

Managing medicines for adults receiving social care in the community

NICE guideline NG67

Methods, evidence and recommendations

March 2017

Final for publication

*National Institute for Health and Care
Excellence*

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Acknowledgements

The Committee would like to thank Denise Wilcock, Safeguarding Practice Consultant, Bury Council for her contribution to the development of the guideline.

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 care and 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 social 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 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 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 2015 and 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 care workers directly employed by people who use social care and support services (unregulated activity).

There is no single organisation which is responsible in law for managing medicines for adults receiving social care in the community. However, each health and social care organisation and practitioner has their own responsibilities.

Prescribers have a duty to prescribe, monitor and evaluate medicines. They also have a professional duty to communicate changes in a person's medicines to the person, a carer, care worker or other health professional as appropriate. Prescribers are required to follow their own regulator's professional standards, for example, the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) (2013).

Those who supply medicines (supplying pharmacists) have duties under the [Medicines Act 1968](#) to ensure that medicines are supplied in accordance with the prescription and to take into account a person's need for support with taking their medicines, for example, under the [Equality Act 2010](#).

Care workers can legally give medicines under the [Medicines Act 1968](#), provided they are suitably trained and act strictly in accordance with the directions of the prescriber.

Providers have legal duties under [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#) which include ensuring that the medicines support needs and preferences of a person are assessed, reasonably met and reviewed when appropriate. They also have a duty to ensure that they employ sufficient numbers of suitably qualified, competent, skilled and experienced staff.

Social care commissioners also have legal duties under the [Care Act 2014](#) to ensure that they assess, and commission care that meets, an adult's needs (where that adult is eligible for such care).

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.](#)
- [Equality Act 2010.](#)
- [The Human Medicines Regulations 2012.](#)
- [The Misuse of Drugs \(Safe Custody\) Regulations 1973.](#)
- [Misuse of Drugs Act 1971.](#)

1.3 Terms used in the guideline

Carer

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

Care worker

A person who is employed to provide care and support to people in their own home^a. This includes home care workers, personal assistants (who are directly employed by people who use services) and other support workers.

Commissioner

An organisation who undertakes 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. Services are regularly evaluated as part of the commissioning process.

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, care workers, case managers, care coordinators and social workers. When specific recommendations are made for a particular group, this is specified in the recommendation.

^a This includes extra care housing, Shared Lives Scheme (formerly Adult Placement Scheme) living arrangements, sheltered housing (such as supported housing or specialist accommodation), supported living and temporary accommodation (such as for people who are homeless).

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.

Medicines support

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.

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's care plan

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

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](#)
- receive any social care component of an NHS Continuing Care package
- [self-fund](#) their own care and support.

Social care provider

A provider organisation, registered with the Care Quality Commission to provide community adult care services, which directly employs care workers to provide personal care and support in a person's home.

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, [care workers](#), 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.
- 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
 - the person declining 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)
- [Falls in older people: assessing risk and prevention](#). NICE guideline CG161 (2013)
- [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
- evidence statements
- evidence to recommendations
- recommendations and research recommendations.

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 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

Section	Type of review	Review question
		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 review 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). For guidelines, the [AGREE II Instrument](#) was used. All guidelines were assessed by one reviewer and scores independently checked by a second reviewer. The

overall score across the 6 domains was used to give an overall assessment of the quality of the evidence. Guidelines with an overall score of >75% were rated high quality, 60-75% moderate quality, 59-45% low quality and <45% very low quality.

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 was subject to a 4-week public consultation. This allowed stakeholders, members of the public and other NICE teams to peer review the draft guideline as part of the quality assurance process. All comments received from registered stakeholders within the specified deadline were 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 Technologies Programme to develop this guideline.

4 Guideline summary

4.1 Recommendations

4.1.1 Full list of recommendations

The recommendations in this guideline assume that the responsibilities for providing medicines support have been agreed between the relevant NHS and local authority commissioners. The term 'medicines support' is defined as any support that enables a person to manage their medicines. This varies for different people depending on their specific needs. The guideline aims to ensure that medicines are managed safely and effectively for all adults receiving social care in the community. People living in residential or nursing care homes are covered by NICE's guideline on [managing medicines in care homes](#).

Before any medicines support is provided by a [social care provider](#), commissioning and contractual arrangements need to be discussed, agreed and recorded as part of the local care planning process. This is to ensure that it is clear who is responsible and accountable for the decisions being made, and which providers will deliver each aspect of medicines support.

The person or organisation responsible for implementing a recommendation is clearly stated, except when it is not possible to specify. This will be for commissioners and providers to consider and determine locally.

Governance for managing medicines safely and effectively

1. Health and social care commissioners and providers should review their local governance arrangements to ensure that it is clear who is accountable and responsible for providing [medicines support](#).
2. When social care providers have responsibilities for medicines support, they 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 social 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
 - medicines-related staff training and assessment of competency.

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 an essential part of this, with help from family members or carers

if needed. The term 'medicines support' is defined as 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 overall assessment indicates the need to do so, and this has been agreed as part of local governance arrangements.
5. Ensure that people assessing a person's medicines support needs (for example, social workers) have the necessary knowledge, skills and experience.
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 or [parenteral nutrition](#)
 - who 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 the person's medicines support needs. If the person needs medicines support include the following information in the [provider's care plan](#):
 - the person's needs and preferences
 - the person's expectations for confidentiality and advance care planning
 - how [consent](#) for decisions about medicines 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 it is agreed that more than one care provider is involved
 - when the medicines support will be reviewed, for example, after 6 weeks.
8. 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 the provider's care plan or sooner if there are changes in the person's circumstances, such as:
 - changes to their medicines regimen

- a concern is raised
- 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 care workers and other social care practitioners.

9. Social care providers should notify a person's general practice and [supplying pharmacy](#) when starting to provide [medicines support](#), including details of who to contact about their medicines (the person or a named contact).
10. 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 social care provider.
11. 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.
12. Health professionals should provide ongoing advice and support about a person's medicines and check if any changes or extra support may be helpful, for example, by checking if:
 - the person's medicines regimen can be simplified
 - information about [time-sensitive medicines](#) has been shared
 - 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.
13. 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:
 - there is local agreement between health and social care that this support will be provided by a care worker
 - 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 care worker is trained and assessed as competent (see also the section on [training and competency](#)).
14. Health professionals should continue to monitor and evaluate the safety and effectiveness of a person's medicines when medicines support is provided by a 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^b.

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.

15. When social care providers have responsibilities for [medicines support](#), they should have robust processes for communicating and sharing information about a person's medicines^a that take account of the person's expectations for confidentiality. This includes communication with:
 - the person and their family members or carers
 - care workers and other social care practitioners
 - health professionals, for example, the person's GP or [supplying pharmacist](#)
 - other agencies, for example, when care is shared or the person moves between care settings.
16. 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.
17. 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.
18. Prescribers should communicate changes to a person's medicines (for example, when stopping or starting a medicine) by:
 - informing the person or their named contact **and**
 - providing written instructions of the change or issuing a new prescription **and**
 - informing the person's supplying pharmacy, if this is needed and agreed with the person and/or their family members or carers.
19. When changes to a person's medicines need to be made verbally to avoid delays in treatment (for example, by telephone, video-link or online), prescribers should give written confirmation as soon as possible. Written confirmation should be sent by an agreed method, for example, a secure fax or secure email.
20. When social care providers have responsibilities for medicines support, they should have robust processes for handling changes to a person's medicines received verbally from a prescriber, including:
 - recording details of the requested change (including who requested the change, the date and time of the request, and who received the request)
 - reading back the information that has been recorded to the prescriber requesting the change to confirm it is correct (including spelling the name of the medicine)

^b 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.

