



Safe use of medicines





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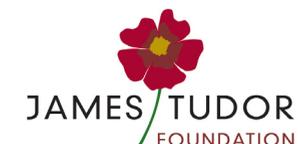
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Chapter 1: Introduction

By Gerry Armitage and Hadar Zaman





Context

This third edition of the *Safe use of medicines toolkit*¹ responds to the changes and developments in medicines management while adhering to the enduring principles of good governance in this high-risk element of children's palliative care. Medicines continue to be the most common clinical intervention in healthcare and prescribing the second highest source of expenditure across healthcare sectors. Medication-related harm can and does have fatal consequences despite an increased emphasis on adverse drug events as demonstrated by the World Health Organisation (2018). Their goal of improved medication safety for children remains a work in progress.

The context of medicines provision is in flux. For many healthcare professionals prescribing is now an electronic process. Robotic dispensing is not uncommon – especially in larger institutions, and barcode medicines administration is increasingly popular. Such new technologies create new types of error and consequently, vigilance is essential.

The complex nature of children's palliative care increases risk wherever and whenever the service is provided, often to children and young people with life-limiting conditions who require multiple medications and care from different professionals across different settings. Care is sometimes offered by lone practitioners, and their role is often intertwined with the contribution made by family carers – many of whom play an active role in medicines administration. For those involved, the co-ordination of such complex care is a continuing challenge.

Additionally, these children and young people are likely to experience numerous changes in the location or level of their care; changes known as care transitions. It is well known that the transition period can threaten patient safety, a threat which can be exacerbated by the number and variety of staff involved. This toolkit provides guidance on this topic of care transitions, which is also recognised as a global patient safety priority.



Audience

This toolkit is intended for all those involved with children's medicines in palliative care. The content and structure of each chapter is written by leaders in their respective areas and should act as a helpful guide to doctors, nurses, pharmacists, and others such as healthcare assistants. The toolkit is largely aimed at those working in children's hospice settings but is also intended to be a source of guidance for clinicians working in other settings who are involved in managing the medicines of children with life-limiting conditions or who require end of life care. This will include staff in children's wards or high dependency units, children's community teams, and those outside of healthcare (such as education) who routinely offer support to children with multiple, complex needs.

The authors also recognise the importance of broader organisational competence. Evidence has clearly demonstrated the need to embed patient safety at the heart of care. To achieve improved health related outcomes, organisations must promote and maintain open, learning-centred cultures and ensure that their leaders value patient safety as one of the key organisational priorities. In organisations where patient safety has been promoted and championed from '*top down and bottom up*' there is clear association with improved patient safety and clinical outcomes.



Structure and working definitions

We have largely retained the structure from the previous edition, but updated the entire content in line with recent developments/learning. We have tried to make the content as accessible as possible. Each chapter includes questions to stimulate reflection, bite-sized key messages (knowledge bites), section summaries, goals for practice, and clinical examples. The case study examples have been selected by clinicians working in children's palliative care and aim to capture front line perspectives that tease out underpinning concepts and show translational change in practice, which we hope will inspire new practice and continuous service development. We're keen to hear about service innovations and the implementation of this toolkit in your service through our Digital Care Forum – you can register or login **here**. Each chapter concludes with a comprehensive list of references and weblinks. Appendices include a series of training modules, additional information and operational definitions.

1. Previously the resource was entitled 'Medicines Management Toolkit'.

Unless otherwise specified we have used the term ‘child or young person’ to describe children under the age of 18 as defined in the Children Act (2004). We use the term ‘young adult’ to describe those aged over 18 in the care of a children’s hospice or palliative care service.

We have used the modified definition of medicines management, originally applied to the acute hospital setting:

“The entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of [patient] care”.
(The Audit Commission, 2001)

Medicines optimisation differs from medicines management in a number of ways but most importantly medicines optimisation focuses on patient-centred outcomes rather than organisational process and systems. Since the publication of the last toolkit, medicines optimisation has been at the forefront of clinical care through the publication of specific NICE guidance (NICE, 2015). We ensure that both of these important topics are addressed and an equal emphasis is placed on the harmonious relationship between the two, although we do not offer dedicated sections on either topic. The chapter authors are keen to point out that effective medicines management systems are enablers in the delivery of high-quality medicines optimisation. Organisations therefore should not solely focus on one area or the other as both are inextricably linked, indeed we would caution that any separation of the two could compromise patient care.

We advocate that effective medicines management and optimisation should be child and family centred, taking individual characteristics and needs into account.

Some families may want their child to receive complementary or alternative therapies, which can put service staff in a difficult position as they balance the child’s safety, the family’s wishes, and their own accountability. We have again made special comment on the challenges of administering such therapies in the chapters on **regulatory compliance** and **staff and carer competencies**.



Chapter summaries

Chapter 2 (Regulatory compliance) addresses the regulations concerning medicines management which have been updated in light of current policy.

Chapter 3 (Staff and carer competencies) looks at the issue of competence as it applies to registered and non-registered roles. The authors have included the concepts of organisational competence and good governance to support hospice services when regulators assess the quality of their leadership, and their organisational governance. There are set questions in the chapter to provoke further improvement in organisational audit and service evaluation, and practice-based scenarios to highlight the role of organisational and practitioner-led reflection.

Chapter 4 (Learning from error) addresses the subject of medication errors. The epidemiology of medication safety is updated, followed by consideration of the recent shift towards developing resilience for medication safety, and learning from what has gone well. There is a new section on the implications of working with families in medicines management, and the inherent risks of clinical decision-making. Human factors thinking and human factors working steer the overall approach in this chapter, which shares common ground with crew resource management; the latter is also revisited through a refreshed approach to effective team working. The error reporting process is updated as part of an overarching focus on learning which culminates in a section on **organisational learning**.

Chapter 5 (Transitions in care) is dedicated to the important subject of care transitions – the various interfaces of care that are an integral part of a young persons’ journey through a healthcare system. The effective management of transitions is paramount for patient safety, and central to any strategies that support safe and effective care transitions. Collaborative medicines management between medical, nursing and pharmacy personnel during transitions is associated with high quality care and actively reduces the risk of harm.

Chapter 6 (Non-medical prescribing and advanced clinical practice) includes perspectives from practitioners working in palliative care across a wide range of settings. Prescribing competency has been added, using the Royal Pharmaceutical Society’s Prescribing Competency Framework. There is essential advice on how non-medical prescribing can help organisations to demonstrate compliance to reflect the key lines of enquiry used by the Care Quality Commission. A new section has been added on advanced clinical practice in the context of children’s palliative care. Finally, the section on clinical assessment and history taking has been enhanced, adding mnemonics, practice models and case studies.

Chapter 7 (Controlled drugs) is a new chapter dedicated to controlled drugs (CDs). The Shipman and Gosport inquiries are summarised, the classification of CDs reviewed, and practical advice offered specific to each class of CD. There is a specific section on governance and monitoring as part of an increasing emphasis on management processes.

One key recommendation in this toolkit is that each service and their accompanying community team consider having a Medicines Management Group to avoid a particular care service working in isolation, especially as a high volume of controlled drugs are used in services. This group would consist of a representative from senior management, a medical prescriber (ranging from a resident paediatrician, to a GP who has contact with the service), a hospice-based nurse, outreach nurse, and a pharmacist. We also advise that the Medicines Management Group include representatives from local information networks and perhaps the nearest Clinical Commissioning Group/Primary Care Network/Integrated Care System in England. The latter organisations are synonymous with Local Health Boards in Wales, NHS Boards in Scotland, and Health and Social Care Trusts in Northern Ireland. This group would be the main forum for periodically discussing medicines management and optimisation and new treatments, medicines safety, and any related learning. The notion of a Medicines Champion might also be considered where a more senior team member has a specific remit for monitoring local developments, informing policy, learning from error and embracing new, evidence-based interventions. Finally, the chapters collectively address the five Key Lines of Enquiry (KLOE) adopted by the Care Quality Commission (CQC) in the context of medicines management, to guide their assessment of the standards of quality and safety across all healthcare providers in England. The KLOE provide the structure of the CQC's approach to assessment in five domains: assessing whether services are safe, effective, caring, responsive and well-led.



The aims of this toolkit are to:

- provide the underlying knowledge and skills for the assessment and management of medicines-related risk, recognising the physiological and intellectual differences between adults and children
- underpin this knowledge with an understanding of the key threats to child safety in high-risk processes such as providing complex medicines across the service, using a human factors perspective as part of an open culture which celebrates learning
- develop guidance for medicines reconciliation and transcribing to improve medicines management at care transitions (ie when a child's level of care or care setting changes)
- encourage the sharing of notable local practice across children's palliative care services, eg, through local or national networks, publication or conference presentation
- enable the production of medicines management policies in each local service that share a common evidence base, common principles and shared standards

These local policies should:

- provide staff with guidance on each component of the medication pathway including: prescribing (by a range of staff), reconciliation and transcribing, storage, administration/self-administration and record keeping
- enable individual organisations to improve and add detail to the current procedures for medicines management
- identify specific competencies related to each of the above components of the medication pathway

- provide a process for reporting and learning from medication safety incidents and good practice
- develop a potential framework for effective clinical governance and a service-wide approach to medication safety and quality management



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Audit Commission (2001). *A spoonful of sugar: medicines management in NHS hospitals*. Audit Commission: London.

Children Act (2004) C31. **Children Act 2004 (legislation.gov.uk)**. Accessed 8 March 2021

NICE (2015). www.nice.org.uk/guidance/ng5/chapter/Introduction Accessed 11 April 2021

World Health Organisation (2018). Global Patient Safety Challenge: Medication without harm. Accessed 28 March 2021

To read more about medicines optimisation: www.nhs.uk/about-the-nhs-website/professionals/healthandcareprofessionals/your-pages/documents/rps-medicines-optimisation.pdf Accessed 11 April 2021



Chapter 2: Regulatory compliance

By Hadar Zaman, Rachel Urban
and Carmel Caldicott

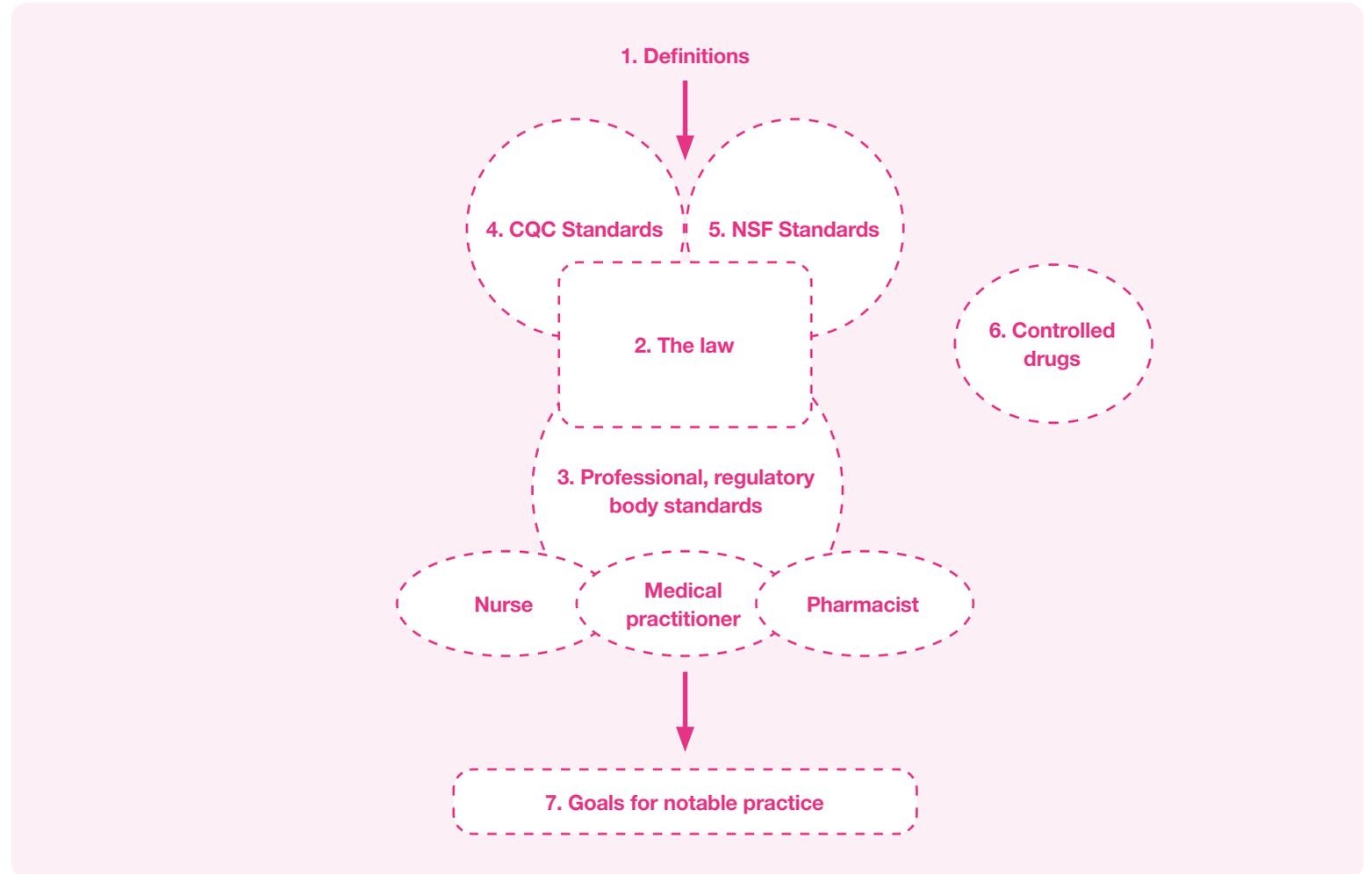


Healthcare professionals in the UK are regulated by government appointed professional bodies. These professional bodies publish standards for practice in order to fulfil their legal duty to protect the public. Professional practice concerning medicines handling and administration is subject to both the law and professional body standards; these are two critical considerations for practitioners working in children's palliative care services.

This chapter covers:

- Defenitions of some key terms
- The standards and guidance available to healthcare professionals through legislation and via the professional regulatory and statutory bodies
- Guidance for the medical practitioner, the pharmacist and the nurse
- The guidance issued by NICE and the Care Quality Commission

This chapter differs from others in the document in that there are no direct examples from practice or case studies. We have devised a reader's map of the content of this chapter and how each of the numbered sections are related. Some of the professional body standards covered in this chapter are also discussed in more depth in other chapters; reference is made to these when appropriate. The management of controlled drugs is included as a separate chapter (**Chapter 7**) in order to bring together the many elements of regulation, law and professional guidance relating to this one aspect of practice. The conclusion takes the form of goals for notable practice.





Definitions

We have set out below some of the terms that are used in this section:

Compliance aid: A compliance aid is a device to aid adherence to a prescribed medication regime. The device might be purchased by a parent, carer or young person for their own use, filled from containers of dispensed medication. Alternatively, a monitored dose container or a daily/weekly dosing aid might be dispensed, labelled and sealed by a pharmacist. Sealed compliance aids are generally referred to as monitored dosage systems. Compliance aids also include other aids to the child or young person, such as large print labels, auto-droppers etc.

Controlled drugs (CDs): These are medicines whose management is governed by the Misuse of Drugs Act 1971 and its associated regulations.

Dispensing: To label from stock and supply a clinically appropriate medicine to a child, parent or carer, for self-administration or administration by another professional. Dispensing is usually done against a written prescription.

General sales list medicines (GSLs): These are medicines that need neither a prescription nor the supervision of a pharmacist and can be obtained from retail outlets.

Licensed medication: The Medicines and Healthcare Products Regulatory Agency (MHRA) operates a system of licensing before medicines are marketed. However, the Medicines Act allows certain exemptions from licensing. These are:

- the manufacture and supply of unlicensed relevant medicinal products for individual children (commonly known as 'specials')
- the importation and supply of unlicensed relevant medicinal products for individual children or clients
- herbal remedies

The Medicines Act allows exemptions for certain healthcare groups and professionals – including occupational health schemes and midwives – to sell, supply and administer particular medicines directly to patients or clients. Provided that the requirements of any conditions attached to such exemptions are met, a patient group direction (see below) is not required.

Medicines chart: The record by which medicinal products administered to a child are recorded. Also known as the medicines administration record (MAR).

Medicines and Healthcare products Regulatory Agency (MHRA): The government agency responsible for ensuring that medicines and medical devices are effective and safe.

Off-label: A term commonly used to describe medication that is licensed but used outside its licensed indications.

Patient group direction (PGD): Written instructions for the supply or administration of named medicines to specific groups of children who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained in the NICE Guidelines (2017) www.nice.org.uk/Guidance/MPG2. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. Supplying or administering medicines from a PGD is not a form of prescribing.

Patient information leaflet (PIL): Information sheet produced by the manufacturer of the medicine and legally required to be supplied with all licensed medicines that should be brought to the parent or child's attention when administering a medicinal product.

Patient-specific direction: Written instructions from a doctor, dentist or non-medical prescriber for a medicine to be supplied or administered to a named person. This could be demonstrated by a simple request in the child or young person's notes, or by an entry on the child or young person's drug chart.

Pharmacy-only medicines (Ps): These can only be purchased from a registered pharmacy. The sale must be by or under the supervision of a pharmacist.

Prescription-only medicines (POMs): These are medicinal products that may only be sold or supplied to a child on the instruction of an appropriate practitioner. An appropriate practitioner is a doctor, a dentist, a supplementary prescriber or a nurse or pharmacist authorised to be an independent prescriber.

Summary of product characteristics: Information on medicinal products dispensed may be found in the Electronic Medicines Compendium at www.medicines.org.uk.



Transcribing (transposing): Any act by which medicinal products are transferred from one form of written direction to administer to another is known as transcribing. This includes discharge letters, transfer letters and copying child administration charts onto new charts (whether handwritten or computer generated).

Unlicensed medicines: This term refers to medicines that are not licensed for any indication or age group. A drug may not be licensed because it is undergoing a clinical trial, it has been imported, prepared extemporaneously or prepared under a special manufacturing license. It could be that the product is not a medicine but is being used to treat a rare medical condition. This is not the same as a medicine being prescribed 'off-label' (see definition).

Yellow Card Scheme: If a child or young person experiences an adverse reaction to a medication, then it is the duty of the healthcare worker to:

- record details in the child or young person's notes
- notify the prescriber (if the healthcare worker did not prescribe the drug themselves)
- report the incident via the Yellow Card Scheme immediately

Yellow cards are found in a section at the back of the British National Formulary (BNF) and online at <https://yellowcard.mhra.gov.uk>.



Knowledge bite

Accountability, the law and professional guidance

Effective medicines optimisation should comply with relevant legislation and with the standards set by a government-appointed professional regulatory body such as the Nursing and Midwifery Council (NMC), the General Pharmaceutical Council (GPhC) and the General Medical Council (GMC). Health professionals are accountable in law and could be subject to criminal proceedings or civil courts if medicines management does not comply with legislation. The professional regulatory body can hold a professional to account and action could be taken in respect of their professional registration if their standards are not met. Health professionals are also accountable to their employing organisation; policy and guidance set by employing organisation should be treated as mandatory. Hospice services must also meet the standards set by the relevant care regulator. Additional guidance from the government departments and professional organisations is published to support organisational policy setting and decision making for individual practitioners.



Legislation

In the table on the next page we have set out some of the key legislation that relates to the safe use of medicines. Detailed information about legislation can be found at: www.legislation.gov.uk



Key Legislation	
Act and dates	Summary
Medicines Act 1968	This was the first comprehensive legislation on medicines in the UK. The combination of this primary legislation and various statutory instruments (secondary legislation) since 1968 provides the legal framework for the manufacture, licensing, prescribing, supply and administration of medicines. Among recent statutory instruments of particular relevance to registered nurses, midwives and specialist community public health nurses is the Prescription Only Medicines (Human Use) Order 1997, SI No1830. This consolidates all previous secondary legislation on prescription-only medicines and lists all medicines in this category. It also sets out who may prescribe them. The sections on exemptions are of particular relevance to midwives, including those in independent practice, and to nurses working in occupational health settings. The Medicines Act 1968 classifies medicines into the categories of controlled drugs, prescription-only medicines, pharmacy medicines and general sales list medicines.
Misuse of Drugs Act 1971	The Misuse of Drugs Act (MDA) 1971 and its associated regulations provide the statutory framework for the regulation of controlled drugs (CDs). The primary purpose of the MDA is to prevent misuse of CDs. The Act makes it unlawful to possess or supply a CD unless an exception or exemption applies. A CD is defined as any drug listed in schedule 2 of the Act.
Misuse of Drugs (Safe Custody) Regulations 1973	These regulations impose controls on the storage of CDs. The degree of control depends on the premises where the drugs are stored. All Schedule 2 and some Schedule 3 CDs should be stored securely in accordance with the safe custody regulations. These regulations state that such CDs must be stored in a cabinet or safe, locked with a key. It should be made from metal, with suitable hinges and fixed to a wall or floor with rag bolts that are not accessible from outside the cabinet.
Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002	The use of CDs in medicine is permitted by the Misuse of Drug Regulations (MDR), under which drugs are classified in five schedules according to the different levels of control required. Schedule 1 CDs are subject to the highest level of control, whereas schedule 5 CDs are subject to a much lower level of control. Classification depends on the degree of therapeutic benefit versus harm when misused. The regulations authorise and govern certain activities that would otherwise be illegal under the Misuse of Drugs Act. The healthcare professionals who may legitimately possess and supply CDs are identified and the controls around prescribing, administration, safe custody, dispensing, record keeping and destruction or disposal are established.
Dangerous Drugs, England, Scotland: The Controlled Drugs (Supervision of Management and Use) Regulations 2006 and Health Act 2006 Updated 2013	These regulations set out the requirements for NHS bodies and independent healthcare bodies to appoint an accountable officer. They also describe the duties and responsibilities of accountable officers to improve the safe management and use of CDs. The regulations require specific bodies to co-operate with each other, including information sharing, about concerns relating to the use and management of CDs. They also set out the arrangements relating to powers of entry and inspection. The Health Act 2006 specifies who may be appointed as an accountable officer. These regulations were updated in 2013 to reflect the new NHS structures. Information about the changes is available at www.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf
Human Medicines Regulations 2012	These regulations consolidate the law of the United Kingdom concerning medicinal products for human use.



