stimulate and manage their local market to benefit the whole population.

Social care and support provided to people in the community may include both regulated and unregulated activity. All agencies in England that provide personal care to people in their own homes must register with the CQC and are subject to fundamental standards, monitoring and inspection to make sure they are meeting the national standards (Regulated Activities). The fundamental standards replaced the earlier CQC essential standards in April 2015and reflect changes in the law, recommended by an Inquiry by Sir Robert Francis. The standards specify what level of care everyone has the right to expect when they receive it. They also build upon the 2013 NHS Mandate in focusing on quality of life for people and on 'the person as a whole, rather than on specific conditions'.

CQC guidance for providers on meeting the regulations articulates what is expected of providers under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2009. There is no regulation of self-commissioned personal assistants or other home care workers directly employed by people who use social care and support services (unregulated activity).

1.2.1 Legislation related to this guideline

The following legislation and regulations relating to this guideline have been published by the UK Government, although this is not intended to be a comprehensive list:

- The Care Act 2014.
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- Health and Social Care Act 2012.
- The Controlled Waste (England and Wales) Regulations 2012.
- Care Quality Commission (Registration) Regulations 2009.
- Health and Social Care Act 2008.
- Mental Capacity Act 2005.
- The Data Protection Act 1998.
- Disability Discrimination Act 1995.
- The Misuse of Drugs (Safe Custody) Regulations 1973.
- Misuse of Drugs Act 1971.
- Medicines Act 1968.

1.3 Terms used in the guideline

Carer

The term ‘carer’ is used to define an informal, unpaid carer only (see also ‘home care worker’).

Commissioner

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

Health and social care practitioners

The term 'health and social care practitioners' is used to define the wider health and social care team of health professionals and social care practitioners. Health professionals include, but are not limited to, GPs, pharmacists, hospital consultants, community nurses, specialist nurses and mental health professionals. Social care practitioners include, but are not limited to, home care workers, personal assistants, case managers, care coordinators and social workers. When specific recommendations are made for a particular group, this is specified in the recommendation.

Home care plan

A written plan that sets out the home care support that providers and the person have agreed will be put in place, following the local authority assessment of overall need. It includes details of both personal care and practical support.

Home care provider

A provider organisation, registered with the Care Quality Commission as a home care agency, which directly employs home care workers to provide care and support in a person’s home (see provider / care provider)**.**

Home care worker

A person employed by a home care provider to provide care and support to people in their own home (also see ‘personal assistant’).

Medicine

The term ‘medicine’ includes all prescription and non-prescription (over-the-counter) healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.

Person or people

The terms ‘person’ or ‘people’ are used to define the adult or adults who are receiving social care in the community.

Provider / care provider

Providers are organisations that directly provide health or social care services to people (for example, home care providers, community pharmacies, general practices, dispensing doctors, community health providers, voluntary agencies and charities). When specific recommendations are made for a particular care provider, this is specified in the recommendation.

Social care in the community

For the purpose of this guideline, social care in the community is defined as care and support in their own home for adults:

- who the local authority has to discharge a duty or responsibility under either the Care Act 2014 or the Mental Health Act 1983
- who receive any social care component of an NHS Continuing Care package
- who self-fund their own care and support.

1.4 Person-centred care

This guideline offers best practice advice on managing medicines for people receiving social care in the community. This guideline assumes that practitioners using it, will read it alongside the Care Act 2014 (and its associated regulations), the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and other relevant legislation and statutory guidance. It is also written to reflect the rights and responsibilities that people and practitioners have as set out in the NHS Constitution for England. Care and support should take into account individual needs and preferences. People should have the opportunity to make informed decisions about their care, in partnership with health and social care practitioners. Practitioners should recognise that each person is an individual, with their own needs, wishes and priorities. They should treat everyone they care for with dignity, respect and sensitivity.

Health professionals should follow the Department of Health's advice on consent. If a person does not have capacity to make decisions, health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards.

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

1.5 Strength of recommendations

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

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

1.5.1 Interventions that must (or must not) be used

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

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

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

1.5.3 Interventions that could be used

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

2 Development of a NICE guideline

2.1 What is a NICE guideline

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

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

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

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

The guidelines are produced using the following steps:

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

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

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

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

2.2 Remit

NICE received the remit for the guideline from the Department of Health. The NICE Medicines and Prescribing Programme was responsible for the development of the guideline.

2.3 Who developed the guideline

A multidisciplinary Committee comprising health and social care practitioners and lay members developed this guideline (see Guideline developers for more information).

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

The Committee met regularly during the development of the guideline. At the start of the guideline development process all Committee members declared interests in line with the NICE code of practice on declaring and dealing with conflicts of interest (Conflict of interest policy), this included any consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent Committee meetings, members declared arising conflicts of interest.

Members were either required to withdraw for all or for part of the discussion if their declared interest made it appropriate to do so. The details of declared interests and the actions taken are shown in appendix A.

If a member's declared interest could be a conflict in the development of the guideline, the Chair asked the member to either withdraw completely or for part of the discussion in line with the NICE Conflict of interest policy and Developing NICE guidelines: the manual (2014) (see chapter 3). The details of declared interests and the actions taken are shown in appendix A.

Staff from the NICE Medicines and Prescribing Programme provided methodological support and guidance for the development process. The team working on the guideline included an assistant project manager, systematic reviewers (medicines advisers), social care adviser, information scientists and a project lead. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost effectiveness analysis where appropriate, and drafted the guideline in collaboration with the Committee.

2.4 Purpose and audience

The purpose of this guideline is to provide recommendations on the systems and processes for managing medicines for adults receiving social care in the community. Social care in the community is defined as care and support in their own home for adults:

- who the local authority has to discharge a duty or responsibility under either the Care Act 2014 or the Mental Health Act 1983
- who receive any social care component of an NHS Continuing Care package
- who self-fund their own care and support.

This guideline is for adults receiving social care in the community and:

- their families and carers.
- providers of services (for example, home care providers, community pharmacies, general practices, dispensing doctors, community health providers, voluntary agencies and charities).
- social care practitioners for example, home care workers, personal assistants, case managers, care coordinators and social workers).
- health professionals (for example, GPs, pharmacists, hospital consultants, community nurses, specialist nurses and mental health professionals).

- commissioners of services (for example, local authorities and clinical commissioning groups).
- organisations that regulate or monitor how services are provided (for example, the Care Quality Commission [CQC]).

It is anticipated that health and social care commissioners and providers will need to work together to ensure that people benefit from the recommendations in this guideline.

2.5 What this guideline covers

This guideline covers the following population:

- Adults (aged 18 years and over) who take or use medicines and who are receiving social care in the community (and their families and carers).

This guideline covers the following setting:

- People's own homes, including:
  - extra care housing
  - Shared Lives Scheme (formerly Adult Placement Scheme) living arrangements
  - sheltered housing (such as supported housing or specialist accommodation)
  - supported living
  - temporary accommodation (such as people who are homeless).

This guideline covers the following key issues:

- Person-centred medicines assessment to identify and manage the type of medicines support needed.
- Handling medicines, including processes for:
  - ordering medicines
  - supplying medicines
  - transporting medicines
  - storing medicines
  - disposing of medicines (including waste medicines).
- Administering medicines, including:
  - supporting people to look after and take their medicines themselves (self-administration)
  - to people in their home when they unable to look after and take their medicines themselves
  - to people without their knowledge (covert administration)
  - non-prescription (over-the-counter) medicines (homely remedies).
- Identifying, reporting and learning from medicines-related problems, including:
  - raising concerns about inappropriate or incorrect medicines use
  - reporting adverse effects of medicines
  - learning from medicines-related incidents, such as medication errors
  - refusal by the person to take their medicines.
- Medicines-related communication, documentation and information sharing about a person's medicines.
- Roles and responsibilities of organisations and health and social care practitioners, including:
  - knowledge and skills (competency) of health and social care practitioners
  - multi-agency coordination of medicines-related support

- monitoring and evaluation of medicines-related support.

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

2.6 What this guideline does not cover

This guideline does not cover the following settings:

- Day services.
- Hospices.
- Inpatient hospital settings.
- Other hospital settings, including accident and emergency departments and outpatient departments.
- Residential or nursing care homes (these are covered by the NICE guideline on Managing medicines in care homes).
- Secure environments, such as prisons.

This guideline does not cover the following issues:

- Specific named medicines.
- Specific clinical conditions, including multimorbidity and those conditions that are likely to need additional social care and support (for example, dementia and stroke rehabilitation) (see the NICE guideline on Multimorbidity).
- Shared decision-making (see the NICE guidelines on Patient experience in adult NHS services and Medicines optimisation).

2.7 Related NICE guidelines

2.7.1 Published NICE guidelines

- Multimorbidity: clinical assessment and management. NICE guideline NG56 (2016)
- Transition between inpatient mental health settings and community and care home settings. NICE guideline NG53 (2016)
- Controlled drugs: safe use and management. NICE guideline NG46 (2016)
- Transition from children's to adults' services for young people using health or social care services. NICE guideline NG43 (2016)
- Transition between inpatient hospital settings and community or care home settings for adults with social care needs. NICE guideline NG27 (2015)
- Older people with social care needs and multiple long-term conditions. NICE guideline NG22 (2015)
- Home care: delivering personal care and practical support to older people living in their own homes. NICE guideline NG21 (2015)
- Antimicrobial stewardship. NICE guideline NG15 (2015)
- Medicines optimisation. NICE guideline NG5 (2015)
- Drug allergy. NICE guideline CG183 (2014)
- Managing medicines in care homes. NICE guideline SC1 (2014)
- Patient experience in adult NHS services. NICE guideline CG138 (2012)
- Service user experience in adult mental health. NICE guideline CG136 (2011)
- Medicines adherence. NICE guideline CG76 (2009)

2.7.2 NICE guidelines in development

- Intermediate care including reablement. NICE guideline. Publication expected July 2017
- People's experience in adult social care services: improving the experience of care for people using adult social care services. NICE guideline. Publication expected January 2018
- Supporting decision making for people who may lack capacity. NICE guideline. Publication expected July 2018

3 Methods

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

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

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

Additional information is provided in the appendices for each review question (where appropriate), including:

- Evidence tables
- Full health economic report.

3.1 Developing the review questions and outcomes

3.1.1 Review questions

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

During the scoping phase, 6 review questions were identified to assess the effectiveness and cost-effectiveness of interventions, systems or processes. Review questions are usually best answered by randomised controlled trials (RCTs), because this is most likely to give an unbiased estimate of the effects of an intervention. However, in line with the Developing NICE guidelines: the manual (2014), the nature of this topic means that the best available evidence on which to produce the guideline is likely to include evidence other than RCTs.

The Committee discussed the review questions at Committee meetings and agreed the final wording of the review questions; see table 1.

Table 1 Final review questions

Section	Type of review	Review question
5	Intervention	What interventions, systems and processes for person-centred medicines assessment are effective and cost effective to identify and manage the type of medicines support needed for a person receiving social care in the community?
6	Intervention	What interventions, systems and processes are effective and cost effective for safely ordering, supplying, transporting, storing and disposing of medicines for a person receiving social care in the community?
7	Intervention	What interventions, systems and processes are effective and cost-effective in supporting safe and effective self-administration, or

Section	Type of review	Review question
		administration, of medicines for a person receiving social care in the community?
8	Intervention	What interventions, systems and processes are effective and cost effective for identifying, reporting and learning from medicines-related problems for a person receiving social care in the community?
9	Intervention	What interventions, systems and processes for improving communication, documentation and information sharing about medicines are effective and cost-effective for people receiving social care in the community?
10	Intervention	What are the roles and responsibilities of organisations and health and social care practitioners in supporting the safe and effective use of medicines for people receiving social care in the community?

3.1.2 Writing the review protocols

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

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

Each review protocol includes:

- The review question
- Objectives of the evidence review
- Type of review
- Language
- Legislation and regulation
- Policy and guidance
- Study design/evidence type
- Status
- Population
- Intervention
- Comparator
- Outcomes
- Other criteria for inclusion or exclusion of evidence
- Search strategies
- Review strategies
- Identified papers from scoping search and Committee experience that address the review question

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

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

3.2 Searching for evidence

3.2.1 Literature searching

Scoping searches were undertaken in March 2015 in order to identify legislation, regulations, national policy and guidance, including key publications relevant to the topic. A list of sources searched can be found in appendix C.1.

A systematic literature search was carried out by an information specialist from NICE information services in September 2015 to identify published evidence relevant to all the review questions (see appendix C.1). Searches were carried out according to the methods described in chapter 5 of Developing NICE guidelines: the manual (2014).

Databases were searched using relevant medical subject headings and free-text terms. Studies published in languages other than English were not reviewed. The searches were restricted from 2005 to September 2015, as the Committee agreed that evidence published before this date was unlikely to take account of recent legislative and regulatory changes affecting social care.

The following databases were searched for all questions:

- Cochrane Database of Systematic Reviews – CDSR (Wiley)
- Cochrane Central Register of Controlled Trials – CENTRAL (Wiley)
- Database of Abstracts of Reviews of Effects – DARE (Wiley)
- Health Technology Assessment Database – HTA (Wiley)
- EMBASE (Ovid)
- MEDLINE (Ovid)
- MEDLINE In-Process (Ovid)
- PubMed (NLM)
- Applied Social Science Index and Abstracts – ASSIA (ProQuest)
- Social Care Online (SCIE)
- Social Policy and Practice (Ovid)
- Social Services Abstracts (ProQuest)

Sources searched to identify economic evaluations:

- NHS Economic Evaluation Database – NHS EED (Wiley)
- EconLit (Ovid)
- EMBASE (Ovid)
- MEDLINE (Ovid)
- MEDLINE In-Process (Ovid)

Search filters to retrieve economic evaluations and quality of life papers were appended to the population search terms in MEDLINE, MEDLINE In-Process and EMBASE to identify relevant evidence.

The evidence search strategies can be found in appendix C.1.

3.3 Reviewing the evidence

Although 6 separate review questions and protocols were developed for this guideline, due to the large overlap in literature search results from separate searches, a single literature search strategy was developed. This systematic literature search identified 38,547 references and 9629 economic references. The evidence retrieved from the literature search was systematically reviewed against each review protocol. Evidence identified was screened by title and abstract (first sift). Evidence that did not meet the inclusion criteria for any of the review protocols was excluded. Full papers of the included evidence (550 clinical references and 56 economic references) were requested.

Overall, 608 full text papers were reviewed against the inclusion and exclusion criteria as described in the review protocols. 542 references and 56 economic references were excluded because they did not meet the eligibility criteria (second sift). A list of excluded studies and reasons for their exclusion is given in appendices C.5 and C.6. A total of 10 references were included for the full guideline, including 4 key evidence sources that are included within each of the 6 review questions.

Relevant data from each included reference were extracted and included in the 'Summary of included evidence' table for the relevant review protocol. These tables can be found in the relevant 'Evidence review' section. An overview of the systematic review process followed is detailed in chapter 5 of Developing NICE guidelines: the manual (2014).

The consort diagram can be found in appendix C.3.

3.3.1 Inclusion and exclusion criteria

Selection of relevant evidence was carried out by applying the inclusion and exclusion criteria listed in the review protocols (see appendix C.2). All 542 studies excluded at the 2nd sift, including reasons for exclusion can be found in appendix C.5. Any evidence where there was any uncertainty about inclusion, particularly in relation to the population, were discussed and agreed by both medicines advisers. There were no disagreements on the final decision for inclusion or exclusion of these studies.

3.3.2 Types of evidence

Only evidence in the English language from the UK or other countries with similar health and social care systems was considered. For all review questions the following types of evidence were considered in the reviews:

- NICE accredited guidance.
- Systematic review of randomised controlled trials (RCTs).
- RCTs.
- Other national guidance.
- Systematic reviews of non-randomised controlled trials.
- Non-randomised controlled trials.
- Observational studies.
- Qualitative studies.
- Cross-sectional surveys.
- Economic analyses.

Relevant legislation or policies identified in the literature search was also used to inform the guideline.

Conference abstracts were not considered as part of the evidence reviews.

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

3.3.3 Appraising the quality of evidence

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

The GRADE framework was not considered appropriate for the evidence identified in this guideline. All references were quality assessed by both systematic reviewers using the appropriate NICE methodology checklist; see appendix H in Developing NICE guidelines: the manual (2014).

3.3.4 Evidence statements (summarising and presenting results for effectiveness)

Evidence statements were developed to include a summary of the key features of the evidence. For each question, evidence statements for clinical and cost effectiveness were summaries of the evidence, produced to support the Committee in their review of the evidence and decision-making when linking evidence to recommendations.

3.4 Evidence of cost-effectiveness

The Committee needs to make recommendations based on the best available evidence of clinical effectiveness, cost effectiveness and overall resource impact. Guideline recommendations should be based on the balance between the estimated costs of the interventions or services in relation to their expected benefits, compared with an alternative (that is, their 'cost effectiveness'). In general, the Committee will want to be increasingly certain of the cost effectiveness of a recommendation as the cost of implementation increases. Therefore, the Committee may require more robust evidence on the clinical effectiveness and cost effectiveness of recommendations that are expected to have a substantial impact on resources; any uncertainties must be offset by a compelling argument in favour of the recommendation. The cost impact or savings potential of a recommendation should not be the sole reason for the Committee's decision. .

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

3.5 Developing recommendations

The Committee reviewed the evidence of clinical effectiveness (no evidence was found for the cost effectiveness of interventions) in the context of each of the 6 review questions to develop recommendations that would provide national guidance and advice to commissioners, providers and health and social care practitioners.

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

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

The Committee then considered any potential and actual resource impact of any interventions and considered how this impacted on the decisions made after presentation of

the clinical effectiveness evidence. The recommendation wording reflects the quality of the evidence, the confidence the Committee had in the evidence presented and the Committee's values and preferences in line with the agreed prioritised outcomes.

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

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

3.6 Validation review

3.6.1 Validation process

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

3.6.2 Updating the guideline

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

3.6.3 Disclaimer

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

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

3.6.4 Funding

NICE commissioned the NICE Medicines and Prescribing Programme to develop this guideline.

4 Guideline summary

4.1 Recommendations

4.1.1 Full list of recommendations

The recommendations clearly detail the intended audience for the recommendation when possible. However, in some cases the Committee was not able to specify which person or organisation was responsible. This will be for commissioners and providers to consider and determine locally.

Policies for managing medicines safely and effectively

1. Home care providers should have a documented medicines policy based on current legislation and best available evidence. The content of this policy will depend on the responsibilities of the home care provider, but it is likely to include processes for:
    - assessing a person's medicines support needs
    - supporting people to take their medicines, including 'when required', time-sensitive and over-the-counter medicines
    - joint working with other health and social care providers
    - sharing information about a person's medicines
    - ensuring that records are accurate and up to date
    - managing concerns about medicines, including medicines-related safeguarding incidents
    - giving medicines to people without their knowledge (covert administration)
    - ordering and supplying medicines
    - transporting, storing and disposing of medicines
    - staff training and assessing competency.
2. Home care commissioners and providers should review their medicines policies, processes and local governance arrangements, and ensure that these are clear about who is accountable and responsible for managing medicines safely and effectively.

Assessing and reviewing a person's medicines support needs

Many people want to actively participate in their own care. Enabling and supporting people to manage their medicines is usually preferred, with help from family members or carers if needed. The term 'medicines support' is used to define any support that enables a person to manage their medicines. This varies for different people depending on their specific needs.

3. Assess a person's medicines support needs as part of the overall assessment of their needs and preferences for care and treatment.
4. Do not take responsibility for managing a person's medicines unless the medicines assessment indicates the need to do so (see also recommendation 8 on when home care workers should provide medicines support).
5. Home care commissioners and providers should ensure that people assessing a person's medicines support needs, including social workers, have the necessary knowledge, skills and experience (see also recommendation 65 on training and competency).

6. Engage with the person (and their family members or carers if this has been agreed with the person) when assessing a person's medicines support needs. Focus on how the person can be supported to manage their own medicines, taking into account:
    - the person's needs and preferences, including their social, cultural, emotional, religious and spiritual needs
    - the person's expectations for confidentiality and advance care planning
    - the person's understanding of why they are taking their medicines
    - what they are able to do and what support is needed, for example, reading medicine labels, using inhalers or applying creams
    - how they currently manage their medicines, for example, how they order, store and take their medicines
    - whether they have any problems taking their medicines, particularly if they are taking multiple medicines
    - whether they have nutritional and hydration needs, including the need for nutritional supplements and/or parenteral nutrition
    - who will be the person to contact about their medicines (ideally the person themselves, if they choose to and are able to, or a family member, carer or care coordinator)
    - the time and resources likely to be needed.
7. Record the discussions and decisions about medicines support in the person's home care plan. If the person needs medicines support include:
    - the person's needs and preferences
    - the person's expectations for confidentiality and advance care planning
    - how consent will be sought
    - details of who to contact about their medicines (the person or a named contact)
    - what support is needed for each medicine
    - how the medicines support will be given
    - who will be responsible for providing medicines support, particularly when more than one care provider is involved
    - when the medicines support will be reviewed, for example, after 6 weeks.
8. Home care workers should only provide the medicines support that has been agreed and documented in the person's home care plan (see also recommendation 38 on when home care workers should give medicines).
9. Review a person's medicines support to check whether it is meeting their needs and preferences. This should be carried out at the time specified in their home care plan or sooner if there are changes in the person's circumstances, such as:
    - changes to their medicines regimen
    - a hospital admission

- a life event, such as a bereavement.

Joint working between health and social care

Joint working enables people to receive integrated, person-centred support. Health professionals working in primary and secondary care have an important role in advising and supporting home care workers and other social care practitioners.

10. Home care providers should notify a person's general practice and community pharmacy when starting to provide medicines support, including details of who to contact about medicines (the person or a named contact).

11. General practices should record details of the person's medicines support and who to contact about their medicines (the person or a named contact) in their medical record, when notified that a person is receiving medicines support from a home care provider.

12. Home care workers and other social care practitioners should seek advice about medicines from people with specialist experience, such as the prescriber, a pharmacist or another health professional, when it is needed.

13. Health professionals should provide ongoing advice and support to the person about their medicines and check if any changes to their medicines or extra support may be helpful, for example, by checking whether:

    - the person's medicines regimen can be simplified
    - any medicines can be stopped
    - the formulation of a medicine can be changed
    - support can be provided for problems with medicines adherence
    - a review of the person's medicines may be needed.

14. When specific skills are needed to give a medicine (for example, using a percutaneous endoscopic gastrostomy [PEG] tube), health professionals should only delegate the task of giving the medicine to a home care worker when:

    - the person (or their family member or carer if they have lasting power of attorney) has given their consent
    - the responsibilities of each person are agreed and recorded
    - the home care worker is trained and assessed as competent (see also recommendation 65 on training and competency).

15. Health professionals should continue to monitor and evaluate the safety and effectiveness of a person's medicines when the task of giving a medicine has been delegated to a home care worker.

Sharing information about a person's medicines

It is important that information about medicines is shared with the person and their family members or carers, and between health and social care practitioners, to support high-quality care[a].

[a] Take into account the 5 rules set out in the Health and Social Care Information Centre's A guide to confidentiality in health and social care (2013) when sharing information.

For guidance on medicines-related communication and medicines reconciliation when a person is transferred from one care setting to another, see the NICE guideline on medicines optimisation.