- asking the prescriber requesting the change to repeat the request to someone else (for example, to the person and/or a family member or carer) whenever possible.

Ensuring that records are accurate and up to date

Poor record keeping can put people receiving medicines support and care workers at risk. Social 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.

21. When social care providers have responsibilities for [medicines support](#), they should have robust processes for recording a 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.
22. Care workers must record the medicines support given to a person for each individual medicine on every 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 30 on [raising concerns](#)).
23. Care workers should use a [medicines administration record](#) to record any medicines support that they give to a person. This should ideally be a printed record provided by the supplying pharmacist, dispensing doctor or social care provider (if they have the resources to produce them) (see also recommendation 58 on [supplying medicines administration records](#)).
24. When social care providers have responsibilities for medicines support, they should have robust processes to ensure that medicines administration records are accurate and up to date. For example, changes should only be made and checked by people who are trained and assessed as competent to do so (see also the section on [training and competency](#)).
25. Ensure that medicines administration records include:
 - the person's name, date of birth and any other available person-specific identifiers, such as the person's NHS number
 - 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 and any known drug allergies.

26. 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 [provider's 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 [medicines-related problems](#) effectively when they happen are important to minimise harm and guide future care.

27. When social care providers have responsibilities for [medicines support](#), they 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.
28. When social care providers have responsibilities for medicines support, they 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 care workers to report their concerns.
29. Social care commissioners and providers should review their medicines-related problems over a period of time to identify and address any trends that may have led to incidents. They should share this learning with:
- people working in the organisation
 - people receiving medicines support, their family members and carers
 - people working in related services, for example, GPs, [supplying pharmacies](#) and community health providers.
30. Care workers should raise any concerns about a person's medicines with the social care provider. 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](#) (including falls after changes to medicines; see the NICE guideline on [falls in older people](#))
 - the person stockpiling their medicines
 - [medication errors](#) or [near misses](#)
 - possible misuse or diversion of medicines
 - the person's [mental capacity](#) to make decisions about their medicines
 - changes to the person's physical or mental health.
31. 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.
32. Health and social care practitioners should encourage and support people and/or their family members or carers to raise any concerns about their medicines. They should explain how to 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 [provider's care plan](#).

- 33.** Health and social care providers should ensure that people and/or their family members or carers, and 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.

- 34.** Social care providers should have robust processes for care workers who are supporting people to take their medicines, including:
- the 6 rights (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](#).
- 35.** Care workers should only provide the [medicines support](#) that has been agreed and documented in the [provider's care plan](#).
- 36.** Prescribers, supplying pharmacists and dispensing doctors should provide clear written directions on the prescription and dispensing label on how each prescribed medicine should be taken or given, including:
- for time-sensitive medicines:
 - what the medicine is for
 - what dose should be taken
 - what time the dose should be taken, as agreed with the person
 - for 'when required' medicines:
 - what the medicine is for
 - what dose should be taken (avoiding variable doses unless the person or their family member or carer can direct the care worker)
 - the minimum time between doses
 - the maximum number of doses to be given (for example, in a 24-hour period).

37. Social care providers should record any additional information to help manage time-sensitive and 'when required' medicines in the provider's care plan.
38. Care workers should only give a medicine to a person if:
 - there is authorisation and clear instructions to give the medicine, for example on the dispensing label of a prescribed medicine **and**
 - the 6 R's of administration have been met (see also recommendation 34) **and**
 - they have been trained and assessed as competent to give the medicine (see also the section on [training and competency](#)).
39. Before supporting a person to take a dose of their medicine, care workers should ask the person if they have already taken the dose and check the written records to ensure that the dose has not already been given.
40. Care workers should ask the person if they are ready to take their medicine, before removing it from its packaging, unless this has been agreed and it is recorded in the provider's care plan.
41. Care workers should give medicines directly from the container they are supplied in. They should not leave doses out for a person to take later unless this has been agreed with the person after a risk assessment and it is recorded in the provider's care plan.
42. When a person declines to take a medicine, 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 30 and 31 on [raising concerns or seeking advice](#)).
43. [Supplying pharmacists](#) and dispensing doctors must supply a patient information leaflet for each medicine supplied, in line with [The Human Medicines Regulations 2012](#). This includes medicines supplied in [monitored dosage systems](#).
44. Social care providers 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.
45. Social care providers should ensure that 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)

Covert administration of medicines is when medicines are given in a disguised form without the knowledge or consent of the person receiving them.

46. Ensure that [covert administration](#) of medicines only takes place in accordance with the requirements of the [Mental Capacity Act 2005](#) and good practice frameworks ([Mental Capacity Act 2005: Code of Practice](#)) to protect both the person and care workers.
47. Care workers must not give, or make the decision to give, medicines by covert administration, unless there is clear authorisation and instructions to do this in the [provider's care plan](#), in line with the Mental Capacity Act 2005.
48. Ensure that the process for covert administration clearly defines who should be involved in, and responsible for, decision-making, including:

- assessing a person's [mental capacity](#) to make a specific decision about their medicines
- seeking advice from the prescriber about other options, for example, whether the medicine could be stopped
- holding a best interests meeting to agree whether giving medicines covertly is in the person's best interests
- recording any decisions and who was involved in decision-making
- agreeing where records of the decision are kept and who has access
- 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 provider's care plan
- ensuring care workers are trained and assessed as competent to give the medicine covertly (see also the section on [training and competency](#))
- when the decision to give medicines covertly will be reviewed.

Ordering and supplying medicines

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

49. Social 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 [provider's care plan](#). This should be the person, if they agree and are able to, with support from family members, carers or care workers (if needed).
50. When social care providers are responsible for ordering a person's medicines they must ensure that the correct amounts of the medicines are available when required, in line with Regulation 12 of [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#).
51. When social care providers are responsible for ordering a person's medicines they should not delegate this task to the [supplying pharmacist](#) (or another provider), unless this has been requested and agreed with the person and/or their family members or carers.
52. When social care providers are responsible for ordering a person's medicines they should ensure that 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 the section on [training and competency](#)).
53. When ordering a person's medicines, 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 the medicines ordered and those supplied.