Knowledge bite

Children's own medicine and the law

On many occasions, health professionals working in a children's hospice service will administer the child's own medicine. Once it has been dispensed, this medicine is no longer subject to the Medicines Act (1968). However, it is good practice to store, record and administer the child's own medicines with the same care and standards that apply to stock medicines and local policy should reflect that standard.



The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Children's hospices provide a wide range of personalised care services delivered through a multi-disciplinary team with the aim of improving a child's quality of life. The CQC is the independent regulator of health and social care services in England, including the hospice sector. Regular checks, known as comprehensive inspections, are carried out to make sure that services are providing care and support which is safe, effective, caring, responsive to service users' needs and well led. Hospice providers provide assurances in respect of the standard, quality and safety of services delivered. The inspection team collects evidence against the key lines of enquiry by:

- seeking the views of the people who use the service, or their representatives
- gathering information from the leadership team and staff, individually and in groups
- observing care and individual care pathways
- examining a range of records including care records, incidents, complaints and policies.

The standards of medicines management required by the CQC are reflected in Regulation 12: Safe care and treatment of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12 section 2g which is specific to medicines management. This details that service users (children and their parents) will get their medicines at the times they need them, and in a safe way. Wherever possible service users will have information about the medicine being prescribed made available either to them or to others acting on their behalf. Providers who comply with the regulations will handle and prescribe medicines safely, securely and appropriately. The full guidance that accompanies the Care Quality Commission standards is available at: www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment

The CQC has issued guidance to hospice providers on how the inspection is undertaken and what to expect.

www.cqc.org.uk/sites/default/files/20200212_Sector_specific_guidance_Hospices_for_children_and_young_people_v1.pdf



Knowledge bite

Protection against unsafe use of medicines

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12 (Safe Care and Treatment) describes that the registered person (a health professional in this instance) must protect service users against the risk associated with the unsafe use and management of medicines, by making appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines for the purpose of the regulated activity.

Service providers should be aware that current advice from CQC inspectors in relation to medication errors requiring medical attention/transfer to hospital should be reported under Registration Regulations 2009 Regulation 18:

Notification of other incidents which describes how people who use services can be confident that important events that affect their health, welfare and safety are reported to CQC so that, if necessary, action can be taken.

Readers in other countries should refer to the equivalent guidance in the relevant regulatory body.



Standards set by professional bodies

Healthcare professionals working in a children's hospice are subject to standards set by their own specific professional regulatory body. Nurses are regulated by the Nursing and Midwifery Council (NMC), pharmacists by the General Pharmaceutical Council (GPhC), medical staff by the General Medical Council (GMC) and other health professionals by the Health Care and Professions Council (HCPC). The standards set by the professional bodies are intended to promote the public interest. Professional body standards should be regarded as mandatory, taking their authority from the legislation that underpins the function of the regulatory body.

The NMC *Standards for Medicines Management* were withdrawn on 28 January 2019. They now endorse the following guidance which has been co-produced with other agencies.

- *Professional guidance on the safe and secure handling of medicines* (Royal Pharmaceutical Society, RPS) – guidance for all healthcare professionals covering areas such as the storage, transportation and disposal of medicines.
- *Professional guidance on the administration of medicines in healthcare settings* – this guidance, co-produced by the Royal Pharmaceutical Society (RPS) and Royal College of Nursing (RCN), provides principles-based guidance to ensure the safe administration of medicines by healthcare professionals.
- *Advisory guidance on administration of medicines by nursing associates* – Health Education England (HEE) guidance.

Alongside this guidance, most local NHS trusts and other employers will also have their own guidance on safe and effective medicines handling, which employees should always check and follow when considering their actions.

Regulation and the nurse

Medicines administration is not just about complying with the written direction of a prescriber; it is a process that requires the exercise of professional judgement. All directions to administer or supply a medicine should be checked by the registered practitioner, applying their knowledge of the medicines to be administered and the child's clinical condition. The nurse may supply or administer medication on the direction of a medical practitioner or a non-medical independent or supplementary prescriber.

A nurse may supply or administer medicines in accordance with:

- a patient-specific direction
- a prescription form
- a child's medicines administration chart
- a patient group direction (restricted to staff who have undergone appropriate training and have been identified by the organisation as competent)
- a Medicines Act exemption (this only applies to specific groups of staff, such as midwives and occupational health nurses)
- a homely remedy protocol. These are protocols agreed by the organisation to supply remedies for minor ailments, for example the use of paracetamol for headaches. Over-the-counter (OTC), general sales list or pharmacy-only (P) medicines may be supplied under a homely remedy protocol. Prescription-only medicines (POMs) may not be supplied under these protocols

Medication for use in an emergency

There are certain drugs which may be administered in an emergency for the purpose of saving life. Some of the drugs below, such as adrenaline and naloxone are more commonly used in hospices, so hospices should have specific policies for their use.

- Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate injection
- Atropine sulphate, pralidoxime mesilate and avizafone injection
- Chlorphenamine injection
- Dicobalt edetate injection
- Glucagon injection
- Glucose injection
- Hydrocortisone injection
- Naloxone hydrochloride
- Pralidoxime chloride injection
- Pralidoxime mesilate injection
- Promethazine hydrochloride injection
- Sodium nitrite injection
- Sodium thiosulphate injection
- Sterile pralidoxime

Email, fax or text may be used to confirm changes to a prescription when a change in dose is considered necessary and the prescriber is not available in person to issue a new prescription or direction. A verbal order alone is not sufficient.

The nurse is responsible for ensuring confidentiality and GDPR compliance and for recording when the information was received. The email, fax or text should be fastened to the original medication chart.

The prescriber must re-issue the prescription or complete and sign the administration chart within 24 hours (72 hours maximum over bank holidays and weekends).

Remote prescribing

A prescriber may need to prescribe remotely for a child for a previously unprescribed medicine, for example for palliative care in a remote rural area. This must be backed up in writing or via a written direction in a patient's notes. Email or text may be used to confirm the prescription before administration. The RCN also allows Whatsapp to be used due to its end to end encryption. The nurse must ensure that the prescriber has all relevant information and must also document the communication. Prescribers may not prescribe remotely if they have not assessed the child for care. But in practice the prescriber may have assessed the child or young person recently and so be in a position to make an informed prescribing decision.

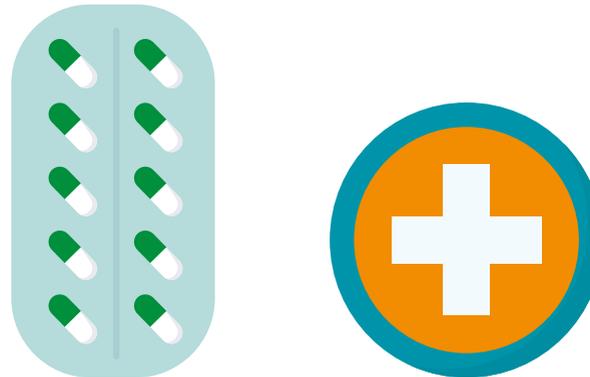
Protocols must ensure that child confidentiality and GDPR is protected and that there is adequate documentation. This should include the message in full, the telephone number it was sent from, the time sent, any response given, the date and the signature of the nurse receiving the text. Text messages must be read by a second person and the documentation signed to confirm that it agrees with the text message. The text message must be documented as a child contact. Text messages should then be deleted to ensure confidentiality/GDPR/compliance.

The prescriber must issue the written prescription or complete and sign the administration chart within 24 hours (72 hours maximum over bank holidays and weekends).

Electronic patient records are making it increasingly easy to prescribe remotely. Patient specific directions ie an authorisation by a prescriber written directly into the patient notes by logging on remotely is a preferred option.

Administration

All registered nurses are accountable for their actions and omissions. You must exercise professional judgement when administering or overseeing the administration of a medicine. Please refer also to the sections on delegation and self-administration within this chapter.



The nurse should always:

- check identity
- check allergies/sensitivities
- understand therapeutic use, dosage, side-effects, precautions and contraindications of the medicines to be administered
- be aware of any existing individual care plan
- check that the prescription and the label on the medicine are unambiguous
- check expiry dates
- consider dosage, weight of the child if appropriate, route, method of administration and timing
- consider the context of the child's condition and other therapy before administering or withholding the medicine
- contact the prescriber or another authorised prescriber when contraindications or reactions are discovered, or when assessment suggests that the medicine is no longer suitable
- assess the child, parent or carer's understanding of how to use compliance aids and his/her ability to do so safely
- avoid preparing substances in advance of use or administering medicines drawn into a syringe or container by another practitioner when not in their presence
- immediately complete clear, accurate records of any medicines administered, withheld or refused. Signatures must be clear and legible, and the reason(s) for withholding medicines should be recorded. Normally, a single signature is all that is needed when administering a prescription-only, general sales list or pharmacy-only medication



Knowledge bite

The 7 Rs of administration

1. Right Dose
2. Right Drug
3. Right Client
4. Right Time
5. Right Reason
6. Right Route
7. Right Documentation

Use of a child's own medicines

Registered nurses may use the child's own medicines, which may include prescribed medicines, over-the-counter medicines, homely remedies and complementary therapies (refer to sections on administration, self-administration and complementary therapies elsewhere in this chapter). These products, including controlled drugs, must only be used for that child. They remain the child's property and must not be removed without their permission.

The nurse is responsible for asking to see the medicinal product, checking suitability for use, establishing if it is prescribed and explaining if it will or will not be used and why. If the child or parent refuses consent for use of medicines or refuses to dispose of medicines that are unsuitable or no longer required, the nurse has a responsibility to document the refusal in the child's notes.

The nurse must ensure that suitable storage facilities are provided and that the storage is documented in the child's notes. The storage cabinet must be kept locked and the key kept in a secure place. If the child is moved to another care area, the medicines must be transferred with the child.

Delegation

The registered practitioner is responsible for applying the principles of medicines administration but may delegate the task of giving the medicinal product or assisting the child to a (competent) unregistered practitioner. Nurses should not normally delegate the task of administering a controlled drug. Students must always be directly supervised when administering medicines.

A registered nurse delegating the task of supporting a child to take their medicine is accountable for this action and must be satisfied that the individual has an appropriate level of training and competence to carry out the task. A clear policy should be in place that takes the child's cognition and capacity into account. The registered nurse is responsible for record keeping when delegating the administration of medicines. For further information about delegation see **Chapter 3**.

See also Health Education England. Advisory Guidance Administration of Medicines by Nursing Associates. www.hee.nhs.uk/sites/default/files/documents/Advisory%20guidance%20-%20administration%20of%20medicines%20by%20nursing%20associates.pdf

Self-administration or parent/carer-administration

The nurse remains responsible for monitoring the child or parent who is self-administering medicines and for checking that medicines have been taken as prescribed.

The storage cabinet must be kept locked and the key kept in a secure place. The key may be kept by the child or parent in a secure place if they are self-administering.

The registered nurse is responsible for the ongoing assessment of a child who is self-administering and for acting upon changes in a child's condition. The nurse may assess a child's suitability to self-administer. Suitability can be assessed at three levels:

- **At level 1** the nurse remains responsible for the safe storage of the medicine, the supervision of administration and ensuring that the child understands the medicinal product.
- **At level 2** the nurse is responsible for the safe storage of the medicine and ensuring that the child can access the medicine when it is needed. The child self-administers under the supervision of the nurse.
- **At level 3** the child accepts responsibility for storage and administration of the medicine. The nurse checks compliance verbally. Children or parents/carers should be reassessed on a regular basis to ensure that they are still capable of self-administration, and these reassessments should be documented.

When parents are administering medicines to a child, the nurse is responsible for checking the medicine has been administered. Nurses should ideally check this by direct observation but can also do so when appropriate by questioning the child or parent/carer. The administration record should be signed and annotated 'child self-administered' or 'parent administered'.

Administration by parents should be carefully controlled, with clear communication and documentation to avoid error. Unsupervised administration by parents must be approved by the registrant/nurse in charge following assessment of the parent's suitability. Local policy must be in place and adhered to. Arrangements over holding keys to secure storage and return of the keys must be agreed. The medicines must be correctly labelled before discharge or return to the pharmacy. Self-administration is also discussed in **Chapter 3**.

Titration

It is permissible for the nurse to titrate and administer doses from a prescribed range according to child responses and symptom control (especially in palliative care). The nurse must be competent to interpret test results and make appropriate assessments.

Unlicensed medication and administration of medicines outside the terms of a licence

Unlicensed medication refers to medicines that do not carry any marketing authorisation; they are not licensed for any indication or age group. The person who prescribes and supplies these medicines carries additional liability for any harm that may ensue. A registered practitioner may administer unlicensed medicines but the parent or child must understand that the medicine is unlicensed and give consent.

Unlicensed medicines may be administered in accordance with a patient-specific direction, but not from a patient group direction. Medication which is licensed but used outside its licensed indications (commonly known as off-label) may be administered under a patient group direction only where such use is exceptional, justified by best practice, and where the status of the product is clearly described. Unlicensed medications are frequently used in palliative care. When prescribing a medicine for use outside the terms of its license, prescribers must be satisfied that it would better serve the patient's needs than an appropriately licensed alternative and that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. Where common practice is not being followed, the reasons for prescribing the medicine should be documented in the child or young person's clinical record.

A registered practitioner should be satisfied that s/he has enough information to administer unlicensed/off-label medicines safely. Where possible, there needs to be acceptable published evidence for the use of such products for the intended indication.

The British National Formulary for children (BNFC) provides useful information about the administration of off-label medication for children. More information on unlicensed and off-label drugs can be found in www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567

Storage and transport

Medicines must be stored in accordance with the instructions on the information leaflet that accompanies any UK licensed medication, or those on the label. Registered practitioners may transport medication to a child if the child or their representative is unable to collect it.

Medicines that have not been prescribed

The nurse should not administer a child's own medication that has not been prescribed – or medicines that have been obtained over the internet. Quality, safety and correct storage cannot be assured when such medicines are used, and there will be no redress from the manufacturer if adverse reactions occur. If the online pharmacy service is a registered pharmacy premises, subject to UK standards, then it is acceptable to administer the medicine.

Child's own medication that has been purchased abroad and does not have a UK licence

The nurse should try to identify the source of the original prescription and be assured of its authenticity. Alternatively, the nurse should seek the parent or child's consent to have a similar drug, with a UK licence, prescribed. If consent is gained the nurse should request a prescription from a qualified prescriber.

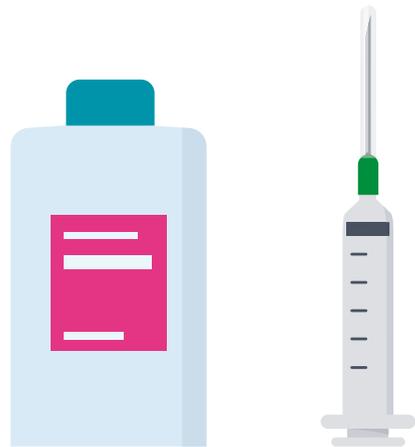
In an emergency situation or when a child will only agree to take an unlicensed product, the nurse may administer the product. A contemporaneous record must be kept. The hospice service should have a locally agreed policy in place.

Complementary and alternative therapies

Registered nurses who choose to administer complementary therapies, for example herbal remedies or homeopathic medicines, must be qualified and competent to practise their administration. The child or parent must give informed consent to the use of any complementary therapy.

All complementary therapies should be recorded on the child's medicines charts. All practitioners should be aware that complementary therapies may interact with other medicinal products and be satisfied that they are safe to be administered.

The nurse should ensure that their employer has accepted vicarious liability for any therapies that s/he undertakes. If this does not occur, the nurse must ensure that s/he has indemnity insurance to cover his/her practice.



The professional guidance on administration of medicines can also be applied if a child wants to use complementary therapies. A suitably qualified practitioner should establish if the medicine has been prescribed or not, check that it is suitable for use by the child and establish if it has been prescribed. The practitioner should explain if the therapy will or will not be used and why.

For more information about the use of complementary therapies, refer to **Chapter 3**.

Compliance aids

Nurses should assess a child's suitability to use a compliance aid. A locally recognised assessment tool should be used to identify that the child is able to understand how to use the compliance aid safely. The aid should ideally be dispensed, labelled and sealed by a pharmacist.

The nurse may repackage dispensed medication into a compliance aid. But this increases the risk of error and may change the properties of the medication. This activity should be covered by a standard operating procedure. It is recommended that the nurse should confirm with the dispensing pharmacist that it is appropriate to repackage medication in this way and that labelling is in line with legislation.

Crushing medicines

The crushing of medicines may alter their therapeutic properties and may not comply with the product licence. The nurse should seek advice from a pharmacist and ensure it is in the child's best interest.

Further information and guidance about crushing medication for administration can be found in the NEWT guidelines. Your organisation will need to sign up to this resource.

www.newtguidelines.com/index.html

Disguising medication

This is also known as covert administration of medicine. It is not good practice to disguise medication with the intention of leading the child or parent to believe they are not receiving medication when in fact they are. The nurse is not solely accountable for the decision to disguise medication, but should be part of a MDT making sure it is in the child's best interests. Nurses and midwives involved in decisions relating to administration of medicines in this way must act within the professional guidance (from NICE, RPS, CQC) and ascertain and record the support, or otherwise, of the rest of the multi-professional team, and parent/carers and others where appropriate. The organisation should have an appropriate assessment process and policy in place relating to covert administration. It is inadvisable for nurses and midwives to decide to administer medication in this way in isolation. They will need to refer to local and national policies and apply the requirements of the law, particularly in relation to capacity. The covert administration of medicines is only likely to be necessary or appropriate in the case of children who actively refuse medication but who are judged not to have the capacity to understand the consequences of their refusal (Mental Capacity Act, 2005). Guidance from the RPS and RCN on disguising medication is available with the joint professional guidance published on administration of medicines.

Preparation of substances for injection

Nurses should not prepare substances for injection in advance, nor should the nurse administer medication prepared by another practitioner not in their presence. It is acceptable to administer prepared medication from a central intravenous additive service that is clearly labelled for the child. The summary of product characteristics or child information leaflet should indicate that it has to be prepared in advance.

A registered nurse may draw up medication in advance and delegate the administration to a family member or healthcare assistant. But this named individual must be assessed as competent. The nurse is accountable for the delegation, and a risk assessment must be documented in the child's notes. When a nurse prepares substances for injection by another practitioner, for example in an emergency situation, the nurse must be sure the practitioner has carried out the appropriate checks.

Intravenous (IV) medication

IV medication should be checked by two registered practitioners, one of whom is to administer the IV medication. In exceptional circumstances, where this is not possible, the nurse should check with another competent person who knows the child – a parent, for example, or the child themselves. Any dose calculation must be independently checked. The nurse is responsible for monitoring the child undergoing IV therapy.

Further information is available from:

- Child Safety Observatory (2007 and 2009) Safety in doses: medication safety incidents in the NHS
https://nationalpatientsafetysuite.vctms.co.uk/assets/content/35497/story_content/external_files/NRLS-0486-safety-in-doses-PSO-2007-v1.pdf.pdf
- RCPCH www.rcpch.ac.uk/resources/medusa-injectable-medicines-guide
- RCN www.rcn.org.uk/professional-development/publications/pub-007033

Adverse events related to medicines

Please refer to the **Chapter 4 (Learning from error)**, but note that in terms of regulatory compliance, you must take action to remedy harm caused by errors or adverse drug reactions. Action must be documented and then reported as soon as possible. Errors should be reported to the prescriber and manager/employer. Adverse reactions should be reported to the prescriber and notified via the yellow card scheme (<https://yellowcard.mhra.gov.uk>).

Disposal

Disposal must be carried out in accordance with legislation. In primary care, medicines should be returned to the pharmacy for disposal. Stock medicines should be disposed of according to local protocol as clinical waste. Community pharmacies cannot accept medicines for homes registered to provide nursing care. For further information refer to paragraph 'disposing of controlled drugs' below.



Regulation and the medical practitioner/prescriber

The General Medical Council (GMC) regulates medical practitioners. It gives them clear guidance on the prescribing of medicines in *Good Practice in Prescribing Medicines* (updated 2013) www.gmc-uk.org/-/media/documents/prescribing-guidance_pdf-59055247.pdf and covers the following topics:

Principles of prescribing

Doctors with full registration who hold a licence to practise may prescribe all medicines, but not those drugs in Schedule 1 of the *Misuse of Drugs Regulations 2001*. Doctors should only prescribe drugs to meet the identified needs of the child or young person, and never for their own convenience or simply because the child, parent or carer demand them. All prescribers should avoid treating themselves or those close to them.

Keeping up-to-date and prescribing in the child's best interests

Doctors or prescribers should be familiar with the latest guidance in the BNF for Children available at <https://bnfc.nice.org.uk>. This includes guidance on the use, side-effects and contraindications of medicines. Guidance about the clinical effectiveness and cost-effectiveness of interventions is published by the National Institute for Health and Care Excellence (NICE) in England and Wales; in Wales additionally by the All-Wales Medicines Strategy Group; in Northern Ireland by the Department of Health, Social Services and Public Safety and in Scotland by the Scottish Medicines Consortium and NHS Quality Improvement Scotland (including the Scottish Intercollegiate Guidelines Network).

The doctor or prescriber should:

- be in possession of, or take, an adequate history from the child or parent/carer
- reach agreement with the child and parents on the use of any proposed medication and the management of the condition, by exchanging information and clarifying any concerns
- establish the child's priorities, preferences and concerns and encourage the child and parents to ask questions about the taking of medicines and the proposed treatment. Other treatment options should be discussed, and the doctor should be satisfied that the child and parent(s) have been given appropriate, understandable information. This information should cover any common or potentially serious side-effects, what to do when side-effects occur, interactions with other medicines, and the dosage and administration of the medicine. The doctor must be satisfied that the child and parent/carers understand how the medicine should be taken and are able to take the medicine as prescribed.