16. Home care providers should have robust processes for communicating and sharing information about a person's medicines[1], including advance care planning, that takes account of the person's expectations for confidentiality. This includes communication with:
    - the person and their family members or carers
    - home care workers and other social care practitioners
    - health professionals, for example, the person's GP or community pharmacist
    - other agencies, for example, when care is shared or the person moves between care settings.
17. If a person has cognitive decline or fluctuating mental capacity, ensure that the person and their family members or carers are actively involved in discussions and decision-making. Record the person's views and preferences to help make decisions in the person's best interest if they lack capacity to make decisions in the future.
18. Follow the advice on sharing information about medicines when a person is transferred from one care setting to another in the NICE guideline on medicines optimisation.
19. Prescribers should communicate changes to a person's medicines (for example, when stopping or starting a medicine) by:
    - issuing a new prescription **and**
    - informing the person or their named contact **and**
    - informing the person's community pharmacist, if this is agreed with the person and/or their family members or carers.
20. Prescribers should ensure that changes to a person's medicines are only given verbally in exceptional circumstances. Follow up any verbal changes with written confirmation to the home care provider as soon as possible. Written confirmation should be sent by an agreed method of communication, for example, a secure fax or secure e-mail.
21. Home care providers should have robust processes for receiving and recording verbal changes to a person's medicines, which should include:
    - recording details of the requested change (including who requested the change, the date and time of the request and who took the request)
    - reading back the information that has been recorded to the person requesting the change to confirm it is correct (including spelling the name of the medicine)
    - ensuring the person requesting the change repeats the request to another person (for example, the person and/or a family member or carer).

Ensuring that records are accurate and up to date

Poor record keeping can put people receiving medicines support and home care workers at risk. Home care providers are required by law (The Health and Social Care Act 2008

(Regulated Activities) Regulations 2014) to securely maintain accurate and up-to-date records about medicines for each person receiving medicines support.

22. When medicines support is provided, home care providers should have robust processes for recording the person's current medicines. These should ensure that records are:
    - accurate and kept up to date
    - accessible, in line with the person's expectations for confidentiality.
23. Home care workers must record the medicines support given to a person on each occasion, in line with Regulation 17 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This includes details of all support for prescribed and over-the-counter medicines, such as:
    - reminding a person to take their medicine
    - giving the person their medicine
    - recording whether the person has taken or declined their medicine (see also recommendation 32 on reporting concerns or seeking advice).
24. Home care workers should use a printed medicines administration record to record any medicines that they give to a person. This record should ideally be provided by a community pharmacist or the dispensing doctor (see also recommendation 56 on supplying medicines).
25. Ensure that a medicines administration record includes:
    - the name of the person
    - the name, formulation and strength of the medicine(s)
    - how often or the time the medicine should be taken
    - how the medicine is taken or used (route of administration)
    - the name of the person's GP practice
    - any stop or review date
    - any additional information, such as specific instructions for giving a medicine.
26. Home care providers should have robust processes to ensure that medicines administration records are accurate and up to date. For example, handwritten records or changes should only be made and checked by people who are trained and assessed as competent to do so (see also recommendation 65 on training and competency).
27. When a family member or carer gives a medicine (for example, during a day out), agree with the person and/or their family member or carer how this will be recorded. Include this information in the person's home care plan.

Managing concerns about medicines

Medicines use can be complex, particularly when people have several long-term conditions and are taking multiple medicines. Enabling people to raise any concerns about their medicines, and managing them effectively when they happen is important to minimise harm and guide future care.

28. Home care providers must have robust processes for medicines-related safeguarding incidents, in line with Regulation 13 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. For guidance on ensuring safety and safeguarding people using home care services, see the NICE guideline on home care.

29. Home care providers should have robust processes for identifying, reporting, reviewing and learning from medicines-related problems. These processes should support a person-centred, 'fair blame' culture that actively encourages people and/or their family members or carers and home care workers to report their concerns.

30. Home care providers should review any of their medicines-related problems over a period of time to identify and address any trends that may have led to incidents. Share this learning with:

    - people working in the organisation
    - people receiving medicines support, their family members and carers
    - home care commissioners
    - people working in related services, for example, GPs, community pharmacists and community health providers.

31. Home care workers should report any concerns about a person's medicines to the home care provider or seek advice from the prescriber or another health professional. These concerns may include:

    - the person declining to take their medicine
    - medicines not being taken in accordance with the prescriber's instructions
    - possible adverse effects
    - the person stockpiling their medicines
    - medication errors or near misses
    - possible misuse or diversion of medicines
    - concerns about the person's mental capacity
    - changes to the person's physical or mental health.

32. Home care workers and other social care practitioners should advise people and/or their family members or carers to seek advice from a health professional (for example, the prescriber or a pharmacist) if they have clinical questions about medicines.

33. Health and social care practitioners should encourage and support people and/or their family members or carers to raise any concerns about their medicines. Explain how they can seek help or make a complaint, including who to complain to and the role of advocacy services (if needed) and record this information in the person's home care plan.

34. Health and social care providers should ensure that people and/or their family members or carers, and home care workers know how to report adverse effects of medicines, including using the Medicines and Healthcare products Regulatory Agency's yellow card scheme.

Supporting people to take their medicines

Supporting people to take their medicines may involve helping people to take their medicines themselves (self-administration) or giving people their medicines (administration).

For guidance on self-management of medicines, see the recommendations on self-management plans in the NICE guideline on medicines optimisation.

35. Home care providers should have robust processes for home care workers who are supporting people to take their medicines. These should include:
    - the 6 R's of administration:
        - right person
        - right medicine
        - right route
        - right dose
        - right time
        - person's right to decline
    - what to do if the person is having a meal or sleeping
    - what to do if the person is going to be away for a short time, for example, visiting family
    - how to give specific formulations of medicines, for example, patches, creams, inhalers, eye drops and liquids
    - using the correct equipment, for example, oral syringes for small doses of liquid medicines
    - giving time-sensitive or 'when required' medicines
    - what to do if the person has declining or fluctuating mental capacity.
36. Prescribers and community pharmacists (or dispensing doctors) should provide clear written directions on the prescription and dispensing label on how each medicine should be taken or given. For time-sensitive and 'when required' medicines, this should include (if relevant):
    - what dose should be taken (avoiding variable doses unless the person or their family member or carer can direct the home care worker)
    - what time the dose should be taken
    - the minimum time between doses
    - the maximum number of doses to be given (for example, in a 24-hour period).
37. Home care workers should only give a medicine to a person if:
    - there is a clearly documented agreement from the home care provider in the home care plan **and**
    - there are clear directions from the prescriber **and**

- they have been trained and assessed as competent to give the medicine (see also recommendation 65 on training and competency).

38. Before supporting a person to take a dose of their medicine, home care workers should ask the person if they have already taken the dose or check the written records to ensure that the dose has not already been given.

39. Home care workers should ask the person if they want to take their medicine before removing it from its packaging.

40. When giving medicines supplied by a health professional (for example, a community pharmacist), home care workers should give them directly from the container they are supplied in. Do not leave doses out for a person to take later unless this has been agreed with the person after a risk assessment and is recorded in their home care plan.

41. When a person declines to take a medicine, home care workers should consider waiting a short while before offering it again. They should ask about other factors that may cause the person to decline their medicine, such as being in pain or discomfort (see also recommendation 32 on reporting concerns or seeking advice).

42. Health and social care practitioners should ensure that an up-to-date patient information leaflet for each prescribed medicine is kept in the person's home. This includes medicines supplied in monitored dosage systems.

43. Home care providers should ensure that home care workers are able to prioritise their visits for people who need support with time-sensitive medicines.

Giving medicines to people without their knowledge (covert administration)

In exceptional circumstances, it may be necessary to give medicines to people covertly. This is when medicines are given in a disguised form without the knowledge or consent of the person receiving them.

44. Home care providers must ensure that medicines given to people without their knowledge (covert administration) only takes place in the context of existing legal and good practice frameworks to protect both the person and home care workers.

45. Health and social care practitioners should ensure that the process for covert administration clearly defines who should be involved in, and responsible for, decision-making. The process should include:

- assessing mental capacity
- seeking advice from the prescriber about other options, for example, whether the medicine could be stopped
- holding a best interests meeting involving a family member or carer, the prescriber and a pharmacist to agree whether giving medicines covertly is in the person's best interests
- recording any decisions and who was involved in decision-making
- planning how medicines will be given covertly, for example, by seeking advice from a pharmacist
- providing authorisation and clear instructions for home care workers in the person's home care plan when they are giving medicines covertly

- ensuring home care workers are trained and assessed as competent to give the medicine covertly (see also recommendation 65 on training and competency)
- regularly reviewing whether covert administration is needed.

46. Home care workers should not give medicines to a person covertly unless authorisation and instructions of how this should be carried out are clearly documented in the person's home care plan.

Ordering and supplying medicines

Responsibility for ordering medicines usually stays with the person and/or their family members or carers. However, if a home care provider is responsible, effective medicines management systems need to be in place.

47. Home care providers should agree with the person and/or their family members or carers who will be responsible for ordering medicines, and record this information in the person's home care plan. This should be the person, if they agree and are able to, with support from family members, carers or home care workers (if needed).

48. Home care providers that are responsible for ordering a person's medicines must ensure that the correct amounts of the medicines are available when needed, in line with Regulation 12 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

49. Home care providers that are responsible for ordering a person's medicines should not delegate this task to the supplying pharmacy (or another provider), unless this has been agreed with the person and/or their family members or carers.

50. Home care providers that are responsible for ordering a person's medicines should ensure that home care workers:

- have enough time allocated for checking which medicines are needed, ordering medicines and checking that the correct medicines have been supplied
- are trained and assessed as competent to do so (see also recommendation 65 on training and competency).

51. When ordering a person's medicines, home care workers should:

- record when medicines have been ordered, including the name, strength and quantity of the medicine
- record when medicines have been supplied
- check for any discrepancies between what was ordered and what was supplied.

52. Home care providers should ensure that home care workers know what action to take if a discrepancy is noted between what was ordered and what was supplied.

53. Community pharmacists (or dispensing doctors) should supply medicines in their original packaging and make reasonable adjustments to support the person to manage their medicines, in line with the Disability Discrimination Act 1995.

54. Consider using a monitored dosage system only when an assessment by a health professional (for example, a community pharmacist) has been carried out, in line with the Disability Discrimination Act 1995, and a specific need has been identified to

support medicines adherence. Take account of the person's needs and preferences and involve the person and/or their family members or carers and the home care provider in decision-making.

55. Community pharmacists (or dispensing doctors) should consider supplying printed medicines administration records for a person receiving medicines support from a home care provider (see also recommendation 25 on record keeping).

56. Home care providers should have robust processes for obtaining over-the-counter medicines that have been requested by the person. These should include:

- ensuring that the person understands and accepts any risk associated with taking the medicine
- what information needs to be recorded, for example, the name, strength and quantity of the medicine
- when to seek advice from a health professional.

57. Home care workers should not obtain or buy an over-the-counter medicine for a person based on symptoms described by the person or their family members or carers.

Transporting, storing and disposing of medicines

Responsibility for transporting, storing and disposing of medicines usually stays with the person and/or their family members or carers. However, if a home care provider is responsible, effective medicines management systems need to be in place.

58. Agree with the person and/or their family members or carers who will be responsible for transporting medicines to or from the person's home. If the home care provider is involved, carry out a risk assessment of transport arrangements.

59. Agree with the person how their medicines should be stored and disposed of. Encourage the person to take responsibility for this, if they agree and are able to, with support from family members, carers or home care workers, if needed. Record this information in the person's care plan.

60. Home care providers that are responsible for storing a person's medicines should have robust processes to ensure there is safe access to medicines, particularly for controlled drugs. These should include:

- identifying who should have authorised access to the medicines
- ensuring there is a safe storage place or cupboard for storing medicines, including those supplied in monitored dosage systems
- assessing the need for secure storage, for example, in a lockable cupboard
- identifying the need for fridge storage
- reviewing storage needs, for example, if the person has declining or fluctuating mental capacity.

61. Health and social care practitioners should provide advice and information about how to store controlled drugs safely, in line with the recommendation on storing controlled drugs in the NICE guideline on controlled drugs.

62. When a person is assessed to be at risk because of unsecured access to their medicines, home care providers should agree with the person and/or their family

members or carers whether secure home storage (a lockable cupboard) or central storage (not in the home) is needed.

63. When home care providers are responsible for disposing of any unwanted, damaged, out-of-date or part-used medicines, they must have robust processes, in line with The Controlled Waste (England and Wales) Regulations 2012. These processes should include:

- obtaining agreement from the person (or their family member or carer)
- how the medicines will be disposed of, usually by returning them to a pharmacy for disposal
- any special considerations, for example, for disposing of controlled drugs, needles and syringes
- what records will be made, for example, the name and quantity of medicine, the name of the person returning the medicine, the date returned and the name of the pharmacy.

Training and competency

If a person is receiving medicines support from a home care provider, this is usually provided by a home care worker. Appropriate training, support and competency assessment is essential to ensure the safety, quality and consistency of care.

64. Home care providers should have robust processes for managing medicines to ensure that home care workers:

- receive appropriate training and support
- have the necessary knowledge and skills
- are assessed as competent to give the medicines support being asked of them, including through direct observation
- update their knowledge and skills at least annually.

65. Follow the advice on recruiting, training and supporting home care workers in the NICE guideline on home care.

4.1.2 Research recommendations

There were no research recommendations identified for this guideline.

5 Person-centred medicines assessment

5.1 Introduction

Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 states that the care and treatment that people receive, must be appropriate, meet their needs and reflect their preferences.

The regulations also state the responsibilities of a home care provider, which include:

- carrying out, together with the person receiving care (or someone acting legally on their behalf), an assessment of their needs and preferences for care and treatment
- designing the care or treatment of the person receiving care with a view to satisfying their preferences and ensuring their needs are met.

The CQC (2015) say that this regulation describes the actions that home care providers must take to ensure that each person receives appropriate person-centred care and treatment that is based on an assessment of their needs and preferences.

Regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 states that care and treatment must be provided in a safe way for service users. Section (2)(a) requires the home care provider (registered person) to assess the risks to the health and safety of people from the care or treatment they receive. Assessments, planning and the delivery of care needs to be based on a balance of the needs and safety of people using the service and their rights and preferences.

Guidance on assessment in home care

The DH (2016) Care and support statutory guidance, chapters 6 and 7, contains information on the specific assessment of individuals. This guidance is not specific to medicines assessment but the principles of the guidance do apply, including:

- needs and carers assessment
- advocacy and capacity duties
- supporting a person's involvement in assessment
- self-supported assessment
- looking at a person's strengths
- fluctuating needs, including:
  - whether needs are likely to fluctuate (the frequency and degree of fluctuation)
  - what their on-going needs are likely to be
- the need for trained assessors
- record keeping and delegation of assessments.

The NICE guideline on Home care (NG21) contains recommendations about planning home care including:

- general principles for assessment
- the need for personalised care (service user and carer advocacy and involvement in decision making)
- assessing user preference and needs
- balancing risk and preference
- liaising with health services and telecare.

5.2 Review question

What interventions, systems and processes for person-centred medicines assessment are effective and cost effective to identify and manage the type of medicines support needed for a person receiving social care in the community?

5.3 Evidence review

5.3.1 Clinical evidence

The aim of this review question was to review the effectiveness and cost effectiveness of interventions, systems and processes for assessing or risk assessing medicines support needed for adults receiving social care in the community. The guideline Committee agreed that the objectives of this review were to:

- determine the effectiveness of medicines assessment interventions and approaches to identify the type of medicines support needed
- identify which people receiving social care in the community need additional support with their medicines
- determine when the medicines assessment should be carried out and what should it include
- determine who should be involved in the medicines assessment
- identify what the triggers are for reviewing the medicines assessment.

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection of included evidence. Three guidelines met the eligibility criteria for this review question and were included. One additional guideline (CQC 2015) was identified by the Committee and was relevant for inclusion. No identified studies met the eligibility criteria.

The included evidence is summarised in table 2. Due to a lack of evidence related to specific outcomes the GRADE framework was not considered appropriate. The guidelines were quality assessed using the AGREE II criteria. One guideline (CQC 2015) was found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, National Mental Health Development Unit [NMHDU 2010) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008]).

A narrative summary of the available evidence is presented.

No evidence was identified for the effectiveness of medicines assessment interventions and approaches to identify the type of medicines support needed, identifying which people receiving social care in the community need additional support with their medicines and triggers for reviewing a medicines assessment.

1 **Table 2: Summary of included guidelines**

Evidence	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers safe care and treatment.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Moderate quality
Housing Learning and Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated [2]	Aimed at practitioners, commissioners, care service managers and housing managers in extra care housing. Key areas: • guidance and best practice recommendations • additional medication considerations • dangers and pitfalls. • key learning points • frequently asked questions • reference material and resources.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis	Key areas: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice for medicines management schemes used by crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management used by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care	Key areas: • the principles that underpin safe handling of medicines in every social care setting • the general practical aspects of medicine handling • the general aspects of medicine management relating to specific care services	• Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation governing the handling of medicines	Low quality

Evidence	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
		• policies, procedures, systems and devices 'medicines toolkit'.		
Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS); Social Care Institute for Excellence (SCIE) [1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 [2] Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)				

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

Overview

In line with Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and evidence from other guidelines (RPS 2007, HLIN 2008) the amount of support a person receiving care needs with their medicines must be clearly identified through an assessment of needs and any risk. The RPS (2007) suggests that the amount of support and the responsibilities of the homecare worker should be written in the plan of care for each person.

Carrying out a medicines assessment

Evidence from the HLIN (2008) guidance suggests that when and how to carry out a medicines assessment is determined by the policy of the registered home care provider, although if the assessment is complex the home care provider may wish to involve the person's GP.

The CQC (2015) recommends that the individual responsible for assessing a person's care and treatment needs and preferences should have the required levels of skill and knowledge for that particular task. Evidence from the CQC (2015) also recommends that if a risk assessment (relating to the health, safety and welfare of people using services) is to be completed and/or reviewed this should be done by people with the qualifications, skills, competence and experience to do so (see section 10.5).

The HLIN (2008) also suggests that for people receiving direct payments who employ personal assistants, the person receiving care (or someone acting legally on their behalf) will be responsible for assessing their own risks.

Who should be involved in a medicines assessment?

Evidence from the CQC (2015) states that every person receiving care, or someone acting legally on their behalf, must be involved in an assessment of their needs and preferences and should be as involved in the assessment as much as they wish to be. The CQC states that home care providers should give them information and support when needed to help make sure they understand the choices about their care.

The CQC (2015) also state that where home care providers have shared responsibility for providing care and treatment with other organisations (for example through partnership working, integrated care or multidisciplinary assessments) they should take into account information from all relevant health and social care teams, staff and services.

The CQC (2015) state that where a person receiving care 'lacks the mental capacity to make specific decisions about their care and treatment, and no lawful representative has been appointed, their best interests must be established and acted on in accordance with the Mental Capacity Act 2005. Other forms of authority such as advance decisions must also be taken into account.'

Evidence from HLIN (2008) and RPS (2007) related to multi-compartment compliance aids states that people can be assessed by a pharmacist to determine the support needed to manage their medicines themselves (see section 6.5) under the Disability Discrimination Act 1995.

What should the medicines assessment include?

The CQC (2015) require that assessment, planning and delivery of care and treatment should balance the needs and safety of people using the service and their rights and preferences.

Evidence from the CQC (2015) states that an assessment should:

- take into account current legislation
- consider relevant nationally recognised evidence based guidance
- consider the health and personal care needs of the person receiving care, as well as their:
  - social
  - cultural
  - emotional
  - religious and spiritual needs.
- assess the nutritional and hydration needs of the individual including the need for and use of prescribed nutritional supplements and/or parenteral nutrition
- consider issues common to people with diseases or conditions that can result in poor outcomes for them if not addressed (for example continence support needs in people with dementia).

Evidence from the RPS (2007), HLIN (2008) and NMHDU (2010) suggests that the assessment and risk assessment for medicines could consider:

- the ability of the person receiving care to self-administer each of their medicines
- whether the person receiving care wants to take responsibility for looking after and taking medicines
- whether the person receiving care knows:
  - what medicines they take
  - what they are for
  - how and when to take them
  - what is likely to happen if they omit them
  - understands the need for safe storage
- how medicines will be stored including risks posed by storage in the home:
  - environment such as temperature and humidity
  - risk of unauthorised access to the medicines by other people (including children)
  - risk of problems caused by allowing large amounts of medicines to build up over time (for example out-of-date medicines or risk of diversion or misuse going unnoticed)
- how adherent
- the individual is with their medicines
- an assessment of an individual's risk to themselves posed by their possession of their medicines for those individuals under the care of mental health teams, in need of crisis intervention.

Documenting medicines assessments

Regulation 9(3)(d) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 state that homecare providers must keep a record of 'all assessments, care and treatment plans, and decisions made by people who use the service and/or those acting on their behalf.'

Reviewing medicines assessments

Evidence from the CQC (2015) recommends that assessments should be reviewed regularly and whenever needed throughout the person's care and treatment. The CQC also state that assessment, planning and delivery of care and treatment should include arrangements to respond to changes in people's needs in a timely way.

Evidence suggests (CQC 2015, HLIN 2008) that this is to ensure that people's goals or plans are being met and are still relevant, including when people:

- have changes to their medicines
- transfer or move between services
- use respite care
- are admitted or discharged from hospital.

In certain circumstances, evidence states (CQC 2015, HLIN 2008, NMHDU 2010) that a process of ongoing or continuing assessment and review is needed. This may include:

- the ability of a person to self-administer their own medicine
- the ongoing review of a person's nutrition and hydration needs (including prescribed nutritional supplements)
- the risk of suicide or self-harm and whether it is safe to leave medicine with a person during a mental health crisis.

5.3.2 Health economic evidence

A systematic literature search (appendix C.1) was undertaken to identify cost-effectiveness studies evaluating the interventions, systems and processes for person-centred medicines assessment to identify and manage the type of medicines support needed for a person receiving social care in the community?

This search identified 9,629 records, of which 9,624 were excluded based upon their title and abstract. The full papers of 5 records were assessed and excluded at this stage. The excluded studies and the reason for exclusion are shown in appendix B.

5.4 Evidence statements

In line with legislation, and low to moderate quality evidence from guidance, adults receiving social care in the community should have an assessment of their needs and preferences related to medicines. Additionally any identified risks related should be assessed.

Moderate quality evidence from guidance recommends that home care provider organisations should ensure that the person responsible for carrying out a medicines assessment, or medicines related risk assessment, should have the required knowledge, skills, qualifications and competence and experience to do so.

Low quality evidence from guidance suggests that individuals who directly employ their home care worker are responsible for self-assessing their own medicines needs and risk.

Moderate quality evidence from guidance recommends that the person receiving care (or someone acting legally on their behalf), relevant health and social care staff or services and a pharmacist (particularly where the needs for monitored dosage systems are being assessed) should be involved in the assessment of medicines needs and risk.

Moderate and low quality evidence from guidance suggests that a medicines assessment should:

- take account of current legislation

- take account of evidence based guidance
- consider the health and personal care needs (as well as social, cultural, emotional, religious and spiritual needs)
- take account of nutritional and hydration needs
- consider condition specific needs (such as continence needs in dementia or timing of certain medicines for Parkinson's disease).

Low quality evidence from guidance suggests that a medicines risk assessment should consider:

- the abilities of the person receiving care to take each of their medicines
- the preferences of the person and whether they want to take responsibility for looking after and taking their medicines
- whether the individual understands their medicines
- the risk posed by storage of medicines in the home
- whether the person is adherent with their medicines
- whether the possession of medicines by the person poses a risk (particularly in mental health crisis).

In line with legislation a record of all medicines assessments and medicines-related risk assessments should be kept.

Moderate quality evidence from guidance recommends that medicines assessments should be reviewed regularly and whenever needed throughout a person's care and treatment and should take account of a person's changing needs in a timely way.

Moderate and low quality evidence from guidance recommends that ongoing review of medicines assessment may be more appropriate when there are problems with self-administration, when nutritional and hydration needs are involved or when there is a risk of suicide or self-harm.

5.4.1 Health economic evidence

No economic evidence was identified for this review question.