54. Social care providers should ensure that care workers know what action to take if a discrepancy is noted between the medicines ordered and those supplied.
55. Supplying pharmacists and dispensing doctors should supply medicines in their [original packaging](#). They must make reasonable adjustments to the supplied packaging to help the person manage their medicines (for example, childproof tops), in line with the [Equality Act 2010](#).
56. Consider using a [monitored dosage system](#) only when an assessment by a health professional (for example, a pharmacist) has been carried out, in line with the Equality Act 2010, 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 social care provider in decision-making.
57. Supplying pharmacists and dispensing doctors should provide a description of the appearance of each individual medicine supplied in a monitored dosage system.
58. Supplying pharmacists and dispensing doctors should consider supplying printed [medicines administration records](#) for a person receiving [medicines support](#) from a social care provider (see also recommendation 23 on [record keeping](#)).
59. When social care providers have responsibilities for medicines support, they should have robust processes for managing [over-the-counter](#) medicines that are requested by a person, including:
 - seeking advice from a pharmacist or another health professional
 - 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.

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 it has been agreed that a social care provider is responsible, effective medicines management systems need to be in place.

60. 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 a social care provider is involved, carry out a risk assessment of transport arrangements.
61. 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 [provider's care plan](#).
62. When a person is assessed to be at risk because of unsecured access to their medicines, social care providers should agree with the person and/or their family members or carers whether secure home storage is needed, for example, in a lockable cupboard.
63. When social care providers are responsible for storing a person's medicines, they should have robust processes to ensure there is safe access to medicines, particularly for controlled drugs (for more information see NICE's guideline on [controlled drugs](#)). These should include:

- identifying who should have authorised access to the medicines
 - seeking advice from a health professional about how to store medicines safely, if needed
 - 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](#).
- 64.** When social 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 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 disposal of controlled drugs, needles and syringes
 - what information needs to be recorded, 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

Appropriate training, support and competency assessment for managing medicines is essential to ensure the safety, quality and consistency of care.

- 65.** When social care providers are responsible for [medicines support](#), they should have robust processes for medicines-related training and competency assessment for care workers, to ensure that they:
- 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 assessment through direct observation
 - have an annual review of their knowledge, skills and competencies.
- 66.** 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 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 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 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 social care

The Department of Health's [Care and support statutory guidance](#) (2016), 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 [NMH DU 2010) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008)) (see section 3.3.3 and appendix F).

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.

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.	<ul style="list-style-type: none"> 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: <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls. </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> key learning points frequently asked questions reference material and resources. </td> </tr> </table>	<ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls. 	<ul style="list-style-type: none"> key learning points frequently asked questions reference material and resources. 	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems) 	Very low quality
<ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls. 	<ul style="list-style-type: none"> key learning points frequently asked questions reference material and resources. 					
National Mental Health Development Unit (2010) UK	Medicines management for people with mental health crisis	Key areas: <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
		<ul style="list-style-type: none"> • 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 care provider, although if the assessment is complex the 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 10.3).

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 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 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 under the [Equality Act 2010](#).

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 NMH DU (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, NMH DU 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 related risks should be assessed.

Moderate quality evidence from guidance recommends that care providers 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 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	<p>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:</p> <ul style="list-style-type: none">• service user-reported outcomes• carer-reported outcomes• medicines-related problems• health and social care utilisation. <p>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 support 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</p>
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	<p>do, or might be able to do, in terms of managing or taking their medicines themselves, with appropriate support if needed.</p> <p>The Committee concluded that most adults receiving social care will take responsibility for managing their own medicines, although an assessment may identify areas in where support is needed, for example through a medication review (see the NICE guideline on medicines optimisation [NG5]).</p>
<p>Trade-off between benefits and harms</p>	<p>Policies and processes for medicines assessment</p> <p>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 reflect their preferences, social care commissioners and care providers should have policies and processes in place for assessing medicines-related needs and risk.</p> <p>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.</p> <p>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.</p> <p>Carrying out a medicines assessment</p> <p>The Committee heard that many initial (first contact) assessments for social care support are undertaken by social workers or social work assistants who have minimal or no training in medicines and may not have 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, which may lead to inadequate support in relation to medicines.</p> <p>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 needs help and support with their medicines, without having an in depth understanding of medicines.</p> <p>The Committee agreed that social workers and social work assistants undertaking the initial assessment could consider asking the following questions about medicines:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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 a care provider.

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 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 care provider ([self-funding](#)), the provider should ask adequate questions to ensure that medicines support needs are identified.

The Committee was aware that if a person qualifies for social care and support, a 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, in line with legislation (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014). 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 medicine support needs. The Committee agreed that care providers should support individuals to understand choices about their care such as who should be involved in the medicines assessment process.

The Committee agreed that in many cases adequate assessment of a person's medicines support needs 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 [supplying pharmacist](#),

community nursing services or other 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 supplying pharmacist (see section 6.3).

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 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 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, NMH DU 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 person's medicines (a named person) recorded in the 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

	<p>The Committee discussed and agreed that in line with legislation, care providers must make and keep records of all medicines assessments in the care plan and the record should include the agreed amount of support for each medicine and the responsibilities of the care worker (see section 9.5).</p> <p>The Committee concluded that care providers should record the discussions and decisions about what medicines support (if any) will be provided for each medicine in the care plan, including:</p> <ul style="list-style-type: none"> • 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. <p>Reviewing medicines assessments</p> <p>The Committee was aware that most funded social care undergoes a process where the 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 CQC.</p> <p>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:</p> <ul style="list-style-type: none"> • 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). <p>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 care workers are alert to, and report changes:</p> <ul style="list-style-type: none"> • 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).
<p>Trade-off between net health benefit and resource use</p>	<p>No economic evidence was identified. No resource impacts were identified for the recommendations in this section.</p>
<p>Quality of evidence</p>	<p>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.</p>

Evidence was obtained from professional guidelines to support social care (HLIN 2008, NMHJU 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 8

Recommendation 56

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 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. 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 care provider and the care manager are jointly responsible for the safe and appropriate handling of medicines (RPS 2007) (see section 10.3).

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

The guideline 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) (see section 3.3.3 and appendix F).

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) <i>UK</i>	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.	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems) 	Moderate quality
Housing Learning and Improvement Network (2008) <i>UK</i>	Specialist housing for older people where care services are provided or facilitated ²	<p>Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas:</p> <ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls key learning points frequently asked questions reference material and resources. 	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems) 	Very low quality
National Mental Health Development Unit (2010) <i>UK</i>	Medicines management for people with mental health crisis	<p>Key areas:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Those in crisis being maintained in their own community Improved coping Reduced stigma 	Low quality
Royal Pharmaceutical Society (2007) <i>UK</i>	People who receive social care	<p>Key areas:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
		<ul style="list-style-type: none"> • 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 care worker is required to undertake (HLIN 2008) (see section 10.3).

6.3.1.2 Ordering medicines

Evidence suggests that it is not usually appropriate for care workers to influence how the person chooses to obtain their medicines (RPS 2007, HLIN 2008). However, the 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 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 10.3).

The 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 care provider is responsible for ordering a person’s medicines, this should be done by the 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 care manager to ensure that there is a system in place to obtain medicines in a reasonable time frame (RPS 2007) (see section 10.3).

Appropriate systems and processes need to be in place when a 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 care provider receives a request to change treatment over the telephone and not in writing (a verbal order). The care provider should have processes in place to clearly communicate and document any such changes (RPS 2007) (see section 9.3).

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 care provider makes sure that unwanted medicines are disposed of safely (see section 6.3).