Keeping the child's general practitioner informed

If the child or parent does not want their general practitioner to be informed, or has no general practitioner, then the prescriber must take steps to ensure that the child or young person is not suffering from any medical condition or receiving any other treatment that would make the prescription of any medicines unsuitable or dangerous. The prescriber must also take responsibility for providing all necessary aftercare for the child or young person until another doctor agrees to take over.

Prescribing unlicensed medicines and medicines for use outside the terms of their licence (off-label)

Prescribers and NMPs can prescribe unlicensed medicines. They may also prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently when prescribing for children receiving palliative care. Pharmaceutical companies do not always test their medicines on children. As a consequence, they cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.

Doctors/NMPs who decide to prescribe unlicensed medicines or to prescribe off-label must:

- be satisfied that an alternative, appropriately licensed medicine would not meet the child or young person's needs
- be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
- take responsibility for prescribing the unlicensed or off-label medicine and for overseeing the child's care, including monitoring and any follow-up treatment (further information is available in the guidance regarding responsibility for prescribing medicines for hospital outpatients)
- record the medicine prescribed in the child's notes, identifying the reasons why this medication has been prescribed and used

For further information consult the Royal College of Paediatrics and Child Health (RCPCH) statement on the use of unlicensed medicines (2013). This is available at: www.rcpch.ac.uk/resources/use-unlicensed-medicines-or-licensed-medicines-unlicensed-applications-paediatric

Information for children and parents/carers about the licence for their medicines

Some medicines are routinely used outside the scope of their licence – in treating children, for example. It is good practice to give as much information as children and parents/carers require or may see as significant when prescribing medicines outside the terms of the licence. Where children or parents express concern, the prescriber should also explain, in broad terms, the reasons why medicines are not licensed for their proposed use and provide written information, including the leaflets on the use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice produced by the Royal College of Paediatrics and Child Health/ Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines. However, the prescriber must explain the reasons for prescribing a medicine that is unlicensed or being used outside the scope of its licence where there is little research or other evidence of current practice to support its use, or where the use of the medicine is innovative. For specific information on prescribing medicines for children see the websites of the RCPCH, British National Formulary for Children or Medicines for Children website (www.medicinesforchildren.org.uk/search-for-a-leaflet).



Remote prescribing via telephone, email, video link or a website

From time to time it may be appropriate to remotely prescribe medicines and treatment for children, instead of doing so face-to-face. This may occur where the prescriber has responsibility for the care of the child, is deputising for another doctor who holds that responsibility or has prior knowledge and understanding of the child's condition/s and medical history and authority to access the child's records. In all circumstances, prescribers must ensure that they have an appropriate dialogue with the child and their parents or carers. This is required to:

- establish the child's current medical conditions and history and any concurrent or recent use of other medications, including non-prescription medicines
- carry out an adequate assessment of the child's condition
- identify the likely cause of the child's condition
- ensure that there is sufficient justification to prescribe the medicines/treatment proposed

Where appropriate the prescriber should discuss other treatment options with the child and their parents or carers and ensure that the treatment and/or medicines chosen are not contraindicated. It is also the responsibility of the medical practitioner to make a clear, accurate and legible record of all medicines prescribed.

If the prescriber is not providing continuing care for the child, does not have access to the child's medical records, or is not deputising for another doctor, the advice above should still be followed. In addition, the prescriber should:

- give the child or parent/carer his/her name and registration (could be NMC) number and explain the processes involved in remote consultations
- establish a dialogue with the child or parent/carer, using a questionnaire, to ensure that the prescriber has sufficient information about the child to ensure safe prescribing
- make appropriate arrangements to follow the progress of the child
- monitor the effectiveness of the treatment and/or review the diagnosis
- inform the child's general practitioner or follow the advice above if the child or parent/carer objects to the general practitioner being informed
- make a clear record of the medicines prescribed

Where none of these conditions can be satisfied, remote means should not be used to prescribe medicine for a child.

Good Practice in Prescribing Medicines (published by GMC) also includes further guidance on:

- Patient group directions
- Procedures to simplify the work involved in issuing repeat prescriptions
- Repeat dispensing
- Prescribing controlled drugs for yourself or someone close to you
- Prescribing for children to whom you also dispense
- Other published regulations, guidance and information relevant to prescribing

Regulation and the pharmacist

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. The GPhC provides standards for conduct, performance and ethics for pharmacists. These standards (updated in 2017) relate to nine key areas:

1. Providing person-centred care
2. Working in partnership with others
3. Communicating effectively
4. Maintaining, developing and using their professional knowledge and skills
5. Using professional judgement
6. Behaving in a professional manner
7. Respecting and maintaining the person's confidentiality and privacy
8. Speaking up when they have concerns or when things go wrong
9. Demonstrating leadership

The standards are available at:
www.pharmacyregulation.org/standards

The GPhC does not dictate how the standards should be applied. Pharmacists are professionally accountable and responsible for their own practice and are expected to undertake a risk/benefit analysis when faced with conflicting legal and professional responsibilities. Every pharmacist is expected to make decisions based on the GPhC standards with the best interest of the public and child in mind.

Goals for notable practice

- Ensure your organisation has effective leadership and teams to ensure medicines management is well led and has continuous review/updates.
- Ensure an open and honest culture in which reporting concerns and raising incidents is valued as part of organisational learning and improvement.
- Have an awareness of the law underpinning medicines management, the professional standards you should meet when managing medicines and the standards expected by the Care Quality Commission.
- Have an understanding and awareness of local policy and standard operating procedures, and work within them.
- Only administer medicines that have been prescribed by an appropriately qualified practitioner, from a patient group direction or from a homely remedy protocol.
- Ensure that children and parents are given information about their medicines and that it is at an appropriate level to ensure their understanding of the treatment. Parents and children should be involved in decision making about medicines management and supported to take their medicines as prescribed.
- Be aware of controlled drugs policy and standard operating procedures and ensure these are implemented.
- Be aware of your responsibility and accountability in medicines management, particularly when delegating tasks.
- When delegating tasks to healthcare assistants or when supporting children and parents to self-administer, ensure that an assessment of their competence has been undertaken, documented and reassessed as necessary.
- Remember that you work as part of a team; all medicines management activities should be clearly documented to reduce risk and promote continuity of care.



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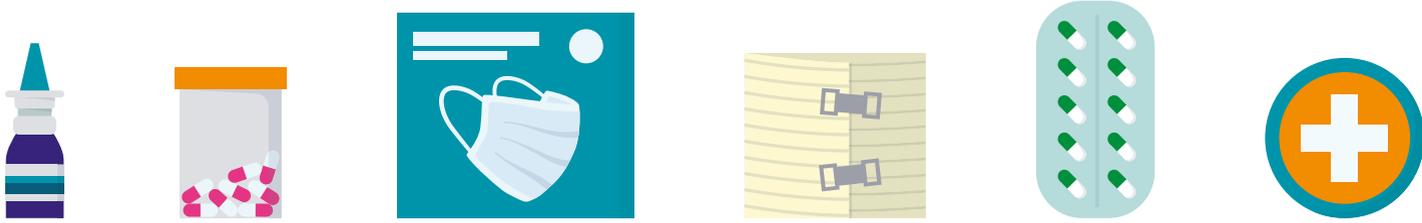
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Chapter 3: Staff and carer competencies

By Linda Maynard and Juliet Le Breuilly



Children’s hospice services provide care across a variety of settings, including residential, home care and in acute hospital wards. Staff groups working within these settings can be diverse, coming from a broad range of professional backgrounds. In order to ensure safe medicines management, it is essential that each member of the multi-disciplinary team has the requisite competencies to fulfill their role, regardless of their qualifications or status.

Regulatory vehicles such as the Care Quality Commission (CQC) in England, the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland, the Healthcare Improvement Scotland (HIS) and the Health Inspectorate Wales (HIW) offer a framework which can support organisations in providing safe patient care. Competence in medicines management is a fundamental element of the framework allowing an organisation to consider and articulate how they are providing safe, competent staff through, for example, evidence of minimum training standards, policy documentation and appraisal.

Whilst the principles of safety and quality care should be consistent across settings, standards such as those promoted by CQC allow individual organisations to put context specific structures in place to support staff competence. Organisations can tailor their governance, and risk management strategies to reflect the scope of care provided allowing for strong clinical and organisational leadership and accountability for staff competence. This is the area which has seen professional guidance change since the previous toolkit and promotes the concept that well-led services are integral to services providing safe care (RPS, 2019; CQC, 2020).

This chapter is designed to be a guide for any children’s palliative care service. Individual practitioners and their organisations can use the guidance to independently evaluate and review the structure and frameworks they have in place to support competence in medicine management at the patient bedside, irrespective of the context of clinical care. Moreover, the principles of competent practice may support benchmarking and validation of existing good practice and highlight areas for practice and governance development.

This chapter covers:

- Organisational and practitioner responsibilities for patient safety in medicines management
- Managing risk associated with medicines management
- A definition of clinical competence
- Why medicines competencies are important
- Examples from areas of practice
- Links to competency frameworks and exemplars (Appendices)

There has been substantial change in guidance surrounding competence and responsibility since the previous edition of the toolkit. There is greater emphasis on the presence of organisational workforce systems and the need for providers to demonstrate effective leadership and ability to safely manage services, including medicines management.

All registered providers of healthcare, including those delivering children’s palliative care, must have organisational systems in place to ensure care and treatment is provided in a safe way for service users. The proper and safe management of medicines is prescribed in law (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Health and Social Care Act (2012).

Identifying hazards and doing all that is reasonably practicable in assessing and mitigating risks associated with medicines management is key to ensuring safe care and treatment. Organisations must, therefore, have clinical governance systems in place which provide support for staff and assurance to service users. Regulated activity 12 can be used as a checklist for organisations to benchmark medicines management practice www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment. See section on regulatory compliance in **Chapter 2**.

A primary hazard for medicines management in any context is “ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely” and “ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way” www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment#full-regulation. One way to provide support for staff and assurance for children and families is the development and use of clinical practice competencies.

Sector specific guidance found in the key lines of enquiry (KLOE) for children's hospices from the Care Quality Commission have been developed to support the regulatory process and can also serve as a tool to benchmark and evaluate services. "How does the Provider ensure the proper and safe use of medicines (KLOE S4)" has a helpful checklist of questions and resources as set out in **Chapter 2**. www.cqc.org.uk/sites/default/files/20200212_Sector_specific_guidance_Hospices_for_children_and_young_people_v1.pdf.

There has been a corresponding shift towards generic guidance relating to individual responsibility and accountability, such as, for example, those listed in the previous chapter (RPS, RCN, HEE, RPH). Defining the role and responsibilities of an 'Authorised Practitioner' in medicines management in organisational policy (rather than individual professional roles such as doctor or nurse) supports the use of generic guidance. Whilst it is acknowledged that there is flexibility in the practice and strategic development of services, principles of safety, risk management and the cycle of quality improvement of care should be consistent. It is fundamental for practitioners to demonstrate competence to practice as this is a statutory requirement under the terms of Registration (and renewal or Revalidation) with their relevant professional body and to improve public protection by making sure that practitioners remain fit to practice.

There is no nationally agreed medicines management competency framework. Any provider developing their own, such as those outlined in **Appendix 3**, should incorporate the key elements described in **Chapter 2**.

Context specific competencies, where there are additional potential hazards which require additional risk management controls, should have separate competency framework items. Complex areas of care require specific policy and procedure and articulated responsibility defined in job roles/descriptions. These include areas of practice such as: single checking of controlled drugs, infrequently used medicines or medical devices used to administer medication; or service developments such as developing the role of the non-medical prescriber; or non-professionally registered practitioners (eg care assistant; health care support worker; assistant practitioner roles) in administration of medicines.

Any competencies relating to medicines management should be designed to ensure that authorised practitioners are competent against written evidence-based standards and include areas which ensure a holistic child and family centred caring approach in all contexts of clinical care.



Authorised Practitioner (Exemplar from East Anglia's Children's Hospices Medicines Policy)

An Authorised Practitioner (AP) is a registered nurse or care assistant who has completed the EACH Medicine Management Competency training. All Authorised Practitioners must:

- comply with the policy and associated SOPs
- complete training and maintain competence
- highlight their own training requirements
- be accountable for their practice and work within their scope of competence in line with their professional body code of conduct
- report any medicines errors, incidents or near misses in accordance with incident reporting procedures
- evaluate risks associated with their activities appropriately
- raise any medicine-related issues, risks and concerns with a manager or clinical lead
- not take medicines for personal use or give to any child or young person who is not a patient undergoing treatment or care within the service at the time
- be aware of signs that may indicate abuse, diversion or theft of medicines or controlled stationery



What is competence?

Competence can be described as ‘the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely’ (HSE, 2019). Other factors, such as attitude and physical ability, can affect competence in all professional groups. Individual components of competence are defined as:

- **Knowledge** is the understanding of facts, truths and principles gained from formal training and/or experience. Application and sharing of one’s knowledge base is critical to individual and organisational success.
- **Skill** is a developed proficiency or dexterity in mental operations or physical processes that is often acquired through specialised training.
- **Ability** is the power or aptitude to perform physical or mental activities to an approved standard.
- **Individual attributes** are properties, qualities or characteristics of individuals that reflect their unique personal makeup.

Royal College of Nursing competencies (2nd edition, 2018) were developed to support the delivery of high quality, evidence-based care by nurses and health care support workers involved in the care of infants, children and young people requiring palliative care. It defines a competence framework (p.5) as: “the range of knowledge, skills and performance levels required of nurses and supervised health care support workers/assistant practitioners working in a specialty to help them achieve safe, effective and accountable practice” **RCN Competencies: Caring for Infants, Children and Young People requiring Palliative Care** Royal College of Nursing



Competence across the multidisciplinary team

Paediatric palliative care services may involve a diverse multidisciplinary team (MDT) – and within it variations in professional experience and competence. The NICE guidelines (2019) make the distinction between those teams comprised of specialist palliative care services providing palliative care support on a permanent basis and other teams who may be comprised of primary and acute care practitioners, who may rely on the support of specialist teams to provide care.

The breadth of MDT membership is important for two reasons. Firstly, it draws attention to organisations needing to account for broader competence frameworks for non nursing professionals. As discussed in **Chapter 2**, medical staff must have levels of experience and knowledge of medications management to support safe patient care. It may be necessary for specialist members of the team to have competence in specific aspects of medicines management – such as those in allied health professional roles and pharmacists to better support the safe care of children. It is of critical importance that organisational systems are in place to agree the scope of roles and responsibilities and corresponding competence frameworks to support safe patient care.

Secondly, diverse MDT membership draws attention to the complexities of working on an interagency basis with staff who may have differing levels of experience to manage more complex patient needs. This challenges organisations to consider how their clinical governance around medicines management supports external professionals working alongside them. Shared learning and practice development examples can be woven into competence development – but clinical governance must make clear the processes for working together in both a safe and well led manner.



Knowledge bite

Delegation and accountability

All registered health service providers are accountable to the criminal and civil courts to make sure their activities meet legal requirements. In addition, employees are accountable to their employer to follow their contract of duty. Registered practitioners are also accountable to regulatory bodies in terms of standards of practice and patient care.

The law imposes a duty of care on practitioners, whether they are HCAs, APs, nursing associates, students, registered nurses, doctors or others. The duty of care applies whether they are performing straightforward activities such as supporting a child with personal care or undertaking complex medicines administration.

All practitioners must ensure that they perform competently and that they don’t work beyond their level of competence. They must inform a senior member of staff when they are unable to perform competently.

To be accountable, practitioners must:

- have the ability to perform the activity or intervention
- accept responsibility for doing the activity
- have the authority to perform the activity, through delegation and the policies and protocols of the organisation

Adapted from www.rcn.org.uk/professional-development/accountability-and-delegation (RCN, 2017).



Delegation

Registered nurses have a duty of care and a legal liability to children and their families. When delegating an activity, for example to a care assistant, health care support worker or assistant practitioner, the appropriateness of the delegation must be assured. Providers of health care as employers also have responsibilities to ensure that staff are trained and supervised properly until they are competent.



Knowledge bite

Principles of delegation (NMC Code)

The NMC Code (number 11) states that as a registrant you must be accountable for your decisions to delegate tasks and duties to other people and that to achieve this you must:

- only delegate tasks and duties that are within the other person's scope of competence, making sure that they fully understand your instructions
- make sure that everyone you delegate tasks to is adequately supervised and supported so they can provide safe and compassionate care
- confirm that the outcome of any task you have delegated to someone else meets the required standard

Read The Code online: www.nmc.org.uk/standards/code/

Employers accept vicarious liability for their employees. This means that if their employees are working within their sphere of competence and in connection with their employment, the employer is also accountable for their actions.

RCN guidance (RCN, 2017) sets out the following relating to delegation:

- delegation must always be in the best interest of the patient and not performed simply to save time or money
- the support worker must have been suitably trained to perform the intervention
- full records of training given, including dates, should be kept
- evidence that support workers' competence has been assessed should be recorded, preferably against recognised standards such as National Occupational Standards
- there should be clear guidelines and protocols in place so that the support worker is not required to make a standalone clinical judgement
- the role should be within the support worker's job description
- the team and any support staff need to be informed that the activity has been delegated
- the person who delegates the activity must ensure that an appropriate level of supervision is available and that the support worker has the opportunity for mentorship. The level of supervision and feedback needed depends on the recorded knowledge and competence of the support worker, the needs of the patient, the service setting and the activities assigned
- support workers must have ongoing development to make sure their competency is maintained
- the whole process must be assessed to identify any risks

Appendix 4 shows an example of a flow chart for delegation which outlines practitioner and organisational responsibilities.



Nursing Associates

Since the publication of the 2014 toolkit, nursing associates have become active members of the paediatric palliative care team **Nursing Associates – The Nursing and Midwifery Council (nmc.org.uk)**. Nursing associate practise is regulated by the Nursing and Midwifery Council and, as with nursing colleagues, nursing associates must be aware of the limits of their ability and role boundaries, acknowledge their professional limitations, and make accountable decisions about their ability to practice in a safe and effective manner. This is reflected in the most recent revision of the NMC Code (2018) and in the Standards of Proficiency for Nursing Associates (NMC, 2018). As with registered nurse roles, nursing associates are expected to develop their knowledge, skills and competence beyond their initial qualification throughout their careers.

Nursing associate roles may be seen in two phases, as trainee and as qualified. A qualified nursing associate can demonstrate competence in medicines management through the common competence frameworks used across an organisation. These frameworks will have specified learning and competence expectations on induction to the role and clear timescales for revising and updating knowledge to ensure competence is maintained. It has been recommended that, to mitigate risks, individual organisations may wish to identify safety critical medicines by name, developing local policies to identify the scope of practice for any staff involved with the named medication. This may be relevant for organisations to consider in the context of higher risk medications such as administration of Buccal Midazolam in urgent epilepsy management.



Developing competencies in specific medication practice areas: Three case studies

While this toolkit acknowledges the importance of standardising clinical practice and any corresponding competencies across the UK, there are elements of medicines management in hospice care for which it may not be appropriate or in the child or young person's best interests to apply a generic competency framework.

This section offers suggestions to support the development of context specific competencies. It provides three exemplars of clinical governance principles being applied to organisational and practitioner competence:

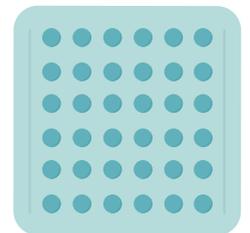
1. Medicines management related to continuous subcutaneous infusion (CSCI) delivered over 24 hours.
2. Use of strong opioids for the management of pain and dyspnoea in the home/community setting for administration by parents/ carers.
3. Developing the authorised practitioner role for non-professionally registered care assistants in an inpatient hospice setting.

Exemplar 1: Management of medicines via continuous subcutaneous infusion (CSCI) devices (syringe drivers)

Continuous subcutaneous infusions (CSCIs) are used in palliative care when other routes of administration are unsuitable or inappropriate. This is an area of practice to which staff may only be periodically exposed, with sometimes long gaps between any experience. Therefore, specific competency development and associated training is essential.

Professional groups using mechanical devices for continuous administration of medicines including controlled drugs should complete training in setting up the specific devices used by their service. They should have their competence confirmed and seek specialist advice if needed when setting up devices for continuous administration (NICE, 2016). As this is a complex intervention and frequently used mechanism for the administration of CDs, competence and compliance with all requirements related to CDs should form part of an overall risk assessment.

Evidence based policy and associated clinical procedures should be in place that describe how to mitigate risks associated with all aspects of syringe driver management. This is a fundamental principle supporting staff competence and will support the delivery of safe medicines management.



The following questions can be used as a competency checklist to benchmark or audit syringe driver management practice as part of an organisational quality improvement cycle.

1. Are specific models of syringe drivers identified and managed within an organisational medical devices policy and asset register which includes all elements of equipment maintenance and annual servicing?
2. Is there an organisational policy/system in place?
3. Is there a governance assurance system in place and ability to respond to Clinical Safety Alerts associated with syringe drivers in a timely way?
4. Is there an incident management system in place to monitor, review and learn from clinical incidents or near misses to maximise patient safety associated with syringe driver use?
5. Is there a policy/clinical procedure/protocol in place which supports the use of designated make and model of syringe driver(s) and associated subcutaneous access devices and single use disposable equipment in all contexts where clinical care is provided?
6. Does the Medicines Safety Officer (as described in **Chapter 4** on use of syringe drivers) have governance and oversight responsibility for all elements of clinical practice and prescribing practice associated with syringe driver use?
7. Does the medicines management policy guide safe practice and high quality standards and support the holistic medicine management process for medicines, including CDs, which are administered via syringe driver? Does the policy include:
 - a. baseline training, competency and confidence assessment for individuals according to their scope of professional practice in relation to medicines use with a syringe driver?