5.5 Evidence to recommendations

Table 3: Linking evidence to recommendations

Relative values of different outcomes	The Committee discussed the relative importance all of the outcomes agreed for this review question (see Appendix C.2.1) and agreed that the following outcomes were critical and important for decision making: • Service user-reported outcomes • Carer-reported outcomes • Medicines-related problems • Health and social care utilisation. No studies were identified that included the critical or important outcomes identified for this review question. However the Committee agreed that the most important outcome was the need to carry out a person-centred assessment of medicines-related needs. The assessment helps ensure that people receive appropriate support to enable them to manage their medicines in the way that they choose. The Committee discussed and agreed that assessment should focus on the strengths and abilities of what the person can do, or might be able to do, in terms of managing or taking their medicines

	themselves, with appropriate support. The Committee concluded that most people receiving social care will take responsibility for managing their own medicines, although an assessment of medicines support needs may identify areas in which that management may be made easier, for example through a medication review (see the NICE guideline on medicines optimisation [NG5]) or interventions that can be used to support a person to be independent (see section 7.5).
Trade-off between benefits and harms	**Policies and processes for medicines assessment** The Committee discussed the evidence from guidance (HLIN 2008) and agreed that in order to provide care and treatment that is appropriate, and meets the person's needs and reflects their preferences, social care commissioners and home care providers should have policies and processes in place for assessing medicines-related needs and risk. **Accessing medicines assessments** The Committee discussed how people may be referred for an assessment of their need for support with managing their medicines. The Committee was aware that the Department of Health's Care and support guidance (2016) identifies that people may ask for a care and support assessment themselves or be referred for assessment by third parties (for example by a health professional or family member). The Committee was also aware that a person may not know that they are able to access to an assessment of their care and support needs. The Committee concluded that health professionals should consider whether the person (or their family carer) will be able to manage their medicines themselves or whether they may need to be directed to, or referred for, an assessment of their needs for additional support. **Carrying out a medicines assessment** **First contact assessment** The Committee heard that many initial (first contact) assessments for social care support are undertaken by social workers or social work assistants who have very little or no training in medicines and who often have little confidence in asking questions about medicines. The Committee was also aware that these assessments are often very limited in scope as medicines support is a small part of the overall assessment process leading to poor initial support for the individual. The Committee agreed that while it was appropriate for social workers and social work assistants to undertake the initial assessment process, they could ask questions which would highlight where a person has inadequate medicine-related social care support but they would not need in depth understanding of medicines. The Committee agreed that social workers and social work assistants undertaking the initial assessment could consider asking the following questions about medicines: • Do you take any medicines (including any that are shop bought), if so how many different medicines, including any tablets, creams, eye drops, inhalers, creams? • Do you have any problems taking or managing your medicines? For example: ○ forgetting to order or collect your medicine(s) ○ running out, or having too much, of your medicine(s) ○ have difficulty opening, preparing, taking or applying your medicine(s)

- have any problems disposing of unwanted, unused or out-of-date medicines?

- Does anyone normally help you with your medicine(s), for example a friend or relative reminding or helping you to take your medicine(s)
- Does taking any of your medicine(s) cause you any problems (for example tiredness or makes you feel unwell).

The Committee understood that it may not always be appropriate for the social worker or social work assistant to provide answers to the questions by themselves. The Committee discussed and concluded that employers of social workers and social work assistants who undertake initial assessments of medicines-related support should have systems and processes in place to enable social care staff to access necessary support from health professionals when addressing medicines-related issues outside the scope of social care.

The Committee heard that a more in depth assessment of the medicines-related support needs can lead to improved ways for the person to manage their own medicines, rather than a need for increased support from the home care provider.

The Committee agreed that health professionals who are made aware of newly identified problems with a person's medicines should follow the NICE guideline recommendations on medication review (see the NICE guideline on medicines optimisation [NG5]).

Home care provider responsibilities for medicines assessment

The Committee was aware that it is the legal duty (under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) of the home care provider to undertake an assessment of a person's medicines-related needs and obtain information about the person's medicines.

The Committee agreed that when care is privately purchased through a home care provider (self-funding), the provider should ask adequate questions to ensure that medicines needs are identified.

The Committee was aware that if a person qualifies for social care and support then in line with legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) a home care provider will, together with the person undertake an assessment of their needs and preferences and that the person carrying the assessment will be trained and competent to do so. The Committee concluded that a person's medicine support needs should be assessed as part of this overall assessment.

Who to involve in a medicines assessment

The Committee discussed the evidence from guidance (CQC 2015) and agreed that the person receiving care (and if the person wishes someone acting on their behalf a family carer, friend, relative or advocate) should always, in so much as they wish, be included in any assessment of medicines-related support needs. The Committee agreed that home care providers should support individuals to understand choices about their care such as who should be involved in the medicines assessment process.

The Committee discussed that if the person is not able to give the home care provider all the information about their medicines then there is a risk that the home care provider will not be able to assess the person's needs and plan care.

The Committee agreed that in many cases adequate assessment of a person's medicines-related needs for support will require input from both health and social care staff (multi-disciplinary team), particularly where an individual has complex or specialist needs.

The Committee was aware that it is the legal responsibility (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 12(i)) of all care providers to ensure that they undertake, or participate in; assessment of a person's needs and care planning, even though there may be financial implications for the service or health professionals carrying out the medicines-related assessment.

The Committee discussed the importance of medicines-related assessments taking into account the views of other relevant health and social care teams, staff or services, such as the GP, the person's preferred community pharmacist, community nursing services or other home care providers. When considering whether an individualised assessment for a monitored dosage system or monitored dosage system is needed, this should involve the person's community pharmacist (see section 5.5).

The Committee discussed and agreed that when decisions about care and treatment need to be made following assessment, if there is any concern about the mental capacity of the person then the requirements of the Mental Capacity Act 2005 and the associated Mental Capacity Act Code of Practice must be adhered to.

What the medicines assessment should include

The Committee discussed and agreed that a home care provider's assessment of a person's medicines-related needs, preferences and risks must comply with current legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and nationally recognised evidence based practice (CQC 2015).

The Committee discussed the evidence from guidance (CQC 2015) and agreed that a home care provider's medicines assessment should take into account the health and personal care needs of the individual as well as related social, cultural, emotional, religious and spiritual beliefs (for example taking medicines during periods of religious fasting).

The Committee discussed whether the assessment should take into account the nutritional or hydration needs of the person receiving care. The Committee agreed that if the needs were related to the medicines being taken then this was appropriate (for example ensuring that a drink is available for taking a medicine or identifying whether medicines should be taken before, with or after food).

The Committee agreed that the assessment should take account of medicines that need to be given at specific times or intervals, such as some medicines for Parkinson's Disease (see also the NICE guideline on home care [NG21] for recommendations on the importance of dose timing).

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008, NMHDU 2010) and following discussion concluded that the assessment should take into account:

- the person's needs and preferences, including their expectations for confidentiality and advanced care planning
- the person's understanding of why they are taking their medicines
- what they are able to do and what support is needed, for example reading

medicine labels, using inhalers or applying creams

- how they currently manage their medicines, for example how they order, store and take their medicines
- whether they have any problems taking their medicines, particularly if they are taking multiple medicines
- the time and resources likely to be required.

The Committee concluded that in line with the NICE guideline on home care [NG21], the details of who to contact in the case of any concerns regarding the persons medicines (a named person) recorded in the home care plan. The Committee agreed that ideally this would be the person themselves or a family member or a named care coordinator.

Recording medicines assessments

The Committee discussed and agreed that in line with legislation home care providers must make and keep records of all medicines assessments in the home care plan and the record should include the agreed amount of support for each medicine and the responsibilities of the home care worker (see section 9.5).

The Committee concluded that home care providers should record the discussions and decisions about what medicines support (if any) will be provided for each medicine in the person's home care plan, including:

- the person's needs and preferences, including their expectations for confidentiality and advance care planning
- how consent will be sought
- who will be the named person to contact about medicines
- how the medicines support will be given
- who will be responsible for providing the medicines support, particularly when more than one care provider is involved
- when the medicines support will be reviewed, for example after 6 weeks.

Reviewing medicines assessments

The Committee was aware that most funded social care undergoes a process where the home care provider and social care commissioner refine and agree with the person what support is needed once the care package is in place. The Committee was aware that the NICE guideline on home care [NG21] states that an initial review of the home care plan should be undertaken within 6 weeks, then regularly but at least annually. However, the Committee agreed that any support for medicines should be reviewed at this time or more frequently if needed, in line with guidance from the Care Quality Commission.

The Committee concluded that assessment, planning and delivery needs to be responsive to changes in the person's needs, wishes and preferences for example when:

- changes are made to the person's medicines
- the person transfers or moves between care services (including when they are admitted or discharged from hospital)
- there are life events that may impact on their medicines-related support needs (for example changes in their physical or mental health or following an admission to hospital).

The Committee also concluded that some assessments will be required to be reviewed regularly. Therefore the Committee agreed it is important for all people, that home care workers are alert to, and report changes:

	• in a person's ability to manage or take their medicines themselves (as this may indicate a decline in cognitive function or loss of mental capacity) • in the person's ability to maintain their own hydration and nutrition needs (as they may become unable to take their medicines themselves) • whenever there is an increased risk of self-harm (for example during mental health crisis).
Trade-off between net health benefit and resource use	No economic evidence was identified. No resource impacts were identified for the recommendations in this section.
Quality of evidence	The quality of the included evidence was assessed using the AGREE II criteria and was found to be moderate to very low quality overall (see table 2). No clinical studies were identified by the literature searches that were subsequently included as evidence for this review question. Evidence was obtained from professional guidelines to support social care (HLIN 2008, NMHDU 2010 and RPS 2007) and 1 guideline (CQC 2015) that supports provider compliance with regulations: • Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) (as amended), and • The Care Quality Commission (Registration) Regulations 2009 (Part 4) (as amended). Additionally, legislative frameworks (identified through scoping and the expert knowledge of the Committee) have been used where appropriate.

5.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendation 1

Recommendations 3 to 7

Recommendation 9

Recommendation 54

6 Handling medicines

6.1 Introduction

According to a Department of Health-funded report on the evaluation of the scale, causes and costs of waste medicines (2010), the cost of waste prescription medicines in primary and community care in England is estimated to be £300 million per year, with up to half of that figure likely to be avoidable. An estimated £90 million of unused prescription medicines are retained in people's homes at any one time.

The Care Quality Commission (CQC) guidance for providers (2015), on meeting regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that people using a service and/or those lawfully acting on their behalf must be given opportunities to manage as much of their care and treatment as they wish and are able to, and should be actively encouraged to do so. This may include managing their medicines.

The CQC guidance for providers (2015), on meeting regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that care and treatment must be provided in a safe way for service users, including the safe and proper management of medicines.

Guidance from the Royal Pharmaceutical Society (RPS) (2007) identified 8 core principles relating to the safe and appropriate handing of medicines that apply to every social care setting. Three principles are relevant to this review question:

- 'people who use social care services have freedom of choice in relation to their provider of pharmaceutical care and services including dispensed medicines
- medicines are available when the individual needs them and the home care provider makes sure that unwanted medicines are disposed of safely
- medicines are stored safely.'

People receiving social care in the community are usually responsible for looking after their own medicines. Home care workers (including directly employed personal assistants) and informal carers often help people to look after their medicines. This may be because the person is not able to do this, for example if they have a mental health condition or dementia (Northern Ireland Social Care Council 2013).

When social care organisations look after medicines for the people they care for, the home care provider and the home care manager are jointly responsible for the safe and appropriate handling of medicines (RPS 2007) (see section 10.5).

6.2 Review question

What interventions, systems and processes are effective and cost effective for safely ordering, supplying, transporting, storing and disposing of medicines for a person receiving social care in the community?

6.3 Evidence review

6.3.1 Clinical evidence

Theguideline Committee agreed that the objectives of this review were to determine the effectiveness of interventions, systems and processes for:

- ordering medicines and when those systems and processes should be used
- supplying acute and repeat medicines (for example, when monitored dosage systems should be used)
- supplying over-the-counter or prescribed medicines
- transporting medicines (for example, a care worker or family member or carer collecting medicines from the pharmacy and transporting them to a person's home)
- storing medicines safely at home
- disposing of medicines (including waste medicines).

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection process of included evidence. Three guidelines met the eligibility criteria for this review question and were included. One additional guideline (CQC 2015) was identified by the Committee and was relevant for inclusion. No identified studies met the eligibility criteria.

The included evidence is summarised in table 4. The included guidelines were quality assessed using the AGREE II criteria. One guideline (CQC 2015) was found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, National Mental Health Development Unit [NMHDU]) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008).

Table 4: Summary of included guidelines

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers safe care and treatment.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Moderate quality
Housing Learning and Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated [2]	Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas: • guidance and best practice recommendations • additional medication considerations • dangers and pitfalls • key learning points • frequently asked questions • reference material and resources.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis	Key areas: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice in medicines management schemes, crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care	Key areas: • the principles that underpin safe handling of medicines in every social care setting • the general practical aspects of medicine handling • the general aspects of medicine management relating to specific care services	• Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation governing the handling of medicines	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
		• policies, procedures, systems and devices 'medicines toolkit'.		

Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS); Social Care Institute for Excellence (SCIE)
[1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
[2] Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

6.3.1.1 Policies for the safe handling of medicines

The CQC guidance for providers (2015), on meeting regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that staff 'must follow policies and procedures about managing medicines, including those related to infection control.' These policies and procedures should be in line with current legislation and guidance and address:

- supply and ordering
- storage, dispensing and preparation
- administration
- disposal
- recording.

Evidence suggests that it is important for care workers to have a written medicines policy and processes for helping people to manage their medicines in their own homes (HLIN 2008, RPS 2007). In relation to handling medicines this should set out:

- how to support people to take responsibility for their own medicines
- what action should be taken if a person becomes unwell and is unable to take full responsibility for their medicines
- discussing the provision of medicine storage on an individual basis
- treatment of minor ailments.

In addition, there should be detailed written processes in place for any medicines-related task that a home care worker is required to undertake (HLIN 2008) (see section 10.5).

6.3.1.2 Ordering medicines

Evidence suggests that it is not usually appropriate for home care workers to influence how the person chooses to obtain their medicines (RPS 2007, HLIN 2008). However, the home care worker may need to prompt the person or their family member or carer when medicines are running out (RPS 2007). Some people (for example, people with severe mental health needs or advancing dementia) may need support with ordering their medicines (for example, by arranging delivery or collection of medicines from a local pharmacy) (HLIN 2008). Where home care workers visit the person's home they may need to clarify who is responsible for ordering medicines, unless this forms part of the care package (RPS 2007) (see section 10.5).

The home care provider may not be responsible for ordering medicines and may not be informed about any changes to the person's medicines (RPS 2007). However, when a home care provider is responsible for ordering a person's medicines, this should be done by the home care provider themselves and not delegated, for example to community pharmacy staff. Although not generally recommended as good practice, there may be some exceptions, for example if the person needs a monitored dosage system. It is the responsibility of the home care manager to ensure that there is a system in place to obtain medicines in a reasonable time frame (RPS 2007) (see section 10.5).

Appropriate systems and processes need to be in place when a home care provider acts on behalf of a person receiving care to order prescription medicines, for example by:

- requesting a repeat prescription from the GP practice
- requesting a repeat prescription through a community pharmacy collection service
- obtaining a medicine prescribed as a 'one off' (acute prescription).

The RPS guidance (2007) suggests this process for ordering should include:

- contacting the GP practice to find out the most suitable way to order medicines, particularly how many days the practice needs to process prescription requests
- checking what medicines the person has and ordering only what is needed before the next time medicines are due to be ordered. This is particularly important for medicines where it may be difficult to predict how much the person will need, for example when required medicines and topical medicines
- checking written prescriptions when they are received from the GP practice against the request list, before the medicines are dispensed
- ensuring that any unexpected changes are checked with the GP before the medicines are dispensed
- taking prescriptions to the community pharmacy in sufficient time so the person receiving care does not run out of their medicines.
- having a separate process to deal quickly and efficiently with acute prescriptions to ensure that the new medicine is started as soon as possible, within 24 hours at the latest.

No evidence was identified on the most appropriate method of ordering medicines, for example:

- using a repeat prescription order form (also known as the 'right-hand side' of the prescription form [FP10])
- using a medicines administration record (MAR chart)
- using a managed repeat prescription system
- using an e-mail ordering system.

Appropriate systems and processes also need to be in place when a home care provider receives a request to change treatment over the telephone and not in writing (a verbal order). The home care provider should have processes in place to clearly communicate and document any such changes (RPS 2007) (see section 9.3.1).

6.3.1.3 Supplying medicines

For the purpose of this guideline, supply is defined as providing a medicine(s) to a person or their family member or carer for administration, for example, a pharmacist or dispensing doctor supplying a medicine in accordance with a written prescription.

The CQC guidance for providers (2015), on meeting regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that where medicines are supplied by the service provider, they must ensure that there are sufficient quantities of these to ensure the safety of service users and to meet their needs. All dispensed medicines must meet legal requirements, including secondary dispensing (re-packaging a medicine that has already been dispensed by a pharmacist or a dispensing doctor).

Principle 1 of the RPS guidance (2007) states that people who use social care services have freedom of choice in relation to their provider of pharmaceutical care and services including dispensed medicines. This means that people should be able to choose which pharmacy (or dispensing doctor) supplies their medicines. Furthermore, principle 5 states that medicines are available when the individual needs them and the home care provider makes sure that unwanted medicines are disposed of safely (see section 6.3.1).

The service provider supplying medicines (for example, a community pharmacy) should ensure that people's medicines are available in the necessary quantities at all times to prevent the risks associated with medicines that are not administered as prescribed. This includes when people manage their own medicines. Poor and delayed access to appropriate medicines may exacerbate a health problem and reduce the possibility of successful home treatment (NMHDU 2010).

In order to ensure continuity of supply, evidence suggests that arrangements with a local community pharmacy or dispensing doctor should be made in advance (RPS 2007). Community pharmacies may offer a prescription collection and home delivery service (HLIN 2008).

The NMHDU guidance (2010) in crisis resolution and home treatment teams recommends that all dispensing should be undertaken in a timely and flexible manner by a pharmacy supply service (hospital and/or community) that meets the dispensing needs of people, carers and staff .

Sufficient supplies of medicines should be available in case of emergencies (RPS 2007). In crisis resolution and home treatment teams, the NMHDU guidance (2010) recommends that processes are developed to enable rapid access to supplies of medicines outside regular working hours, for example accessing medicines held in stock or using an out of hours pharmacy service.

Evidence from guidance (RPS 2007) suggests that if the home care provider is responsible for ordering medicines, staff in the care service should check the dispensed medicines when received against the list of prescribed medicines. If there are any discrepancies from what was expected, this should be checked with the supplying community pharmacist or dispensing doctor before any medicines are administered.

No evidence was identified on the most appropriate system for supplying medicines to people receiving care, for example:

- standard dispensing supply, such as manufacturer's original packaging and solid dosage forms dispensed into bottles from bulk containers
- monitored dosage systems.

However, people or their family members or carer's adding medicines to pharmacist-filled compliance aids was recognised as a risk to the person's safety (HLIN 2008).

6.3.1.4 Transporting medicines

The CQC guidance for providers (2015), on meeting regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that the equipment, medicines and/or medical devices that are necessary to meet people's needs should be available when they are transferred between services or providers.

No evidence was identified on interventions, systems and processes for transporting medicines safely and appropriately (for example, a home care worker or family member or carer collecting medicines from a community pharmacy and transporting them to a person's home).

6.3.1.5 Storing medicines

Principle 6 of the RPS guidance (2007) is that medicines are stored safely. People receiving care should be able to choose to look after their own medicines and decide where and how to store them (RPS 2007). It is not usually appropriate for a care worker to influence how and where the person chooses to store medicines in the home (RPS 2007).

Evidence suggests that a number of different scenarios may exist, including:

- a person looks after and stores their medicines in their own home
- a person's medicines are stored in their own home, but they do not have access to them and a home care provider is responsible
- a home care provider is responsible for storing a person's medicines in a central location (i.e. not in the person's home).

Evidence suggests that medicines storage should be considered and provided on an individual basis (RPS 2007, HLIN 2008). For people with a mental health need or dementia, it may not be appropriate for the person to have access to their medicines (HLIN 2008). In these circumstances, a lockable cupboard in the person's home would be needed which the person did not have access.

All medicines should be stored in the person's home and only in exceptional circumstances where a risk assessment has identified a risk to the person by storing it there, should medicines be stored in a central location. Evidence suggests that the risk assessment process should look at the possibility of abuse of medicines due to excess medicines building up in a person's home and accessibility by the person or other people. This may be particularly important in settings where there may be greater accessibility to medicines, for example in extra care housing (HLIN 2008) (see section 10.5).

When a home care provider is responsible for medicines storage, appropriate storage facilities (such as a medicines cupboard(s) or room) that meets national standards for safe and secure handling of medicines are needed (RPS 2007, NMHDU 2010). Evidence suggests the following needs to be taken into account:

- there should be a secure, designated place for storing medicines in a cool and dry environment (RPS 2007, HLIN 2008)
  - some places in the home are not suitable for storing medicines, for example damp or steamy places such as kitchens or bathrooms
  - room temperature should not exceed 25°C
- only members of staff who are authorised to handle medicines should have access to keys for the medicines cupboard(s) or room:
  - accessibility of medicines for people receiving care is an area for risk assessment (HLIN 2008)
  - keys should not be part of the master system
- only medicines should be stored in a medicine cupboard. It should not be used as a safe for valuables or as a food cupboard.

For medicines stored in the person's home, these systems are unnecessary (HLIN 2008).

The RPS guidance states that storage requirements for the following need particular consideration:

- controlled drugs – see the NICE guideline on controlled drugs [NG46] which covers all settings, including peoples own homes
- nutritional supplements
- medicines that need refrigeration
- dressings, ostomy products and catheters
- medicines supplied in monitored dosage systems, which need more storage space.

Some medicines must be stored in a refrigerator, although a separate medicines fridge in a person's home is not necessary (RPS 2007, HLIN 2008). The RPS guidance (2007) recommends that home care workers know which medicines need to be kept in a fridge (this is stated on the patient information leaflet supplied with a medicine). Home care workers should check that the person's fridge appears to be working correctly if there are medicines stored in it.

When a home care provider is responsible for medicines storage:

- medicines that require fridge storage should be labelled as such
- the temperature of the medicine refrigerator should be monitored daily when it is in use (using a maximum/minimum thermometer), and recorded
- the fridge should be cleaned and defrosted regularly
- there should be written procedures of action to take if the temperature is outside the normal range or if the fridge breaks down (RPS 2007).

In exceptional circumstances, if it was inappropriate for the person to have access, a central lockable medicines fridge would be needed (HLIN 2008).

6.3.1.6 Disposing of medicines

For the purpose of this guideline, disposing of medicines is defined as the safe removal and/or destruction (where legally permitted) of unwanted, damaged, out-of-date or part-used medicines from the person's home.

Principle 5 of the RPS guidance (2007) states that '…the home care provider makes sure that unwanted medicines are disposed of safely'. All care settings should have a written policy for the safe disposal of surplus, unwanted or expired medicines. When (home) care workers are responsible for the disposal, a complete record of medicines should be made (RPS 2007).

It is not usually appropriate for care workers to influence how a person's medicines that are no longer in use are disposed of (RPS 2007, HLIN 2008).

Evidence suggests (RPS 2007, HLIN 2008) that the following needs to be taken into account:

- waste medicines that are no longer needed should be disposed of safely so that they cannot accidentally be taken by other people
- part-used medicines that have been dispensed for one person, but are no longer needed, must not be used for other people
- the recommended method for disposing of medicines should be by returning them to the service provider who supplied the medicines (usually the community pharmacist), to ensure disposal is in accordance with waste regulations.

Only in exceptional circumstances would a care worker remove medicines from a person's home for disposal. This would only be appropriate if:

- it was included in the home care provider's medicines policy
- written permission had been obtained from the person receiving care and the care worker's line manager (HLIN 2008).