The service provider 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. Poor and delayed access to appropriate medicines may exacerbate a health problem and reduce the possibility of successful home treatment (NMH DU 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 NMH DU 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 NMH DU 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 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 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 care provider is responsible
- a 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 to 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 10.3).

When a care provider is responsible for medicines storage, appropriate storage facilities (such as a medicines cupboard(s)) that meets national standards for safe and secure handling of medicines are needed (RPS 2007, NMHJU 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):
 - 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 people's 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 care workers know which medicines need to be kept in a fridge (this is stated on the [patient information leaflet](#) supplied with a medicine). Care workers should check that the person's fridge appears to be working correctly if there are medicines stored in it.

When a 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 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 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 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 care worker to buy or administer an over-the-counter medicine (HLIN 2008). The care provider may have responsibility for making this decision, for example if the person is unable to make the choice (RPS 2007, HLIN 2008).

Care providers should have policies and processes in place for 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 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 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 9.3).

6.3.1.8 Training and competency

Care workers who are supporting people with their medicines 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, NMH DU 2010) (see section 10.3).

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, 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 care providers with implementing legislation and other guidance (low quality) suggests that 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 care worker prompts, provides support or acts on behalf of a person receiving care.

Guidance from the CQC to support 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 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 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

<p>Relative values of different outcomes</p>	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>Other outcomes identified by the Committee considered important for decision-making, but not critical:</p> <ul style="list-style-type: none"> • 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. <p>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).</p>
<p>Trade-off between benefits and harms</p>	<p>Policies for the safe handling of medicines</p> <p>The Committee discussed and agreed that in line with the NICE home care [NG21] guideline recommendations care providers should have a policy for managing medicines.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 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 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 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 discussed how poor arrangements for ordering medicines can lead to medicines being lost, supplies running out or over ordering, potentially leading to stockpiling and waste.

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 care provider should agree the medicines-related support needs for ordering medicines with the person and document this in the 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 care worker). Additionally, care providers that are responsible for ordering a person's medicines should not delegate this task to the supplying pharmacist (or other provider), unless this has been agreed with the person and/or their family members or carers.

The Committee concluded that care providers should ensure that 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.

The Committee agreed that the care provider should ensure that 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 discussed the evidence from guidance (RPS 2007) and concluded that where care staff are responsible for ordering and checking the supply of medicines to the person's 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 care providers should have a process for care staff to follow if a discrepancy is noted (for example checking with the prescriber or supplying pharmacist before supporting the person to take their medicine).

The Committee agreed that where a care provider is responsible for helping a person to take their medicines, the supplying pharmacist or dispensing doctor 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 supplying medicines to people in their own homes:

- [original packaging](#)
- 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 packaging can cause problems with the stability of some medicines. Monitored dosage systems can also cause problems for care staff when a specific medicine is declined or stopped (as there can be difficulties identifying which medicine it is) and if a tablet is dropped on the floor there is no replacement. The Committee concluded that a description of each individual medicine should be provided by the supplying pharmacist or dispensing doctor for each individual medicine contained within the system to help address this issue.

The Committee was aware that the dispensing label on original packaging is the authority to administer each medicine. However, the labels or directions for each medicine supplied in monitored dosage systems is not always clear. In some cases, the Committee were aware that non-pharmacy supplied compliance aids do not appropriately labelled.

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. The use of monitored dosage systems should be considered following an individual assessment of the person's needs.

The Committee concluded that supplying pharmacists or dispensing doctors should supply medicines in original packaging and make reasonable adjustments to the supplied packaging, in line with legislation (the [Equality Act 2010](#)). For example, supplying containers with child proof tops instead of click-lock tops. 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 agreed that the person receiving care and/or their family members or carers and the care provider should

be involved in decision-making and the person's needs and preferences should be taken into account.

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 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 care workers.

The Committee agreed that when care providers are responsible for transporting medicines they may need to carry out a risk assessment, for example to assess the need for temperature control or the risk of diversion (see the NICE guideline on [controlled drugs](#) [NG46]).

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 care workers if needed.

The Committee concluded that the arrangements for the storage of a person's medicine should be agreed with the person and recorded in the care plan. When it is agreed that a 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. See the NICE guideline on controlled drugs NG46 for information on the storage of controlled drugs.

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 care providers should take advice from health professionals on appropriate storage. 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 is needed, for example in a lockable cupboard.

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) and agreed that where the care provider is responsible for the storage of refrigerated medicine, they should consider how the medicine

will be stored in the fridge (for example a separate space or container within the fridge) and how this will be monitored

The Committee concluded that 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.

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](#). 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.

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 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.

	<p>Handling over-the-counter medicines</p> <p>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 care record or care plan.</p> <p>The Committee heard that problems with over-the-counter medicines can occur when:</p> <ul style="list-style-type: none"> • 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 • care workers are unaware of the need to record the support given for taking over-the-counter medicines. <p>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.</p> <p>The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) suggesting that 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 care workers who are not medically trained to make such choices. The Committee agreed that 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. Care workers should advise the person to seek advice from a health professional if needed.</p> <p>The Committee concluded that the care provider should have robust processes in place for care workers on:</p> <ul style="list-style-type: none"> • when to seek advice from a health professional • 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.
<p>Trade-off between net health benefit and resource use</p>	<p>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.</p> <p>No other resource implications were identified from the recommendations made in this evidence review.</p>
<p>Quality of evidence</p>	<p>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 4). No clinical studies were identified by the literature searches that were subsequently included as evidence for this review question.</p> <p>Evidence was obtained from professional guidelines to support social care (HLIN 2008, NMH DU 2010 and RPS 2007) and one guideline (CQC 2015) that supports provider compliance with regulation (Health</p>

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

Recommendation 21

Recommendation 43

Recommendations 49 to 64

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

The guideline 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).

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 (see section 3.3.3 and appendix F). 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 and 1 research briefing were found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008, 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) <i>UK</i>	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) <i>UK</i>	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: <ul style="list-style-type: none"> • 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) <i>UK</i>	Medicines management for people with mental health crisis.	This document covers: <ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Those in crisis being maintained in their own community • Improved coping • Reduced stigma 	Low quality
Royal Pharmaceutical Society (2007) <i>UK</i>	People who receive social care.	This guidance has recommendations covering: <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Principles of safe and appropriate handling of medicines (medicines-related problems) • A guide to good practice and current legislation 	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality of guideline (AGREE II)
		<ul style="list-style-type: none"> • Policies, procedures, systems and devices 'medicines toolkit'. 	governing the handling of 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) <i>UK</i>	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 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 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 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 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 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 offer 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).

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 (NMH DU 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 NMH DU (2010) also identified that during a mental health crisis the responsibility for the administration of medicines may need to be taken over by the 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 9.3). 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 care worker assists them to self-administer.

The HLIN (2008) guidance recommends that an organisation’s medicines policy should record whether the care provider allows its care workers to support medicines administration, and if so which medicines a care worker is able to administer following appropriate training (see section 10.3).

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 5.3).

The RPS (2007) guidance states that the ‘level of support and resulting responsibility of the care worker should be written in the care plan for each person’ (see [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 5.3 and 9.3).