- b. a range of competency assessment methods such as: self-assessment, formal and informal training, reflective practice, and assessment in practice?
- c. provision of written information (co-produced where possible) for children and parents for children who require medicines to be administered via syringe driver in all contexts where care is provided? For example, how to access nursing support 24/7 when required and how to troubleshoot common problems with a syringe driver when care is delivered at home or in the community

For the individual practitioner the following questions can be a useful mechanism to validate knowledge and skill and in identifying areas for learning and development associated with syringe driver practice:

1. Can I articulate my professional accountability and responsibilities regarding all aspects of medicines management associated with syringe driver use related to my role and organisational context?
2. Am I familiar with all the relevant policies and clinical standard operating procedures associated with syringe driver management and administration of medicines via the continuous subcutaneous route. Do I know how/where to access reference copies?
3. Do I have the required underpinning theoretical knowledge, understanding and practical application skills to manage a child requiring continuous subcutaneous infusion of medicines, including CDs, wherever the child is being cared for? For example, relating to:
 - a. choice of syringe and pump set up
 - b. syringe preparation for one drug only and syringe preparation when there is a prescriber direction to mix two, three or four drugs in the syringe and ensuring that unlicensed medicines discussion has taken place

- c. syringe placement and pre-loading before connecting to the child or young person's device
 - d. fitting the syringe into the pump and starting the syringe driver
 - e. using the KeyPad Lock
 - f. temporary interruption of infusion, changing battery while infusion in progress and resuming the infusion
 - g. infusion set changes
 - h. observation and monitoring while pump in progress and documentation
 - i. troubleshooting and pump alarm guide
 - j. what to do when a child dies
 - k. pump cleaning/decontamination.
4. Do I know how to and when to seek expert clinical and pharmacy advice if needed?
 5. Do I know what to do if I make an error or have a near miss associated with medicines given by syringe driver?
 6. Do I know what to do and how to report an adverse incident with syringe driver equipment or medicine?
 7. Can I provide sufficient (written) information and explanation to the child or parent/carer about syringe driver use to seek consent to insert a subcutaneous access device and set up a syringe driver with the child and/or responsible parent?
 8. Do I know how to clearly and effectively document care and management associated with administration of medication via CSCI?

An example of the documentation from EACH is included in **Appendix 5**.



Knowledge bite

Competency in use of syringe drivers

- Attention to baseline training structure
- Training around CD medications
- Training in use and troubleshooting of syringe drivers
- Training in incident management
- Training in how to educate parents and carers in commencing CSCI – how is this recorded and what assessments are you asking families to make?

Exemplar 2: Administration of medicines in the home for management of pain, agitation, respiratory distress by parents/carers

Organisational policy and procedure is required to guide practice when buccal administration of opioids is planned to manage a neonate, child's or young person's pain or respiratory distress. Wherever the preferred care environment it is essential to carry out an individual risk assessment for preparation, safe storage, administration and disposal of buccal medication. Training and assessment of competency is also an essential component of risk assessment and is required to prepare and administer medication in this form and to teach parents/carers all aspects of safe practice if the context of care is the home environment (Norman and Maynard, 2019). Self-administration by patient and/or parental competence to administer is discussed in **Chapter 2**.

The following questions can be used as a competency checklist to benchmark or audit medicines management practice for the provision of palliative care and support in the home environment to children and their family as part of organisational quality improvement cycle.

1. Does the organisation have mechanisms of co-production and partnership-working with young people/parents/carers which support self-administration and parent management of medicines in inpatient settings and at home, informed by specific risk assessment?
2. Is there a written record of service user/parental training and competence?
3. Is there an organisational policy/system in place and ability to respond in a timely way to Clinical Safety Alerts that relate to pharmaceutical and disposable medical equipment?
4. Is there an incident management system in place to monitor, review and learn from medicines incidents or near misses to maximise patient safety associated with medicines managed in the home and in particular when medicines for symptom management/end of life care are prescribed and used outside of standard/usual practice?
5. Is there a policy/clinical procedure/best practice standards protocol in place which supports the use of designated medicines to manage a specific child's symptoms? For example, buccal diamorphine for management of pain and/or dyspnoea, buccal midazolam for anxiety/agitation?
6. Does the Medicines Safety Officer have governance and oversight responsibility for all elements of medicines management in the context of home care? Does this include anticipatory prescribing and when medicines are prepared in advance and stored in the home ready for timely use (eg individual dose syringes for buccal administration by a competent parent or carer)? Does this include medication reconciliation and record keeping and the provision of a Patient Information Leaflet (PIL)?

7. Does the medicines management policy guide safe practice and high quality standards and support the holistic medicine management process for medicines, including CDs, and medicines prescribed in anticipation and stored in 'just in case' boxes which are administered or ready to be administered in the home environment? Does the policy include:
 - a. baseline training, competency and confidence assessment for individual practitioners according to their scope of professional practice in relation to medicines, including use of anticipatory medicines?
 - b. a range of competency assessment methods such as: self-assessment, formal and informal training, reflective practice, and assessment in practice?
 - c. provision of written information (co-produced where possible) for children and parents/carers where it is required that medicines are administered in the home? Does the information include processes associated with anticipatory medicines, for example, how to access nursing support 24/7 when required?

For the individual practitioner the following questions can be a useful mechanism to validate knowledge and skills and in identifying areas for learning and development associated with medicines management in the home or community environment.

1. Can I articulate my professional accountability and responsibilities regarding all aspects of medicines management use related to my role and organisational context?
2. Can I explain how parents are empowered and enabled in their role as expert carers in relation to managing their child's medicines and symptom control or end of life care needs?

3. Am I familiar with all the relevant policies and clinical standard operating procedures associated with management and administration of medicines via specific administration routes including the buccal, intranasal, subcutaneous route (including reconciliation and record keeping), and do I know how/where to access reference copies?
4. Do I have the required underpinning theoretical knowledge and practical application skills to manage a child requiring a variety of medicines, including CDs, and administration routes in the child and family context of care?
5. Do I know how to and when to seek expert clinical and pharmacy advice if needed?
6. Do I know what to do if I make an error or have a near miss associated with medicines managed in the home?
7. Do I know what to do and how to report an adverse incident with equipment or medicine?
8. Do I know what mechanisms are in place for co-producing information and guidance with young people/parents/carers relating to medicines in the home?

Exemplar 3: Competencies in non-registered staff

Health Care Assistants (HCAs) or their equivalents are a significant part of the workforce in children's hospice services. The Royal College of Nursing is clear that they are valued and integral members of the nursing team, and that they should be supported to develop the knowledge and skills required to deliver competent person-centred care. HCAs will usually provide care as a consequence of delegation. Registered practitioners will commonly delegate duties to non-registered staff in the best interests of the child or young person but remain ultimately responsible for the overall care of that child or young person.

Supervision of staff can be part of delegation when the registered practitioner is present, but this may not always be necessary provided the registered practitioner is satisfied that the healthcare assistant has been suitably trained to perform the task.

Notable practice point

East Anglia's Children's Hospices (EACH) has developed a programme in medicines management for HCAs involved in administering medication to children and young people. This includes:

- understanding legislation governing the ordering, storage and disposal of medications including controlled drugs
- verification of prescription, reconciliation of medicines and transcribing medications
- safe administration of medicines
- documentation and record keeping relating to medicines

Senior care assistants (SCAs) play an important role within EACH in the process of medicines administration for children and young people. SCAs are recognised as authorised practitioners who may undertake single-handed checking procedures in the home and hospice, once they have successfully completed a Medicines Administration Course of study (as a unit in NVQ3 qualification, EACH medicines competency) and been assessed competent as part of their role. This is outlined in their job description.

This learning and development programme has been designed to support new care assistants with their professional development, to build their confidence in working with children, young people and families requiring palliative and end of life care, and to ensure all staff can demonstrate competence in both core and specialist areas of practice.

The programme has been developed by EACH based on the standards in the RCN Competences Palliative Care for Children and Young People (2018), Future Nurse standards for nurses (NMC 2018), Meeting health needs in the community (RCN) and the CHAS competency framework.

The programme is used in conjunction with the EACH Orientation/Induction Plan, induction and mandatory training programmes and EACH policies and procedures.

The programme can be completed over a period of six months to one year, timing is often influenced by level of exposure to clinical situations.

The SCA is required to work for an agreed period in a supernumerary status and is supported by experienced nursing mentors.

The roles and responsibilities of mentors are to:

- orientate to the hospice service
- observe, assess and evaluate performance and help set objectives and develop the SCA's own individual learning plan
- work alongside the SCA on a regular basis
- meet monthly with the SCA to review progress, identify further learning activities and complete documentation
- inform line manager of SCA progress.

SCA role and responsibilities are to:

- undertake induction, mandatory and clinical skills training completing workbooks as required
- be responsible for own professional and clinical development
- reflect on own performance and record achievements
- identify learning needs through self-assessment
- attend a monthly meeting with their mentor and record a summary of the meeting in their learning log
- ensure documentation is available for their mentor to complete
- devise individual learning plans and complete actions in the agreed time alongside their mentor
- inform their line manager of progress.

The following two case reflections illustrate how they have developed personally and professionally from the medicines development programme to become authorised practitioners.

Case reflection 1: Tina Howlett, Senior Care Assistant, East Anglia's Children's Hospices

"The EACH medicine management programme has given me confidence in calculations of medication. Completing the programme gave me a better understanding of controlled drugs, how to use the BNF and transcribing MAR charts which alternately has helped me further develop the role I have when caring for children and young people using long term ventilation.

Within my role I have found being able to administer medicines has reduced the pressure on the nurses on the shift. From the CYP point of view, having a senior care assistant who is providing the care for the day and able to give the medication means the CYP is able to go out on trips for the day. This previously would have been less feasible due to a nurse needing to be available for administering medications.

I found the group activities in the programme when completing medication calculations very helpful. I didn't feel confident with my mathematic skills prior to the training and found working as a group really helped me develop on this skill as we were able to help with ways of working out calculations. There was a real mixture of age groups within the programme I completed which helped as there were lots of different learning styles.

I thought the medicines programme would have been even better if we were able to spend more one to one time with the clinical educators. There was a large group when I completed the programme and the education team were stretched to their limits training on all areas of the programme. Nursing staff could have been given more guidance on how to support us, as we often needed to explain to them how the competency booklets worked. I was lucky that I provide nurses with training for children using long term ventilation so I have allocated 1:1 time with nurses so I utilised these care sessions to complete my practice and sign off".

Case reflection 2: Jo Bishop, Senior Care Assistant, East Anglia's Children's Hospices

"I feel that by doing this programme I have more of a purpose on the care floor. What I mean is that previously as a band 4 if I saw the nurse had lots of medications to do and was struggling (say 3 CYPs all had several meds at the same time) I was not able to support them. Now I can have a conversation with the nurses at the start of the shift to decide what they are happy for me to do and what they would prefer to do themselves and go from there. This means that there is less pressure on the nurse, and I feel much more useful to the shift in general, plus I feel there is a lower risk of medication errors because of feeling the need to be rushing. I have also been supported by the nurses (one in particular) to have my knowledge tested since being signed off. They will often randomly ask a question about a medication, such as what it is for or how much I was giving in mls for the dose – which ensures I keep alert. This has been really useful and has meant that I have had to keep the information fresh in my mind.

Since being signed off (and prior to COVID) this has meant that children who are considered stable have been able to go out more, even if there hasn't been a nurse available. We have managed to have trips to the zoo for example, that went really well and we did not have the nurse with us (but available via phone). It's also meant we can support children traveling to school without having another nurse, therefore making it more cost efficient for EACH. It has also made the admission process more efficient as we can do the whole thing so there is continuity with parent – rather than saying I can do this, but the nurse needs to do that bit and so on (unless a medication change for example).

What I liked was that we did the programme over a few weeks. We had one section then a break to get our heads around that part, then did the next. For me that was really useful as it meant I could have classroom-based learning then later that week put it into practice. I also found it useful doing 'buddies' for medications with various nurses as they all have different ways of explaining things. When I found the ones who helped me the most I tried to stick with them. I struggled with remembering the order of the medicines equation, but one nurse described it with a bit of a story (a shopping trip!). It really helped me remember and now every time I do the equation I start off in a shop – to many that's probably crazy but to me it made sense! The different learning styles of the nurses helped me learn different 'tricks of the trade' from different people".



Knowledge bite

The medicines equation

What you want, divided by, what you have, multiplied by the quantity/volume

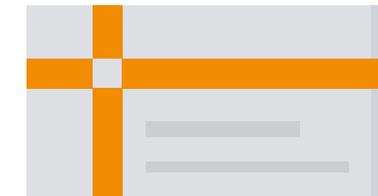
How to calculate drug doses and infusion rates accurately | Nursing Times



Useful resources

Skills for Health provide sector wide support and online resources. Their website has links to e-learning resources, competencies and many other practical tools to support medication management skill building. <https://skillsforhealth.org.uk/info-hub>

E-learning for health also provide useful resources www.e-lfh.org.uk





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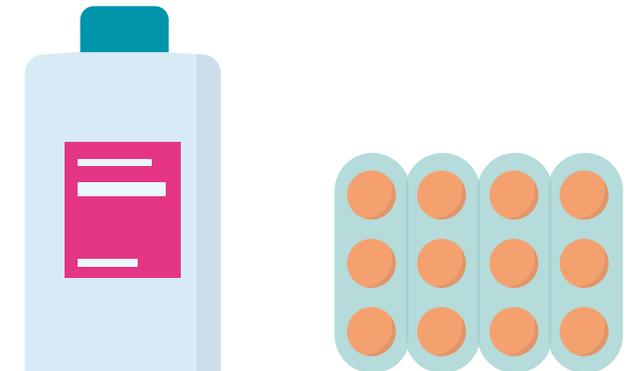
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Chapter 4: Learning from error

By Gerry Armitage



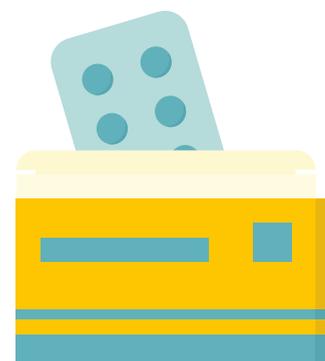
Children’s palliative care services support a diverse range of children, young people and their families. Some will be almost entirely cared for by their families with minimal support from the services, while others will require a level of support comparable with that given in a high dependency or intensive care unit.

Since the previous edition of this toolkit, children’s palliative care services have continued to provide substantial high dependency care. In turn, the consequences for children, their families, and the various health professionals supporting them remain challenging. Polypharmacy and challenging medicines regimes are not uncommon, lowering the threshold for medication error and preventable harm. However, there has been a change of emphasis around organisational safety since the last edition which has additional implications for medicines management and children’s palliative care services.

There is now an increasing emphasis on creating resilience both in an organisational, and patient or family context (Fylan et al, 2018) which centres on the ability to recover from the many threats to patient safety. It is acknowledged that working openly and collaboratively with families is deeply engrained in the culture of children’s palliative care, but it can also be a mainstay in maintaining and improving safety. This new focus highlights the need for learning from episodes of care that have not only resulted in a failure but also those episodes that have resulted in good outcomes; this idea is known as positive deviance (Lawton et al, 2014). Demonstrating organisational learning is now a significant priority for all those who provide healthcare.

This chapter covers:

- operational definitions for error management and a refreshed overview of the epidemiology of medication error
- the increasing emphasis on resilience in medication safety
- the role of families in advancing patient safety
- a human factors perspective to enhance situational awareness and team communication to prevent error
- the concept of crew resource management and team working (decision-making and communication in high-risk settings)
- advances in error reporting: principles of good practice including a grading scale for harm events
- organisational and individual learning
- the medication safety officer
- goals for notable practice



Introduction

Effective medicines management is essential in achieving quality and safety in healthcare. Medication errors can occur at any stage in the medication pathway, a process which is characterised by close coupling, complexity, variability, and with specific reference to child healthcare – the child’s increased vulnerability due to their immature physiology and consequently, their reduced drug tolerance (Kahn and Abramson, 2018; MSD, 2021). A closely coupled process is where, if a failure or error occurs, it can quickly and unpredictably cascade through the medicines management system – the steps of which are interdependent. This is directly comparable to the interdependent steps of prescribing, dispensing and administration. Furthermore, if medicines administration is being led by the child’s family, there are inherent risks in the delegation of responsibility and the sharing of medicines management.

While most errors result in near misses, or potential adverse events (no harm to the recipient), some will result in harm, ie, an adverse drug event (DH, 2004). I have chosen one of the most common definitions of error: “the failure of a planned action to be completed as intended – without the intervention of some unforeseeable event; or the use of a wrong plan to achieve an aim” (Reason 1990, p9).

A medication error can then be interpreted as the failure of a planned action such as medicines administration (or the use of a wrong treatment plan) that does not achieve the intended aims. It is also worth acknowledging that errors can relate to prescribing, transcribing, product labelling, packaging, medication names, dispensing, distribution, administration, education, monitoring and shared management. Errors have one of two outcomes, a near miss or harm event. A discrepancy is another term, often used in the context of medicines reconciliation and can lead to error or harm (see **Chapter 5: Transitions in care**). Rehearsal of these definitions

provides the foundation for accurate error reporting, investigation and data management. The financial and personal costs to all those involved in errors can be considerable (Sirreyeh et al, 2010), a recent estimate of the financial cost of preventable adverse drug events in NHS England was over £98 million per year (Elliot et al, 2020).

The increased media attention around preventable harm since the reported problems at Mid-Staffordshire hospital (Francis Inquiry, 2013) has impacted on many UK health services; it has certainly led to increased scrutiny from external regulators and a much sharper focus on safety. This is apparent in subsequent reports and policies such as the Berwick Review (2013) and the direction of the National Quality Board, refreshed in 2014, which embraces human factors through a published concordat rubber stamping the importance of a human factors approach to all aspects of safety. I will clarify the concept of human factors in this chapter and offer examples from hospice settings. Berwick prompted many organisations to be more open, systematise their learning from incidents, monitor variation in care processes and outcomes, and more closely involve patients or families in safety. These principles drive medication safety in any practice setting, alongside the NHS Patient Safety Strategy which earmarks three overarching aims: improving safety by using intelligent data from multiple sources, equipping those we care for and our staff to play their part in improving safety across the whole system through their involvement, and designing and delivering sustainable, effective improvements (NHSE/NHSI, 2019).

At the heart of these safety policies is the aim of eliminating preventable harm through well planned system-wide improvements, while accepting that errors will sometimes occur. Nabhan et al (2012) provide clinicians with an accessible means of deciding what preventable harm means in practice:

- The presence of identifiable, modifiable cause(s) of harm.
- Harm where a reasonable adaptation to a care process will prevent recurrence of harm.
- The causes can be traced before the harm occurred and an intervention could prevent the harm.

Nabhan et al also remind readers that there is rarely one isolated cause. The literature on accident causation reveals that accidents (or incidents) almost always have several interacting contributory factors at different levels in an organisation. These range from individual or team plans or actions, to their immediate environment, and beyond to the conditions of the surrounding organisation – such as its systems, processes, policies and culture (Reason, 2008). The most common contributory factors in patient safety incidents in hospital settings have been described by Lawton et al (2012), in medication errors in patients' homes by Harkenan et al (2020); and in medication errors in hospitalized children by Manias et al, (2013).

However, in common with the definition of error above, we accept that sometimes treatment will lead to harm that cannot be prevented or foreseen. A good example of this is an adverse drug reaction when a routinely used drug is being given for the first time to a child.



Epidemiology of medication errors

This section has been updated to reflect the current epidemiology of medication safety. As in previous editions, there remains a paucity of studies that have examined the incidence and prevalence of medication errors in children's palliative care. In response, this chapter largely covers the implications for children's hospices by reviewing the existing evidence across healthcare. The most relevant data has been reviewed from both secondary and primary care, before turning to children's health care including critical care, to better understand the likely risks for an entire children's palliative care service. A summary of existing knowledge about medication safety in hospice care completes the epidemiology section, with a final reference to children's palliative care.

Medication errors in adult healthcare

Medication error remains the most common category of medical error, presenting a real and present risk to patients wherever they receive care. A study of two medical admission units in the NHS estimated that 11.2% of admissions were due to adverse drug events, 47% of which were judged preventable (Kongkaew et al, 2013).

Since the second edition of the toolkit, far more medicines are prescribed electronically, and it is inevitable that this innovation will eventually become the norm in children's hospices. Slight et al (2019) carried out a large-scale medication record review study across four wards in a UK university teaching hospital over two years. Described as the largest UK medication error study to date, research pharmacists tracked all patients from admission during four seven to ten week study periods, following the implementation and optimisation of an electronic prescribing system – established three years earlier. Error rates per admission, per time-period

ranged from 1.43 to 1.70. The most common error type was specific to medicine reconciliation, followed by dosing error and avoidable treatment delay. Different error types often occurred in clusters (eg, dose and frequency errors). The work of Slight et al clearly demonstrates that admission is a critical time in the patient's hospitalisation, as are all care transitions (eg, discharge, transfer); a point of reflection for all staff in children's hospices where the same transitions occur.

The United States Institute for Safe Medication Practices have recently published their top ten medication hazards and although these data are also drawn from acute adult hospital settings, some have relevance to children's hospices; particularly: use of extended-release opioids, medication loss in intravenous tubing when using small infusion pumps, and the long-standing problem of error-prone abbreviations and symbols.

A rapid review of medication errors in primary care in the United Kingdom (Elliott et al, 2020), found an error rate between 0.2% and 90.6%; and that 71% of medication errors occur in primary care, the location where most medicines are prescribed. They reported that prescribing was the most common source of clinically significant medication error (33.9%), and prescribing errors together with monitoring errors were found to have the greatest potential to lead to either moderate or severe harm. An international systematic review of medication errors in adult primary care (Assiri et al, 2018) investigated the prevalence of prescribing errors and reported a similarly wide range of 2-94%; such extreme ranges are thought to be due to variation in error definitions, investigative methods and outcome measures, a variation which has unfortunately been evident for several decades. As in hospital settings, the most common patient-related risk factors appear to be the number of medicines prescribed (polypharmacy) and the patient's age, but also the number of physicians involved. The authors concluded that patient education, staff training, increasing the effectiveness of monitoring medicines (including technological interventions), and error reporting are key areas for improvement.