6.3.1.7 Handling over-the-counter medicines

If a person is living at home, they can choose whether to buy over-the-counter medicines (also known as homely remedies), for example paracetamol for pain relief. People retain that choice when they receive social care in the community and it is not usually appropriate for a home care worker to influence the choice of over-the-counter medicines that the person wants to buy. However, problems may arise when a person asks a home care worker to buy or administer an over-the-counter medicine (HLIN 2008). The home care provider may have responsibility for making this decision, for example if the person is unable to make the choice (RPS 2007, HLIN 2008).

Home care provider should have policies and processes in place for home care workers in the event that treatment with over-the-counter medicines may be needed, this should include:

- getting advice from a doctor, pharmacist or nurse
- clearly defining the minor ailments that home care workers are able to treat, for example, headache, heartburn, cough
- choosing the medicines that are suitable for the people they provide care for
- developing a detailed procedure for home care workers to follow, including what they must not do, such as offering advice on the treatment of minor ailments
- making sure that people receiving care, their family members and/or carers and prescribers understand the policy
- keeping records of the purchase, administration and disposal (RPS 2007) (see section 9.5).

6.3.1.8 Training and competency

Home care workers must be appropriately trained in the handling and use of medicines, and have their competence assessed. For this review question, training covering supply, storage and disposal of medicines is included (RPS 2007, HLIN 2008, NMHDU 2010) (see section 10.5).

6.3.2 Health economic evidence

No economic evidence was identified for this review question.

6.4 Evidence statements

In order to comply with legislation, home care providers must ensure that people receiving care or those lawfully acting on their behalf must be given opportunities to manage as much of their care and treatment (including their medicines) as they wish and are able to, and should be actively encouraged to do so.

Guidance from the CQC to support home care providers with implementing legislation and other guidance (low quality) suggests that home care providers have a written medicines policy which includes ordering, supplying, storing and disposing of medicines. Detailed processes should be in place for all people working within the policy.

Low quality guidance suggests that robust and transparent systems and processes need to be in place for ordering medicines in this setting, particularly when a home care worker prompts, provides support or acts on behalf of a person receiving care.

Guidance from the CQC to support home care providers with implementing legislation and other guidance (low to very low quality) suggests that robust and transparent systems and processes need to be in place for supplying medicines, to ensure that sufficient quantities of medicines are available at all times.

No evidence was identified on systems and processes for transporting medicines safely and effectively in this setting.

Low quality guidance suggests that medicines storage should be considered and provided on an individual basis, taking account of the person's ability to safely store and look after their own medicines. Robust and transparent systems and processes need to be in place for storing medicines.

Low quality guidance suggests that robust and transparent systems and processes need to be in place for the safe disposal of surplus, unwanted or expired medicines, particularly when a home care provider is responsible for disposal.

Low quality guidance suggests that robust and transparent systems and processes need to be in place for when treatment with over-the-counter medicines is needed for the person receiving care.

Low to very low quality guidance suggests that home care workers must be appropriately trained in the handling of medicines and have their competence assessed.

6.4.1 Health economic evidence

No health economic evidence was identified.

6.5 Evidence to recommendations

Table 5: Linking evidence to recommendations

Relative values of different outcomes	The Committee discussed the relative importance all of the outcomes agreed for this review question (see Appendix C2.2– Review Protocol A) and agreed that the following outcomes were of critical importance for decision making: • service user-reported outcomes • health and social care practitioner-reported outcomes (taking into account the difference between trained and untrained carer perspectives) • medicines-related problems • compliance with legislation, regulation and national policy. Other outcomes identified by the Committee considered important for decision-making, but not critical: • carer-reported outcomes • health and social care related quality of life • health and social care utilisation, including hospital admissions and attendance at accident and emergency departments, walk-in centres and out-of-hours providers • mortality • clinical outcomes, including problematic polypharmacy • economic outcomes. The literature search did not identify any studies measuring outcomes specified in the protocol. The Committee therefore discussed the importance of health or social care workers assessing the needs and preferences of a person receiving care to determine what support may be required when handling their medicines (see section 5.5).
Trade-off between benefits and harms	**Policies for the safe handling of medicines** The Committee discussed and agreed that in line with the NICE home care [NG21] guideline recommendations home care providers should have a policy for managing medicines. The Committee discussed the evidence from guidance relating to the handling of medicines (CQC 2015, HLIN 2008 and RPS 2007) and agreed that the policy should include documented processes for the safe handling of medicines based on current legislation and best available evidence. The policy should include processes for: • ordering medicines • supplying medicines • transporting medicines

- receiving, storing and disposing of medicines
- over-the-counter medicines.

The Committee discussed the need for governance of a medicines policy and agreed that home care providers should review their medicines management policies and processes to ensure that they are up to date and that it is clear who is accountable and responsible for using medicines safely (see section 10.5).

The Committee discussed medicines policies for individuals self-funding their care or directly employing a home care worker (or personal assistant). The Committee agreed that it would be impractical for each individual to develop a medicines policy. The Committee agreed it would be useful for the person and the home care worker to have access to a guide covering ordering, supplying, transporting, receiving, storing and disposal of medicines, although developing such a guide would be outside the scope of this guideline.

Ordering medicines

The Committee was aware that, in line with guidance (RPS 2007 HLIN 2008), people will most often manage the ordering of their own medicines. The Committee discussed what should happen when a person is assessed as needing assistance with the ordering of medicines.

The Committee concluded that the home care provider should agree the medicines-related support needs for ordering medicines with the person and document this in the home care plan. This includes agreeing who will take responsibility for ordering medicines (for example the person themselves if they choose to and are able to do so, with appropriate support from family members and carers, or if needed a home care worker). Additionally, home care providers that are responsible for ordering a person's medicines should not delegate this task to the supplying pharmacy (or other provider), unless this has been agreed with the person and/or their family members or carers.

The Committee concluded that home care providers should ensure that home care workers with responsibility for ordering medicines and checking medicines received into a person's home have sufficient time during their visit to undertake these tasks (see also supplying medicines).

The Committee agreed that the home care provider should ensure that home care staff undertaking or supporting the ordering of medicines have the training and competence to do so (see section 10.5).

Supplying medicines

The Committee discussed the evidence from guidance (CQC 2015) and agreed that organisations responsible for the ordering and/or supply of medicines to the home of a person receiving social care in the community should ensure that medicines are available, in the necessary quantities, when they are needed.

The Committee agreed that this may require home care providers and community pharmacies or dispensing doctors having arrangements in place to ensure continuity of supply or access to specific medicines (such as 24 hour access to medicines held in stock depending on the needs of the person.

The Committee discussed how poorly arranged agreements for ordering medicines can lead to medicines being lost, supplies running out or over ordering, potentially leading to stockpiling and waste. The Committee concluded that home care providers that are responsible for ordering a person's medicines must ensure that the correct amounts of the medicines are available when needed.

The Committee discussed the evidence from guidance (RPS 2007) and concluded that where home care staff are responsible for ordering and checking the supply of medicines to the persons home, the list of supplied medicines should be checked against a list of what was ordered or prescribed including the name, strength and quantity of the medicines ordered.

The Committee also concluded that home care providers should have a process for home care staff to follow if a discrepancy is noted (for example checking with the prescriber or community pharmacy before supporting the person to take their medicine).

The Committee agreed that where a home care provider is responsible for helping a person to take their medicines, the community pharmacy should consider supplying printed medicines administration records wherever possible (see section 9.5).

Monitored dosage systems (MDS)

The Committee heard that there are 2 widely used systems for the supply of medicines to people in their own homes:

- original packs
- monitored dosage systems (including multi-compartment compliance aids).

The Committee was aware that the NICE guideline on managing medicines in care homes [SC1] had compared the risks and benefits of the 2 systems and agreed that these were applicable to this population also.

The Committee discussed how removal of medicines from original packs can cause problems with the stability of some medicines. Monitored dosage systems can also cause problems for home care staff when a specific medicine is refused or stopped (as there can be difficulties identifying which medicine it is).

The Committee was aware that the dispensing label on original packs is the authority to administer each medicine and that in practice the labels or directions for each medicine should be on monitored dosage systems although this is not always clear. In some cases non pharmacy filled aids do not have labels on at all.

The Committee was also aware that Improving patient outcomes through the better use of multi-compartment compliance aids (Royal Pharmaceutical Society, 2013) suggests that monitored dosage systems should not automatically be the intervention of choice for all residents. The use of monitored dosage systems should be considered following an individual assessment of the resident's needs.

The Committee concluded that where a person has not had their

individual needs assessed, community pharmacists (or dispensing doctors) should supply original packs of medicines and make reasonable adjustments in line with legislation.

The Committee further concluded that monitored dosage systems should be used for the benefit of the person receiving care rather than for the ease of carers and that the benefits of use should outweigh the risks. The Committee recommended that monitored dosage systems should be considered only when an assessment has been carried out, in line with legislation and when a specific need has been identified to support medicines adherence.

The Committee discussed that when considering the use of a monitored dosage system health and social care practitioners should:

- involve the person receiving care and/or their family members or carers and the home care provider in decision-making and take account of their needs and preferences
- take into account the most appropriate form of supply for each medicine the person is taking based on their needs.

The Committee agreed that those providers involved in the supply of medicines for people receiving social care in the community should be aware of the 8 recommendations set out in the Royal Pharmaceutical Society (2013) publication Improving patient outcomes: The better use of multi-compartment compliance aids.

Transporting medicines

The Committee discussed and agreed that following an assessment of the person's medicines support needs and preferences, it should be agreed with the person and/or their family members or carers and documented who will be responsible for transporting medicines from pharmacy to the person's home.

The Committee discussed, based upon their experience, whether home care workers who are responsible for transporting medicines should go straight from the community pharmacy to the person's home when in possession of their medicines; however the Committee agreed that a degree of flexibility was necessary given the competing demands on the time of home care workers.

The Committee agreed that when home care providers are responsible for transporting specific medicines they may need to consider risk assessing this, including the:

- need for temperature control
- security and risk of diversion (see the NICE guideline on controlled drugs [NG46]), for example the requirement for tamper proof containers.

Storing medicines

The Committee agreed that, in line with guidance (RPS 2007), in most cases people receiving care should be able to decide where and how to store their medicines with appropriate support from family members, carers or home care workers in needed.

The Committee was aware that there may be a tension between the requirements for a provider to ensure that the medicines for which they are responsible are stored safely and the ability of the person to choose

how their medicines are stored in their own home.

The Committee concluded that the arrangements for the storage of a person's medicine should be agreed with the person and recorded in the home care plan. When it is agreed that a home care provider is responsible for storing a person's medicines then, the Committee concluded that they should have robust processes to ensure there is safe access to medicines, particularly for controlled drugs.

The Committee was aware that there is legislation for the safe storage of certain medicines (for example the Medicines Act 1968, the Misuse of Drugs Act 1971 and The Misuse of Drugs (Safe Custody) Regulations 1973), but in most cases this legislation does not apply to people's homes. For the storage of controlled drugs please see the NICE guideline on controlled drugs [NG46].

The Committee discussed that any assessment when a home care provider is responsible for storing a person's medicines should take into account:

- the person's needs and preferences
- the need for storage to meet national standards and the specific storage requirements for the individuals' medicines (for example using the information on storage provided on the patient information leaflet supplied with the medicine)
- the environment in which medicines are stored (for example cool and dry, avoiding damp conditions)
- whether the storage is large enough to accommodate larger or bulky items (for example monitored dosage systems, nutritional supplements, dressings, ostomy products and catheters)
- the need for locked (secure) storage of medicines to prevent unauthorised access, diversion or misuse (for example visiting children or other residents in shared housing)
- only storing medicines in the cupboard or area designated for medicines.

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) and agreed that in some circumstances it may not be suitable for a person receiving care to have access to their medicines, for example individuals who have a mental health crises or dementia and/or where there is a risk of accidental or deliberate self-harm. In these circumstances home care providers should take advice from health professionals on whether provision of suitable secure home storage (a lockable cupboard) or central storage (not in the home) is needed.

The Committee concluded that when a person is assessed to be at risk because of unsecured access to their medicines, it should be agreed with the person and/or their family members or carers whether secure home storage (a lockable cupboard) or central storage (not in the home) is required.

The Committee discussed and agreed that a separate medicines fridge in a person's home is not generally required. Although sometimes medicines requiring temperature control may be held in a centrally located medicines fridge for either safety reasons or due to the need for stable temperature control. The Committee agreed that home care workers should ensure that a home fridge, being considered for the storage of medicines, is functioning.

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) and agreed that where the home care provider is responsible for the storage of medicines in a centrally located fridge (i.e. not in the person's home) and is using a fridge for the storage of medicines they should:

- consider how the medicine will be stored in the fridge (for example a separate space or container within the fridge)
- monitor and record the temperature of the refrigerator daily when in use (using a maximum/minimum thermometer)
- clean and defrost the fridge regularly
- have written procedures for staff to follow when the temperature is outside of the expected range or the fridge breaks down.

The Committee concluded that home care providers that are responsible for storing a person's medicines should have robust processes to ensure there is safe access to medicines, particularly for controlled drugs. This should include:

- identifying who should have authorised access to the medicines
- ensuring there is a safe storage place or cupboard for storing medicines, including those supplied in monitored dosage systems
- identifying the need for fridge storage
- assessing the need for secure storage, for example in a lockable cupboard
- reviewing storage requirements, for example if the person has declining cognitive function or fluctuating capacity.

The Committee discussed the need for anticipatory planning for the safe storage of medicines in the event that a person receiving care who manages their medicines storage has, for example, a change in their mental capacity (such as, a person with dementia). These plans should take into account the preferences of the individual receiving care assessed when they do have capacity and any potential risks posed by their medicines.

Disposing of medicines

The Committee was aware that the disposal of medicines from a person's home is covered under Schedule 1 of The Controlled Waste (England and Wales) Regulations 2012 and is defined as clinical waste (Schedule 1, section (b) definition contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent). Separate legislation applies to controlled drugs and this is covered by the NICE guideline on controlled drugs [NG46].

The Controlled Waste (England and Wales) Regulations 2012 class clinical waste as 'industrial waste' except when they are produced at a domestic property used wholly for residential purposes when it is to be treated as domestic waste. The Committee discussed that although this means that waste medicines can be disposed of with household waste, it is considered by the Department for Environment, Food and Rural Affairs (2013) to be best practice to return such medicines to a pharmacy where possible. Additionally the Committee was aware that collection charges may be made by local authorities for clinical waste produced at a domestic property.

The Committee discussed the risk of potential harm from stockpiling medicines that were unwanted, damaged, out-of-date, and part-used, no longer needed or were over-ordered. The Committee discussed the

evidence from guidance (RPS 2007, HLIN 2008) that states that as medicines are the property of the person receiving care, their consent is required before they can be returned to a pharmacy. Therefore the Committee agreed that in the first instance the responsibility for the disposal of medicines should be the person receiving care (or someone acting legally on their behalf).

The Committee concluded that when home care providers are responsible for disposing of any unwanted, damaged, out-of-date or part used medicines, they must have robust processes in line with legislation. This process should include:

- obtaining agreement from the person (or their family member or carer)
- how the medicines will be disposed of, ideally by returning them to a pharmacy for disposal
- any special considerations, for example, for disposing of controlled drugs, needles and syringes
- what records will be made, for example, the name and quantity of medicine, the name of the person returning the medicine, the date returned and the name of the pharmacy.

Handling over-the-counter medicines

The Committee heard the evidence from guidance (RPS 2007, HLIN 2008) regarding arrangements for over-the-counter medicines. The Committee noted that if a person receiving care is regularly taking an over-the-counter medicine themselves without support, this should preferably be recorded in the person's home care record or home care plan.

The Committee heard that problems with over-the-counter medicines can occur when:

- home care workers try to obtain advice on the safety of over-the-counter medicines or alternative medicines
- other individuals (for example friends and relatives) buy over-the-counter medicines which a home care worker is expected to help a person receiving care take
- home care workers are unaware of the need to document the support given for taking over-the-counter medicines.

The Committee agreed that while a person receiving care may need support to select or choose an over-the-counter medicine the responsibility for its selection and the taking of the medicine remains with the person.

The Committee concluded that when a person is able to request the specific over-the-counter remedy they wish to purchase, and providing the home care provider permits staff to do so, this may be acceptable practice providing the home care provider has robust processes in place for home care workers on:

- ensuring that the person understands and accepts any risk associated with taking the medicine
- what information needs to be recorded, for example, the name and quantity of the medicine
- when to seek advice from a health professional.

The Committee discussed the evidence from guidance (RPS 2007, HLIN

	2008) suggesting that home care providers may have responsibility for selecting over-the-counter medicines for purchase if the person receiving care is unable to make the choice themselves. The Committee discussed whether it was appropriate for home care workers who are not medically trained to make such choices. The Committee concluded that home care workers should not obtain or buy an over-the-counter medicine based on symptoms described by a person or their family members or carers. Home care workers should advise the person to seek advice from a health professional if needed.
Trade-off between net health benefit and resource use	No economic evidence was identified. The Committee identified that clinical waste removal from domestic properties by local authority may incur a collection charge to the householder; however the collection of clinical waste in this way is not considered best practice and should preferably be returned to a pharmacy. No other resource implications were identified from the recommendations made in this section.
Quality of evidence	The quality of the included evidence was assessed using the AGREE II criteria and was found to be moderate to very low overall (see table one). No clinical studies were identified by the literature searches that were subsequently included as evidence for this review question. Evidence was obtained from professional guidelines to support social care (HLIN 2008, NMHDU 2010 and RPS 2007) and one guideline (CQC 2015) that supports provider compliance with regulation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) (as amended) and the Care Quality Commission (Registration) Regulations 2009 (Part 4) (as amended)). Additionally legislative frameworks (not identified through searching but through scoping and the expert knowledge of the Committee) have been used where appropriate.

6.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendations 1 to 2

Recommendation 12

Recommendation 42

Recommendations 47 to 60

Recommendation 62 to 63

7 Administering medicines

7.1 Introduction

The Care Quality Commission in the Guidance for compliance on meeting the regulations (2015) state that 'Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure that people are safe.'

Guidance from the Royal Pharmaceutical Society (RPS) (2007) identified 8 core principles relating to the safe and appropriate handing of medicines that apply to every social care setting. Two principles are relevant to this review question:

- 'Care staff know which medicines each person has and the social care service keeps a complete account of medicines
- Medicines are given safely and correctly, and care staff preserve the dignity and privacy of the individual when they give medicines to them'.

7.2 Review question

What interventions, systems and processes are effective and cost-effective in supporting safe and effective self-administration, or administration, of medicines for a person receiving social care in the community?

7.3 Evidence review

7.3.1 Clinical evidence

Theguideline Committee agreed that the objectives of this review were to determine:

- what interventions and approaches are effective in supporting people to look after and take their medicines themselves (self-administer)
- what interventions, systems and processes are effective for care workers administering, supporting or monitoring the administration of medicines
- the effect of informal carers administering, supporting or monitoring the administration of medicines
- the effect of health professionals administering, supporting or monitoring the administration of medicines
- what interventions, systems and processes are effective for administering medicines to people without their knowledge when this in their best interest (covert administration)
- what interventions, systems and processes are effective for administering non-prescription medicines (over-the-counter medicines or homely remedies).

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection of included evidence. Three guidelines met the eligibility criteria for this review question and were included. One additional guideline (CQC 2015) was identified by the Committee and was relevant for inclusion. One study (a research briefing) also met the eligibility criteria (SCIE 2005).

The included evidence is summarised in table 6. The guidelines were quality assessed using the AGREE II criteria. One guideline (CQC 2015) was found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, Housing Learning and Improvement Network [HLIN] 2008) and 1 guideline and 1 research briefing were found to be of very low quality (National Mental Health Development Unit and College of Mental Health Pharmacy 2010, Social Care Institute of Excellence [SCIE] 2005 –

assessed using the NICE methodology checklist for systematic reviews; see appendix H in Developing NICE guidelines: the manual (2014).).

Table 6: Summary of included guidelines

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality of guideline (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities.[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers Safe care and treatment.	Principles of safe and appropriate handling of medicines (medicines-related problems).	Moderate quality
Housing Learning & Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated. [2]	A factsheet aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. The factsheet covers: • Guidance and best practice recommendations • Additional Medication Considerations • Dangers and pitfalls • Key learning points • Frequently asked questions • Reference Material and Resources.	Principles of safe and appropriate handling of medicines (medicines-related problems).	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis.	This document covers: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice for medicines management schemes for by crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management on by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care.	This guidance has recommendations covering: • The principles that underpin safe handling of medicines in every social care setting • The general practical aspects of medicine handling • The general aspects of medicine management relating to specific care services • Policies, procedures, systems and devices 'medicines	• Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation governing the handling of	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality of guideline (AGREE II)
		toolkit'.	medicines.	

Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS)
[1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
[2]Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)

Table 7: Summary of included studies

Evidence source	Population	Recommendations / key areas covered	Key critical and important outcomes	Quality of study
Social Care Institute for Excellence (2005) *UK*	Older people (aged 65 years or older) who live at home and are taking prescribed medication.	This research briefing examines the policy literature and the findings of the research into why older people living at home may intentionally or unintentionally fail to take all of their prescribed medication when they need to, and what measures may be effective in helping them to achieve compliance with the prescribed doses.	Medicines adherence, compliance and concordance.	Very low quality

Abbreviations: Social Care Institute for Excellence (SCIE)

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

7.3.1.1 Policies for giving or helping people to take their medicines

The Care Quality Commission (CQC) guidance for providers (CQC 2015), on compliance with regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, states that 'Staff must follow policies and procedures about managing medicines, including those related to infection control. These policies and procedures should be in line with current legislation and guidance and address:

- supply and ordering
- storage, dispensing and preparation
- administration
- disposal
- recording'.

Both the Housing and Learning Improvement Network (HLIN 2008) and the Royal Pharmaceutical Society (RPS 2007) guidance recommend the use of written policies on the administration of medicines by support or home care workers. The guidance state that the policy should cover:

- whether the provider organisation allows administration or supported self-administration
- which tasks and medicines a home care worker can administer (following appropriate training)
- simple easy-to-follow written procedures that set out exactly how to give medicines.

The RPS (2007) state that 'it is good practice to monitor that home care workers follow these procedures' and that care providers 'should also monitor periodically how well staff follow this procedure.' The RPS also recommend that home care providers should 'Make sure that the people you care for, their relatives and GPs know what your policy is' in relation to over-the-counter and homely remedies.)

7.3.1.2 Consent to taking medicines

The RPS (2007) states that 'whenever possible people in care settings should be responsible for looking after and taking their own medicines but some will be given medicines by care workers'.

Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 states that 'Care and treatment of service users must only be provided with the consent of the relevant person' whilst making provision for the age, mental health and mental capacity of the individual (for example under the Mental Capacity Act 2005).

The CQC Guidance for providers on meeting the regulations (2015) states (in relation to regulation 11) that 'The intention of this regulation is to make sure that all people using the service, and those lawfully acting on their behalf, have given consent before any care or treatment is provided. Providers must make sure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for.'

The CQC (2015) also state that 'Policies and procedures for obtaining consent to care and treatment must reflect current legislation and guidance, and staff must follow them at all times.' The RPS (2007) states there should be written processes for care staff to follow when a person refuses to take a medicine that the doctor has prescribed.

Evidence from both HLIN (2008) and the RPS (2007) guidance state that home care workers should only give medicines with the person's consent. The CQC (2015) state that 'Consent may be implied and include non-verbal communication such as sign language.'

The CQC (2015) also provide some general guidance on obtaining consent in Guidance for providers on meeting the regulations (2015).

The RPS (2007) guidance sets out some specific considerations for consent to medicines administration for home care workers:

- ask the person if they want their medicine before taking it out of its pack
- If the person refuses their medicine, and this is an important medicine, it may be better to wait a little while and offering them the medicine again a short time later
- If the person continues to refuse their medicine, never force the medicine on them and this includes hiding medicine in food or drinks, but it may be necessary to contact the GP for further advice (see section 7.3.1.8).