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 child 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 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 Care workers giving medicines to people

The HLIN (2008) guidance recognises that sometimes people may require their medicines to be administered by a 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 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 NMH DU (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 5.3)
- 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 6.3)
- 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 NMH DU (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

Care workers should be trained and competent if they are responsible for managing and administering medicines (CQC 2015, RPS 2007) (see section 10.3).

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 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 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 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 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, care providers must have a policy on the administration of medicines. Low quality evidence suggests this should be a written policy which covers administration and self-administration. Care workers' adherence to the policy should be monitored.

In order to comply with legislation, care workers must 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 declines to give consent a care worker should wait a short time and ask again. If the medicine is still declined, advice from a healthcare professional should be sought.

In order to comply with legislation, if a 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 must act in accordance with the requirements of the Mental Capacity Act 2005.

In order to comply with legislation, care providers must make reasonable adjustments to support a person to manage their own medicines. Low quality evidence suggests that 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 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 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 must 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 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 of different outcomes	<p>The Committee discussed the relative importance all of the outcomes agreed for this review question (see Appendix C.2.3) and agreed that the following outcomes were of critical importance:</p> <ul style="list-style-type: none">• service user-reported outcomes• carer-reported outcomes• medicines-related problems• health and social care utilisation.
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	<p>Other outcomes identified by the Committee considered important for decision-making, but not critical:</p> <ul style="list-style-type: none"> • 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. <p>No evidence measuring specific outcomes were identified by the literature search.</p>
<p>Trade-off between benefits and harms</p>	<p>Policies for supporting people to take their medicines</p> <p>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 care providers have policies and processes in place for administering medicines in line with current legislation and guidance. The Committee agreed this should include what support care workers are allowed to give when helping people to take their medicines, including ‘when required’, time sensitive and over-the-counter medicines</p> <p>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).</p> <p>Agreeing and recording medicines support</p> <p>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 for medicines support (see section 5.5).</p> <p>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 care provider should agree the type of support that will be provided for each medicine and this agreement should be recorded in the care plan (see also section 5.5).</p> <p>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.</p> <p>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.</p> <p>The Committee concluded that 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:</p>

- 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 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 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 care workers.

The Committee considered the evidence from the RPS (2007) document and agreed that it would be best practice for 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 declines the medicine. However, the Committee were mindful that a person being repeatedly asked if they wished to take their medicine may be frustrating and so an agreement about when to ask may need to be documented in the person's care plan.

The Committee discussed what action a care worker should take when a person receiving care declines a medicine. The Committee agreed that if a person declines a prescribed medicine, care workers should wait a few minutes before offering it again. The Committee concluded that care workers should consider asking 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 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 care worker has, as part of the agreed plan of care, a responsibility for supporting a person with their medicines then any declined medicine should be recorded. Any continued declining of the medicine should be reported to the care worker's manager. The Committee concluded that care providers should have procedures in place for reporting continued declining of medicines to the prescriber. The Committee agreed that this should not be the role of the 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).

The Committee discussed the support that can be offered by health professionals to ensure that medicines are taken as intended. They agreed that they should provide advice and offer support when needed, 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 care workers to have access to information about the medicines within the monitored dosage systems (see also section 6.3).

The Committee agreed that medicines should only be given from the container they are supplied in (see also section 6.3) and never given from devices that are filled by the person's friends or family members.

Leaving medicines out to be taken later

The Committee discussed whether it was acceptable for doses to be left out for a person to take later. The Committee agreed that this would not be normal practice in health care but was accepted practice in social care, due to a need for medicines to be given outside of arranged visit times, as supported by RPS guidance (2007). The Committee agreed that doses should not be left out for a person receiving care to take later, unless this has been risk assessed and agreed with them as part of their care plan.

Care workers supporting people to take their medicines

The Committee discussed the evidence from guidance (RPS 2007, HLIN 2008) and concluded that care providers should have robust processes for 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) care workers must be trained and assessed as competent by the service provider before giving any medicines. Additionally, care workers should only give a medicine when there is a clearly documented agreement to do so in the care plan and there is authorisation and clear instructions about how the medicine should be used (for example, on the label of a prescribed medicine), and the 6 R's of administration have been met.

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](#) [2010] 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 care providers should have policies and procedures in place to allow care workers to prioritise visits for people requiring support with [time-sensitive](#) medicines.

The Committee also discussed that care providers medicines policy should include policies and procedures for 'when required' medicines. The Committee discussed the difficulty of a care worker knowing when to give 'when required' medicines and what for (indication) as often these are not recorded for the care worker, this can be especially difficult when the person receiving care has difficulty communicating their wishes.

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 care provider should ensure that any additional information needed to ensure that the medicines are given as intended should be recorded in the person's care plan. The prescriber and supplying pharmacy (or dispensing doctor) should provide clear written directions on the prescription and dispensing label on how each medicine should be given.

The information recorded should include (where relevant):

- what the medicine is to be taken for
- when the dose should be offered
- what the dose should be (avoiding variable doses unless the person can direct the 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 care workers (for example, information on [adverse effects](#) 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.

The Committee also agreed that, in line with legislation ([The Human Medicines Regulations 2012](#)), supplying pharmacists and dispensing doctors must ensure that a patient information leaflet is supplied for each medicine dispensed, this includes when medicines are 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 care worker. The Committee agreed that where this happens this should be recorded and communicated with the 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 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](#). 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 care providers should have policies and processes in place regarding the covert administration of medicines. The Committee were aware that in many cases covert administration of medicines is a breach of a medicines product license and so the opinion of a pharmacist should be sought.

The Committee discussed the context in which a 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 has been assessed in line with the [Mental Capacity Act 2005](#) and [Mental Capacity Act Code of Practice](#) and has been found to lack the mental capacity to make a specific decision about the medicine themselves, and
- the prescriber has determined that the medicine is clinically needed and has taken steps to ensure that the person has been assessed in line with the requirements of the [Mental Capacity Act 2005, and](#)
- 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).

The Committee discussed their experience from practice and recognised that care workers must not give, or make a decision to give medicines covertly, unless there is explicit authorisation and instructions in the care plan, in line with the Mental Capacity Act 2005.

The Committee concluded that health professionals, care providers and 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 care workers administering the medicine, as covert administration may represent a deprivation of liberty. See [Deprivation of Liberty Safeguards \(DoLS\) at a glance](#), Social Care Institute for Excellence (2015).

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:

- assessing a person's mental capacity to make a specific decision about their medicines
- seeking advice from the prescriber about other options, for example, whether the medicine could be stopped
- holding a best interests meeting to agree whether giving medicines covertly is in the person's best interests
- recording any decisions and who was involved in decision-making

	<ul style="list-style-type: none"> • agreeing where records of the decision are kept and who is able to have access • planning how medicines will be given covertly, for example, by seeking advice from a pharmacist • providing authorisation and clear instructions for care workers in the person's care plan • ensuring care workers are trained and assessed as competent to give the medicine covertly (see also recommendation 65 on training and competency) • when the decision to give medicines covertly will be reviewed.
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	<p>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.</p> <p>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.</p> <p>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.</p>

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

Recommendation 7

Recommendation 11 to 12

Recommendation 22 to 27

Recommendations 34 to 47

Recommendation 56

Recommendation 65

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 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 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 4 classes of medicines (antithrombotics, anticoagulants, non-steroidal anti-inflammatory drugs [NSAIDs] and diuretics) were associated with around half of preventable hospital admission (Howard RL et al., 2007). The 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 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 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 the person declining 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 [NMH DU 2010]) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008) (see section 3.3.3 and appendix F).