Medication error rates in child healthcare

Zed et al (2013) published a qualitative systematic review of children's hospital admissions, reporting that adverse drug events accounted for between 0.16% and 4% of admissions, and that between 20% and 67% of these were preventable. Sutherland et al (2019) reviewed the prevalence and nature of drug related problems in hospitalised children in the UK, demonstrating that adverse drug events are the most common drug related problem. One in 15 children experience a clinically significant prescribing error, and in critical care units this is increased to one in 10 (Sutherland et al, 2019); it is also clear that adverse drug events are increased in intensive care settings (Gates et al, 2019). The percentage of critical care events judged as preventable is currently unknown. A recent systematic review has confirmed the high-risk nature of critical care, establishing an error rate of 14.6 per medication order in children's intensive and neonatal care (Alghamadi et al, 2019).

As with medication errors in the adult population, errors in children's healthcare can occur at any point in the medication process; prescribing, transcribing, dispensing, or administration – and can quickly travel through the process as indicated in the introduction to this chapter. Prescribing is undoubtedly a process with inherent risks, between five and 27% of prescriptions leading to errors (Rinke et al 2014; Stang et al 2018). However, most errors occur at the medication administration stage, occurring on one in six administrations (Sutherland et al, 2019).

Medication errors in children: Summary of types and causes

Sutcliffe et al (2014) systematically reviewed paediatric medication errors in UK primary and hospital care; they found that off label prescribing in primary care was common practice, and often resulted in dosing errors – the most common error type in child healthcare, followed by omission errors. They also noted that in the parenteral nutrition process – which is not unusual in children's palliative care, the most common errors concerned product preparation, transcription and wrong drug or labelling errors. Gates et al (2019) published an international systematic review and meta-analysis of medication errors in paediatric inpatients, centering on preventable adverse drug harm events, and comparing wards to critical care settings. Most studies examined prescribing errors and concluded that electronic prescribing can reduce error rates but that this has proven to be inconsistent. They added that such technologies can reduce adverse drug events, but these should be carefully co-designed with users to optimise their effectiveness.

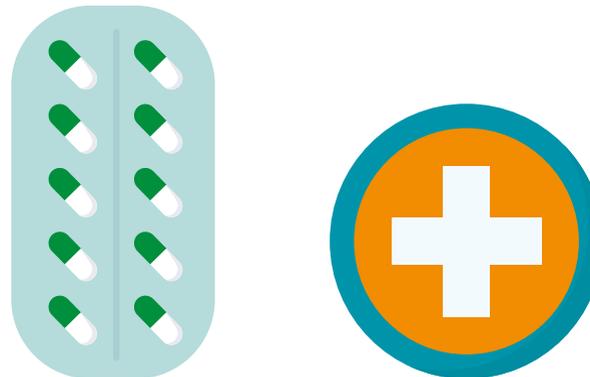
The prescribing and administration processes are made more challenging due to dose calculations and a wide range of administration rates (Sutherland et al, 2019). They caution that largely paper-based systems reduce the accuracy and completeness of prescriptions. Off-label and unlicensed medicines were implicated in many adverse reactions. The authors stressed that electronic prescribing systems – due to poor design and implementation – may not reduce dosing errors, confirming the recommendations of Gates et al.

Alghamedi et al (2019) identified dosing errors and the use of anti-infective medications as the two areas of greatest concern in critical care. The authors added that lack of both guidance and paediatric formularies contribute to error and that a multi-system approach is vital – acknowledging the various points in the overall medicines delivery process and their complex interplay. While there is now a growing intelligence of the nature and causes of hospital medication-related adverse events, the situation in children's primary care is less clear.

What we know about medication errors across the hospice sector

In the last edition, I remarked on the rarity of primary and secondary patient safety research in the hospice sector. A systematic review of opioid medication errors in oncology and palliative care (Heneka et al, 2015), reiterated the lack of studies specific to medication safety despite opioids and other high-risk medications being routinely used in practice. However, more studies are now emerging. A literature search identified several studies published by Deitz and colleagues at the Munich University Hospital; although set in adult palliative care in Germany – they are of some relevance to young people and offer a measure of transferable learning. The scale of the challenge is clearer. Medication errors (leading to adverse drug events) continue to be one of the most common medical errors in palliative care. Interrogation of the NHS national database of serious incidents in the specialism over a 12-year period, show that medication errors are second only to pressure ulcers in precipitating harm (Yardley et al, 2018). Following a literature review (Dietz et al, 2010) and national staff survey, Dietz et al (2014) indicated that communication failures (especially concerning symptom control), system failures, and advance care planning were common factors in error causation.

There are a growing number of children with life-limiting or life-threatening conditions (Fraser, 2020) who may require hospice or palliative care. Up to 30% of these children are prescribed at least five unique medicines, and 10% at least 10 (Taylor et al, 2020). In addition, Jarvis et al (2017) attempted to identify the instability of children with a LLC, finding that age – especially if less than one year, being female, South Asian, black or of other minority ethnic groups are influential factors. These data confirm the vulnerability of this group of very complex children to medication errors.



Knowledge bite

Epidemiology of medication errors

- Medication errors are common, children are especially vulnerable.
- Dosing errors are common error types.
- Polypharmacy, complexity of care and life-limiting conditions increase the risk of error.
- The percentage of preventable events involving children's medicines is unknown.
- Care transitions can increase the risk of error.
- Medicines reconciliation can be a source of error as well as a means of error capture.
- The processes of prescribing and administration are more likely to produce errors than dispensing.
- Vigilance is required when managing off label and unlicensed medicines.
- Medicines management processes are rapidly becoming digital for eg through electronic prescribing.



Resilience and systems

The Latin origin of the word ‘resilience’ literally means ‘bouncing back’. There are countless publications and research studies that have considered individual resilience, however, the focus here is institutional, or system resilience and how resilience can improve medication safety.

A system is defined as an interdependent group of items forming a unified whole (Walton, 2006 National Patient Safety Education Framework, Australia – in WHO Patient Safety Curriculum). The system in healthcare is typically complex, the many interdependent parts sometimes behaving inconsistently. There are unknown unknowns, and despite their experience, clinicians may be unable to predict how a routinely provided service might respond to changing circumstances. In such a complex system, the causes behind a harm event might only be obvious in hindsight (Snowden & Boone, 2007). An example is the pre-school child on CPAP (Continuous Positive Airway Pressure) at home. A child’s behaviour at this age can be hard to predict, but a pre-school child with full reliance on a piped oxygen via a restrictive nasal or face mask, who yearns for independence, makes the possibility of repeated oxygen disconnection very real; and very difficult to prevent.

Resilient organisations are those which offer an ‘intrinsic resistance’ (Carthey et al, 2001) to the many threats to their normal functioning. Medication safety examples include an electronic prescribing system (EPS) allied to a highly skilled, continually updated workforce, including an on call service which allows rapid prescribing and dispensing; and the EPS has inbuilt alerts for contra-indications, allergy status, and safe paediatric dose parameters. The EPS exists alongside an electronic reporting system for medication safety incidents providing immediate and intermediate feedback, and a multi-disciplinary *learning from incidents group* which reviews every incident and produces summary lessons for organisational learning, which are then circulated to all staff.

Carthey identifies three cultural drivers behind resilience: competence, commitment, and cognizance or foresight (Carthey et al, 2001); these are also key characteristics of effective teams in a resilient organisation. Competence refers to the skills and knowledge held by teams; commitment to the personal and professional motivation to provide the best possible care, and cognizance is the ability to look ahead and predict challenges to both the system and to those being cared for before they manifest as harm events. Cognizance is often seen in near miss incidents where the system (be it personnel, technical or both) prevents an error translating into a harm event. Near misses are often free lessons in recovery (Reason, 2011); unfortunately, clinical teams do not tend to complete near miss reports so the lessons are lost. I have explored some of the key obstacles to medication incident reporting, which have been replicated in numerous other studies, they include: cumbersome systems, lack of feedback and inherited blame for reporters (Armitage et al, 2010).

The following example illustrates organisational resilience, the team here have looked at ‘work as done’, where improvement comes from adaptation, understanding that practice is complex, and although humans (health professionals) are fallible they are a ready-made resource for resilience (Hollnagel, 2015), especially when working together. Staff vigilance led to the adaptation described in the following case study, rather than as a response to error or a harm even.



Case study: Resilience

From Jackie Collins, Governance Lead Nurse, Naomi House

- A young person arrived for a first stay with multiple medications including several intravenous drugs, including controlled drugs.
- Information was unclear about his prescription, and his clinical history was limited.
- Concern was raised about the volume of medications he was prescribed and reportedly taking.
- Concerted efforts were made to discuss the management of his medications with his GP. However, the young person had two different addresses (a home and university location) and his medicines were prescribed by three different health professionals (hospital-based, community-based, and via a locum GP).
- An elective decision was made to prescribe the bare minimum of medications to manage during his stay, and allow the young person to take some responsibility for self-administration with staff and family support.
- Frequent monitoring of his symptoms during his stay allowed an accurate assessment of his response.
- Following this situation, we agreed that all future admissions would be supported by clear, contemporary prescriptions based on an accurate medical history.
- Pre-admission calls would also be made as standard practice to establish current medication management to reduce the likelihood of poor medicines management during a stay.
- Liaison with those professionals involved in this young person's care highlighted the concerns about the volume of medication and the requirement for regular medical review in the community. An urgent case review, undertaken by the registered GP, mandated this process.



Family/carer involvement in safety

The reciprocal benefits of family presence and more latterly involvement in child healthcare have been extensively reported and led to the humanizing of children's healthcare. Families are now included in key aspects of palliative care. The involvement revolution now includes giving carers (and patients) a role in improving healthcare safety and quality. I have worked on two national studies to advance carer and patient involvement in patient safety (Armitage et al, 2017; Fylan et al, 2018); the second of these advanced the involvement of adult patients and their carers in medication safety and found that carers can build, enhance and maintain system resilience. The underpinning premise is to harness the power of carers (and patients) as constant observers of care, and sometimes care participants. A simple analogy is families as smoke detectors ie, early warning systems (Bacon, 2010).

There is now some data on patients' perceptions of errors in their palliative care; an early example is offered by Kiesewetter et al (2016), who carried out a small interview-based study in Germany, which revealed (in common with studies of adult patients' views of errors in other healthcare settings), concerns about professional communication. However, the attention given to professional attitudes and values, especially concerns around a lack of trust, empathy, autonomy (to make their own decisions) and patient-centeredness – suggest that what is seen as a communication error by patients is rather different to mainstream healthcare. These concerns may have relevance to children's palliative care and specifically the families involved, as well as a relationship with other published work in children's nursing. Smith et al (2015) reviewed a wide range of nursing literature to build a practical framework for parental involvement in the care of children with long term conditions. Their conclusions may have some resonance to improving safety, and in turn medication safety. In summary, Smith et al proposed that careful attention should be paid to eliciting and responding to parental concerns, the exchange of information, and incorporating parental knowledge into the whole process of care. This is reflected in the following example of care at a children's hospice service, which is also a reminder to care for the precious resource that is a child's family.

Case study: Family involvement

From Dr Pat Carragher, Medical Director, CHAS

The parents of children with life-limiting conditions invariably bring with them an extensive memory of medications their child has received, and any interactions between the medications. Helpfully, they are often witness to the obvious but also more subtle changes in their child's condition, and the accompanying response to their medications. Medical and independent prescribing staff in their history taking; pharmacists during medicines reconciliation; and nurses in their transcribing and administration of medicines, should always take this sometimes-hidden knowledge into account.

Consideration of the parent's context of care is also valuable; they are often charged with implementing new medication regimes at home where the child's best interests should be balanced with an understanding of how the family can continue to function. This can mean giving permission to parents to challenge clinical decisions. For example, a medical director in a hospice service has seen medication routinely prescribed every six hours in an intensive care unit (offering 24-hour uninterrupted care), at 04.00, 10.00, 16.00 and 22.00, continued after discharge home. Consequently, parents have set their alarm at 03.55 to administer medication. If the child is young and without a gastrostomy, then an alternative administration regime of 08.00, 14.00 18.00 and 22.00 is a possible alternative, dependent on the medication. There is more to this than maintaining parental well-being. This is about reducing the risk of medication errors. Firstly, it is known from studies of healthcare professionals, that fatigue from sleep deprivation can reduce cognitive function (Harrison and Horne, 2000); second, that the cumulative effect is significant (ie night after night); and finally, that rote tasks such as medicines administration rather than complex tasks are more susceptible to errors (AHRQ, 2019). There are no known studies of the same for parents but making the same conclusions for them is reasonable.



Human factors

The Clinical Human Factors Group, through the 2009 National 'Patient Safety First' Campaign, defined human factors as "encompassing all those factors that can influence people and their behaviour". They added that "in a work context, human factors are the environmental, organisational [and] job factors, and individual characteristics, which influence behaviour at work." The Patient Safety First Guide on Human Factors, which remains a high quality source of information, is in two volumes, and available at:

'How to' Guide to Human Factors – Volume 1 | CHFG – Clinical Human Factors Group

'How to' Guide to Human Factors – Volume 2 | CHFG – Clinical Human Factors Group

The above definition underpins the contributory factors approach to analysis of error causation mentioned previously, the premise being that multiple contributory factors generate errors. These involve individuals at the sharp end of practice through to the organisational decisions that form policies, and beyond the boundaries of a local service, to the behaviours and processes of partnering organisations (eg, hospitals and general practices) – all of which have a bearing on the care of children receiving palliative care.

Moreover, the human factors approach provides a means of understanding human error in the context of human vulnerability, and to enhance human performance through the design of effective systems. Human factors should be about learning from errors, modifying our defences and focusing on preventative strategies. It should not be about blaming individual practitioners, unless they have been reckless or negligent (Reason, 2000). It is outlined in the following examples, firstly, where the design of a safety critical process was modified to incorporate a structured checklist – leading to a systems change. The checklist is one means of improving team communication and not simply a list to check (Gwande, 2011). Second, a visual alert was integrated into an error-prone process.

Case study: A human factors approach: use of structured checklist

From Carmel Caldicott and Ann Smallman, Acorns Children's Hospices

Previous practice: The process of admission is usually undertaken by a registered nurse, with a second nurse being allocated to check the medicines on admission. This is intended to identify any inaccuracies or discrepancies at the start of the stay and correct them before the parent/carer leaves.

Current practice: We use a safety checklist to standardise medicines reconciliation¹, transcribe onto a MARS (Medicine Administration Record) to simplify the check, and ask key questions including:

- Any incorrect/out of date dose labels due to recent review with consultant or other clinician?
- Any expired/soon to be expired medication?
- Any medicines omitted?
- Any newly prescribed medicines?
- Is there enough medication for the duration of the stay?

On one occasion a newly dispensed medicine had a pharmacy dispensing label stating Melatonin 1mg/5ml. The child was to have 3mgs at night; suggesting 15mls. On closer inspection, the manufacturer's label stated 1mg/1ml, therefore the correct administration volume would be 3mls (if 15mgs had been given this would have been 5 times more than required).

Using communication from the parent, a consultant letter, and a previous drug chart as evidence for medicines reconciliation, we confirmed that the correct dose was 3mgs. The label was corrected on site by a non-medical prescriber (NMP) and the child admitted. The NMP investigated the inaccuracy through contacting the pharmacy named on the label. An incident was raised at the pharmacy and the report identified complacency on the part of the pharmacist, no independent check, and in turn a protocol violation. This was fed back to the family involved.

1. The full medicines reconciliation list has additional questions and is under continuing development.

Case study: A human factors approach: use of visual prompt

From Carmel Caldicott and Ann Smallman, Acorns Children's Hospices

Over a two-year period, one to two incident reports per month (over three sites) showed breaks in the cold chain for fridge stored medicines.

Previous practice: Nurses removed baskets of medicines from the individuals' locked medicine cupboards along with the MARS chart and checked medicines prior to administration. If a fridge item was identified as being required, they would collect from the fridge, check the label and withdraw the correct amount. The medicines would then be returned to the locked cabinet, incorrectly including the fridge item.

Current practice: FRIDGE ITEM was written in red on the chart next to the item for refrigeration, visually enhanced by red caps on the bottles to be refrigerated, and more widely through staff handovers and organisational memos.

The red cap must be removed to access the bottle contents and replaced when returning to the fridge. If a red cap is seen in a basket or left on a counter, it provides a visual prompt to return to the fridge. Red caps are not used anywhere else.

This was piloted in the Walsall hospice and there have been no further incidents; it was then rolled out to the Worcester Hospice and to date there have been no further incidents there.





Knowledge bite

Helpful guidance for the development and successful implementation of checklists is available

Checklists should:

- be supported by the whole organisation in which they are implemented
- be technically accurate yet adapted to the workforce and workflow
- clarify the roles all participants hold in the checking process
- identify any priorities and consider colour-coding the list

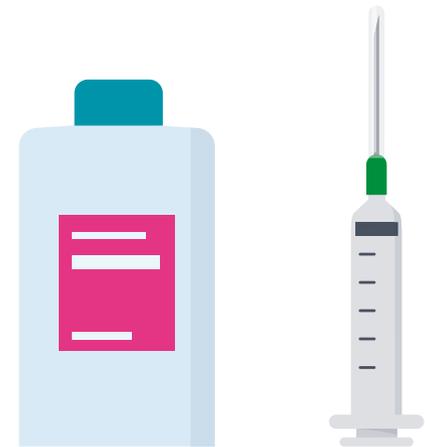
Local conditions, context and culture can either improve or jeopardize outcomes.

See: Clay-Williams and Colligan (2015). BMJ QS 24 428-431.

Humans are vulnerable to faulty decision-making. For many years, psychologists have written about our inclination to take mental short cuts to manage what are sometimes quite complex situations. In psychology these mental shortcuts or cognitive biases, are generally known as heuristics (Reason, 2008). While these shortcuts allow us to operate automatically, ie, without thinking too much about a task such as driving a car, and to manage significant workloads at pace, they can be counterproductive. We typically draw on previous experience, using our memory bank. Let us consider hiring a new car after several year's absence from driving. All very well until a problem emerges and we typically draw on experience for a resolution. For example, we look for the handbrake lever to perform a hill start but it is nowhere to be seen. But, in recent models, there is sometimes no handbrake lever. At the handover, the driver was asked if he was familiar with the car model to which he confidently said he was, he neither asked about the handbrake nor did the hire firm employee inform him. The employee was probably aware that an increasing number of cars (60%) now contain an electric handbrake – operated by a small button. The thinking pathway is paved with problematic assumptions.

There is no doubt that these heuristics play a part in the plans and actions of health professionals. A helpful summary of the most common biases is available from the Joint Commission (2016). The confirmation bias (or 'I knew it all along' bias), can be seen in deciding a medical diagnosis, and can be amplified by the availability bias. A doctor approaches a patient and assesses their signs and symptoms, these form a distinct pattern that she has seen recently, the recall of information is already filtered to match her existing assumptions and other diagnostic options are dismissed. She also successfully diagnosed this condition, albeit relatively rare, in the last year, and was praised by her seniors for doing so – the emotional power of this past event (indicating influence of the availability bias) enhances the confirmation bias.

Acknowledging these biases and being aware of their potential to increase the risk of error, improves situational awareness – an important competency in the human factors approach to work. Situational awareness is a systematic means to assess and address factors such as patient deterioration in complex healthcare settings. The situation-aware practitioner should recognise the potential threats to a child while they are receiving medicines, understand the meaning of these threats, and anticipate their impact over time to generate potential solutions – THINK AHEAD. This should ultimately lead to a more appropriate and timely escalation of concerns to senior team members and the better co-ordination of care.



Case study: Decision-making

From Dr Pat Carragher, Medical Director, CHAS

A senior doctor in a hospice service suggested that a significant risk is the non-prescription of opioids because of fear of their possible side effects, and if prescribed – a further concern about the lengthy and detailed conversation which may be required before administration. This misplaced caution is equally true of parents who, like prescribers, can be afraid to allow the use of morphine-related medications for fear of respiratory depression and other side effects that they may have heard about from various sources (Siden, 2003).

Yet, for both groups, particularly when dyspnoeic doses are being prescribed and administered, these medications can be a lot safer than alternatives (eg gabapentin), and clinicians need to remember that most doses of enteral morphine are not classed as controlled medications. The decision to avoid opiates can be influenced by confirmation bias (the clinician looks for or interprets information that confirms their beliefs) and the availability heuristic (the parent involved has read web posts about a child's fatal respiratory arrest following an increase in opiate dosage in a newspaper report, forming a vivid memory, and crystallising the assumption that this could happen more frequently than existing evidence demonstrates).

Effective decision-making is vital to medication safety. Introducing or modifying these medications should be based on honest, clear, evidence-based discussions that bring together front-line clinicians who have palliative care training and who have regular contact with the family, ideally with the paediatric pharmacist present. Everyone involved should leave the discussion with a clear understanding of why opiates are being used and how, as well as the benefits, and any potential adverse consequences.

Furthermore, raised stress levels increase the potency of these biases. In an emergency, medications are often prescribed strictly in line, with the Children's British National Formulary (cBNF) specific to age bands but without considering the broader clinical context – a level of fixation bias. In children's palliative care, where the weight of a child is often on the 3rd centile, this can lead to overdoses, including medications such as paracetamol and ibuprofen, but for many other medications too. Overcoming fixation bias is best achieved by inviting critical comment through honest, experienced peers, ideally one who is outside the immediate situation with 'fresh eyes'.

2. Situation, Background, Assessment, Recommendations, Readback (of information shared). See **SBAR improves communication and safety climate and decreases incident reports due to communication errors in an anaesthetic clinic: a prospective intervention study** | *BMJ Open* Accessed 19 Feb 2021.



Team working for medication safety and learning: Crew resource management and briefings or huddles

The last edition covered the topic of Crew Resource Management (CRM) drawing on an example from aviation; the continuing inclusion of CRM is based on its close relationship to human factors.

For the purposes of this toolkit and drawing on the work of Gross et al, (2019) who has posed fundamental questions about the meaning of CRM in healthcare, CRM is seen as an overarching safety concept that helps healthcare organisations *manage* human factors (and any related training or development). While Gross et al express some uncertainty about meaning, the CRM literature nevertheless provides a very practical basis for improving safety.

CRM is used alongside similar terms such as team resource management, and crisis resource management; however, the non-technical skills apparent in CRM and similar approaches are not just for crises but for routine practice (Reason, 2008).