The RPS (2007) also identifies that it is important to find out what a person's preferences are about taking medicines, and highlights the following that should be considered in the planning of personalised care:

- social (for example not taking medicines in public)
- cultural (for example embarrassment about being helped to take their medicines by a member of the opposite sex)
- religious considerations (for example taking fasting in to consideration).

7.3.1.3 Helping people to take their medicines

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 9 (1) states that 'The care and treatment of service users must –

(a) be appropriate
(b) meet their needs, and
(c) reflect their preferences'.

The CQC (2015) states that 'the intention of this regulation is to make sure that people using a service have care or treatment that is personalised specifically for them'. The CQC states that this includes making 'any reasonable adjustments and provide support to help them understand and make informed decisions about their care and treatment options, including the extent to which they may wish to manage these options themselves.'

The RPS (2007) guidance states that where medicines are concerned adults should take responsibility for them whenever possible. This, the RPS asserts, 'preserves independence regardless of the social care environment.'

Evidence from the National Mental Health Development Unit (NMHDU 2010) identified that an important component in mental health crisis care 'is the ability of patients to manage their medicines in order to maintain independence and avoid admission to hospital.

The NMHDU (2010) also identified that during a mental health crisis the responsibility for the administration of medicines may need to be taken over by the home care worker (for example to prevent self-harm). They state that arrangements for administration or self-administration need to be clearly documented and reviewed regularly (see section 9.5). If the person is to self-administer there needs to be agreement about the extent to which this is supervised and recorded.

Self-administration of medicines

The RPS (2007) describes self-administration of medicines as 'not an all-or-nothing situation.' For example, some people might choose to keep and use some of their own medicines but may need help with others. Alternatively, a person might be able to manage their medicines provided that a home care worker assists them to self-administer.

The HLIN (2008) guidance recommends that an organisation's medicines policy should record whether the home care provider allows its care workers to support medicines administration, and if so which medicines a home care worker is able to administer following appropriate training (see section 10.5).

The RPS (2007) identify the need for a robust system of risk assessment which explores whether a person wants to take responsibility for looking after and taking their medicines as well as understands what medicines they take, what they are for, how and when they should take them and the risks of not taking them (see section 5.5).

The RPS (2007) guidance states that the 'level of support and resulting responsibility of the care worker should be written in the home care plan for each person' (for home care plan please terms used in this guideline). The RPS guidance recommends including a plan for monitoring the ongoing ability of the person to self-administer medicines without constantly invading their privacy. The RPS recommends that records of this should be part of a regular review of the person's care (see sections 5.5 and 9.5).

Interventions for helping people take their medicines

Evidence from the Social Care Institute for Excellence (SCIE) research briefing (2005) found that the following interventions have been found to be effective in reminding older people, who want to take their medicines as prescribed:

- alarm clocks
- positioning medicines in visible places
- taking medicines at routine times, for example at meal times
- simplifying medicine regimens
- educating older patients about the importance of their medicines
- providing personalised instruction and written information about their medicines (including suitable formats for those with visual impairment such as large print or braille labelling)
- making medicines available in appropriate containers, for example containers without chid proof tops or blister packs.

The SCIE Research briefing (2005) asserts that 'reminders, compliance aids and supervision are the most effective means of improving compliance among older patients with cognitive impairments.'

The RPS (2007) states that if a person is unable to swallow (or requires their medicines to be given via a feeding tube) then a health professional should be consulted to find out if a suitable liquid formulation is available. The RPS (2007) also states that tablets should not normally be crushed, and capsules should not be opened, in order to make them easier to swallow as this can affect the way the medicine works.

Monitored dosage systems

The RPS has issued guidance on the use of multi-compartment compliance aids which defines them as 'a repackaging system for solid dosage form medicines, such as tablets and capsules, where the medicines are removed from manufacturer's original packaging and repackaged into the multi-compartment compliance aid.' This definition used includes monitored dosage systems (MDS) and daily dose reminders.

Evidence from the RPS (2007) states that 'MDS or compliance aids can sometimes be used to help people to take their own medicines safely'. However, they caution that 'safe practice is not guaranteed by use of a system alone but is promoted by only allowing care workers who are trained and competent to give medicines'.

Evidence from the HLIN (2008) guidance states that home care workers should not repackage a person's medicines into a compliance aid as there is a high risk of error (this is known as secondary dispensing).

7.3.1.4 Home care workers giving medicines to people

The HLIN (2008) guidance recognises that sometimes people may require their medicines to be administered by a home care worker.

The CQC in its Guidance for providers on meeting the regulations (2015) states that 'Medicines must be… managed safely and administered appropriately to make sure people are safe'. The RPS (2007) defines safe administration of medicines as medicines being 'given in such a way as to maximise benefit and to avoid causing harm' to a person.

The RPS (2007) sets out a number of core principles relating to safe and appropriate handling of medicines. Principle 4 states that medicines should be 'given safely and correctly, and care staff preserve the dignity and privacy of the individuals when they give medicines to them.'

Evidence from the RPS (2007) and HLIN (2008) states that the home care worker will be responsible for selecting and giving the:

- right person (only giving medicines to the person they were prescribed for)
- right dose
- right medicine
- right time
- in the right way (correct route of administration).

Evidence from the NMHDU (2010) identified 2 issues relating to carers during episodes of mental health crisis, it found that:

- carers frequently are involved in administering medicines
- it is common for more than one family member to be involved in managing medicines.

The RPS (2007) guidance sets out specific procedures for medicines administration additionally the RPS set out a number of additional specific considerations for certain medicines:

- 'state that some medicines need to be given at specific times, for example before, with or after food
- some illness can only be controlled with very precise dose timings, for example some medicines for Parkinson's disease have to be taken five times during the day, some people's fits are only controlled if they take their tablets at set times (see section 5.5)
- some medicines such as methotrexate need special care to protect the person who is giving the medicines
- medicines must be given from the container they are supplied in. i.e. they should be administered from original pharmacy filled and labelled containers (see section 6.5)
- doses of medicines must not be put out in advance of administration (secondary dispensing) due to the risk of error'.

However, the RPS state that in home care 'if it has been agreed with the patient and it is the home care plan, doses can be left out for that individual to take at a later time.'

The NMHDU (2010) evidence for administration of medicines for people experiencing a mental health crisis recommends that carers should:

- be supported to understand issues such as side effect profiles of particular medicines,
- be supported to understand basic information on frequency and dosage of the medicines
- have direct access to a clinical pharmacist for information and advice.

Giving or helping people to take controlled drugs

In April 2016, NICE published a guideline on controlled drugs [NG46] which provides recommendations on the safe management and use of controlled drugs. It covers all settings, including people's own homes, where publically funded health and social care is delivered. .

7.3.1.5 Competence of staff giving or helping people to take their medicine

Home care workers should be trained and competent if they are responsible for managing and administering medicines (CQC 2015, RPS 2007) (see section 10.5).

7.3.1.6 Giving 'when required' medicines

Evidence from the HLIN (2008) and RPS (2007) guidance states that for medicines that are prescribed on a "when required" basis, and to support home care workers, there should be an administration record or protocol stating:

- what the medicine is for
- when the medicine should be given
- what the dose should be (or how many tablets should be given)
- how often doses can be given
- the maximum number of doses that can be given in 24 hours.

The HLIN (2008) guidance highlights the difficulty of a home care worker assessing if a "when required" medicine is needed if the person receiving care cannot communicate their wishes.

The RPS (2007) guidance highlights that medicines that need to be taken "when required" should not be put into monitored dosage systems.

7.3.1.7 Giving over-the-counter medicines

Over-the-counter (OTC) medicines are those that can be purchased without prescription for the treatment of minor ailments (for example paracetamol for headache), complementary or alternative therapies and vitamins and supplements (see section 6.5).

7.3.1.8 Giving medicines to people without their knowledge (covert administration)

For the purpose of this guideline 'covert administration of medicines' is defined as being when 'medicines are administered in a disguised form without the knowledge or consent of the person receiving them (for example, medicines added to food or drinks).'

The CQC (2015) states that 'When it is agreed to be in a person's best interests, the arrangements for giving medicines covertly must be in accordance with the Mental Capacity Act 2005.' The RPS (2007) states that 'covert administration of medicines should only take place within the context of existing legal and best practice frameworks to protect the person receiving the medicines and the care workers involved in giving the medicines.'

The RPS (2007) states that covert administration of medicines is 'sometimes necessary and justified, but should never be given to people who are capable of deciding about their

medical treatment' (those people who have mental capacity to make decisions for themselves).

The HLIN (2008) guidance advises that it should also only be undertaken if the home care provider permits its staff to administer medicines covertly.

7.3.2 Health economic evidence

No economic evidence was identified for this review question.

7.4 Evidence statements

In order to comply with legislation, home care providers should have a policy on the administration of medicines. Low quality evidence suggests this should be a written policy which covers administration and self-administration. Home care workers adherence to the policy should be monitored.

In order to comply with legislation, home care workers should seek consent from the person receiving care before supporting self-administration or administering or giving their medicines. Low quality evidence suggests that if a person refuses consent a home care worker should wait a little while and ask again, if the medicine is still refused the advice a healthcare professional should be sought.

In order to comply with legislation, if a home care worker believes that the person receiving care is unable to give consent to taking a medicine, due to a lack of capacity, then they should act in accordance with the requirements of the Mental Capacity Act 2005.

In order to comply with legislation, home care providers should make reasonable adjustments to support a person to manage their own medicines. Low quality evidence suggests that home care providers should assess, agree with the person and record the level of support required to manage their medicines. These arrangements should be monitored and reviewed.

Low and very low quality evidence suggests that some interventions may be useful in reminding or aiding a person receiving care to take their own medicines.

Low quality evidence suggests that home care workers administering, or helping a person to self-administer medicines, should ensure they are giving the right person, the right dose of the right medicine, at the right time via the right route (the 5R's).

Low quality evidence suggests that home care providers have a written statement for 'when required' medicines; it should cover what they are for, when to administer, dosage, frequency of administration and the maximum dose in 24 hours.

In order to comply with legislation, medicines should not be administered covertly unless a best interest's decision has made a determination that this necessary in line with the requirements of the Mental Capacity Act 2005. Low quality evidence suggests that home care providers should have a clear policy on 'covert administration' of medicines.

7.4.1 Economic evidence

No economic evidence was identified for this review question.

7.5 Evidence to recommendations

Table 8: Linking evidence to recommendations

Relative values	The Committee discussed the relative importance all of the outcomes agreed

of different outcomes	for this review question (see Appendix C.2.3) and agreed that the following outcomes were of critical importance: • Service user-reported outcomes • Carer-reported outcomes • Medicines-related problems • Health and social care utilisation. Other outcomes identified by the Committee considered important for decision-making, but not critical: • Health and social care practitioner-reported outcomes, such as satisfaction, views and experience • Health and social care related quality of life • Mortality • Clinical outcomes, including problematic polypharmacy • Economic outcomes • Compliance with legislation, regulation and national policy. No evidence measuring specific outcomes were identified by the literature search.
Trade-off between benefits and harms	**Policies for supporting people to take their medicines** The Committee was aware that the NICE guideline on Home care [NG21] recommends that home care providers should have a medicines management policy. The Committee was also aware that the CQC (2015) guidance for compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 12, recommends that home care providers have in place policies and processes for the administration of medicines in line with current legislation and guidance. The Committee concluded that home care providers must have in place policies and processes for home care workers giving, or supporting people to take their medicines that include: • what support home care workers are allowed to give when helping people to take their medicines, including 'when required', time sensitive and over-the-counter medicines • simple, easy-to-follow documented processes for giving medicines • be available to the person receiving care and other persons involved in their care (such as, their GP or other health professionals, family or other carers). The Committee concluded that it would not be practical to recommend that individuals who fund their own social care and who need support in managing their medicines have such a policy in place (see section 6.5). **Agreeing and recording support for medicines** The Committee agreed that in principle there should be an assumption that a person receiving care is able to manage and take their own medicines unless the person either expresses a need for assistance or is assessed as having a need (see section 5.5). The Committee agreed that people often have different support needs for each of their medicines. The Committee agreed that where a need for assistance is identified the person receiving care and the home care provider should agree the type of support that will be provided for each medicine and this agreement should be recorded in the home care plan (see also section 5.5). The Committee discussed that while clinical evidence was often separated into medical concepts of administering, self-administering or prompting a person to take their medicines in practice these terms overlap greatly and often lead to

inadequate assessment of the nature of medicines support needed by the person and inadequate recording of this support.

In line with legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 17), the Committee agreed that all care and treatment must be recorded including administration, supported self-administration or prompting someone to take their medicines. The Committee further agreed that the only time a documented record of support with medicines does not need to be made is when a person is managing their medicines independently.

The Committee recognised that clarity is needed when recording the level of support needed and given by home care workers to help people take their medicines. The Committee agreed that it should be clear what support a home care worker was signing to say they had given (for example on a medicines administration record).

The Committee concluded that home care workers must record the medicines support given to a person on each occasion, in line with legislation. This includes prescribed and over-the-counter medicines. For example:

- reminding the person to take their medicine
- giving the person their medicine and recording that they have taken or chose not to take it
- or if the plan of care was to open the medicines container for a particular medicine for an individual to take themselves the record indicates that this is the support that has been given.

Consent to taking medicines

The Committee was aware that the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 require that a person receiving care must give lawful consent before a home care worker provides support to help them take their medicines; the Committee agreed that this may include implied consent or non-verbal consent.

The Committee discussed and agreed that home care providers should have clear policies and procedures for obtaining consent to care and treatment in line with current legislation (for example the Mental Capacity Act 2005) and these policies and procedures must be followed by home care workers.

The Committee considered the evidence from the RPS (2007) document and agreed that it would be best practice for home care workers to ask the person receiving care if they want their medicine before removing it from its packaging as this would reduce waste of the medicine if the person refuses the medicine.

The Committee discussed what action a home care worker should take when a person receiving care declines a medicine. The Committee concluded that if a person declines a prescribed medicine, home care workers should wait a few minutes before offering it again. The Committee also concluded that home care workers should consider simple assessment of why someone has chosen to decline their medicines, such as being in pain or discomfort which may have led to the person declining the medicine before offering the medicine again.

The Committee also concluded that before offering a person their medicine home care workers supporting people to take their medicines should check (verbally with the person or from written records) that the medicine has not already been given or taken, and if it has been taken that it was taken at the correct time.

The Committee agreed that the person receiving care has a right to decline any medicine. The Committee agreed that if a home care worker has, as part of the agreed plan of care, a responsibility for supporting a person with their medicines then the declination should be recorded and continued declining of the medicine should be reported to their manager. The Committee concluded that home care providers should have procedures in place for the home care provider to report continued declining of medicines to the prescriber. The Committee agreed that this should not be the role of the home care worker.

The Committee discussed what should happen if a person receiving care sometimes declines to consent to their medicines because they have, at times, reduced ability to make decisions for themselves (fluctuating mental capacity). The Committee agreed that the wishes and preferences of the person receiving care regarding their medicine should be recorded when the person is able to communicate them. The Committee agreed that this will help inform a best interest decision for the person in the event of any future loss of capacity (anticipatory planning).

Interventions for supporting people to take their medicines

The Committee agreed that the evidence from the SCIE (2005) evidence brief on interventions found to be effective in reminding people to take their medicines was generalisable to the wider social care population.

However, the Committee was aware of the NICE guideline on medicines adherence [CG76] which states that although adherence can be improved, no specific intervention can be recommended for all people. The Committee agreed with the recommendation that interventions to increase adherence should be tailored to the specific difficulties with adherence the person receiving care is experiencing.

The Committee discussed whether or not the RPS (2007) evidence about people who were unable to swallow medicines or had medicines via a feeding tube was relevant to the guideline population.

The Committee agreed that in some circumstances the need to support people receiving care with alternative formulations of their medicines would be relevant (for example liquid formulations, crushed tablets or opened capsules).

The Committee agreed that home care workers should seek advice from a health care professional before, for example, crushing tablets or opening capsules.

The Committee concluded that health professionals should provide advice and offer support to help with adherence to medicines, for example, by assessing whether:

- the person's medicines regimen can be simplified
- any medicines can be stopped
- the dosage form of a medicine can be changed
- support can be provided for problems with medicines adherence
- a review of the person's medicines may be needed.

Monitored dosage systems

The Committee discussed the use of monitored dosage systems. The Committee agreed that when monitored dosage systems are used to support people to take their medicines there was a need for home care workers to have access to information about the medicines within the monitored dosage systems (see section 6.5). The Committee also discussed whether it would be

possible for a physical description of each tablet or capsule included in a monitored dosage systems to be available to home care workers to enable the recording of specific events (for example to help a home care worker identify a tablet that has been refused from among a number of medicines included within a monitored dosage systems). The Committee agreed that the patient information leaflet for each medicine included in the monitored dosage system contains both information about the medicine and a description of the medicine.

The Committee agreed that medicines should only be given from the container they are supplied in (see section 6.5) and never given from devices that are filled by the person's friends or family.

Doses should not be left out for a person receiving care to take later (secondary dispensed) unless this has been agreed with them as part of their home care plan.

The Committee was aware of the RPS (2015) document Improving patient outcomes through the better use of multi-compartment compliance aids and agreed that although not specific to the population for this guideline, the recommendations will be relevant when the use of a monitored dosage system is being considered.

Home care workers supporting people to take their medicines

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) and concluded that home care providers should have robust processes for home care workers who are supporting people to take their medicines and who are responsible for selecting and giving the:

- right person
- right dose
- right medicine
- right time
- right way (right route of administration).

These are known as the 5R's of administration; however the Committee also concluded that persons receiving medicines support have the right to decline their medicines which would therefore include the 'right to decline' – '6Rs' (see consent).

The Committee concluded that in line with legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 18) home care workers must be trained and assessed as competent by the service provider before giving any medicines. Additionally, home care workers should only give a medicine when there is a clearly documented agreement to do so in the home care plan and there are clear directions from the prescriber as to how the medicine should be used.

The Committee recognised that health professionals should refer to the appropriate regulator for guidance on delegating support for medicines (for example nurses should refer to the NMC Standards for medicines management [2008] document).

The Committee discussed the issue of medicines that need to be taken at a specific time of day (for example some medicines for treating Parkinson's disease and epilepsy). The Committee concluded that home care providers should have policies and procedures in place to allow home care workers to prioritise visits for people requiring support with time-sensitive medicines.

The Committee also discussed that home care providers medicines policy

should include policies and procedures for 'when required' medicines. The Committee discussed the difficulty of a home care worker knowing when to give 'when required' medicines, especially when the person receiving care has difficulty communicating their wishes (see section 6.5).

The Committee concluded that if a person requiring medicines support starts taking a prescribed medicine which has to be taken at a specific time, or times of day, or a 'when required' medicine then the prescriber should and community pharmacist should provide clear written directions on the prescription and dispensing label on how each medicine should be given. This should include (where relevant):

- when the dose should be offered
- what the dose should be (avoiding variable doses unless the person can direct the home care worker)
- the minimum timings between doses
- the maximum number of doses to be given (for example, in a 24 hour period).

The Committee discussed and agreed that the patient information leaflet issued with original packs of medicines by the manufacturer was a potentially useful source of information for home care workers (for example, information on adverse effects (see section 8.5) or special instructions such as to be taken after food). The Committee concluded that a patient information leaflet for each prescribed medicine a person is taking should be kept in the home of the person receiving care, including medicines supplied in monitored dosage systems.

Family members and/or carers supporting people to take their medicines

The Committee discussed what should happen when a family member or carer gives a person their medicines which would either normally be offered or given by a home care worker. The Committee agreed that where this happens this should be recorded and communicated with the home care workers to prevent accidental overdose.

The Committee concluded that the nature of the records should be agreed with the person and/or their family and that this information should be kept in the person's home care plan.

The Committee agreed that the evidence from the NMHDU (2010) document regarding carers having direct access to a clinical pharmacist during mental health crises was appropriate but was not generalisable beyond the setting of mental health crisis care.

Covert administration of medicines

The Committee discussed and agreed that in exceptional circumstances it may be necessary to give medicines to people by covert administration. Home care workers should not give medicines to a person covertly if that person has the capacity to make decisions about their care and treatment. The Committee concluded that home care providers should have policies and processes in place regarding the covert administration of medicines.

The Committee discussed the context in which a home care worker might be asked to administer medicines covertly. The Committee agreed that covert administration of medicines is an option, but only when:

- the person lacks the mental capacity to make a specific decision about the medicine themselves
- the prescriber has determined that the medicine is clinically needed

	• other options have been explored (such as temporarily stopping the medicine until the person has recovered their capacity to make an informed decision about taking the medicine) • authorisation and instruction for the covert administration of medicines are clearly documented in the person's home care plan. The Committee also discussed and agreed that health professionals, home care providers and home care workers should ensure that covert administration of medicines only takes place in the context of current legislation (Mental capacity Act 2005) and good practice frameworks (Mental Capacity Act Code of Practice) to protect both the person receiving care and the home care workers administering the medicine. The Committee discussed and agreed that health and social care practitioners should work together to ensure that the process for covert administration of medicines to persons receiving care includes: • defining who is involved in, and responsible for, decision making • assessing mental capacity to make a specific decision about their medicine(s) • holding a best interest's meeting involving a family member or carer, the prescriber and a pharmacist to agree whether giving medicines covertly is in the person's best interests • recording the decision and who was involved in the decision making • planning how medicines will be given covertly, for example, by seeking advice from a pharmacist • providing clear information for home care workers in the person's home care plan • ensuring home care workers are trained and assessed as competent to give the medicine covertly • regularly reviewing whether covert administration is needed.
Trade-off between net health benefit and resource use	No economic evidence was identified for this review question. No recommendations for this review question were identified by the Committee as requiring significant additional resources. The Committee recognised that failure to administer medicines safely will have an impact on health service utilisation through unplanned contact and admission, but found no data to quantify or otherwise assess the impact of improved systems and processes.
Quality of evidence	No published research studies were identified which met the inclusion criteria for this review question. The quality of the included guideline evidence was assessed using the AGREE II criteria and was found to be moderate to very low overall. One guideline of moderate (CQC 2015) supports the implementation of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3) (as amended) and the Care Quality Commission (Registration) Regulations 2009 (Part 4) (as amended), and therefore the recommended actions are required by legislation and regulation. The quality of the included research briefing (SCIE) was assessed using the NICE methodology checklist for systematic reviews and found to be of very low quality.

7.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendation 1

Recommendation 3 to 4

Recommendation 7 to 8

Recommendation 12 to 13

Recommendation 17

Recommendation 23

Recommendation 27

Recommendations 35 to 46

Recommendation 54

Recommendation 64

8 Identifying, reporting and learning from medicines-related problems

8.1 Introduction

The Care Quality Commission (CQC) states, in relation to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (regulation 12: Safe care and treatment) that care and treatment must be provided in a safe way for service users. This includes the need for home care providers to ensure the proper and safe management of medicines.

The CQC states in regulation 12, that there may be inherent risks associated with delivering care and treatment, but home care providers should be able to 'demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment'.

For the purpose of this guideline, the guideline Committee agreed that the term 'medicines-related problems' included:

- potentially avoidable medicines-related hospital admissions
- prescribing errors
- dispensing errors
- administration errors (e.g. missed or delayed doses, inappropriate or incorrect administration)
- monitoring errors (e.g. inadequate review or follow-up, incomplete or inaccurate documentation)
- adverse events, incident reporting and significant events
- near misses (a prevented medicines related patient safety incident which could have led to patient harm)
- deliberate withholding of medicines or deliberate attempt to harm
- restraint or covert administration has been used inappropriately
- misuse, such as missing or diverted medicines
- other unintended or unexpected incidents that were specifically related to medicines use, which could have, or did, lead to harm (including death).