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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls key learning points frequently asked questions reference material and resources. 	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> the principles that underpin safe handling of medicines in every social care setting 	<ul style="list-style-type: none"> 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)
		<ul style="list-style-type: none"> 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'. 	<ul style="list-style-type: none"> 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)				

Table 10: Summary of included studies

Study	Study type	Population	Intervention	Comparison	Key critical and important outcomes
Bonugli (2014) <i>USA</i>	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	<ul style="list-style-type: none"> Service user-reported outcomes Carer-reported outcomes Medicines-related problems
Sino (2013) <i>Netherlands</i>	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.	<ul style="list-style-type: none"> 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 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,
- care workers follow those procedures
- 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 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, 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 care provider) and to any relevant external authorities or body.

The RPS (2007) and HLIN (2008) advises care providers should have a clear incident reporting system with serious incidents being reported the regulatory authority. Additionally the RPS suggests that 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 care providers should not ignore medicines problems but should encourage an open culture for reporting medicines problems that allows 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) states that care providers should have systems in place for investigating incidents involving medicines-related problems, and for ensuring that staff are competent to:

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

The RPS (2007) advises that 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 care providers should decide whether they need to offer training to an individual or review existing procedures following incidents.

Evidence from HLIN (2008) suggests that 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 care providers should have policies and procedures in place for 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 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 5.3).

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 care workers and people receiving care or someone acting on their behalf to raise a concern about medicines.

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

Low quality evidence suggests that 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 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 care providers with 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 care providers should have a clear system or process for reporting medicines-related problems within their organisation. Care providers should have a process for reporting incidents to external authorities when required. Low quality evidence suggests that care providers should encourage an open culture of reporting by staff.

Moderate quality evidence from a guideline recommends that 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 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 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

<p>Relative values of different outcomes</p>	<p>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 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:</p> <ul style="list-style-type: none"> • 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). <p>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:</p> <ul style="list-style-type: none"> • service user-reported outcomes • carer-reported outcomes • health and social care practitioner-reported outcomes • medicines-related problems • health and social care utilisation.
<p>Trade-off between benefits and harms</p>	<p>Policy and processes for raising concerns about medicines-related problems</p> <p>The Committee was aware that sometimes medicines-related problems are not reported by care workers due to fear of being blamed for mistakes or accused of poor care. The Committee agreed that care providers should promote a fair blame culture to encourage open reporting and investigation of medicines-related problems.</p> <p>The Committee concluded that 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:</p> <ul style="list-style-type: none"> • raising concerns about a person's medicines • safeguarding people from medicines-related harm. <p>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.</p> <p>Raising concerns about medicines-related problems</p> <p>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,</p>

complain or give feedback about medicines-related issues as care providers systems for doing so can be unclear.

Furthermore, the Committee discussed the importance of 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 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 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 care workers know how to report adverse effects of medicines, including the using the MHRA [Yellow Card Scheme](#).

The Committee recognised that care workers have an important role in identifying medicines-related problems. Care providers should encourage care workers to raise concerns about medicines, although the Committee was mindful that often care workers do not have the prerequisite knowledge to answer questions about a person's medicines. The Committee concluded that 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 care workers often encounter such as people becoming unwell or having fluctuating capacity to make decisions about their medicines. The Committee agreed that care workers should be vigilant as to the physical or mental condition of the individual and report changes to their line manager or employer (care provider).

The Committee concluded that care workers should raise any concerns about a person's medicines to their care provider. These concerns may include:

- the person declining to take their medicine
- medicines not being taken in accordance with the prescribers instructions
- possible adverse effects, including falls after changes to medicines
- 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 also concluded that a medicines-related concern may be a prompt or trigger for a reassessment of a person's need and preferences for care (see section 5.5).

The Committee discussed the need for care workers to be mindful of consent and the person's expectations for confidentiality when raising concerns about medicines. The Committee concluded that 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).

	<p>Reviewing and learning from medicines-related problems</p> <p>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 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.</p> <p>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 care staff or other relevant stakeholders in order to prevent similar occurrences in future.</p> <p>They also discussed and agreed that home care commissioners and providers should review their 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:</p> <ul style="list-style-type: none"> • people in the organisation • people receiving medicines support, their family members and carers • people working in related services, for example, GPs, supplying pharmacists and community health providers. <p>Helping to keep people safe from medicines-related harm (safeguarding)</p> <p>The Committee agreed that care providers and 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)).</p> <p>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].</p>
<p>Trade-off between net health benefit and resource use</p>	<p>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.</p>
<p>Quality of evidence</p>	<p>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]) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008).</p> <p>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).</p>

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

Recommendation 12

Recommendation 16

Recommendation 22

Recommendations 27 to 33

Recommendation 42

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

Care providers 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 (NMH DU 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 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 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 [NMH DU] 2010) and 1 guideline was found to be of very low quality (Housing Learning and Improvement Network [HLIN] 2008) (see section 3.3.3 and appendix F).

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) <i>UK</i>	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.	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems). 	Moderate quality
Housing Learning and Improvement Network (2008) <i>UK</i>	Specialist housing for older people where care services are provided or facilitated ²	<p>Aimed at practitioners, commissioners, care services managers and housing managers in extra care housing. Key areas:</p> <ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls key learning points frequently asked questions reference material and resources. 	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems). 	Very low quality
National Mental Health Development Unit (2010) <i>UK</i>	Medicines management for people with mental health crisis	<p>Key areas:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Those in crisis being maintained in their own community Improved coping Reduced stigma 	Low quality
Royal Pharmaceutical Society (2007) <i>UK</i>	People who receive social care	<p>Key areas:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems) 	Low quality

Evidence source	Population	Recommendations / key areas covered	Key aims and objectives	Quality assessment (AGREE II)
		<ul style="list-style-type: none"> • policies, procedures, systems and devices 'medicines toolkit'. 	<ul style="list-style-type: none"> • 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)

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, information sharing 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 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 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 care workers, 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 care provider is responsible for managing their medicines, the care worker should make a record of the medicines that were sent with them. 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 care worker.

Evidence (RPS 2007) also suggests that when 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 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.

Care workers obtaining advice from a health professional

Evidence from guidance (RPS 2007) suggests that one of the principles of safe and appropriate handling of medicines in social care is that social care services and 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.

Care workers receiving and recording verbal changes to medicines (remote prescribing)

Evidence from the RPS (2007) suggests that 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 care worker or a carer).

The RPS (2007) recommend that 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 care worker took the telephone call
- the time of the call
- the name of the person who called.