CRM is about: proficiency (competence), team formation and maintenance, problem solving, decision making and situational awareness (Tullo, 2010). Here is a summary of the nature of CRM but also how to achieve effective CRM in complex, high risk workplaces such as healthcare:

- Team leaders accept challenge based on expertise and situational awareness – not rank or grade, this can help trap errors.
- Teams should demonstrate competence; and compliance [with standard operating procedures unless they present a threat to safety]
- Team members should employ effective communication strategies, including structured handovers such as SBARR², and hold patient safety briefings to clarify team members' roles; their working; and to offer positive feedback. Checklists can augment handovers.
- Debriefings following an incident should examine what went wrong, not who went wrong.
- Teams should monitor routine practice, through constant vigilance.
- Teams should be well led; leaders should demonstrate receptiveness, adaptability, cognizance, and positive role modelling (Tullo, 2010).

Patient safety briefings, also known as ‘huddles’ which can include important medicines updates have gathered considerable traction since the last edition and have been evaluated for their impact, showing raised safety standards (Joint Commission, 2021). Although these reports have drawn on data from acute healthcare settings, the principles can be transferred. There is a resource on medication safety huddles (Wilbur and Scarborough, 2005), and their overall focus on prevention rather than learning from a past event, should increase system resilience.

One constant from the last edition is primarily to see CRM as a tool to improve communication. It should also be a reflection of the way in which children’s hospices routinely function, the traits of CRM evident in the overall approach to treatment and care. Additionally, these traits should be apparent in the staff development process, how the organisation sets the safety culture, and achieves continuous improvement. Below, Kate McCusker firstly offers an example of how teamworking was changed to flatten a hierarchical process and increase vigilance in critical activities. The second example also addresses an inappropriate hierarchy but also increases team competence and uses role modelling to good effect.

3. See Miake-Lye BA et al. In-patient falls prevention programme. *Annals of Internal Medicine* March 5th 2013 **Inpatient Fall Prevention Programs as a Patient Safety Strategy: A Systematic Review: *Annals of Internal Medicine: Vol 158, No 5_Part_2*** (acpjournals.org).

Case study: Teamwork From Kate McCusker, CHAS

It was custom and practice in a hospice for the team leader to always carry the controlled drug keys, the team leader could, however, delegate holding the keys to a junior if there was a critical task to undertake but this was unlikely. The team leader was called away in the middle of setting up a continuous subcutaneous infusion (CSCI) of diamorphine and midazolam as she was holding the keys. Each of the two medicines required a specific dosage, but the interruption led to the team leader incorrectly switching the doses.

The error was spotted as the infusion pump was being attached to the child during administration checks (right child, right dose, right time etc), in this incident, nurse(s) who prepared the CSCI also carried out the administration checks and reported the error.

This led to a review as local practice which was found to be unnecessarily restrictive and hierarchical. As only team leaders could routinely hold the keys, this system was increasing the risk of errors through inappropriate ring fencing of a task that was not safety critical and leading to interruptions of safety critical tasks such as infusion preparation. The existing standard operating procedure (SOP) did allow other registered professionals to hold the controlled drug keys through a delegated process, but staff were not aware. To ensure practice matched the SOP, it was sent to all members of the nursing team who were asked to read and confirm they had read the SOP, the SOP was highlighted in Safety Briefings and handovers, and charge nurses confirmed the correct practice in Nurse Practice Development Meetings.

Case study: Team competence and role modelling From Kate McCusker, CHAS

Staff should comply with standard operating procedures (SOPs), if well written, reflecting contemporary practise and underpinned by an evidence base and rationale. However, if these criteria are not met, SOPs can be burdensome, inappropriate, and even dangerous.

In another hospice, staff routinely checked controlled drugs every night shift, using two registered nurses but during the recent pandemic low bed occupancy led to reduced staffing numbers and only one registered nurse per night shift in some situations. To maintain the checks, healthcare assistants (HCAs) were asked to take on the role of checker with a registered nurse. Although this was already permitted through the existing SOP, it was never implemented. This demanded a new approach to make clear that this was possible but also good practice. The change was led by a junior team leader who is also one of several medicines management champions.

The broader benefits of this change, above and beyond more effective resource management include applying the available competence levels of HCAs and allowing junior staff to lead change. This is an explicit indicator of an informed and learning-centred safety culture. The role of champions in implementing safety improvements is seen as an influential element of effective implementation³.



Reporting errors and the incident reporting process

A mainstay in the communication of errors, is incident reporting. One of the barriers to effective incident reporting is an inability to report what should be reported. As discussed, near misses are of value as they are ‘free lessons in recovery’ and largely because they are without harm. Consequently, they are unlikely to arouse among those involved, the emotional impact of an adverse event. All hospice services are encouraged to include transcription errors in their reported errors due to their high-risk nature. NHS England has produced a useful definition of a patient safety incident which applies to all medication safety incidents and would include errors, near misses and adverse events:

“Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them supports the NHS to learn from mistakes and to take action to keep patients safe” **NHS England – Report a patient safety incident** (NHS England)

While this definition would also include adverse drug reactions, these are reported using a specific system, see: **Yellow Card Scheme – MHRA**

Aware of the limits of learning from past incidents such as memory recall and the relatively small number of incidents compared to caring interventions, the more recent idea of learning from what goes well, or ‘positive deviance’ will be discussed under organisational learning.

Error reporting

Since the last edition of the toolkit, further questions have been raised about the effectiveness of incident reporting. The findings and recommendations can be summarised in a few points. Firstly, that in its dominant form, the process does not have any tangible impact on either clinical outcomes and safety culture (Stavropoulou et al, 2015). Implicit within this weakness is the lack of double loop learning (Argyris, 1977) – in short – while there may be consequential improvements in the local unit where the incident occurred, there is likely to be little change to any related organisational or latent factors. Latent factors, as the name suggests, are those factors which dwell, and are sometimes deeply embedded in an organisation – their effect encapsulated in the term ‘resident pathogens’ (Reason, 2000). Stavropoulou et al’s systematic review offers a way forward which includes clarity about what is reportable, clinical ownership, and integration with other systems. There is common ground between Stavropoulou et al and Leistikow et al, (2017), the latter advocating a concentrated focus on local learning (the team etc.), but also assessing the quality of incident reports using a comprehensive checklist (which is recommended here, including the importance of contributory factors and family involvement), and benchmarking the quality across organisations. Macrae (2016) consolidates the importance of local learning – arguing that incident reporting is not simply about data collection and analysis but should be about clinical participation – promoting open conversations across the team and including management to foster a regime for mutual accountability. Having covered more recent perspectives on reporting, I now turn to the reporting process, how to seek and capture feedback; and how to put in place a systematic approach to incident prevention and monitoring. In any narrative concerning causation, I reiterate that medication safety incidents will arise from multiple contributory factors ranging from a practitioners’ cognitive processes (eg a lapse or memory loss) through local conditions (eg interruptions) or latent factors (eg designated staff-patient ratios, prescribing systems, policies and procedures). The format of how these factors

and how they are recorded will be locally determined but drawing on the evidence-based contributory factors models cited in the introduction, provides a helpful framework.

Each hospice service should have a database of all patient safety incidents (including medication errors, near misses, adverse, preventable and unforeseen events), their rate, contributory factors, and impact. The record should identify the types of action taken – with due emphasis on systems, when the report was signed off by senior management, and with more serious incidents a formal review should be instigated and signed off by a multi-disciplinary panel.

The medication incident rate (total number of incidents over a given time) can be counted, and then compared to all prescribed doses in the same time-period allowing a calculation of the incidence of medication incidents from the point of prescribing, through to the point of administration.

Recording the rate of near miss reporting is also recommended as a proxy measure of the confidence of staff to report, their recognition of learning from near misses and as one sign of an open culture. Furthermore, the grading of severity of impact, can be informed by the NHS system in Table 1. All these recommendations are as applicable to electronic reporting as to a paper-based system.



Scoring the severity of the consequences of an error or unforeseen event

Level of harm	Degree of harm
No harm	No harm
Low	Minimal harm: child required extra observation or minor treatment
Moderate	Short-term harm: child required further treatment, or procedure
Severe	Permanent or long-term harm
Death	Caused by the incident

Notable practice point

The reporting of medication errors (and their outcomes) should be strongly encouraged, both locally and perhaps nationally. Report data should be systematically analysed to promote individual and organisational learning. Families should be told of any error that has impacted on their child and should be made aware of the reporting and learning process, reflecting the latest evidence and the NHS 'statutory duty of candour'. The reporting process is as important as the outcome, it should be owned by teams and management, and demonstrate mutual accountability.

If a hospice service chooses to issue a medication safety newsletter, this could contain a review of the latest information gathered from incident reports and any notable trends; this could include any family feedback and reports of positive action. Such a newsletter can be a helpful tool to drive cultural change towards a more collaborative, learning driven ethos amongst all staff. While children's hospice services are different in terms of their size and ways of working, they will be caring for children with both similar needs and equally challenging drug therapies. Periodic incident reviews could be shared across hospices where a larger sample of errors and adverse events could provide a more representative assessment of the scale and nature of any system failures.



Individual learning through foresight

Staff will be familiar with the process of risk management as part of local processes and systems. However, learning from inherently risky activities that have not met their intended outcomes, should also encourage healthcare professionals to individually develop error wisdom. Healthcare work has been described as a "very personal business" that often lacks the moderation that comes with the automated safeguards of other inherently risky types of work (Reason, 2004). For example, powerboats have a safety lanyard or 'kill switch' which automatically switches the engine off if the sailor falls away from the driving position; and in anesthesia – if the oxygen concentrations dip below a certain (safe) level, the nitrous oxide flow is cut off using a range of devices. Yet so many clinical activities in the hospice service, currently including medicines administration, do not have any safety guards.

The essence of error wisdom is being able to assess one's foresight or mental preparedness. The error-wise professional appreciates that they can reduce the likelihood of making an error but realises they cannot entirely eliminate error from their practice. They will assess their own ability to undertake a given task and assess the environment, but also analyse the task and assess its error potential (Reason 2004). Assessing risk in your practice also complements situational awareness and is a learning process.



Knowledge bite

The three buckets model (Reason, 2004)

Reason advocates the three buckets model to allow healthcare professionals to systematise their personal risk assessment, the model also facilitates situational awareness. Each of the three buckets is filled with what we might call waste matter. The fuller each bucket is, the more likely it is that a healthcare professional will commit an error or fail to recognise and respond to an unsafe situation before a patient is harmed.

The 'self' bucket is the current state of the individual involved, including their level of knowledge, fatigue, and the effect of recent life events. The second bucket is the context of practice, or the immediate practice environment. This environment will sometimes be full of distractions and interruptions, and staff may be hampered by a lack of time or by poor equipment.

The third bucket represents the error potential of the task, ie, how errors can occur at each individual step in a clinical task. Error potential varies widely across the different steps of a task and if the number of steps is high. The idea of error wisdom is very similar to that of foresight or cognizance, and the former NPSA offers a free foresight training resource that applies the three buckets model to several practice scenarios. See: <https://learn.nes.nhs.scot/2067/flying-start-nhs/three-buckets-model-questions>



Self

Context

Task

Notable practice point

Medicines management has considerable potential for error, especially in children's palliative care services where polypharmacy and complex therapy is common. The child may routinely receive complementary alternative medications such as herbal remedies or herbal medications, which are unlicensed in the UK. Staff should be sensitive to the integrity of their organisational systems and their personal mental preparedness when involved in medicines management. This approach to practice should be emphasised in staff training and should be reflected in standard operating procedures.



Organisational learning

The concept of organisational learning is frequently cited in the patient safety literature. In a successful organisation it is essential to leadership, systems and culture, yet for many healthcare professionals it feels elusive to describe and hard to achieve. The idea is wedded to a process of continuous improvement, and using learning at an individual, team and organisational level to discover, correct, and ultimately prevent patient safety incidents.

Some of the topics already covered, such as resilience and positive deviance underpin the idea. While some authors perceive the traditional approach of learning from past events as less helpful, I believe that there is still some merit in the traditional process, if it embraces the contributory factors approach, and includes input from those receiving care or their families – the latter having proved to be both feasible and useful in previously published research (Ward & Armitage, 2012); Armitage et al, 2017). Collecting staff narratives – based on what goes well, rather than tick box reports, is an important means of capturing how individuals and systems adapt their practise in a context of constant change, challenge, and complexity (Sujan, 2018). For reference, the shift from learning through past events to learning from what goes well and the recovery process is described in some of the literature as moving from Safety 1 to Safety 2.

There are several vital ingredients in organisational learning:

- An evidence-based, standardised incident reporting and investigation process which focusses on systems rather than individuals as separate entities; in an open, and just culture (Dekker, 2012).
- Staff being encouraged to report all near miss incidents which have clear learning implications.
- All organisational intelligence on the quality of care (incident reports, complaints, claims, patient and carer feedback, and examples of good care) is subject to systematic, integrated analysis.
- Further intelligence taken from staff and carer narratives of what goes well, this may require some coaching for those involved.
- The results are visible to all staff and carers in a service via an easy-to-understand format with supporting information.

Additionally, some hospices may find themselves relatively isolated. Clinical isolation is now seen as a notable factor in large scale organisational failures (Kirkup, 2018). Based on considerable evidence of the benefits of multi-disciplinary, cross organisational peer review, it is recommended that where possible, individual hospices learn together in larger groupings. Furthermore, hospices should also learn from errors and incidents with external partners through formal collaborations; ideally, through a Medicines Management Group – a point highlighted in **Chapter 1** (page 7).

Some hospice services have embraced organisational learning through specific initiatives and interventions, an example is provided below.

Case study: Organisational learning From Carmel Caldicott, Acorns Children's Hospices

Stimulus for learning

Following several minor but frequent incidents specific to medicines management, team leaders questioned whether the staff profile may have been a contributory factor – the majority working for 10 years or more in one setting. Could this demographic indicate a lower level of staff awareness of contemporary practice? We proposed partnering with external organisations to act as critical friends offering a constructive appraisal.

Our objectives

- Establish a reliable assessment of staff awareness of contemporary practice.
- If awareness was low, develop an improvement strategy.
- Improve, standardise and embed optimal practice.

Our actions

1. Annual visits by the Controlled Drug Local Intelligence Network (CDLIN) police officers ensure compliance with statutory requirements and give advice based on other care providers' approaches to CD management, including the NHS.
2. Annual visits by an external pharmacy provide external oversight of current processes and systems, offer policy updates, and in turn challenge complacency.

3. Monthly Medicine Management Meetings with head/deputy nurses, prescribers, clinical leads and visiting educators, to enable cross organisational learning and provide a forum for quality improvement, informed by national developments (eg, the effective use of buccal diamorphine, updates from Association of Paediatric Palliative Medicine, Master Formulary 5th ed 2020). Minutes are circulated to all staff.
4. Annual visits from the Local Clinical Commissioning Group Prescribing Advisor who provides education sessions (GPs also attend the meeting), the CCG monthly newsletter is also discussed within the meeting.
5. Routine invitation to staff working directly with children and families, if capacity allows, to attend the Monthly Medicines Meeting.

This additional layer of clinical governance through external peer review has raised the profile of the risks associated with medicines management within the staff group and yielded a specific intervention – the implementation of spot checks on MAR charts. Treatment room and daily controlled drug checks show improvement across time.

Our outcomes

- Reduced number of medicines management incidents with a negative impact on children/young people.
- Increased near miss incident reporting (where error was identified prior to any impact).
- Increased incident reporting rate and from a wider range of staff (informal feedback indicates raised confidence to report and increased competence).



Medicines Safety Officers (MSOs)

The Medication Safety Officer role was created in March 2014 following the publication of an NHS England Patient Safety Alert (**‘Improving medication error incident reporting and learning’**). It stated that all healthcare trusts were required to identify a board-level Director (or equivalent) to oversee medication error incident reporting and learning to help healthcare providers increase the quality and frequency of incident reporting for medication errors and medical devices. The alert called on large healthcare provider organisations across a range of healthcare sectors and the independent sector, along with healthcare commissioners, to identify named responsible persons in both medication and medical device safety roles.

Healthcare providers were required to identify a Medication Safety Officer who would be a member of the National Medication Safety Network, support local and national medication error reporting and act as the main contact for medication error-related issues for both NHS England and the Medicines and Healthcare Products Regulatory Agency. Hospices should be connected locally through the MSO network with other hospices, CCGs, community pharmacies and local hospitals where they can share learning from medication errors.

Further information about the role and responsibilities of a MSO can be found by following the link: www.sps.nhs.uk/wp-content/uploads/2016/09/Medication-Safety-Officer-Handbook_v1.2-May18-JH.pdf

Goals for notable practice

The concluding message from the last edition is equally pertinent in this edition: manage medicines in a culture where information is actively sought, responsibilities are shared, failure causes inquiry and feedback, innovation is welcomed, and staff are appropriately trained [after Westrum, 2006].

- A high level of vigilance must be given to medicines, *all of which are potentially hazardous* if previously unused by the child or received in error.
- Be aware of the predominant risks in medicine management according to latest evidence.
- Monitor and review medicines procedures, standards and related competencies for clarity and fitness for purpose, in line with legal requirements.
- Safe storage, clear prescriptions, and meticulous dispensing and administration are imperative.
- Systematise high risk medication preparation and administration – paying particular attention to effective systems for differentiating and checking medicines.
- Be aware of the frailties of human communication and decision-making and how these can impact on medicines management.
- Involve families in medication safety where possible, invite their expertise.
- Report errors identifying contributory factors, whether they result in near misses or adverse events, and demonstrate that learning has occurred through the reporting, investigation and action-taken processes.
- Report what goes well.
- Share learning from errors and incidents across the service, and with families.
- Share learning with other organisations, especially if an error has occurred that involves more than one organisation.



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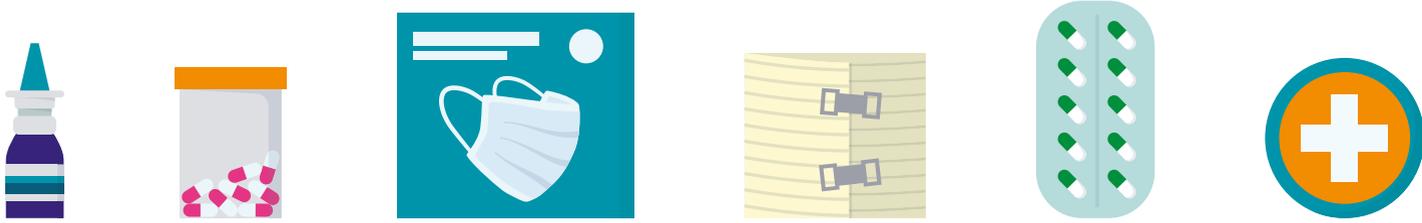
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Chapter 5: Transitions in care

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The patient journey in healthcare has many areas of potential risk, especially where a patient's care is transferred from one setting to another. Over half of all medication errors occur at interfaces of care and most commonly at admission and at discharge (Campbell et al, 2007). For children or young people receiving drug therapy, medicines reconciliation and transcribing of their medication is an integral part of the care they receive, but this can only be done safely when healthcare professionals have the most accurate and reliable information about the child or young person's medication (Burns et al, 2012). Children and young people with complex conditions are usually under the care on average of up to five different providers. For example, a child in a typical day may be cared for at home and then go to a special school and then to respite care and possibly even have an outpatient clinic appointment. As a result of these multi '*transitions*' a patient/carer will need to repeat the child or young person's medicines on numerous occasions.

This chapter covers:

- definitions of medicine reconciliation and transcribing
- an overview of medicines reconciliation and the transcribing process considering the best evidence base to underpin notable practice
- case studies to help the reader put medicine reconciliation and transcribing into practice context
- the necessary knowledge for qualified health professionals to consider an active role in medicines reconciliation and transcribing
- goals for notable practice so as to achieve high quality standards for medicines reconciliation and transcribing

Medication errors, defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer” (Council of Europe: Committee of Experts on Management of Safety and Quality in Health Care, 2005) are estimated to cost \$42 billion per annum globally (Sheikh et al, 2019). Errors are not inevitable; they are provoked by weak systems and as a result of combinations of complex processes, technology and human interaction (World Health Organisation, 2019).

The economic impact of errors is significant and includes cost of resources for the treatment of patients experiencing medication-related harm, the time taken to resolve medicines-related problems and legal proceedings (World Health Organisation, 2019).

There are several factors that can contribute to the occurrence of medication errors (Tang et al, 2007; Alomari, 2015; World Health Organisation, 2016):

- Healthcare professional factors, such as training, clinical knowledge, personal neglect, failure to adhere to guidelines/policy documents and knowledge of the patient.
- Patient factors, such as their characteristics, case complexity and how many medicines they take (polypharmacy).
- Work environment, such as resource availability, staffing, workload and interruptions.

Medication-related problems can also occur alongside medication errors, and include delayed care, inappropriate monitoring, non-adherence to medication, and general confusion about treatment (Johnson et al, 2015; Parekh et al, 2018).



Children as a high-risk group

There are many patient groups that are at greater risk of medication error. Those patients treated with multiple medicines, or with high-risk medicines or those with complex co-morbidities, such as renal impairment, are far more likely to experience medicines-related harm (World Health Organisation, 2019). Polypharmacy, most commonly described as the use of five or more medications daily (Masnoon et al, 2017), also puts patients at increased risk of harm and it is well recognised in clinical practice that children may be on multiple medications to manage their medical conditions (Bogler et al, 2019).

It is thought that the likelihood of errors in paediatric patients is higher due to the need for careful dosage calculation, complicated and differing rates of drug metabolism, the use of unlicensed or off label prescribing, limited appropriate dosing information and low availability of ready-to-administer formulations (Hughes and Edgerton, 2005; Ghaleb and Wong, 2006).



The Third World Health Organisation (WHO) Patient Safety Challenge

Medication errors are internationally recognised as a widespread challenge within modern healthcare and the WHO has set a global target of a 50% reduction in their incidence by 2022 (World Health Organisation, 2017). This is the third WHO Patient Safety Challenge, following the success of their ‘Clean Care is Safer Care’ and ‘Safe Surgery Saves Lives’ campaigns. To help focus the challenge, the WHO has prioritised reducing avoidable medication errors within high risk situations, such as at transitions of care and for high risk patients, such as those who take multiple medicines (polypharmacy). Children and young people cared for in children’s hospices meet both of these criteria.