The Care Quality Commission in its Community adult social care services: provider handbook (2015) identifies the incidence of medicines-related problems and safeguarding alerts and concerns as examples of indicators for the quality and safety of care in adult social care services.

The NICE guideline on medicines optimisation [NG5] contains recommendations for health and social care organisations and practitioners on systems for identifying, reporting and learning from medicines-related patient related safety incidents. The guideline defines medicines-related problems as unintended or unexpected incidents that are specifically related to medicines use, which could have or did lead to patient harm. This may include potentially avoidable medicines-related hospital admissions and re-admissions, medication errors, near misses and potentially avoidable adverse events. It notes that improving learning following medicines-related patient safety incidents is important to guide practice and minimise patient harm.

What is the risk of harm from medicines?

The NICE guideline on medicines optimisation [NG5] reported that some medicines are more likely to cause significant harm to a person, even if used as intended. These 'high risk' medicines included anticoagulants, injectable sedatives, opioid analgesia and insulin. The guideline also identified that just 4 classes of medicines (antithrombotic, anticoagulants, non-steroidal anti-inflammatory drugs (NSAIDs) and diuretics were associated with around half of preventable hospital admission (Howard RL et al., 2007). The guideline Committee was aware that some medicines are also associated with a risk of falling, particularly in older people (National Service Framework for Older People, Department of Health 2001).

The Committee was also aware of the NICE guideline on falls in older people [CG161] and medicines optimisation [NG5] which considered the evidence and made recommendations for medicines review to assess and amend risk of falls.

Being open and transparent (Duty of candour)

Regulation 20(1) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires that home care providers must act in an open and transparent way.

The CQC (2015) state that the intention of this regulation is to make sure that home care providers are open and transparent with people receiving care and any other 'relevant persons' when discussing care and treatment (for example carers or advocates). It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

The CQC (2015) advise that the outcomes of investigations into incidents must be shared with the person concerned and, where relevant, their families, carers and advocates.

8.2 Review question

What interventions, systems and processes are effective and cost effective for identifying, reporting and learning from medicines-related problems for a person receiving social care in the community?

8.3 Evidence review

8.3.1 Clinical evidence

The aim of this review question was to review the effectiveness and cost effectiveness of interventions, systems and processes for identifying, reporting and learning from medicines-related problems for a person receiving social care in the community. The guideline Committee agreed that the objectives of this review were to:

- determine what interventions, systems and processes are effective for raising concerns about medicines-related problems.
- determine what interventions, systems and processes are effective for identifying and reporting medicines-related incidents, including medication errors.
- determine what interventions, systems and processes are effective for identifying and reporting adverse effects of medicines.
- determine how learning from medicines-related problems should be shared and acted upon (for example, reporting under safeguarding processes).
- determine how refusal by the person to take their medicines should be managed.

- identify how a person's mental capacity to safely manage their medicines should be assessed, including when the person has fluctuating capacity (physical capacity may also fluctuate) to manage their medicines.

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection of included evidence. 3 guidelines met the eligibility criteria for this review question and were included. 2 additional guidelines (CQC 2015, DH 2016) were identified by the Committee and were relevant for inclusion. Two studies (one qualitative study and one observational study) were identified that met the eligibility criteria (Bonugli 2014 and Sino 2013).

The included evidence is summarised in table 9. The GRADE framework was not appropriate for the summary of the guidelines; the guidelines were quality assessed using the AGREE II criteria. 2 guidelines (CQC 2015, DH 2016) were found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, National Mental Health Development Unit [NMHDU 2010]) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008).

The quality of the two studies (Bonugli 2014 and Sino 2013), were assessed using the checklists set out in the NICE manual (2014). The GRADE framework was not appropriate for the design of the two studies, one was qualitative in design the other was an observational study, and because they did not relate to other topics covered in the evidence review. Both studies were found to be of low quality.

A narrative summary of the available evidence is presented together with evidence tables for the 2 included studies.

Table 9: Summary of included guidelines

Evidence	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers safe care and treatment.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Moderate quality
Department of Health (2016) *UK*	People in receipt of care and support.	Care and support statutory guidance, chapter on safeguarding under the Care Act (2014), sections 42 - 46.	• Medicines-related problems	Moderate quality
Housing Learning and Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated [2]	Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas: • guidance and best practice recommendations • additional medication considerations • dangers and pitfalls • key learning points • frequently asked questions • reference material and resources.	• Principles of safe and appropriate handling of medicines (medicines-related problems)	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis	Key areas: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice for medicines management schemes for by crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management on by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care	Key areas: • the principles that underpin safe handling of medicines in every social care setting	• Principles of safe and appropriate handling of medicines (medicines-related) problems)	Low quality

Evidence	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
		• the general practical aspects of medicine handling • the general aspects of medicine management relating to specific care services • policies, procedures, systems and devices 'medicines toolkit'.	• A guide to good practice and current legislation governing the handling of medicines	
Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS); Social Care Institute for Excellence (SCIE) [1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 [2] Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)				

1 **Table 10: Summary of included studies**

Study	Study type	Population	Intervention	Comparison	Key critical and important outcomes
Bonugli (2014) *USA*	Qualitative design	Residents and staff of a homeless shelter.	Community based participatory research to identify concerns and facilitators for safe management of medicines in a homeless shelter.	None	• Service user-reported outcomes • Carer-reported outcomes • Medicines-related problems
Sino (2013) *Netherlands*	Observational design	Residents cared for by home care organisations.	Standardised observation checklist for signs and symptoms of potential adverse drug reactions.	Medicines list for each person included in the study and the known side effects as assessed by a panel of pharmacology experts.	• Service user-reported outcomes • Carer-reported outcomes • Medicines-related problems
Both studies were assessed (see section 3.3.3) as being of low methodological quality. These studies are not presented narratively and are documented in evidence tables (see Appendix D).					

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

8.3.1.1 Policy and processes for raising concerns about medicines-related problems

Evidence from the CQC guidance (2015) applies in relation to medicines problems (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) which require that home care providers should ensure that:

- they have in place policies and procedures for anyone to raise concerns about
  - their own care and treatment, or
  - the care and treatment of people they care for or represent
- policies and procedures are in line with current legislation and guidance,
- home care workers follow those procedures
- home care workers have arrangements in place to take appropriate action if there is a clinical or medical emergency.

8.3.1.2 Identifying medicines-related problems

The CQC (2015) identified that home care providers must be compliant with notices issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and through the Central Alerting System (CAS) including:

- relevant Patient Safety Alerts
- recalls
- rapid response report.

Evidence from the RPS (2007) suggests that errors can occur in the prescribing, dispensing or administration of medicines. Whilst the RPS acknowledge that the majority of medicines-related problems do not cause harm to the people receiving care a small number of medicines problems can have serious consequences.

Evidence from the RPS (2007) suggests that even when a person receiving care does not receive support with their medicines, home care workers must be alert to notice if they are taking too much or not enough of their medicines.

8.3.1.3 Reporting medicines-related problems

Evidence from the CQC (2015) requires that any incident that affects the health, safety and welfare of people receiving care must be reported internally (to the home care provider organisation) and to any relevant external authorities or body.

The RPS (2007) and HLIN (2008) advises home care providers should have a clear incident reporting system with serious incidents being reported the regulatory authority. Additionally the RPS suggests that home care workers should immediately report a medicines problem to their line manager or person in charge of the setting (this could be the person they are caring for if they are directly employed).

Evidence from the RPS (2007) and HLIN (2008) suggests that home care providers should not ignore medicines problems but should encourage an open culture for reporting medicines problems that allows home care workers to report issues without the fear of an unjustifiable level of recrimination (a fair blame culture).

Evidence from the RPS (2007) suggests that if a new medicine is given and the person becomes unwell, this could be caused by the medicine and medical help for the person arranged immediately. The RPS states that doctors, nurses, pharmacists, individuals or their carers should report these adverse effects to the Medicine and Healthcare products Regulatory Agency.

8.3.1.4 Learning from medicines-related problems

Evidence from the CQC (2015), HLIN (2008) and RPS (2007) state that home care providers have systems in place for investigating incidents involving medicines-related problems must ensure staff are competent to:

- record, review and thoroughly investigate what has happened
- ensure that action is taken to remedy the situation and record this.

The RPS (2007) advises that home care providers should give information to staff involved in incidents about the incident, causes and outcomes; this should also be shared with others to promote learning, prevent similar problems in the future and make sure that improvements are made as a result. The RPS also suggests that home care providers should decide whether they need to offer training to an individual or review existing procedures following incidents.

Evidence from HLIN (2008) suggests home care providers should consider audit of errors, production of an action plan and lessons to be learnt for the future.

8.3.1.5 Helping to keep people safe from medicines-related harm (safeguarding)

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Regulation 13: Safeguarding service users from abuse and improper treatment) requires that people receiving care be protected from abuse and improper treatment. Evidence from the Department of Health's Care and support statutory guidance (2016) lists misuse of medicines (including withholding medicines) as a form of physical abuse.

Evidence from the DH (2016) recommends that home care providers should have policies and procedures in place for home care staff, which clearly relate to safeguarding, their roles and responsibilities and working within multiagency policies in relation to medicines.

Evidence from the RPS (2007) suggests that any form of control or punishment is not consistent with good care (including neglect and abuse involving inappropriate use of medicines). Principle 8 of the RPS (2007) document states that 'medicines are used to cure or prevent disease, or to relieve symptoms, and not to punish or control behaviour' (for example they should not be used unnecessarily to sedate or restrain people).

Evidence from the CQC guidance (2015) states in relation to safeguarding service users from abuse (this includes misuse of property [for example medicines], ill-treatment, neglect and restriction of liberty [such as chemical restriction misuse of medicines]) that home care providers must have systems and processes for:

- preventing abuse of service users
- to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse
- safeguarding people.

The Department of Health's Care and support statutory guidance (2016) recommends that while a social worker may be involved in safeguarding, a health professional may be best placed to make enquiries and treatment plans relating to medicines management (see section 5.5).

8.3.1.6 Reviewing medicines, including medicines reconciliation

Evidence from the CQC (2015) states that medication reviews should form part of, and be aligned with, the care and treatment assessments, plans or pathways for a person receiving care. The CQC state that medication reviews should be completed and reviewed regularly when there are changes to medicines.

Recommendations on the use of medicines review and medicines reconciliation are available in the NICE guideline on medicines optimisation [NG5] which includes the use of these interventions in the population for this guideline.

8.3.2 Health economic evidence

No economic evidence was identified for this review question.

8.4 Evidence statements

Moderate quality evidence from a guideline recommends policy and procedures should be in place for home care workers and people receiving care or someone acting on their behalf to raise a concerns about a medicines problem.

Moderate quality evidence from a guideline recommends that home care providers should be compliant with patient safety alerts.

Low quality evidence suggests that home care workers should take note of whether people receiving care are taking the right amount of medicines.

Moderate and low quality evidence from guidelines recommends that home care providers should ensure that staff investigating medicines-related incidents should be competent to identify, report and ensure learning following a medicines-related problem.

Low quality evidence from guidelines suggests the findings from medicines-related incidents should be shared by home care providers with home care staff to improve practice. Low quality evidence suggests audits of medicines-related problems should be undertaken.

Moderate and low quality evidence from guidelines recommends that home care providers should have a clear system or process for reporting medicines-related problems within their organisation. Home care providers should have a process for reporting incidents to external authorities when required. Low quality evidence suggests that home care providers should encourage an open culture of reporting by staff.

Moderate quality evidence from a guideline recommends that home care providers have systems and processes in place for preventing, investigating and safeguarding people receiving care from medicines related abuse.

There is a legal duty for home care providers to act in an open and transparent way. They should inform people receiving care or someone acting legally on their behalf about medicines-related incidents, providing information and reasonable support.

Low quality evidence from a single qualitative study suggests barriers to the dispensing of medicines in a homeless shelter, and strategies to overcome those barriers, can be identified through the use of focus groups.

Low quality evidence from a single observational study suggests home care workers may be able to identify adverse effects of medicines using a standardised observation checklist.

8.4.1 Health economic evidence

No economic evidence was identified for this review question.

8.5 Evidence to recommendations

Table 11: Linking evidence to recommendations

Relative values of different outcomes	The Committee noted that a medicines-related problem, as defined in the introduction, was by necessity quite a broad definition. The Committee agreed that in practice home care workers may find it useful to think of examples of the types of problems they typically face and should report to their employer, for example: • accidentally ordering the wrong medicines for a person • receiving the wrong medicines for a person • a person having a bad reaction to medicine you have given • accidentally giving the wrong medicine • accidentally giving the wrong dose of the right medicine • accidentally giving the wrong person a medicine not meant for them • accidentally giving the correct medicine at the wrong time • accidentally giving the medicine by the wrong route (for example swallowing capsules meant for an inhaler device) • a near miss (something which nearly did, or could have, happened that could have led to harm to the person). The Committee discussed the relative importance all of the outcomes agreed for this review question (see Appendix C.2.4) outcomes and agreed that the following outcomes were of critical importance for decision-making: • service user-reported outcomes • carer-reported outcomes • health and social care practitioner-reported outcomes • medicines-related problems • health and social care utilisation.
Trade-off between benefits and harms	**Policy and processes for raising concerns about medicines-related problems** The Committee was aware that sometimes medicines-related problems are not reported by home care workers due to fear of being blamed for mistakes or accused of poor care. The Committee agreed that home care providers should promote a fair blame culture to encourage open reporting and investigation of medicines-related problems. The Committee concluded that home care providers should have in place robust processes for identifying, reporting, reviewing and learning from medicines related problems. This process should support a person-centred, 'fair blame' culture that actively encourages people to report their concerns. This should include processes for: • raising concerns about a person's medicines • safeguarding people from medicines-related harm. The Committee agreed that policies and processes must be in line with current legislation Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and Community adult social care services: provider handbook (2015) CQC guidance. **Raising concerns about medicines-related problems** The Committee was aware from their experience that medicines-related problems come to light as a result of concerns or complaints made by the person receiving care, their family or family carer. The Committee discussed that often people receiving care, their family or family carer struggle to raise concerns, complain or give feedback about medicines-related issues as home care

providers systems for doing so can be unclear.

Furthermore, the Committee discussed the importance of home care workers having a duty to report to their employer any medicines-related care that falls below the required standard or fails to meet the needs of the person, for example when a colleague fails to offer medicines prescribed for the person.

The Committee concluded that people and/or their family members or carers and home care workers should be encouraged and supported to raise any concern about medicines. People should be given information about how they can seek help and/or make a complaint, including who to complain to and the role of advocacy services, if needed. This information should also be recorded in the person's home care plan.

If the person's concern relates to the possible adverse effect of a medicine, the Committee agreed that it is important to ensure that people and /or their family members or carers and home care workers know how to report adverse effects of medicines, including the using the MHRA Yellow Card Scheme.

The Committee recognised that home care workers have an important role in identifying medicines-related problems. Home care providers should encourage home care workers to raise concerns about medicines, although the Committee was mindful that often home care workers do not have the prerequisite knowledge to answer questions about a person's medicines. The Committee concluded that home care workers and other social care practitioners should advise a person to seek advice from a health professional (for example, the prescriber or a pharmacist) if they have any clinical questions about medicines.

The Committee discussed issues that home care workers often encounter such as people becoming unwell or having fluctuating capacity to make decisions about their medicines. The Committee agreed that home care workers should be vigilant as to the physical or mental condition of the individual and report changes to their line manager or employer (home care provider).

The Committee concluded that home care workers should report any concerns about a person's medicines to the home care provider and/or seek advice from the prescriber or other health professional. These concerns may include:

- the person declining to take their medicine
- medicines not being taken in accordance with the prescribers instructions
- possible adverse effects
- the person stockpiling their medicines
- medication errors or near misses
- possible misuse or diversion of medicines
- the person's mental capacity or fluctuating capacity
- changes to the person's physical or mental health.

The Committee discussed the need for home care workers to be mindful of consent and the person's expectations for confidentiality when raising concerns about medicines. The Committee concluded that home care workers should act in accordance with Rule 2 of the HSCIC's A guide to confidentiality in health and social care (2013) which states that care workers should share information when it is needed for the safe and effective care of an individual (see section 9.5).

Reviewing and learning from medicines-related problems

The Committee discussed the importance of learning from medicines-related problems to improve future care. For example, identifying a medicines-related problem may prompt a review and reassessment of the person's medicines

	support needs (see section 5.5).They discussed the evidence and agreed that home care providers and commissioners should have systems in place for reviewing and learning from concerns, complaints and feedback to ensure the care received meets the person's needs and wishes. The Committee agreed that communication and engagement with the person and/or their family member or carer is important when addressing concerns that have been raised about a person's medicines, in line with safeguarding principles. The Committee discussed and agreed that all providers and commissioners should ensure that when a medicines-related problem has occurred and has been investigated, any lessons learnt are shared with home care staff or other relevant stakeholders in order to prevent similar occurrences in future. They also discussed and agreed that home care providers should examine data on medicines-related problems over a period of time to identify and address any trends that may have led to incidents. This learning should be shared widely with: • people in the organisation • people receiving medicines support, their family members and carers • home care commissioners • people working in related services, for example, GPs, community pharmacists and community health providers. **Helping to keep people safe from medicines-related harm (safeguarding)** The Committee agreed that home care providers and home care workers should be aware of their role, responsibilities and local organisational policies for safeguarding and with the role of regulators (for example the Care Quality Commission (2015). The Committee discussed and agreed that home care providers must have robust processes for medicines-related safeguarding incidents, in line with legislation and as recommended in the NICE guideline on home care [NG21].
Trade-off between net health benefit and resource use	No economic studies were identified for inclusion for this review question. The Committee did not identify any significant resource impact from the recommendations in this review question.
Quality of evidence	Guidelines were quality assessed using the AGREE II criteria. 2 guidelines (CQC 2015, DH 2016) were found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, Housing Learning and Improvement Network [HLIN] 2008) and 1 guideline was found to be of very low quality (National Mental Health Development Unit [NMHDU]). The quality of the two studies (Bonugli 2014 and Sino 2013), were assessed using the checklists set out in the NICE manual (2014). Both were found to be of low quality. The Committee agreed that the quality and study design of the study by Bonugli (2014) meant that its findings were not generalisable beyond its setting (a transitional, from homelessness to self-sufficiency, homeless shelter, San Antonio, Texas, USA).

8.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendation 1

1 Recommendation 12

2 Recommendation 17

3 Recommendations 28 to 34

9 Medicines-related communication, documentation and information sharing

9.1 Introduction

Communication and joint working

The NICE guideline on home care [NG21] highlights the importance of communication and joint working between health and social care in relation to medicines. The guideline recommends that health practitioners and home care workers should liaise regularly about a person's medicines. It also recommends that health practitioners should write information and guidance for home care workers about medicines in the home care plan.

Record keeping

Providers of home care are required, under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 17(c), to 'maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided'. The CQC (2015) recommends that records should be created, amended, stored and destroyed in line with legislation (for example the Data Protection Act 1998) and nationally recognised guidance.

The Royal Pharmaceutical Society (RPS 2007) states that clear records help prevent medicines errors. The National Mental Health Development Unit (NMHDU 2010) identify that inaccurate records of medicines may cause risk of harm from patients not receiving their medicines or from the risk of interactions from different medicines.

The RPS (2007) suggests that problems are more likely to occur when:

- people have a long list of prescribed medicines
- some medicines are taken regularly, and others are taken only 'when required'
- the label on the medicines say 'take as directed' and the person cannot explain or cannot remember what this means
- the dose of a medicine is not constant (for example insulin or warfarin where the dose may depend on the results of a blood test)
- situations where more than one prescriber is involved
- people have built up a stock of medicines that a prescriber has asked them to stop taking
- people are unsure or confused about what they should be taking
- people have purchased medicines over-the-counter (for example complementary medicines)
- a new medicine is prescribed or the dose of a medicine is changed
- there are frequent changes to an individual's treatment.

Health professionals supporting people receiving social care in the community with their medicines should follow the NHS Code of practice (Records Management) guidance (Department of Health 2006) and the requirements set by their professional regulator in relation to record keeping and documenting care (for example Registered Nurses should refer to The Code [NMC 2015] and Standards for medicines management [NMC 2008]).

Confidentiality and information sharing

The NICE guideline on home care [NG21] recommends that people using home care services and their carers should be treated with empathy, courtesy, respect and in a dignified way; this includes always respecting their confidentiality and privacy.

The Health and social care act 2008 (Regulated Activities) Regulations 2014 (provision 10[2][a]) requires home care providers to treat the person with dignity and respect and to ensure their privacy. The Health and Social Care Information Centre has produced a general Guide to confidentiality in health and social care (2013), it sets out the obligations about information sharing and confidentiality for care workers providing care in people's homes. The guide also describes the Caldicott principles on when to share, or not share, confidential information.

9.2 Review question

What interventions, systems and processes for improving communication, documentation and information sharing about medicines are effective and cost-effective for adults receiving social care in the community?

9.3 Evidence review

9.3.1 Clinical evidence

The guideline Committee agreed that the objectives of this review were to:

- determine the effectiveness of a documented home care provider medicines policy
- identify what information about medicines needs to be recorded, and by whom. To examine where this information should be recorded (for example, in a person's care and support plan or medicines administration record)
- identify what information about a person's medicines needs to be shared (for example, changes to medicines), and by whom. To determine who this information is to be shared with (for example, between the person receiving care, their families and carers and the care provider)
- determine the medicines information needs of the person, their families and carers.

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection of included evidence. 3 guidelines met the eligibility criteria for this review question and were included. 1 additional guideline (CQC 2015) was identified by the Committee and was relevant for inclusion. No identified studies met the eligibility criteria.

The included evidence is summarised in table 12. The guidelines were quality assessed using the AGREE II criteria. 1 guideline (CQC 2015) was found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007,National Mental Health Development Unit [NMHDU] 2010)) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008).

Table 12: Summary of included guidelines

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers safe care and treatment.	• Principles of safe and appropriate handling of medicines (medicines-related problems).	Moderate quality
Housing Learning and Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated [2]	Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas: • guidance and best practice recommendations • additional medication considerations • dangers and pitfalls • key learning points • frequently asked questions • reference material and resources.	• Principles of safe and appropriate handling of medicines (medicines-related problems).	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis	Key areas: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice for medicines management schemes for by crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management on by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care	Key areas: • the principles that underpin safe handling of medicines in every social care setting • the general practical aspects of medicine handling • the general aspects of medicine management relating to specific care services	• Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation governing	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
		• policies, procedures, systems and devices 'medicines toolkit'.	the handling of medicines	

Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS); Social Care Institute for Excellence (SCIE)

[1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

[2] Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)

1

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

9.3.1.1 Policies and processes for communication, sharing information and record keeping

Evidence from guidance (CQC 2015, HLIN 2008 and RPS 2007) suggests that there should be written policies and procedures for medicines related communication and record-keeping. This should include processes for:

- communication between home care workers and other agencies
- communicating with other settings that the person receiving care may transfer to or visit
- verbal orders for prescribed medicines
- record keeping.

9.3.1.2 Medicines-related communication

Health professionals supporting people receiving social care in the community with their medicines should refer to the requirements set by their professional regulator in relation to communication (for example Doctors should refer to the Communicating information section of Good medical practice (GMC 2013) and Registered Nurses should refer to the Practise effectively section of The Code [NMC 2015].

Evidence from guidance (RPS 2007) suggests there are challenges identifying what medicines a person receiving care is taking in order to support them appropriately. This may be because:

- the home care provider is not responsible for ordering the individuals medicines
- is not officially notified when the individuals treatment is changed
- there may not be a single community pharmacy providing prescriptions for the individual
- the person receiving care may be having medicines support from several different agencies for different treatments.

The RPS (2007) suggests that robust and effective communications are needed between home care workers, home care providers and prescribers.

Sharing information when people transfer between care settings

Evidence from legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) requires that ‘where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.’