9.3.1.3 Medicines-related record keeping

Evidence from guidance (RPS 2007) states that the purpose of keeping records of medicines is so that care staff know which medicines each person is taking and the care provider has a complete account of medicines. Evidence from guidance (RPS 2007) suggests that 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 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, 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 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, NMH DU 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 care worker will provide.

Records for ordering and transporting medicines

Evidence from guidance (RPS 2007) suggests that when 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 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 also section 6.3 about ordering and transporting medicines).

Records for giving people, or reminding them take, medicines

Evidence from guidance (RPS 2007) suggests that 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 care worker is only responsible for ordering the medicines).

(See also section 7.3 about administering medicines).

Records for the disposal of medicines

Evidence from guidance (HLIN 2008 and RPS 2007) suggests that when 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 care worker who arranges for the disposal of the medicines.

(See also section 6.3 about 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 care workers give medicines, they must have a medicines administration record to refer to.

Evidence from guidance (NMH DU 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 (NMH DU 2010, H LIN 2008 and RPS 2007) suggests that when 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 care worker
- receipt or disposal of medicines.

Evidence from guidance (RPS 2007) advises care providers that if they use hand-written medicines administration records (as opposed to printed one provided by a pharmacy or GP practice) 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 care provider, although a pharmacist or dispensing doctor may be prepared to provide them on request.

Staff training and assessment of competency

Evidence from guidance (H LIN 2008 and RPS 2007) recommends that staff training on communication should include record-keeping and confidentiality (see section 10.3)

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)
- care workers being tactful and sensitive (for example, always discreetly discussing bowel and bladder function).

Evidence from guidance (NMH DU 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

Very low to moderate and low quality evidence from guidance recommends that a care provider's medicines policy includes processes for:

- communication between care workers and other agencies

- verbal orders for prescribed medicines
- record keeping.

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

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

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

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

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

Very low to low quality evidence from guidance suggests that 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 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

<p>Relative values of different outcomes</p>	<p>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:</p> <ul style="list-style-type: none"> • service user-reported outcomes • health and social care practitioner-reported outcomes • medicines-related problems • health and social care utilisation. <p>No studies were identified by the literature search for this review questions which included these outcomes.</p>
<p>Trade-off between benefits and harms</p>	<p>Policies for communication and record keeping</p> <p>The Committee discussed the evidence from guidance and agreed that home 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:</p> <ul style="list-style-type: none"> • the person and their family members or carers • 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 care providers should have robust processes for keeping medicines-related records, 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](#)).

Care providers recording a person's medicines

The Committee discussed the evidence from guidance (RPS 2007) that suggests that care workers need to know what medicines a person is taking if it has been agreed that they are not responsible for supporting the person with their medicines. The Committee discussed the practical problems of 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 record of the person's medicines. The Committee also agreed that there were benefits to this record being maintained in the care plan. 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 person (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 care worker to know what medicines they are taking
- a one off recording in the person's care plan setting out the medicines a person is taking is likely to become out of date.

The Committee concluded that care providers are not expected to make and maintain records of a person's medicines where medicines support is not being provided. When medicines support is provided, 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 and are accessible (in line with the person's expectations for confidentiality).

Communication between care providers

The Committee discussed from their experience the need for better communication between care providers for people receiving medicines support. The Committee identified that gaps in communication about medicines present difficulties and potential safety issues, particularly between social care providers, general practice and the supplying 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 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 supplying pharmacist were often unaware that a person had started to receive support with their medicines from a care provider. Additionally, they were often unaware that the assessment of their medicines support needs 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 social care provider, this would facilitate communication when, for example, medicines were started, changed or stopped.

The Committee concluded that social care providers should notify a person's general practice and supplying pharmacist, 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 social care provider.

The Committee was aware from experience that problems can occur when changes to prescriptions are made by the prescriber when people involved in the person's care are not present and are not informed. For example, the home For example, the person receiving care may be unable to pass on information regarding the change (for example, due to poor memory or fluctuating capacity) to their family members or carers or a care worker. The Committee concluded that in such circumstances the prescriber should communicate any changes to the person's medicines by:

- informing the person or the named contact and
- providing written instructions of the change or issuing a new prescription and
- informing the person's supplying pharmacist, if this is needed and 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 care providers 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 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.

Remote prescribing 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 by remote prescribing (for example, by telephone, video-link or online) to a person's prescription including:

- an increased risk of medication errors
- poor audit trail for changes that have been requested.

The Committee also recognised that there is a need for care workers to follow direct instructions from a prescriber, rather than relying on information that has been communicated by a third party, due to the risk of recording error.

The Committee discussed and agreed that the preferred arrangement for any change to a prescription is for written confirmation of the change to be made by the prescriber as soon as possible. The Committee discussed whether a time limit needed to be specified, for example, within 48 or 72 hours. However, they agreed that it should be based upon the need to enable medicines to continue to be given safely. For example, written confirmation of a change may be needed sooner if repeat doses need to be given the same day or may not be needed for a few days if the medicine is taken once weekly.

The Committee agreed that remote prescribing changes should be made only if a delay in notifying the person or care provider of the change (for example, to allow a new written prescription), would result in unsafe care.

The Committee concluded that care providers should have robust processes for receiving, recording and acting on verbal requests to change a person's medicines by remote prescribing, including:

- recording details of the requested change (including who requested the change, the date and time of the request and who received the request)
- reading back the information that has been recorded to the person requesting a change to confirm it is correct (including spelling the name of the medicine)
- the person requesting a change repeats the request to another person wherever possible (for example, the person and/or a family member or carer).

The Committee also concluded that prescribers should follow-up any changes to a person's medicines by remote prescribing 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 handling medicines

The Committee discussed the evidence from guidance (RPS 2007) and agreed that when a 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 care providers already document all care given and some care providers only document when they have given a medicine.

The Committee discussed legislation (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 17) which requires care providers to 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 care workers and its production and the requirement to ensure it is an accurate, complete and contemporaneous record is the responsibility of the care provider. The Committee discussed the evidence and their personal experience of care workers using medicines administration records at length.

The Committee noted that a recommendation for widespread use of medicines administration records would represent a change in practice for some 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 care providers. The Committee concluded that care workers should ideally use a printed medicines administration record to record any medicines given to a person.

The Committee discussed and agreed that because of the limited training and time that care workers have to produce a medicines administration record, it would be safer to use a centrally printed record. This may be produced by the supplying pharmacist, dispensing doctor, hospital pharmacies or the care provider themselves (if they have the resources to produce them). The Committee was aware that the producer would only be able to include those medicines that they are prescribing, supplying or giving 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 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 need to complete 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 care worker is not, for example, giving a duplicate dose.

The Committee discussed what information should be included on the medicines administration record. The Committee were aware of the need for a number of ways of identifying the person (name and date of birth) and also agreed that it would be useful to have the person's NHS number (for example, when contacting the pharmacy with a concern it can facilitate access to the summary care record). However, the Committee recognised that in practice that care providers may not always have access to the NHS number (this requires information sharing from the NHS and agreement from the person). The Committee agreed that a medicines administration record should contain:

- the name and date of birth of the person and any additional person specific identifier such as the person's NHS number
- 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 contact details of the person's GP practice
- any stop or review date
- any additional information, such as specific instructions for administration and any known drug allergy.