The NHS Patient Safety strategy (2019) also has a vision to continuously improve the healthcare culture by minimising blame and focusing on strategies for improvement. They also emphasise the importance of patients and carers as full partners. Patients and their families must become ‘vigilant stakeholders’ in their own safety, rather than passive recipients of care. Families are therefore key to the administration process and can should be engaged to help reduce medication errors (Alomari, 2015).



Medicines errors at transitions of care

Transitions of care, where patients move between healthcare settings and providers (eg hospital to home, home to residential care setting), involve a complex set of processes (World Health Organisation, 2016). Most medication errors that occur at transitions of care are thought to be a consequence of poor communication and medicines reconciliation failure across sectors (Moyer et al, 2010; Johnson et al, 2015). Medication discrepancies, defined by Corbett et al (2010) as “*any difference between the discharge medication list and the medications a patient actually takes once at home*” are especially common at transitions of care (Stone et al, 2010; Gattari et al, 2015). If complete information is not available when a patient transfers from hospital to ambulatory setting, especially if multiple healthcare professionals are involved in that patients care, the patient is put at increased risk of experiencing an adverse event and ultimately hospital readmission (Johnson et al, 2015).

Most studies with a focus on medication discrepancy for paediatric patients, have investigated hospital admission errors (Huynh et al, 2013). One study found that a third suffered potential adverse events from medication discrepancies at hospital admissions (Coffey et al, 2009). One literature review estimates the prevalence of paediatric patients with a medication discrepancy to be between 22 and 72.3% (Huynh et al, 2013). The WHO (2019) estimates that 11-59% of medication discrepancies at admission and discharge were thought to have the potential to cause harm. Other common errors include overdose, wrong transcription between documents (eg medicines administration records), wrong frequency of administration and missed dose (Ghaleb et al, 2006).

Of course, there are multiple challenges to providing effective care across transitions. Leadership and collaboration are required not only within care settings, but across them. Resources must be available to support this, and appropriate education and training (World Health Organisation, 2019).

The role of nurses in transitions of care

Nurses have a responsibility to ensure patient safety and are ideally placed to help manage medication risks (Farre et al, 2017). Hughes and Edgerton (2005) argue that because it is predominantly nurses who administer medications to patients, they are often the last potential barrier between a medication error and serious harm. Activities regularly provided by nurses to ensure successful transitions of care include patient education, advocacy and support (Disabato et al, 2019). Nurses have a crucial role within medicines reconciliation in identifying and resolving unintentional discrepancies (Kwan et al, 2013) and in engaging with patients and their families to promote continuity of care. Kreckman et al (2018) showed a reduction of medication error from 33.9% to 18.7% at hospital admission, 22.9% to 5.0% at discharge and 12.8% to 0.7% at follow-up visit within 30 days of discharge.

The WHO (2019) has identified four key strategies for improving medicines safety at transitions of care:

- Structured medication reconciliation.
- Patient engagement.
- Collaborative medicines management (within the context of a full multi-disciplinary care team).
- The quality and availability of information.

On transfer to the hospice setting, nurses can encourage interventions by clinicians, such as medication review programmes, that could help to reduce inappropriate polypharmacy through assessing each medication for its potential benefit compared to its risks (Sok and Turner, 2015; Bogler et al, 2019). By prioritising those medicines with the lowest benefit-harm ratio for discontinuation, medicines use can be optimised, potentially improving patient outcomes and quality of life.

Other strategies to prevent paediatric medication errors (Ghaleb and Wong, 2006) are:

- improving prescribing processes
- double checking of calculations
- questioning of unusual doses and volumes by nursing staff
- engaging with the patient, parent or caregiver if any queries arise

Whilst practice varies nationally with nurses on the whole assuming the responsibility for managing a young person's medication at transition points, evidence is emerging about the important role pharmacists and pharmacy technicians can play at this point to reduce patient safety incidents. Embedding pharmacists/pharmacy technicians into the hospice clinical team can help to improve the young person's outcomes. Pharmacists/pharmacy technicians can support the hospice in undertaking medicine reconciliation/transcribing, help counsel young people and their families on medicines prescribed, support access to medications and help with writing up post discharge summaries. Pharmacy led medicine reconciliation has been associated with reduced medication discrepancies and errors and for this reason hospices should review how they can work more closely with pharmacists/pharmacy technicians (Stranges et al, 2020).

Medicine reconciliation

The importance and effectiveness of a robust and rigorous medicine reconciliation process is recognised globally as a vital initiative in improving patient safety. The patient journey in healthcare has many areas of potential risk, especially where a patient's care is transferred from one setting to another. It is estimated that 40% of medication errors are directly a result of inadequate medicine reconciliation in handovers during admission, transfer and discharge of which 20% lead to patient harm (Rozich et al, 2004).

Consequently, for children or young people receiving drug therapy, medicines reconciliation and transcribing of their medication is an integral part of the care they receive, but this can only be achieved when healthcare professionals have the most accurate and reliable information about the child's or young person's medication (Burns et al, 2012). Children and young people will access many different healthcare professionals for their care needs so it is essential that hospices have an accurate record of medications prescribed to prevent any harm.

Medicines reconciliation and transcribing have now become an essential part of hospital admissions and discharge systems and the children's palliative care sector should have similar robust systems implemented in their settings. As set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12, the aim is to ensure children and young people receive safe care and treatment, and also that avoidable harm (or risk of harm) from the medication they are prescribed is prevented. Medicines reconciliation is designed to mitigate for this risk. It is important to note that there are considerable similarities in the medicines reconciliation and transcribing process whether a child or young person is admitted to hospital or a hospice.

There are several definitions of medicines reconciliation, although healthcare professionals have yet to reach a consensus regarding a single recognised definition (Burns et al, 2012). The WHO definition is "a process designed to prevent medication errors at patient transition points" (WHO, 2007). However, most definitions involve defining the list of medications the child or young person should be taking, altering records to reflect changes and ensuring the child's parent/carer is aware of the changes. The most commonly cited definition of medicines reconciliation is:

"The process of identifying the most accurate list of a child's or young person's current medicines (including Over The Counter and complimentary medicines) including the name, dosage, frequency and route – and comparing them to the current list in use, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated."

(Institute for Healthcare Improvement, 2005)

NICE guidelines on medicines optimisation state that medicine reconciliation is not only done on admission of a child or young person to a hospice but also when they are discharged back to home, at which point the hospice should inform the GP of any changes to medications. This recommendation poses a challenge for GPs for a variety of reasons as evidence shows that discharge information provided by secondary care can be of variable quality. For this reason hospices should send discharge summaries promptly to GPs and community pharmacies to ensure they have an up to date list of medications that clearly highlights any new medications that have been started or discontinued or any dose changes. NICE guidance also makes it clear that hospices should have a designated health professional lead who has overall organisational responsibility for medicine reconciliation processes (NICE NG5, 2015).



Knowledge bite

NHS England issued a Stage One Patient Safety Alert in August 2014 concerning risks arising from breakdown and failure to act on communication during handover at the time of discharge from secondary care (NHS England, 2014).



Discrepancies

The term ‘discrepancy’ is often used in relation to medicines reconciliation and does not have the same meaning as ‘medication error’. It is important to know that there are both intended and unintended discrepancies, for example deliberately withholding medication for a child due to a clinical reason would be regarded as an intended discrepancy. On the other hand, an unintended discrepancy would be incomplete or inaccurate information being available about the child’s medication on admission to a hospice which results in a child receiving medication which is not prescribed (or failing to receive a medication for which they are prescribed), causing a direct impact on the child’s or young person’s health and clinical outcomes (Hellstrom et al, 2012). Unintentional medication discrepancies can have two possible outcomes (see figure 1).

One possible outcome of an unintentional discrepancy is the development of an adverse drug event and actual harm to the child. The second outcome is the *possibility* of causing harm to the child. This second eventuality is termed a potential adverse drug event (pADE), or a ‘near-miss’ (see **Chapter 4: Learning from error**). The WHO defines a pADE as a “serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted” (also called ‘near miss’ or ‘close call’) (WHO, 2005).

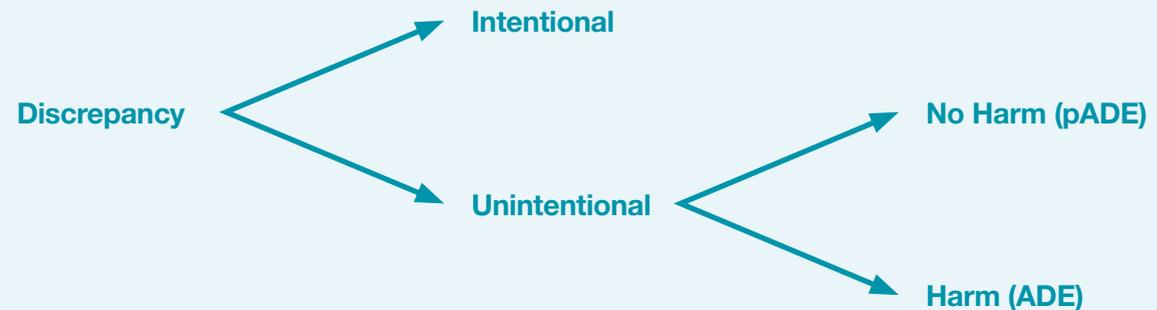
One study conducted by the East and South East Medicines Safety Division investigating medicine reconciliation across 56 NHS trusts found 11,366 unintentional discrepancies between the medication prescribed on admission and what should have been prescribed (Dodds, 2010). More recently it was found that 40-54% of patients experience unintended medication discrepancies upon admission to acute care settings and importantly that 46- 56% of these discrepancies caused substantial clinical problems (Lo et al, 2013). Evidence such as this strongly suggests that at least basic medicine

reconciliation should take place at every transfer of care to reduce any potential harm due to an inappropriate medication regime. This finding is directly supported by healthcare policy (NICE NG5, 2015).

This guidance highlights the importance of ensuring that medicines prescribed or transcribed on admission correspond to those that the patient was taking prior to admission. This guideline identifies key priority areas to ensure organisations such as hospices have trained and competent staff with the necessary knowledge and skills to undertake medicine reconciliation and also ensuring that they have robust systems in place for sharing information about the child when they are discharged back to their GP or other care setting.

In the UK, NICE (2015) issued formal guidance on the importance of ensuring that medicines prescribed or transcribed on admission correspond to those that the patient was taking prior to admission. www.nice.org.uk/guidance/qs120/chapter/Quality-statement-4-Medicines-reconciliation-in-acute-settings

Figure 1: Relationship between discrepancy and adverse drug event



This guideline identified key priority areas for implementation which were to ensure organisations had trained and competent health professionals with the necessary knowledge and skills to undertake medicine reconciliation and ensuring robust systems were in place for sharing information in relation to the child or young person when they are discharged back to their GP or to another care setting.

The Health and Social Care Act 2008 Regulations (2014) require that hospices “*protect service users against the risks associated with the unsafe use and management of medicines and cooperate with other providers*”. Guidance has also been issued by the Care Quality Commission based on the premise that managing medicines when a child or young person transfers from one setting to another is central to safe, high quality care. Effective management of medicines is a requirement of the CQC’s essential standards on quality and safety (outcome 9) as is cooperation with other providers when care is transferred (outcome 6). www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards

In addition to the legal and regulatory guidance, good practice guidance has been issued on ensuring children or young people receive optimal treatment when taking medications. There is an emerging evidence base indicating that the use of medicines as a therapeutic intervention may often be sub-optimal. This has been acknowledged by all key organisations involved in the care of children such as Royal College of Nursing, Royal Pharmaceutical Society and Royal College of General Practitioners, as an issue that needs addressing. These Royal Colleges collaborated to produce the guidance medicines optimisation – helping patients to make the most of medicines (RPS, 2013). www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf



Knowledge bite

WHO and NICE advise that medicine reconciliation should be conducted within 24 hours of admission and within 72 hours, for admissions over the weekend, and has prioritised medicine reconciliation as one of five top patient safety strategies within the ‘action on patient safety’.

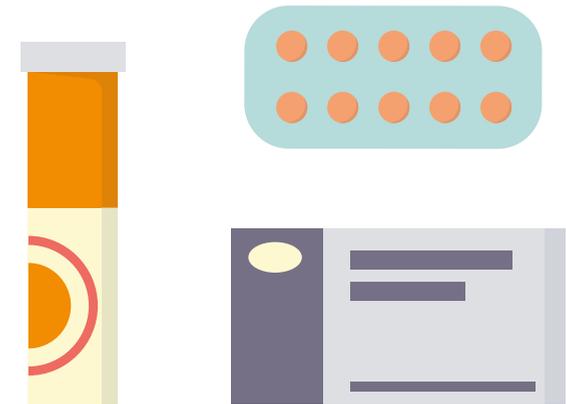
Unintended discrepancies, most commonly omission of clinically relevant medication occurring on admission stands between 39-72%; implementation of medicine reconciliation looks to reduce the risk of a child not receiving the most appropriate medication.

Medicines optimisation is ensuring the right child gets the right choice of medication at the right time and this can be successfully done by accurately conducting the medicine reconciliation process and transcribing at admission and then at discharge. At the heart of medicines optimisation is the child and parent/carer and it is important that they are informed about the correct use of their medicines to ensure maximal benefit. To ensure medicine optimisation becomes a success, a multidisciplinary approach is needed in which all health professionals involved share a common goal, so that the child can get the best out of their medications. For further information on medicines optimisation see www.nice.org.uk/guidance/ng5/chapter/1-Recommendations.



The overarching principles of medicines reconciliation

- Making sure the right child gets the right drug, in the right dose and at the right time, via the right route (ie continuity of treatment).
- Reducing the risk of medication errors occurring when the care of a child is passed from one care setting to another (ie if a child’s care is being taken over by the homecare team or visiting the hospital for a day case to ensure that the team has an up to date list of medicines the child is taking).
- Providing ongoing personalised medicines management care for each child.
- Reducing confusion about the child’s medication regimens (for healthcare professionals as well as for parents/carers).





The benefits of medicine reconciliation

- Improved communication between healthcare professionals and others involved in the care of the child.
- Greater parent/carer involvement in their child's care – thereby helping parents/carers to develop a better understanding of their medicines and an ability to communicate that information to other healthcare professionals.
- A potential reduction in waste medicines due to unnecessary medications not being dispensed.
- Less duplication of effort that can occur if different healthcare professionals have to track the same piece of information, something which is routinely achieved when medicines are effectively reconciled each time a child's care is transferred.
- Improved record keeping – with the minimum dataset of medicines being documented appropriately.
- An increase in the timely availability of accurate medicines information – essential for prompt and appropriate treatment.
- The potential avoidance of medicines-related admission or re-admission to hospital or other care providers which can occur when unreconciled medicines lead to prescribing or medicines administration errors.



Approaches to medicine reconciliation

The National Prescribing Centre (NPC), which has now been merged with NICE, published guidance in 2007 on medicines reconciliation which has been adopted by the majority of health and social care providers. This sets out two stages of medicines reconciliation:

Basic reconciliation (stage 1)

Basic medicines reconciliation involves the collection and accurate identification of a child's current list of medicines including OTC or alternative remedies. An example of basic medicines reconciliation would include medication history-taking at admission to a hospice/ service, where a complete and accurate list of a child's or young person's current medication regimen would be documented within 24 hours of admission.

Full reconciliation (stage 2)

Full medicines reconciliation builds on stage 1 of the process. It involves taking the basic reconciliation information, comparing it (using two or more sources) it to the list of medicines that was most recently available for that child. In addition, it involves identifying any discrepancies (intentional or unintentional) between the two lists and then acting on that information accordingly and resolving any discrepancies identified. In other words, interpreting the outcome of the basic reconciliation in light of a child's or young person's ongoing care plan, then resolving any discrepancies and accurately recording the outcome.



The process for medicines reconciliation

The *NPC guide (Specialist Pharmacy Services: Improving the quality of medicines reconciliation, a best practice resource and toolkit)* suggests that the steps in the process can be remembered by adopting the 'three Cs' approach, endorsed by the Royal College of Nursing. The medicine reconciliation process is not only designed to ensure the correct medication is prescribed on admission but also to ensure the child is discharged on the correct medication and that this information is communicated to all healthcare professionals involved. The need for reconciliation at discharge was endorsed by the CQC report, which identified a need for improvement in the quality of medicines information provided by hospitals to GPs in their discharge summaries (Grimes et al, 2011). It's also important to bear in mind that care which would previously have been provided in an inpatient setting is now increasingly being provided at home.

There is the same need for a full medicines reconciliation process for children who are cared for at home. Healthcare professionals should endeavour to collect the most accurate information from the most reliable sources regarding the child's medication history before the prescribing and administration of any medication. Conducting medicine reconciliation in an inpatient setting will mean that there is access to comprehensive and detailed documentation such as the child's medical notes or electronic health records. It is acknowledged that this may not be available within the home setting, but there will be other useful sources of information that can be used to construct an accurate medication history – such as the patient's own medications, repeat prescriptions or clinical management plans.

The Three C's

The three Cs are defined as:

- Collecting.
- Checking.
- Communicating.

Step 1 – Collecting (basic reconciliation)

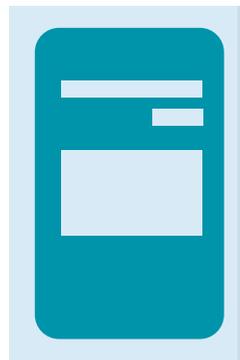
The collecting step involves taking a medication history and collecting other relevant information about the child's or young person's medicines. This information may come from a range of different sources (some potentially more reliable than others). For example:

- a computer print-out from a GP clinical records system
- the tear-off side of a child's GP repeat prescription slip
- verbal information from the child, their family, or a carer
- medical notes from a child's previous admission or discharge letter/prescription from hospital
- community pharmacist patient medication records
- child's own medications that may have been bought in with them at the time of admission
- emergency care summary record (ECS) (Scotland only)
- electronic health records
- clinic letters

The medication history should be collected from the most recent and reliable source. Where possible, information should be cross-checked and verified with another source which can include the parent or carer. The person recording the information should always record the date that the information was obtained and the source of the information. It should also be recorded if there is a discrepancy between what the child is currently prescribed, and what the child is actually taking. The reasons for any variation should be noted if these can be established.

Step 2 – Checking

The checking step involves ensuring that the medicines and doses that are now prescribed for the child or young person are correct. This does not mean that they will be identical to those documented during the basic reconciliation process. For example, a prescriber now responsible for the child may make some intentional changes to their medicines. Any discrepancies will need to be resolved in the final step of the process.



Step 3 – Communicating (full medicines reconciliation)

Communicating is the final step in the process, where any changes that have been made to the child's prescription are documented and dated, ready to be communicated to the next person responsible for the medicines management care of that child. Examples might include:

- when a medicine has been stopped, and for what reason (including topical preparations)
- when a medicine has been withheld for a period of time
- when a medicine has been started, and for what reason
- the intended duration of treatment (eg for antibiotics or steroids especially if it is a decreasing dose)
- when a dose has been changed, and for what reason
- when the route of the medicine has been changed, and for what reason
- when the frequency of the dose has changed, and for what reason
- when the formulation of a medicine has been changed, and for what reason
- when medicine related discrepancies have been identified and resolved in a timely manner using clinical judgement



Sources of information for medicines reconciliation at stage one and/or two

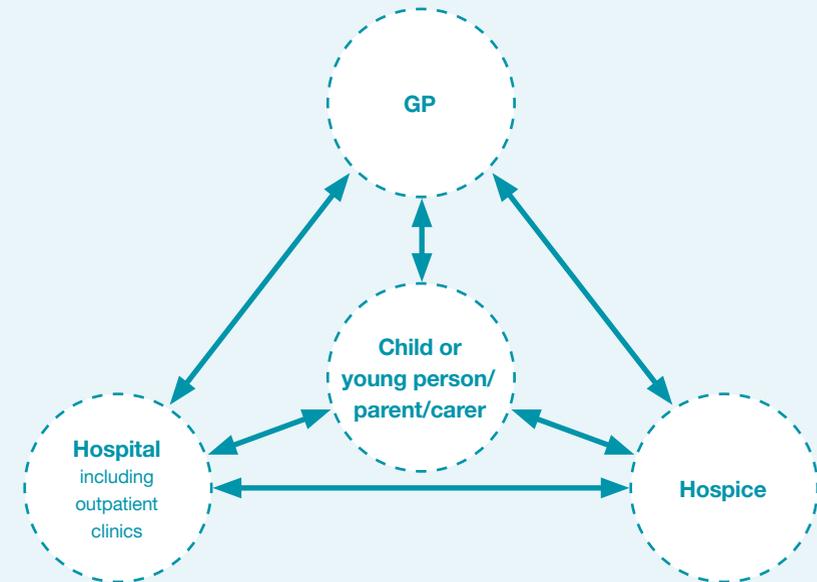
The following sources of medication histories are listed below in no order of preference, as reliability can vary according to the situation. However, it is usually necessary to use two or more sources to establish accurate medicines reconciliation. Medicine reconciliation can be a very complex task. It involves liaising with several sources of information and managing the medication history you receive, reconciling this information with other sources of information to ensure you have a correct and up-to-date medication history and finally highlighting and dealing with any discrepancies that may arise. This is referred to as the triangulation process (see figure 2).

The child/young person and parent/carer

- The child and their family themselves can tell you exactly how they take their medicines. You need to be mindful that they may not initially have fully understood the instructions.
- Always try to establish exactly how a child takes their medicines, as this could be very different from the formal records.
- Parents or carers can be very helpful in establishing an accurate medication history and can also give an insight into how medicines are managed at home. An important point to note is that parents or carers sometimes alter the dosing, timing and administration without seeking healthcare professional approval first. For this purpose, it is essential as a healthcare professional that you build a relationship based on trust and openness with the parent or carers to ensure the best possible care for their child or young person.
- Be aware that parents may talk in milliliters rather than milligrams and that this can be a source of error unless you physically see the product dispensed to them.
- Be mindful of maintaining confidentiality.
- Some children may have a hand-held record of their medicines which is updated by healthcare professionals caring for them. This is more common in children under the care of an oncology or renal team. Take care if this has been hand-written by the parent or carer because errors can be made or information can be misinterpreted and then documented.