Evidence from guidance (CQC 2015) recommends that when people transfer between care settings providers:

- must work actively with other providers to ensure safe care and treatment
- should have arrangements in place to support people moving between services
- should undertake appropriate risk assessments to ensure the person’s safety.

Evidence from guidance (RPS 2007) suggests that when a person receiving care is transferred to another care provider, and the home care provider is responsible for managing their medicines, the home care worker should make a record of the medicines that were sent with them. Home care workers should record the following information:

- the date of transfer
- the name and strength of medicine
- amount or quantity of medicine
- the signature of the home care worker.

Evidence (RPS 2007) also suggests that when home care workers are responsible for supporting people to take their medicines, transferring a copy of the medicines administration record of administration with the individual is essential. This informs the new care provider of which medicines have been taken regularly and what medicines the person may, or has, chosen not to take.

Evidence from guidance (RPS 2007) suggests that all people discharged from hospital should have a complete list of all their current medicines provided at the time of discharge. The RPS (2007) suggests that it is essential that the new list is compared with the list made before admission.

Hospitals normally inform the GP and the person receiving care of all medicines-related changes. Evidence from guidance (RPS 2007) suggests that home care workers responsible for the medicines of a person receiving care should:

- advise the persons supplying pharmacy of any changes as soon as possible
- prepare a new medicines administration record
- arrange for the disposal of any unwanted or discontinued medicines
- request a new prescription for the person as soon as possible.

Home care workers obtaining advice from a health professional

Evidence from guidance (RPS 2007) suggests that one the principles of safe and appropriate handling of medicines in social care is that social care services and home care workers should have access to advice from a pharmacist (principle 7).

The RPS (2007) also suggests that home care workers should have readily available:

- the contact number(s) for the local pharmacy
- a named person to contact.

Home care workers receiving and recording verbal changes to medicines

Evidence from the RPS (2007) suggests that home care providers should have a procedure to communicate verbal changes to medicines clearly (for example a telephone call from a GP).

The RPS (2007) suggests that it is good practice to:

- make a record of the change(s) that have been made, spelling out the name(s) of the medicine(s)
- read back the information about the change(s) that have been written down to the person requesting the change
- ask the person requesting the change to repeat the message to another person, if possible (for example the person receiving care, another home care worker or a carer).

The RPS (2007) recommend that home care workers request written confirmation of the change as soon as possible (for example by fax, letter or by issue of a new prescription). They also suggest that a careful record should be made of:

- which home care worker took the telephone call
- the time of the call
- the name of the person who called.

19.3.1.3 Medicines-related record keeping

Evidence from guidance (RPS 2007) states that the purpose of keeping records of medicines is so that home care staff know which medicines each person receiving care has and the home care provider has a complete account of medicines. Evidence from guidance (RPS 2007) suggests that home care providers need to decide on the way in which a care service keeps records (for example a policy or procedure).

Evidence from guidance (RPS 2007) also suggests that even when home care workers do not routinely give the person their medicines, it is important to know if the person has any medicines, what those medicines are and how they should be taken and what health condition the medicines are being taken for.

Evidence from legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and guidance (CQC 2015 and RPS 2007) states that home care workers should ensure that records about medicines are:

- accurate and complete
- legible
- up to date
- written in ink (indelible)
- record the date and time the care was given
- made at the time at the time the support was given, or as soon as possible afterwards
- be signed and dated to show who has made the record
- be accessible to those who need access.

Evidence from legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and guidance (CQC 2015, NMHDU 2010 and RPS 2007) requires that records should be made of:

- all assessments
- care and treatment plans
- discussions and decisions (including advance decisions)
- all medicines currently prescribed or being taken
- agreements about the amount of support or supervision for each medicine:
  - if the will manage the medicine themselves
  - if and what support the home care worker will provide.

Records for ordering and transporting medicines

Evidence from guidance (RPS 2007) suggests that when home care workers are responsible for looking after the medicines prescribed for a person receiving care, they should be able to identify each medicine and how much of each medicine they have left, at any given time. When a home care worker is responsible for ordering or transporting medicines a person receiving care, they should record:

- when they have requested medicines (prescriptions) on behalf of a service user
- what medicine(s) have been received including the name and strength of the medicine
- how much of the medicine(s) were received
- when the medicine was received (time and date).

(See section 6.3.1 for ordering and transporting medicines).

Records for giving people, or reminding them take, medicines

Evidence from guidance (RPS 2007) suggests that home care workers need to make a record if they:

- remind (prompt) a person to take their medicine
- give a person their medicine
- give a person a quantity of medicine (if the person takes their medicines themselves and the home care worker is only responsible for ordering the medicines).

(See section 7.3.1 for administering medicines).

Records for the disposal of medicines

Evidence from guidance (HLIN 2008 and RPS 2007) suggests that when home care workers are responsible for disposing of medicines a complete record should be made to show that they were disposed of properly, this should include the:

- date of disposal, or return to pharmacy
- name and strength of medicine
- amount disposed of, or returned to pharmacy
- name of the person for whom medicine was prescribed or purchased
- signature of the home care worker who arranges for the disposal of the medicines.

(See section 6.3.1 for disposal of medicines).

Records for controlled drugs

See the NICE guideline on controlled drugs [NG46] which covers all settings, including peoples own homes.

Medicines administration records

The RPS (2007) define a medicines administration record as ‘a document on which details of all medicines given in a care setting are recorded.’ Evidence from guidance (RPS 2007) suggests that the information on the medicines administration record supplements what is in the person’s care plan. The care plan will include personal preferences. The RPS (2007) also recommends that where home care workers give medicines, they must have a medicines administration record to refer to.

Evidence from guidance (NMHDU 2010, HLIN 2008 and RPS 2007) suggests that a medicines administration record should contain the following information:

- the name of the person receiving care
- the names of the medicines that are prescribed
- the form of the medicine (for example tablet or liquid)
- the strength of the medicine (for example hydrocortisone cream 0.5%)
- the dose of medicine to be given
- how often or the time they should be taken
- the route of administration (for example by mouth)
- the name of the prescriber
- any stop or start date
- any additional information (for example the need to give the medicines with food).

Evidence from guidance (NMHDU 2010, HLIN 2008 and RPS 2007) suggests that when home care workers are responsible for giving, or remind a person to take, a medicine they should record:

- the date and time the medicine, or a reminder, was given
- if a medicine is declined (see also section 7.5)
- the name of the home care worker
- receipt or disposal of medicines.

Evidence from guidance (RPS 2007) advises home care providers that if they use hand-written medicines administration records (as opposed to printed one provided by a pharmacy or GP) then there should be a system to check that the details recorded on the medicines administration record are correct. Responsibility for providing medicines administration records rests with the home care provider although a pharmacist or dispensing GP may be prepared to provide them on request.

Staff training and competence

Evidence from guidance (HLIN 2008 and RPS 2007) recommends that staff training on communication should include record-keeping and confidentiality (see section 10.3.1)

9.3.1.4 Confidentiality and information sharing

Evidence from the CQC (2015) states that each person's privacy needs and expectations should be identified, recorded, and met as far as is reasonably possible.

Evidence from the RPS (2007) document principle 4 states that medicines are given safely and correctly, and care staff preserve the dignity and privacy of the individuals when they give medicines to them. The RPS recommends that this includes:

- making every effort to preserve the dignity and privacy of individuals in relation to their medicines
- keeping personal medical information confidential, (for example not storing a person's medicines administration record where other people can see it)
- home care workers being tactful and sensitive (for example always discreetly discussing bowel and bladder function).

Evidence from guidance (NMHDU 2010) suggests that ensuring the person's privacy, dignity and confidentiality during the administration or supply of medicines is a standard that accredited wards would be expected to meet under the Accreditation for Inpatient Mental Health Services (Royal College of Psychiatrists).

9.3.2 Health economic evidence

A systematic literature search (appendix C.1) was undertaken to identify cost-effectiveness studies evaluating the systems interventions and processes for improving communication, documentation and information sharing about medicines are effective and cost-effective for people receiving social care in the community.

This search identified 9,629 records, of which 9,629 were excluded based upon their title and abstract.

9.4 Evidence statements

Moderate and low quality evidence from guidance recommends that a home care provider's medicines policy includes processes for:

- communication between home care workers and other agencies

- communication between home care workers and other care settings
- verbal orders for prescribed medicines
- record keeping.

Low quality evidence from guidance suggests the need for robust communication between home care workers, home care providers and prescribers.

Low quality evidence from guidance suggests that when a home care provider is responsible for a person's medicines they should consider having a process for sharing information about if the person moves between care settings.

Low quality evidence from guidance suggests that home care providers have a process in place for home care workers have access to advice from a pharmacist if needed.

Low quality evidence from guidance suggests that home care providers consider having a documented process in place for home care workers to receive and record verbal changes to a person's medicines from a prescriber.

Low quality evidence from guidance suggests that home care provider consider having documented process in place for creating, amending, storing and disposing of medicines-related records in line with current legislation and best practice.

Low quality evidence from guidance suggests that home care workers giving people medicines should have a medicines administration record, which includes full details of a person's medicines.

Low quality evidence from guidance suggests that home care workers should record on the medicines administration record the date and time a medicine is given, if a medicine has been declined, the name of the home care worker and the receipt or disposal of medicines.

9.4.1 Health economic evidence

No economic evidence was identified for this review question..

9.5 Evidence to recommendations

Table 13: Linking evidence to recommendations

Relative values of different outcomes	The Committee discussed the relative importance of all of the outcomes agreed for this review question (see Appendix C.2.5) and agreed that the following outcomes were critical or important for decision making: • service user-reported outcomes • health and social care practitioner-reported outcomes • medicines-related problems • health and social care utilisation. No studies were identified by the literature search for this review questions which included these outcomes.
Trade-off between benefits and harms	**Policies for communication and record keeping** The Committee discussed the evidence from guidance and agreed that home care providers should have in place robust processes for communicating, sharing information about a person's medicine and record keeping for medicines for which they are providing support, including communication with: • the person and their family members or carers • home care workers and other social care practitioners • health professionals, for example the person's GP or community pharmacist • other agencies, for example when care is shared or the person moves

between care settings.

The Committee concluded that home care providers should have robust processes for how medicines-related records are created, amended, stored and destroyed in line with legislation (for example The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 17 and the data protection act 1998) and nationally recognised guidance (for example Care Quality Commission (2010) Code of Practice on confidential personal information).

Home care providers recording a list of a person's medicines

The Committee discussed the evidence from guidance (RPS 2007) that suggests that home care workers needed to know what medicines a person is taking if it has been agreed that they are not responsible for support the person with them. The Committee discussed the practical problems of home care workers knowing what multiple clients were taking and remembering this.

The Committee agreed that the most effective way to achieve this would be a written list. The Committee also agreed that there were benefits to a list of a person's medicines being maintained in the home care plan, for example if the person lost capacity their medicines needs could be easily identified by carers or if the person became unwell the list could be transferred with the individual (for example as part of a patient held record or 'hospital passport').

However the Committee also identified that problems may occur for example:

- the person may not wish for a home care worker to know what medicines they are taking
- a one off recording of the medicines a person is taking which is written in the home care plan is likely to become out of date which may create problems if the list were then used by the home care provider or other provider of care as a current list of medicines being taken.

The Committee concluded home care providers are not expected to make and maintain lists of a person's medicines where medicines support is not being provided. The Committee also concluded that home care providers should have robust processes for ensuring appropriate access to a list of a person's current medicines (for example, the person's medicines administration record or printed repeat prescription list), when this has been agreed with the person and/or their family members or carers. This should ensure that the:

- list is accurate and kept up-to-date
- list is recorded in the home care plan and in any centrally held records, as necessary
- person's expectations for confidentiality are met.

Communication between providers of care

The Committee discussed from their experience the need for better communication between services for people receiving medicines support. The Committee identified that gaps in communication about medicines present difficulties and potential safety issues, particularly between home care providers, general practice and community pharmacy.

The Committee agreed that in most cases the person receiving social care will be managing their own medicines, often with support from their family members and/or carers. They should be involved in all decisions and kept informed of all changes to their medicines. This enables them to inform home care workers of those decisions and changes.

The Committee was aware that sometimes people:

- are unable to take responsibility for their medicines (for example due to a

decline in cognitive function or fluctuating capacity)
- choose not to take responsibility for their medicines.

The Committee identified that a person's GP and preferred community pharmacy were often unaware that a person had started to receive support with their medicines. Additionally, they were often unaware that assessment of their needs by the home care provider had identified ways of supporting self-management (for example, monitored dosage system or large print labels) or advanced care plans. The Committee agreed that if the GP and pharmacist were aware of the involvement of a home care provider this would facilitate communication when, for example, medicines were started, changed or stopped.

The Committee concluded that home care providers should notify a person's general practice and community pharmacy, when starting to provide medicines support, including who is the named person to contact about medicines.

The Committee also concluded that general practices should record details of the medicines support and the named person to contact about medicines in the person's medical record, when notified that a person is receiving medicines support from a home care provider.

The Committee was aware from experience that problems can occur when changes to prescriptions are made by the prescriber and the home care worker or family member and/or carer is not present and the person receiving care is unable to relay the information about the change (for example due to poor memory or fluctuating capacity). The Committee concluded that in such circumstances the prescriber should communicate any changes to the person's medicines (for example, when stopping or starting a medicine) by:
- issuing a new prescription
- informing the named person to contact about medicines
- informing the person's community pharmacist, if this is agreed with the person and/or their family members or carers.

Sharing information when people transfer between care settings

The Committee was aware that the NICE guideline on medicines optimisation [NG5] contains recommendations for services regarding transfers of care between settings (for example, from home to hospital or day care). They agreed that these recommendations were applicable to all people taking or using medicines and should be implemented.

The Committee discussed the evidence from guidance (CQC 2015) about whose responsibility it is to assemble information about an individual's medicines if the individual is unable to relay this information (for example due to communication difficulties, ill health or changes in cognition or memory).

The Committee discussed that while it may be useful for home care providers to send (for example) the person's medicines administration record to the service taking over their care there are difficulties in doing so, for example:
- the medicines administration record is the legal record of the care provided by the home care provider and often these are not returned to them after the transfer meaning that their records are no longer complete
- the medicines administration record is only a record of what medicines the home care provider support the person to take (for example insulin given by community nursing services may not appear on the medicines administration record as the home care provider does not administer this medicine).

The Committee therefore agreed that while it would useful for home care providers to share any information they hold about a person's medicines when they transfer between settings this may not always be possible. Full details of a

person's medicines may come from a number of care providers if the person is unable to give the information themselves.

The Committee heard that it is the responsibility of the person providing care at the time (for example Ambulance personnel attending the person's home) to ensure that they actively assemble all information about a person's medicines.

The Committee concluded that, in line with legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 12), all providers of care must work together to ensure the current provider of care has timely access to information about the person's medicines regardless of the setting.

Home care workers receiving and recording verbal changes to medicines

The Committee discussed the evidence from guidance (RPS 2007) and agreed that there were often difficulties and safety issues associated with prescribers making verbal changes (for example by phone) to a person's prescription including:

- the risk of errors
- the difficulties of medicines being contained in monitored dosage systems, for example problems identifying and removing medicines contained within it
- possible issues with a lack of audit trail for changes that have been requested.

The Committee discussed and agreed that the preferred arrangement for any change to a prescription for a person's medicines should be a new prescription from the prescriber. The Committee agreed that in exceptional circumstances verbal changes to prescriptions should be made only if a delay in the change, to allow a new written prescription, would result in unsafe care.

The Committee concluded that home care providers should have robust processes for receiving and recording verbal changes to a person's medicines, in exceptional circumstances when written instructions cannot be given. This should include:

- recording details of the requested change (including who requested the change, the date and time of the request and who took the request)
- reading back the information that has been recorded to the person requesting the change to confirm it is correct (including spelling the name(s) of the medicine)
- ensuring the person requesting the change repeats the request to another person (for example, the person or home care provider).

The Committee also concluded that prescribers should follow-up any verbal changes to a person's medicines with written confirmation as soon as possible. Written confirmation should be sent by an agreed method of communication, for example a secure fax or e mail.

Records for ordering and transporting medicines

The Committee discussed the evidence from guidance (RPS 2007) and agreed that when a home care worker is responsible for looking after a person's medicines they should be able to identify each medicine and how much of each medicine is left, they should record:

- when medicines (prescriptions) have been ordered, including the name, quantity and strength of the medicine
- when medicine(s) have been received
- check for any discrepancies between what was ordered and what was supplied.

Records for supporting people to take their medicines

The Committee discussed the evidence from the RPS (2007) and were aware of variation in practice for recording medicines support, for example, giving medicines to people or reminding them to take their medicines. The Committee was aware that some home care providers already document all care given and some home care providers only document when they have given a medicine.

The Committee concluded that in line with legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 17) home care workers must maintain a record of the care and treatment provided. This includes medicines support for prescribed and over-the-counter medicines. For example when:

- reminding (prompting) a person to take their medicine
- giving a person their medicine and recording that they have taken or declined it.

Medicines administration records are the record of medicines-related care provided by home care workers and its production and the requirement to ensure it is an accurate, complete and contemporaneous record is the responsibility of the home care provider. The Committee discussed the evidence for the use of medicines administration records by home care workers. The Committee agreed that despite some limitations, using medicines administration records supports safe care, for example, by helping to prevent duplicate doses of medicines being given.

The Committee noted that a recommendation for widespread use of medicines administration records would represent a change in practice for some home care providers and may have resource implications, however the Committee was aware that they are already used routinely in many areas of England and Wales by home care providers. The Committee concluded that home care workers should ideally use a printed medicines administration record to record any medicines given to a person.

Medicines administration records

The Committee discussed evidence from legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 17) which requires home care providers to record of the care and treatment provided.

The Committee discussed and agreed that because of the limited training and time home care workers have to produce a medicines administration record, it would be safer to use a centrally printed record for example one produced by a community pharmacy, dispensing doctor or, in some areas hospital pharmacies. The Committee was aware that the producer would only be able to include those medicines that they are prescribing or supplying to the person.

The Committee discussed that in exceptional circumstances it is sometimes necessary to produce a hand written medicines administration record or to make amendments to a printed one. The Committee concluded that when hand written medicines administrations records are used or handwritten changes need to be made to the record then the home care provider should have systems and process in place to ensure that the record is correct (for example it is written by someone who is competent to do so and checked by another competent person).

The Committee was aware that the necessity for completion of medicines administration records may cause delay in giving or supporting people to take their medicine. The Committee agreed that the absence of a medicines administration record for a person should not delay medicines being given as it is the label on the medicine packaging that is the legal authority to administer a medicine, not what is recorded on the medicines administration record which is a record of the care given. The medicines administration record should be used to confirm that the home care worker is not, for example, giving a

	duplicate dose. The Committee agreed that a medicines administration record should contain: • the name of the person • the name, form and strength of the medicines • how often or the time they should be taken • how to give or take the medicine • the name of the person's GP practice • any stop or start date • any additional information, such as specific instructions for administration. **Records for the disposal of medicines** The Committee discussed the evidence from guidance (HLIN 2008 and RPS 2007) about disposing or returning to pharmacy unwanted, damaged, out-of-date, and part-used, no longer needed or were over-ordered medicines from a person's home (see section 6.5). The Committee agreed that for the safe disposal and record keeping of controlled drugs, home care providers should follow the recommendations in the NICE guideline on controlled drugs [NG46]. The Committee concluded that when home care providers are responsible for disposing of any unwanted, damaged, out-of-date or part used medicines, they must have processes in line with legislation (The Controlled Waste Regulations 2012). This process should include record keeping, for example, the name and quantity of medicine, the name of the person returning the medicine to a pharmacy and the name of the pharmacy and date of return.
Trade-off between net health benefit and resource use	No economic evidence was identified for this review question. The Committee identified that a recommendation requiring the use of medicines administration records had resource implications for home care providers. The Committee was aware pharmacies, dispensing doctors and hospitals do not have an obligation to produce these records and where they are provided for home care providers this may not necessarily be a free service due to the costs incurred in their production. However, the Committee heard that in some areas medicines administration records are already used routinely by home care providers. No other recommendations made for this review question were thought to have significant resource implications.
Quality of evidence	The guidelines were quality assessed using the AGREE II criteria. 1 guideline (CQC 2015) was found to be of moderate quality, 2 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, Housing Learning and Improvement Network [HLIN] 2008) and 1 guideline was found to be of very low quality (National Mental Health Development Unit [NMHDU]).

9.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendation 1

Recommendations 6 to 7

Recommendations 10 to 12

1 Recommendations 16 to 17

2 Recommendations 19 to 22

3 Recommendations 24 to 26

4 Recommendation 37

5 Recommendation 63

10 Roles and responsibilities of organisations and health and social care practitioners

10.1 Introduction

Under the Care and support statutory guidance (DH 2016) and the Health and Social Care Act 2012 both local authorities and the NHS must promote integration between health and social care. The Care and support statutory guidance recommends this is through:

- planning of services in relation to local needs
- commissioning and joint commissioning of services
- integrating assessment, better use of information and seeking advice
- the delivery or provision of care and support.

The Care Quality Commission (CQC) (2015) state that under regulation 12(2)(g) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 'Staff responsible for the management and administration of medication must be suitably trained and competent and this should be kept under review.'

The Care Certificate contains a set of minimum standards that should be covered during the induction training for new home care workers, although it is also open to existing home care workers to refresh or improve their knowledge. One of the outcomes (standard 13: health and safety) is to understand medicines, the agreed ways of working in relation to medicines and tasks related to medicines that home care workers are not allowed to carry out until they have been assessed as competent.

Skills for Care provide further information for CQC regulated providers regarding medicines and what information about medicines should be covered during induction training for new home care workers.

The NICE guideline on home care [NG21] contains recommendations on the recruitment and training of home care workers.

10.2 Review question

What are the roles and responsibilities of organisations and health and social care practitioners in supporting the safe and effective use of medicines for people receiving social care in the community?

10.3 Evidence review

10.3.1 Clinical evidence

The guideline Committee agreed that the objectives of this review were to:

- determine the roles and responsibilities of organisations and health and social care practitioners, including responsibilities for oversight and investigation, where relevant
- identify what approaches are effective for multi-agency coordination of medicines-related support
- identify what approaches are effective for monitoring and evaluating medicines-related support
- determine what knowledge and skills (competency) are needed by health and social care practitioners.

A systematic literature search was conducted (appendix C.1). See section 3.3 for information on the selection of included evidence. 5 guidelines met the eligibility criteria for this review question and were included. 2 additional guidelines (CQC 2015 and DH 2016) were identified by the Committee and were relevant for inclusion. No identified studies met the eligibility criteria.

The included evidence is summarised in table 14. The guidelines were quality assessed using the AGREE II criteria. 2 guidelines (CQC 2015 and DH 2016) were found to be of moderate quality, 4 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, National Mental Health Development Unit [NMHDU] 2010, Northern Ireland Social Care Council Guidance [NISCC] 2013, Scottish Government 2005) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008). No evidence was found for what approaches are effective for multi-agency coordination of medicines-related support or monitoring and evaluating medicines-related support.