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.

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).

	<p>The Committee agreed that for the safe disposal and record keeping of controlled drugs, care providers should follow the recommendations in the NICE guideline on controlled drugs [NG46].</p> <p>The Committee concluded that when 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.</p>
Trade-off between net health benefit and resource use	<p>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 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, this may not 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 care providers.</p> <p>No other recommendations made for this review question were thought to have significant resource implications.</p>
Quality of evidence	<p>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]).</p>

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 to 2

Recommendations 5 to 7

Recommendations 9 to 24

Recommendation 58

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

The [Care Certificate](#) contains a set of minimum standards that should be covered during the induction training for new care workers, although it is also open to existing 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 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 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 [NMH DU] 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) (see section 3.3.3 and appendix F). No evidence was found for what approaches are effective for multi-agency coordination of medicines-related support or monitoring and evaluating medicines-related support.

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) <i>UK</i>	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.	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems). 	Moderate quality
Department of Health (2016) <i>UK</i>	Local authorities to support the implementation of the Care Act (2014)	Key areas: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Compliance with the requirement of the Care Act 2014. 	Moderate quality
Housing Learning and Improvement Network (2008) <i>UK</i>	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: <ul style="list-style-type: none"> guidance and best practice recommendations additional medication considerations dangers and pitfalls key learning points frequently asked questions reference material and resources. 	<ul style="list-style-type: none"> Principles of safe and appropriate handling of medicines (medicines-related problems). 	Very low quality
National Mental Health Development Unit (2010) <i>UK</i>	Medicines management for people with mental health crisis	Key areas: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
		<ul style="list-style-type: none"> a model framework for better medicines management on by crisis intervention and home treatment teams. 		
Northern Ireland Social Care Council Guidance (2013) <i>UK</i>	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.	<ul style="list-style-type: none"> Honesty, trust and confidence Safeguarding Risk management Records management 	Low quality
Royal Pharmaceutical Society (2007) <i>UK</i>	People who receive social care	Key areas: <ul style="list-style-type: none"> 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'. 	<ul style="list-style-type: none"> 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) <i>Scotland</i>	Care at home	National care standards for those receiving care at home, Key areas: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 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 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 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 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, 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 also section 5.3 about 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 care providers 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 also section 6.3 about ordering and supplying medicines).

The [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#) regulation 17, on good governance, requires 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 also section 9.3 about record keeping).

10.3.1.2 Roles and responsibilities for care workers

Evidence from guidance (Scottish Government 2005) suggests that 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 medicines.
- (See also section 5.3 about person-centred medicines assessment).

Evidence from guidance (NISCC 2014) suggests that 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 also section 7.3 about administering medicines and section 8.3 about medicines-related problems).

Evidence from guidance (NISCC 2014, NMHDU 2010 and Scottish Government 2005) suggests that 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 also section 8.3 about 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 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 also section 5.3.1 about 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:

- social care providers work actively with other providers to ensure that care and treatment is safe for people using services (see also section 8.3 about medicines-related problems)
- social care providers 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 also section 9.3)

- 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 care workers is particularly important when specific skills are needed for care workers to give a medicine (when this has been agreed), for example:

- medicines as suppositories or enemas
- injections
- medicines through a nasogastric 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 care worker and:

- the person has consented to the 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 assessment of competency**

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

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 care providers have sufficient numbers of staff who are suitably qualified, competent, skilled and experienced. 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 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 care workers, in line with their work if this is appropriate.

Where further training is required, evidence from guidance (CQC 2015) recommends that care providers support 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 care providers should actively encourage 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 care providers employing new care workers should follow the [Care Certificate](#) standards to make sure they are supported, skilled and assessed as competent to carry out their roles.

Care provider responsibilities for assessment of skills and competency

Evidence from guidance (CQC 2015, HLIN 2008 and RPS 2007) recommends that 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 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 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.

Care worker responsibilities for training and competency

Evidence from guidance (RPS 2007 and Scottish Government 2005) suggests that 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 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 care workers

Evidence from guidance (HLIN 2008 and RPS 2007) suggests that medicines training for 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 8.3)

- record keeping and quality assurance (see section 9.3)
- accountability and confidentiality (see section 9.3).

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

Care providers

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

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 care providers there should be timely planning of care by the provider to ensure the safety of the person, in line with legislation.

Care providers must employ care workers who are suitably qualified, competent, skilled and experienced, in line with legislation.

Evidence from very low to moderate quality guidance recommends that care providers have processes for assessing the knowledge, skills and competence of care workers in supporting people with their medicines. This includes how and how often assessments will take place, how they will be recorded and the induction for new care workers.

Care workers

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

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

Low quality evidence from guidance suggests that 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	<p>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:</p> <ul style="list-style-type: none"> • service user-reported outcomes • carer-reported outcomes • medicines-related problems • health and social care utilisation. <p>The literature search did not identify any studies measuring outcomes specified in the protocol.</p>
Trade-off between benefits and harms	
Trade-off between net health benefit and resource use	<p>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]).</p> <p>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.</p>
Quality of evidence	<p>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 [NMH DU]).</p>

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 to 2

Recommendation 5

Recommendations 13 to 14

Recommendation 38

Recommendation 48

Recommendation 52

Recommendations 65 to 66

11 References

Bonugli R (2014) Psychiatric nursing faculty partner with residents of a homeless shelter to address medication safety. *Issues in Mental Health Nursing* (35): 220-3

Care Quality Commission (2015) [Guidance for providers on meeting the regulations. Health and Social Care Act 2008](#) [online; accessed 19 January 2016]

Department of Health (2016) [Care and Support Statutory Guidance](#)

Housing Learning and Improvement Network (2008) Medication in Extra Care Housing

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Sino CGM, Bouvy ML, Jansen PA (2013) Signs and symptoms indicative of potential adverse drug reactions in home care patients. *Journal of the American Medical Directors Association* (14): 920-5

Social Care Institute for Excellence (2005) Helping Older People to Take Prescribed Medication in Their Own Home: What works?

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](#) and the Think Local, Act Personal [Care and Support Jargon Buster](#).

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 what care a person would or would not want in the future, if they were unable to make decisions because of illness or a lack of mental capacity to consent. The person may also choose to involve their family members or friends in discussions.

Adverse effects

See [Medicines-related problems](#)

Community pharmacy

A local pharmacy in the community.

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 form 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.

Handling medicines

The ordering, supplying, transporting, storing and disposing of medicines.

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 of a person to make a decision about their own care, 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'.

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](#).

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.

Original packaging

The packaging in which the medicine is supplied by the supplying pharmacy, this could be a manufacturers packaging or pharmacy supplied packaging after larger amounts of medicines have been decanted for individual patient use.

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 [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 own care.

Supplying pharmacist / pharmacy

The pharmacy that supplies a person's medicines. This may be a community pharmacy, hospital pharmacy or a digital supplier (online provider) of pharmacy services.

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 may lead to serious patient harm, for example, insulin injections for diabetes or specific medicines for Parkinson's disease.

Appendices

The appendices are a separate document.