1 **Table 14: Summary of included studies**

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Care Quality Commission (2015) *UK*	People in receipt of care defined as regulated activities[1]	To help providers to comply with the regulations made under the Health and Social Care Act 2008 (HSCA 2008). This includes regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 which covers safe care and treatment.	• Principles of safe and appropriate handling of medicines (medicines-related problems).	Moderate quality
Department of Health (2016) *UK*	Local authorities to support the implementation of the Care Act (2014)	Key areas: • general responsibilities and universal services • first contact and identifying needs • charging and financial assessment • person-centred care and support planning • safeguarding • integration and partnership working • moving between areas: inter-local authority and cross border issues	• Compliance with the requirement of the Care Act 2014.	Moderate quality
Housing Learning and Improvement Network (2008) *UK*	Specialist housing for older people where care services are provided or facilitated [2]	Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas: • guidance and best practice recommendations • additional medication considerations • dangers and pitfalls • key learning points • frequently asked questions • reference material and resources.	• Principles of safe and appropriate handling of medicines (medicines-related problems).	Very low quality
National Mental Health Development Unit (2010) *UK*	Medicines management for people with mental health crisis	Key areas: • an evaluation of medicines management approaches used by crisis intervention and home treatment teams • recommendations for best practice for medicines management schemes for by crisis intervention and home treatment teams • key messages from service users and carers organisations, and • a model framework for better medicines management on by crisis intervention and home treatment teams.	• Those in crisis being maintained in their own community • Improved coping • Reduced stigma	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
Northern Ireland Social Care Council Guidance (2013) *UK*	Social Care Workers' administering medicines including the setting of domiciliary care	Aimed at social care workers and describes their professional responsibility in relation to the administration of medicines.	• Honesty, trust and confidence • Safeguarding • Risk management • Records management	Low quality
Royal Pharmaceutical Society (2007) *UK*	People who receive social care	Key areas: • the principles that underpin safe handling of medicines in every social care setting • the general practical aspects of medicine handling • the general aspects of medicine management relating to specific care services • policies, procedures, systems and devices 'medicines toolkit'.	• Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation governing the handling of medicines	Low quality
Scottish Government (2005) *Scotland*	Care at home	National care standards for those receiving care at home, Key areas: • information and decisions • written agreements • personal planning • management and staffing • lifestyle • eating well • keeping well – healthcare • keeping well – medication • private life • supporting communication • expressing views	• dignity • privacy • choice • safety • realising potential • equality and diversity.	Low quality

Abbreviations: Care Quality Commission (CQC); Royal Pharmaceutical Society (RPS); Department of Health (DH)

[1] As defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

[2] Taken from www.extracarehousing.org.uk/index.aspx (accessed 22/12/2015)

Narrative evidence

Because of a paucity of available evidence from research studies and data and due to the use of evidence from guidelines, the GRADE framework was not considered appropriate, therefore a narrative summary of the available evidence is presented.

10.3.1.1 Roles and responsibilities for home care providers

The general roles and responsibilities for providers registered with the CQC are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Evidence from guidance (HLIN 2008, NISCC 2014, RPS 2007 and Scottish Government 2005) suggests that it is the responsibility of those home care providers who allow staff to administer medicines, to:

- develop medicines policy and processes for every aspect of handling medicines which should include:
  - which medicines related tasks a home care worker may undertake
  - staffing and training requirements
  - exactly how to give medicines
  - how to keep proper records, including recording incidents and complaints
- monitor that care workers are aware of and follow these policies and procedures
- ensure that home care workers are trained and competent
- investigate errors and incidents, including:
  - determining if the cause is poor practice or non-compliance with policies and procedures
  - determining if there are training or competency issues to be addressed.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 9(3), on person-centred care, requires that in addition to undertaking assessment of needs and preferences, home care providers must:

- ensure that the person is enabled and supported (for example through involving a health professional) to understand the medicines they are receiving, including the risks and benefits
- involve and support the person to participate in making decisions about their medicines as far as they are able
- ask the person about whether the support given for their medicines meets their needs and preferences and respond to the feedback.

(See section 5.3.1 for person-centred medicines assessment)

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 12(2) and regulation 17(b) on safe care and treatment and good governance state that providers of home care must:

- assess the risks to people of receiving the care or treatment
- assess and monitor the risks arising from care or treatment
- do all they reasonably can to mitigate any risks
- ensure that medicines are supplied, ensuring that there are sufficient quantities of these to ensure the safety of people and to meet their needs
- ensure the proper and safe management of medicines

(See section 6.3.1 for ordering and supplying medicines).

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 17, on good governance, requires home care providers to:

- maintain securely accurate, complete and contemporaneous record for each person including:
  - the care and treatment provided
  - any decisions taken in relation to the care and treatment
- maintain securely records for staff employed to carry out the care

(See section 9.3.1 for record keeping).

10.3.1.2 Roles and responsibilities for home care workers

Evidence from guidance (Scottish Government 2005) suggests that home care workers should:

- find out and record details of a person's medicines (type and dosage) in their plan
- maintain a record in the person's home
- agree with the person the arrangements made to help them with taking their medication.

(See section 5.3.1for person-centred medicines assessment).

Evidence from guidance (NISCC 2014) suggests that home care workers should:

- always adhere to what they are permitted to do through the service user's care plan
- never deviate from what is on the plan
- inform their employer (or other appropriate authority) where the practice of colleagues may be unsafe or adversely affecting the standards of care.

(See section 7.3.1 for administering medicines and section 8.3.1for identifying, reporting and learning from medicines-related problems).

Evidence from guidance (NISCC 2014, NMHDU 2010 and Scottish Government 2005) suggests that home care workers:

- know which medicines each person has
- maintain clear, accurate and complete record of a person's medicines
- maintain a record when they support people to take, or give them, their medicines
- assess and record a person's adherence to their medicines

(See section 8.3.1 for identifying, reporting and learning from medicines-related problems).

10.3.1.3 Collaborative assessment between health and social care

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 9(3)(a), on person-centred care, requires home care providers to carry out, together with the person, an assessment of their needs and preferences for care and treatment. Evidence from guidance (CQC 2015) states that this should, where other organisations share the responsibility for providing care and treatment to a person, 'take into account information from all relevant teams, staff and services' (see section 5.3.1 for person-centred medicines assessment).

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 12, on safe care and treatment, states that 'where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.' Evidence from guidance (CQC 2015) recommends that:

- home care providers work actively with other providers to ensure that care and treatment is safe for people using services (see section 8. 8.3.15 for identifying, reporting and learning from medicines-related problems).
- providers of care should plan and deliver care in partnership when care is shared.There should be appropriate arrangements to share relevant information promptly and in line with current legislation and guidance (see section 9.5)
- the responsibility for providing safe care rests with the main care provider, at the time care is given
- providers should have systems and processes to support people who are moving between services or to other providers (for example risk assessment and management).

Evidence from guidance (RPS 2007 and HLIN 2008) recommends that joint working between health professionals and home care workers is particularly important when specific skills are needed for home care workers to give a medicine, for example:

- medicines as suppositories or enemas
- injections
- medicines through a Nasogastric (NG) or Percutaneous Endoscopic Gastrostomy (PEG) tube
- medical gases, for example oxygen.

Evidence from guidance (RPS 2007 and HLIN 2008) suggests that giving medicines this way should only happen when the health professional has delegated this activity to an individual home care worker and:

- the person has consented to the home care worker giving the medicine
- the care worker has been trained and assessed as competent by the health care professional to give the medicine and has agreed to do so
- clear roles and responsibilities have been agreed between the services providing care.

10.3.1.4 Staff training and assessing competency

Evidence from guidance (CQC 2015, NISCC 2014 and RPS 2007) recommends that both home care workers and home care providers have a role in ensuring they are trained and competent to give or support a person to take their medicines.

Home care provider responsibilities for training

Evidence from legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 18) and guidance (CQC 2015, HLIN 2008 and RPS 2007) requires that home care providers have sufficient numbers of staff who are suitably qualified, competent, skilled and experienced. Home care providers should:

- provide support, training (including induction training), professional development, supervision and appraisal in order for them to carry out care
- ensure that new home care workers who have never worked in social care before do not give medicines until trained to do so and demonstrate the required or acceptable level of competence to work unsupervised
- provide access to further qualifications for home care workers, in line with their work if this is appropriate.

Where further training is required, evidence from guidance (CQC 2015) recommends that home care providers support home care workers to obtain further qualifications that enable them to perform their role and must not act in a way that prevents or limits them from obtaining further appropriate qualifications.

Evidence from guidance (CQC 2015, NISCC 2014 and RPS 2007) recommends that home care providers should actively encourage home care workers to discuss their training needs openly and should support them to undertake training, learning and development to meet the requirements of their role. The CQC (2015) expect that home care providers employing new home care workers should follow the Care Certificate standards to make sure they are supported, skilled and assessed as competent to carry out their roles.

Home care provider responsibilities for assessment of skills and competency

Evidence from guidance (CQC 2015, HLIN 2008 and RPS 2007) recommends that home care providers should:

- have policies and procedures in place for assessing knowledge, skills and competence and how frequently this will happen
- confirm through formal assessment whether a new home care worker is competent to give medicines
- document all training and competence assessments.

Evidence from guidance (CQC 2015) recommends that the medicines training, learning and development needs of home care workers must be assessed when:

- starting employment (induction)
- training has been completed but training and competence requirements are not met
- during appraisal by an appropriately skilled and experienced person
- in an ongoing way or reviewed at appropriate intervals to ensure competence is maintained.

Home care worker responsibilities for training and competency

Evidence from guidance (RPS 2007 and Scottish Government 2005) suggests that home care workers who give or help people to take their medicines should:

- be suitably, adequately and appropriately trained
- be knowledgeable and assessed as competent
- only give medicines that they have been trained to give
- act strictly in accordance with the directions that the prescriber has given and in line with up-to-date best practice guidance.

Evidence from guidance (CQC 2015, NISCC 2014 and RPS 2007) recommends that home care workers should seek assistance from their provider if they do not feel able or prepared to carry out their role.

Content of medicines training for home care workers

Evidence from guidance (HLIN 2008 and RPS 2007) suggests that medicines training for home care workers, as a minimum, should include:

- supplying medicines
- storing medicines
- disposing of medicines
- safe administration of medicines including:
  - oral medicines (tablets, capsules, liquids)
  - ear, nose and eye drops
  - inhalers
  - medicines applied to the skin (patches and creams)

- knowing what the medicine is intended to do (for example, lowering blood pressure)
- knowing how to identify whether there are any special requirements or precautions for a medicine (for example taking the medicine before food)
- what to do in the event of an adverse effect of a medicine:
  - seeking medical help
  - reporting the incident (see section 8.5)
- record keeping and quality assurance (see section 9.5)
- accountability and confidentiality (see section 9.5).

10.3.2 Health economic evidence

A systematic literature search (appendix C.1) was undertaken to identify cost-effectiveness studies evaluating the systems interventions and processes for the roles and responsibilities of organisations and health and social care practitioners in supporting the safe and effective use of medicines for people receiving social care in the community.

This search identified 9,629 records, of which 9,629 were excluded based upon their title and abstract.

10.4 Evidence statements

Home care providers

Evidence from low quality guidance suggests home care providers should develop a medicines policy for every aspect of handling medicines.

Home care providers must assess and address the risks from the medicines a person is taking, of medicines to meet the person's needs and that they are managed safely in line with legislation.

Home care providers must support the person to understand their medicines, involve them as far as possible in making decisions about their medicines and assess and monitor whether the support provided for medicines is sufficient and addresses any identified risks in line with legislation.

Where care of the person and their medicines is shared, or transferred, between home care providers there should be timely planning of care by the provider to ensure the safety of the person in line with legislation.

Home care providers must employ home care workers to support people with their medicines who are suitably qualified, competent, skilled and experienced in line with legislation.

Evidence from moderate and low quality guidance recommends that home care providers have processes for assessing home care workers knowledge, skills and competence for supporting people with their medicines including how and how often assessments will take place, documentation of assessments and induction for new staff.

Home care workers

Evidence from low quality guidance outlines what medicines training for home care workers should be provided for home care workers.

Evidence from low quality guidance outlines the roles and responsibilities for health and social care practitioners when specific skills are needed for home care workers to give a medicine (for example through a feeding tube).

Evidence from low quality guidance suggests that home care workers should only give medicines they are trained to give and act in accordance with the directions of the prescriber and up-to-date best practice guidance.

Evidence from moderate and low quality guidance recommends that home care workers record in the home care plan the details of a person's medicines, agree with them the plan for taking those medicines and assess those plans to ensure they are meeting the person's needs and preferences.

Evidence from low quality guidance suggests that home care workers should always work within the agreed home care plan and inform their employing home care provider where the practice of colleagues may be unsafe.

Low quality evidence from guidance suggests that home care workers should know what medicines a person has and, should maintain a record about when they give or support a person to take their medicines; and record their adherence to their medicines.

10.4.1 Economic evidence

No relevant economic analyses were identified in relation to the roles and responsibilities of organisations and health and social care practitioners in supporting the safe and effective use of medicines for people receiving social care in the community.

10.5 Evidence to recommendations

Table 15: Linking evidence to recommendations

Relative values of different outcomes	The Committee discussed the relative importance all of the outcomes agreed for this review question (see Appendix C.2.6) and agreed that the following outcomes were critical and important for decision making: • service user-reported outcomes • carer-reported outcomes • medicines-related problems • health and social care utilisation. The literature search did not identify any studies measuring outcomes specified in the protocol.
Trade-off between benefits and harms	**Roles and responsibilities of home care provider organisations** The Committee discussed and agreed that in line with legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) home care providers must ensure that medicines-related care is person-centred, appropriate, meets their needs and reflects their preferences (see section 5.5). The Committee was aware of the recommendations in the NICE guideline on home care [NG21] which also covers the planning and review of home care. The Committee concluded that home care providers should have medicines-related policies and processes covering every aspect of handling medicines in line with the NICE guideline on home care [NG21] which recommends that home care providers should have a medicines management policy (see section 6.5). The Committee agreed that home care providers should ensure that home care workers are aware of and follow these policies and processes (see also the NICE guideline on home care [NG21] which has recommendation on safe care policies and procedures). The Committee also agreed home care providers have the responsibility to investigate medicines-related errors and incidents (see section 8.5). The Committee discussed and agreed that home care providers must ensure that, in line with legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014), the medicines support agreed for a person as written in the home care plan should be reviewed regularly to assess whether it is meeting their needs and preferences (see section 5.5) and the provider should respond to this as necessary. See also the NICE guideline on home care [NG21] which has recommendations on access to and review of home care plans. The Committee also agreed that, in line with legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014), that home care providers must assess, monitor and mitigate the risks relating to the health, safety and welfare of the person that arise as a result of medicines-related care and treatment. See also the NICE guideline on home care [NG21] which has recommendations on Ensuring safety and safeguarding people using home care services.

Roles and responsibilities of home care workers

The Committee discussed the evidence from the NISCC (2014) which suggested that home care workers should always adhere to the agreed home care plan and never deviate from what is on it. The Committee agreed that this did not take into account unforeseen medicines events or incidents and the need for home care workers to take advice in such circumstances. The Committee concluded that home care workers should provide the support agreed in the home care plan, but that the plan should contain advice for the home care worker to follow in the event of a medicines-related problem (see section 8.5 and section 9.5).

Collaborative assessment between health and social care

The Committee identified that health care organisations and health professionals in recognising the needs of home care workers can make a big difference in the quality and safety of the home care that is provided. Particularly with a an increasing shift of care for individuals with complex needs away from more acute care settings to home care.

The Committee was aware that home care providers are often delivering support alongside other providers (for example community healthcare services) who may hold information about a person's medicines. In these circumstances, the Committee agreed, that in line with legislation and guidance (see section 9.5) providers should share information and must work together to maintain the safety of the person.

The Committee concluded that when more than one provider is involved in providing care and treatment to the person then information from all relevant teams, staff and services should be taken in to account. See also the NICE guideline on home care [NG21] which has recommendations on liaison between health and social care practitioners.

The Committee was aware that the NICE guideline on medicines optimisation [NG5] has made recommendations for when people move between care settings that also apply to the population of this guideline (see section 9.5).

The Committee discussed the evidence from guidance (RPS 2007 and HLIN 2008) the need for additional specialist training being required by home care workers to give medicines invasively (for example suppositories, enemas, injections, medicines given via percutaneous endoscopic gastrostomy [PEG] tube or medical gases).The Committee discussed that there are 2 related issues, firstly some home care workers may need training as a group to undertake invasive administration of medicines, and secondly, in some cases such administration may be delegated to a home care worker by a health care professional after specific training.

The Committee agreed that where a training need for a group of home care workers is identified in order that they can undertake such invasive medicines administration then the home care provider is responsible for arranging this training in line with CQC (2015) requirements.

The Committee was aware that there could be risks to the safety of the person if delegation of medicines administration from a health care professional to a home care worker or other family carer is undertaken in an inappropriate manner. The Committee heard that often barriers to the safe delegation of medicines administration tasks are organisational (for example a lack of policies, systems and processes in health and social care organisations to ensure the safe delegation of the administration of medicines).

The Committee agreed that this meant that health care organisations, for example community healthcare trusts should have policies, systems and processes in place to ensure the safe delegation of specific types of medicines administration by health professionals (for example nursing staff delegating administration of medicines should be in line with the requirements of Standard 17 of the NMC Standards for medicines management).

The Committee concluded that when specific skills are needed to give a medicine (for example, giving medicines through a PEG tube), health professionals should only delegate the task of giving the medicine to a home care worker when:

- the person (or their family member or carer if they have lasting power of attorney) has given their consent
- the responsibilities of each person are agreed and recorded
- the person giving the medicine is trained and assessed as competent by the delegating health care professional.

The Committee also concluded that although health professionals can delegate the task of administering medicines they retain the responsibility for monitoring and evaluating the safety and effectiveness of a person's medicines as this is not the role of the home care worker.

Staff training and assessing competency

The Committee discussed the difficulties faced by home care providers in accessing medicines-related training. Often health care providers are seen by those in social care as having the expertise in managing medicines. However social care staff are often unable to access this expertise due to:

- issues around funding of training
- organisational boundaries.

The Committee was aware of a lack of medicines training provision that meets the requirements of the home care provider. The Committee was also mindful that home care workers often having little training, low pay and a wide range of responsibilities in addition to the management of medicines which may make the recruitment and retention of staff difficult.

The Committee was aware that the NICE guideline on home care [NG21] makes recommendations on the recruitment and training of home care workers. The Committee agreed that these recommendations also apply for training and competency requirements, related to the safe handling and administration of medicines, in this guideline.

The Committee discussed the evidence from guidance (HLIN 2008 and RPS 2007) on what medicines-related training for home care workers should cover. The Committee agreed that as a minimum medicines-related training should include the safe administration of medicines, handling medicines (see section 6.5), knowing what to do in the event of a medicines-related problem, medicines-related record keeping and accountability and confidentiality.

The Committee was aware that legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 18) requires home care providers to have enough qualified, competent, skilled and experienced home care workers. The Committee found that in some circumstances healthcare providers have delivered training for home care workers employed by home care providers in their locality. The Committee agreed that medicines-related

	training and assessment of competence is the legal responsibility of the home care provider. However, the delivery and funding of training is likely to need a collaborative approach across health and social care (see the NICE guideline on home care [NG21] recommendations on recruiting and training home care workers). The Committee agreed that home care providers should ensure that they have processes in place to assess the medicines-related training, learning and development needs of home care workers when: • starting employment (at induction) • home care workers have completed medicines training but have failed to meet required competency requirements • during appraisal (at least annually) by an appropriately skilled and experienced individual. The Committee agreed that home care providers should ensure that new home care workers do not give medicines unsupervised unless they are trained and assessed as competent to do so, even if they have previous experience in social care as this does not provide assurance of competence (see the NICE guideline on home care [NG21] recommendations on recruiting and training home care workers). The Committee discussed that one of the issues for home care providers and regulators is the understanding of what knowledge, skills and competencies home care workers should have. The Committee agreed that a competency framework for home care workers may be useful, but this was outside the scope of this guideline. The Committee concluded that this emphasises the need for home care providers to ensure that home care workers: • are suitably, adequately and appropriately trained • are knowledgeable and assessed as competent • only give medicines they are trained to give • act strictly in accordance with the prescribers directions and up-to-date best practice guidance. • have an induction programme in place to prepare home care workers for their role in line with the standards for the Care Certificate.
Trade-off between net health benefit and resource use	No economic evidence was identified for this review question. The Committee agreed that sourcing and funding appropriate training can be challenging. However, both people receiving care and health and care services will benefit from improved safety and reduced medicines-related problems. The Committee agreed that joint working across health and social care was needed (see the NICE guideline on home care [NG21]). The Committee identified that there may be resource implications for community healthcare trusts when specific skills are needed to give a medicines (for example through a feeding tube). However, the Committee noted that in many cases health professionals (for example registered nurses) are already required to provide education, training, support and assessment of competence of the individuals to whom they are delegating the task of giving the medicine, by their professional regulators.
Quality of evidence	The guidelines were quality assessed using the AGREE II criteria. 2 guidelines (CQC 2015 and DH 2016) were found to be of moderate quality, 4 guidelines were found to be of low quality (Royal Pharmaceutical Society [RPS] 2007, Housing Learning and Improvement Network [HLIN] 2008, Northern Ireland Social Care Council Guidance [NISCC] 2013, Scottish Government 2005) and 1 guideline was found to be of very low quality

	(National Mental Health Development Unit [NMHDU]).

10.6 Recommendations & research recommendations

See section 4.1 for a list of all recommendations and appendix E for a summary of the recommendations and how they are linked to the evidence.

Recommendations linked to this review question:

Recommendation 1

Recommendations 14 to 15

Recommendation 37

Recommendation 50

11 References

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12 Glossary

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

Administration

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

Advance care planning

A voluntary process of discussion about future care between a person and their care providers, irrespective of discipline. If the person wishes, their family and friends may be included.

Adverse effects

See Medicines-related problems

Consent

People must provide their consent to any care and support, unless they lack capacity to do so (see 'Mental capacity'). Informed consent is defined as 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. Implied or non-verbal consent is defined as an action implying consent, for example, a person rolling up a sleeve to have their blood pressure measured.

Controlled drugs

Any substance or product for the time being specified in Part I, II or III of Schedule 2 of the Misuse of Drugs Act 1971.

Covert administration

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

Dispensing

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

Disposal (of medicines)

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

Fair blame culture

In health and social care, this enables open and honest reporting of mistakes that are treated as an opportunity to learn to improve care.

Medication error

Medication errors include:

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

Medication review

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

Medicines adherence

The extent to which the person's behaviour matches agreed recommendations from the prescriber.

Medicines administration record (MAR)

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

Medicines-related problems

The term 'medicines-related problems' includes:

- potentially avoidable medicines-related hospital admissions
- prescribing errors
- dispensing errors
- administration errors (e.g. missed or delayed doses, inappropriate or incorrect administration)
- monitoring errors (e.g. inadequate review or follow-up, incomplete or inaccurate documentation)
- adverse events, incident reporting and significant events
- near misses (a prevented medicines related patient safety incident which could have led to patient harm)
- deliberate withholding of medicines or deliberate attempt to harm
- restraint or covert administration has been used inappropriately
- misuse, such as missing or diverted medicines
- other unintended or unexpected incidents that were specifically related to medicines use, which could have, or did, lead to harm (including death).

Mental capacity

The ability to make a decision, 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).

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'.

If someone does not have capacity to make decisions, health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act. Health professionals should also follow the Department of Health's advice on consent. Deprivation of liberty occurring in a home care setting would need to be made via an application to the Court of Protection as Deprivation of Liberty safeguards are explicitly applicable only to care homes and hospitals.

Monitored dosage system

A system for packing medicines, for example, by putting medicines for each time of day in separate blisters or compartments in a box.

Near miss

A prevented medicines-related safeguarding incident which could have led to patient harm.

Over-the-counter medicine

Medicines that can be bought 'over-the-counter' without the need for a prescription.

Parenteral nutrition

Providing nutrients intravenously.

Patient information leaflet

A leaflet which provides information on using the medicine safely.

Personal assistant

A person who is directly employed by people who use services to provide care and support to people in their own home. Personal assistants are not regulated by the Care Quality Commission. Also see home care worker.

Prescribing or prescriber

A person who authorises in writing the supply and administration of a medicine or other healthcare treatment for an individual named person.

Self-administration

When a person looks after and takes their medicines themselves.

Self-funder

People who pay or contribute towards the cost of their home care.

Time-sensitive medicine

A medicine that needs to be given or taken at a specific time, where a delay in receiving the dose or omission of the dose many lead to serious patient harm, for example, insulin injections.

Appendices

The appendices are a separate document.