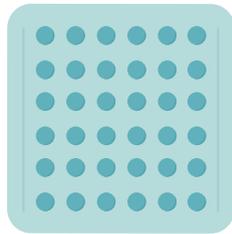
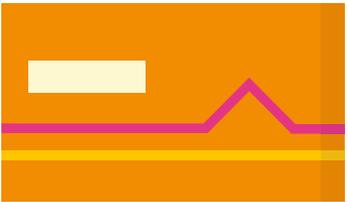
- Some children may also have a seizure management plan which can be useful to refer to as it documents the medicines and doses to be used in case of a seizure.
- Some families may not speak English as their first language, so consider whether a translator is necessary, especially for the admission process.

Figure 2: Diagram demonstrating triangulation of medicines sources and the transfer of medical information between multidisciplinary healthcare professionals that takes place in medicine reconciliation. The child and parent/carer is the common factor and at the heart of this information transfer.



GP surgery

- Ideally, a faxed or email list is preferable to a telephone call as it provides a permanent record and it reduces the risk of transcription errors occurring. Some hospices have direct access to GP records and allow nurses to view the list of medicines directly.
- Be aware of ‘acute medicines’, ‘repeat medicines’ and ‘past medicines’ on the receptionist’s screen.
- Always check when the item was last issued and the quantity issued.
- Specific questioning may be needed for different formulations, for example different types of inhalers (metered-dose, breath-actuated, turbohaler), different calcium preparations (Calcichew®, Calfovite D3®, Adcal D3®), or medicines which are brand specific (aminophylline, theophylline).
- It may be necessary for you to speak to the GP directly to clarify any discrepancies.
- Specifically ask whether there are any ‘screen messages’. Some medications are ‘hospital only’ and do not appear on the usual ‘repeat list’.



Summary care records (SCR)

The availability of SCR has significantly improved efficiency and accuracy of medicine reconciliation. SCR is a live document of the GP electronic health record for the child and contains the following pieces of information which are helpful when conducting medicine reconciliation:

- Acute medications prescribed in the last 12 months.
- Current repeat medications.
- Repeat medications stopped in the last 6 months.
- Allergies.
- Adverse drug reactions.

When using SCR, check when it was last updated (should be updated daily). They do not always state the last date a prescription was issued so clarify this with the young person or parent/carer. Always gain consent from the young person or parent/carer before accessing SCR records and ensure that staff have completed relevant training in relation to SCR. When reviewing medication history on SCR you may come across the terms ‘authorised’ and ‘last issued’. When a medication has been ‘authorised’ the term implies it has been reviewed by a medical prescriber and is suitable for the young person/child. The term ‘last issued’ will be used in conjunction with a date – this date is the last time the GP surgery printed that prescription for the young person/child.

Patient’s own drugs (PODs)

- Encourage families to bring in their child’s medicines from home, preferably with their names on.
- Discuss each medicine with the child and their family to establish what it is for, how long they have been taking it, how frequently they take it, what time they take it and any other additional instruction that may help the staff administer the child’s medication during their stay in the hospice.
- Do not assume that the dispensing label accurately reflects how the child takes the medication.
- Check the date of dispensing, since some parents may bring all their child’s medicines into the hospice, including those stopped, and check each medication with the child and parent/carer to see if they are still taking it.
- Confirm that the medication belongs to the child. It is not uncommon for siblings’ (or parents’) medications to be accidentally brought in.
- Ensure that the medications brought in have not expired. This is especially important for medicines such as Oramorph, Baclofen, eye drops and reconstituted antibiotics as these have shortened expiry dates once they have been opened. A record should be made of the date opened.
- Some parents/carers may only bring in the prescribed medication that the child is taking. It is important to ask them if the child is taking any over-the-counter (OTC) medications such as paracetamol, ibuprofen or hyoscine hydrobromide and also whether they are taking any herbal or homely remedies like St John’s Wort.
- Some parents/carers may only decide to bring in the medications that the child is taking, but this does not necessarily mean they are not prescribed any other medications. They may be deliberately withholding these medications.

Repeat prescriptions

Some parents/carers keep copies of all repeat prescriptions. Many of these may include medicines that have been stopped and do not include information on acute prescriptions.

- The date of issue should always be checked and each item confirmed with the child or parent/carer.
- Check if there have been any recent consultations/acute medications prescribed by the GP (eg antibiotics).
- Check if they have been any changes from other prescribers (ie hospital consultants/specialists).
- If there is any doubt, the GP surgery should be contacted.

GP referral letters

- These are not always reliable as they may not be contemporaneous.
- They are often hand-written by the on-call doctor and may be illegible or incomplete and could be missing doses or formulations of medicines.
- It may be necessary to double-check the drug history with the child, parent/carer or GP surgery in order to confirm its accuracy.

Compliance aids/monitored dosage systems (MDS)¹

- These may be filled by the community pharmacist, district nurses, parents or carers.
- If the pack has been filled by the parent or carer themselves then this cannot be used as a source of information for medicines reconciliation as it will be unlabelled and the contents will not be readily identifiable.
- If dispensed by a community pharmacist, the device should be checked for dispensing labels, which will provide the pharmacy contact details.
- The date of dispensing should also be checked bearing in mind that the medicines may have changed.
- Remember to check 'when required' medicines and medicines that may not be suitable for compliance aids such as liquid medicines, inhalers, eye drops, once weekly tablets, patches.
- Consider contacting the community pharmacist with the child or parent's consent to inform them of the child's admission and to prevent unnecessary repeat dispensing. They may also inform you of the number of compliance aids that have been filled, since these may still be at the child's home. The community pharmacist's contact details should be documented on the drug chart and a discharge plan agreed.

Recent hospital or hospice discharge summary

- Check whether any changes have been made by the GP or hospital consultant since the child's previous discharge from hospital or hospice.
- If the child has been home for more than two weeks they may have visited their GP and changes may have been made.
- Discharge summaries that are more than one month old should not be used as a sole source for a drug history.
- It is important to be mindful that the GP may not have updated the patient records or possibly actioned the discharge notification changes.
- In some cases it may be necessary to investigate additional sources to obtain a complete medication history, for example:
 - Community/hospital pharmacists
 - Specialist nurses (eg asthma nurse, epilepsy nurse)
 - Community children's nursing teams
 - Mental health teams
 - Renal dialysis unit
 - Other hospitals for clinical trials/unlicensed medicines
 - Oncology units

1. a.k.a. blister packs eg Nomad, Dosette, Medisure, Medimax



Medication administration record (MAR) charts

- Some children or young people may be cared for in residential care homes and have their medicine administration recorded on a MAR chart. Be mindful that sometimes acute prescriptions are not recorded on the MAR chart.
- These can be a useful source of information for children or young people transferred from this setting.
- Take care to ensure that there are no pages of the MAR chart missing as this can lead to errors.
- Some community pharmacies produce duplicate labels for MAR charts and these are a more reliable source of information than MAR charts produced by transcribing the details from the child's or young person's medicines labels.



Sources of information for medicines reconciliation at stage one and/or two

Oral steroid medications

1. Indication.
2. Most recent dose.
3. Course details (ie maintenance or reducing dose) and length of therapy where appropriate.

Insulin

1. The drug, brand, administration device and dose should always be checked and annotated on the prescription chart.
2. For children who have an insulin pen, clarify whether it is a pre-filled disposable pen or a penfill cartridge insulin pen.
3. For children on variable dosing based carbohydrate load, an appropriate dosing range should be stated because there are two types of insulin – a slow release formulation or a fast acting preparation.

Oral contraceptives

1. The person undertaking medicines reconciliation should purposely but sensitively ask about contraceptives as they are not always considered as medicines by the young person.

Methotrexate

1. This is prescribed once weekly so the day of administration, strength and number of tablets or injection strength should be confirmed with an appropriate source.
2. Check that this is correct on the drug chart and that the six days of the week when the dose is not to be administered are crossed off.
3. Any associated folic acid prescriptions should also be asked about.

Bisphosphonates

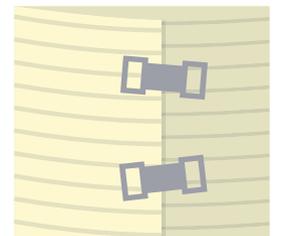
1. The day of administration should be confirmed with an appropriate source.
2. Check that this is correct on the drug chart and that the six days of the week when the dose is not to be administered are crossed off. Bisphosphonates now also come in once a month preparation (Bonviva) so there should be a clear record in the child's drug chart of the day of administration.
3. Ask the child or parent/carer whether they take calcium preparations and confirm which brand.

Inhalers

1. It is important to confirm the name, strength and type of inhaler; do not go by colour of device alone.
2. Confirm if any compliance aids are used (eg spacer device, haleraid®).

Nebulisers

1. Identify whether the child has their own nebuliser machine and nebulisers at home and document this on the drug chart.



Checklist of questions that healthcare professionals can use to support medicines reconciliation

- Does anyone help you with your medicines at home? If so, who? What do they do?
- Do you have any problems obtaining or ordering your repeat prescriptions (NB: relative/carer might help)?
- Do you have a regular community pharmacy that you use?
- Do you have problems getting medicines out of their packages?
- Do you have problems reading the labels?
- Some people forget to take their medicines from time to time. Do you? What do you do to help you remember?
- Some people take more or less of a medicine depending on how they feel. Do you ever do this?
- Most medicines have side effects. Do you have any from your medicines?

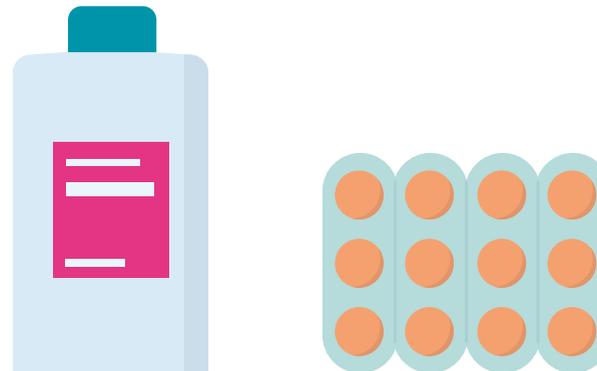
The minimum information available on admission should include:

- complete details of the child – full name, date of birth, weight (regardless of their age), NHS number, GP, date of admission
- presenting condition plus co-morbidities
- a list of medicines currently prescribed, including those bought over the counter
- dose, frequency, strength, timing, specific instructions, formulation and route of the medicines listed
- an indication of medicines that are not intended to be continued
- monitored dosage systems and compliance aid if applicable
- known allergies and previous drug interactions.



Knowledge bite

- Effectively engaging the child or parent/carer at the medicine reconciliation stage has been demonstrated to reduce medication related errors by 85%.
- A child is at most risk of a medication error either on admission or at discharge (transition points of care) and a successful medicine reconciliation process helps to mitigate this risk.
- Medicine reconciliation is not just about ensuring the child receives the correct medication on admission and discharge but also about educating the child or parent/carer about the safe and effective use of medications by providing them with access to reliable, relevant and understandable information about their medications.



Hospice-based case study

A child is admitted to the hospice and his parents bring all of his labelled medications. The hospice nurse checks the medication history with the child's mother and the medications, as well as comparing these against the medication chart from a recent admission. The nurse notices a discrepancy between the strength of glycopyrronium bromide (a bronchodilator which reduces respiratory tract secretions) prescribed on the last admission and that prescribed currently. It is decided to investigate further.

On the last admission the child had been taking glycopyrronium bromide 5mg/5mL oral solution at a dose of 1ml three times daily (3mg daily). At this admission, the family have brought a labelled bottle of glycopyrronium bromide 1mg/5ml oral solution and the child is still taking 1ml three times a day. It seems a little strange to the nurse that the dose had been reduced to a fifth of the original dose in only two weeks.

The nurse asks the child's mum whether she remembers why the glycopyrronium dose was reduced. She states that it hasn't been reduced and he is still taking 1ml three times a day. She is not aware that the strength of liquid supplied has been reduced from 5mg/5ml to 1mg/5ml. However, she does mention that his secretions have become much worse recently.

After further investigation, the nurse is able to identify that the lower strength oral solution (1mg/5ml) has been prescribed in error by the child's GP. The GP did not intend to reduce the dose of glycopyrronium and had not realised that more than one strength was available. The hospice nurse then increases the glycopyrronium strength back up to 5mg/5ml and continues the dose of 1ml three times daily and explains this to the child's mum. On discharge a letter is sent to the GP and community pharmacy confirming that the strength of glycopyrronium was changed back to the initial strength of 5mg/5ml and the original dose of 1ml three times a day.

This case study highlights how effective medicines reconciliation can benefit patients by identifying discrepancies and resolving these on admission. Effective communication with other healthcare professionals minimised the risk of this prescribing error continuing on discharge from the hospice and the child's deterioration in terms of increased secretions was resolved too.

Furthermore, this error was reported through organisational error reporting tools so lessons could be learned and the error not repeated.

Transcribing

The English dictionary defines transcribing as 'the act of making an exact copy usually in writing'. This means that there must always be an original from which the transcribed copy is made. In healthcare, the act of transcribing is usually performed so that medical records, prescription details and other communications are available to the professionals caring for a child. Transcribing is not covered by the Medicines Act 1968, which includes legislation for the administration by another team member under the direction of a prescriber. Therefore, the prescriber is legally responsible for generating the original instruction, and if this instruction is transcribed accurately without any alteration, the person making the transcribed copy does not assume liability.

In the children's palliative care setting, the child's needs and safety are paramount and should be central in the decision as to how best to provide care. In many of the situations where transcribing will be necessary, the medication has been supplied, and would have been taken by the child if they were still at home. The ongoing administration could well be left to the parent, carer – or if competent – the child or young person themselves. It can help to give the young person more ownership of their medication if they self-administer, but this should be discussed in detail with them (see **Chapter 3** for more information on self-administration). Only where there is genuine risk should this right be removed from the child or parent/carer. The need for transcribing is still present even if the child or parent/carer are self-administering the medications.

Moreover, many children's palliative care services receive medical support from general practitioners or paediatricians who are not based on the same site. Medical staff may make daily routine visits and attend when called to see an especially unwell child, with more regular visits only taking place for symptom control or for end of life care admissions. Transcribing of medication is therefore an important part of a child's admission as there would be a significant risk of omitted or delayed administration of prescribed medication while simply waiting for a chart to be written. The risk of the child not receiving their medication may outweigh the risk of administering the drugs from a transcribed chart.



What is transcribing?

Transcribing is defined as “*copying of previously prescribed medicines details to enable their administration in line with legislation (ie in accordance with the instructions of a prescriber)*” (RPS/RCN, 2019). The guidance makes clear that transcribing should only be undertaken by those appropriately trained and assessed as competent to do so. Possible scenarios that could constitute transcribing are when nurses are required to alter doses on medication administration charts or when generating prescriptions. When staff copy medication details from one document to another when the new document is used for a different purpose, it is not classed as transcription. Examples might include requesting a prescription or providing a parent or carer with medication information.

The document states that transcribing should be used only if it is in the child’s best interest to ensure safe and continuous care; ensuring the medication is administered accurately, without undue delay. In a hospice setting transcribing may be used when an independent prescriber is unavailable to prescribe medication, for example during an unplanned emergency admission, and the risk to the child is high.

To ensure that transcribing is taking place safely without causing any harm to the child, children’s palliative care services are responsible for ensuring that there is a rigorous policy for transcribing underpinned by risk assessment that also meets local clinical governance requirements. The policy should clearly document who may transcribe, the clinical situations in which transcribing can be used and the difference between transcribing and prescribing. The policy should also discuss how transcribing errors should be managed if they arise (see **Chapter 4**).

In some nurse-led children’s hospices, transcribing is a key part of the admission process. Nurses transcribe the direction to administer from the child’s own medicines’ labels onto a medication administration record (MAR) chart. There is some overlap between the process of transcribing on admission and the medicines reconciliation process. Children’s hospices that rely on transcribing on admission should ensure that their procedures meet the same standards recommended for medicines reconciliation to ensure that any discrepancies are picked up and rectified as soon after admission as possible and to ensure the safety of the children using their services (see figure 3).



Minimising the need for transcribing

Where possible, children’s hospice and palliative care services should aim to reduce the need for reliance on transcribing by nurses. This could be done by:

- encouraging nurses to undertake a non-medical prescribing course to become qualified independent prescribers, however this does not mitigate for the issue of prescribing repeat medicines that are outside the scope of the nurse’s clinical competence
- using medical cover to prepare medication charts in advance of a child’s admission, where possible (but being mindful that pre-writing the chart without face-to-face contact with the young person or their carer can be a source of error)
- timing admissions for a time of day when a prescriber is on site, where possible
- anticipating the need to re-write medication charts when a prescriber is on site to avoid nurses needing to transcribe charts
- encouraging the development and use of family hand-held and electronic medication records.

Examples where transcribing may be necessary:

(this is not a definitive list but covers most common situations)

- transition from hospital to a hospice
- to allow administration of current prescribed medication
- transition from community homecare to hospice care
- long stay child whose medication chart is complete/full with no space left for marking administration of a medicine(s)
- new drug prescribed off site and delivered to the hospice ie via FP10
- new drug prescribed or dose change via remote prescribing

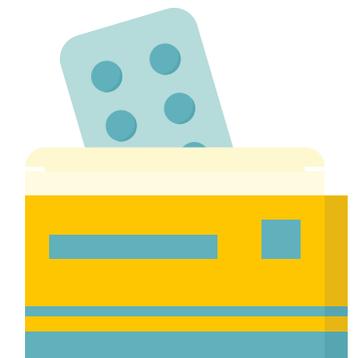
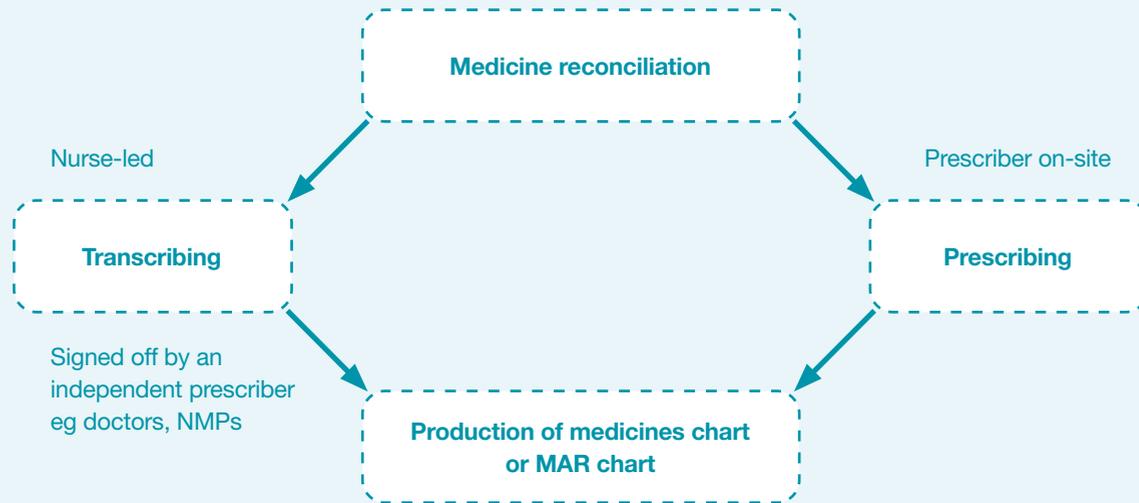


Figure 3: A diagram demonstrating the integral relationship between medicine reconciliation and transcribing in order to produce a drug chart for the child or young person.



Transcribing procedure

The procedure outlined below is written from a perspective where prescribing/transcribing is undertaken on drug cards. In recent times hospitals have transitioned to Electronic Prescribing and Medicines Administration (EPMA) systems as part of the the NHS agenda. The uptake of EPMA systems in hospices is varied and the guidance below will need adapting as these systems are introduced.

Prior to transcribing

- Any healthcare professional who transcribes must be competent and authorised to do so.
- The authorised transcriber must ensure that the situation warrants transcribing or meets the requirements of the individual hospice transcribing policy and the items have been previously prescribed by an independent prescriber.
- The authorised transcriber must familiarise themselves with the child's clinical history to evaluate the accuracy and appropriateness of the medication information provided.



Acceptable sources of information to transcribe from

- Hospital discharge prescription (TTO/TTA – the take-out/away prescription), which must have been written or co-signed by an independent prescriber.
- GP print out or GP letter.
- Symptom management and/or syringe driver plans approved by independent prescribers leading on the child's or young person's care, originating from designated tertiary paediatric palliative care provider service.
- Summary Care Records
- Direct access to GP record
- Previous medication chart (if signed by a prescriber).

The medication information described above must be cross-checked with the child's medicine boxes/bottles/compliance aid. If there is any uncertainty or ambiguity regarding the accuracy of the information, eg due to legibility or mis-match between the information and medicines, transcribing must not take place until a doctor has been contacted and the issue(s) resolved.

After transcribing

The transcriber must:

- attach the original source of medication information to the transcribed document where possible (eg faxed/mailed list of medication from the child's GP)
- record in the child's notes the nature of the circumstances that necessitated transcribing (ie the circumstances that led to transcribing and the actions taken to contact an independent prescriber); details must include names, dates and times

- take all reasonable steps to ensure that the transcribed items have been independently checked by a second member of staff before any medicines are administered. Ideally where pharmacy services are employed within hospice settings, a pharmacist should independently check transcribed charts, where they have not had prior involvement with the transcription, other than medicines reconciliation.
- take all reasonable steps to ensure that the transcribed items will be checked and authorised by an independent prescriber within a designated time period (eg 24 hours or next working day)

Second check

It is best practice that the transcription is independently checked by another registered healthcare professional (eg registered nurse, doctor or pharmacist) involved in the child's care before medicines are administered. Wherever possible, this independent check should be made by an authorised transcriber. The checker must compare the original source of information against the transcription and the labelled medicine boxes/bottles/compliance aid. They must sign or initial each of the transcribed items and co-sign the entry made in the patient's notes.

Verification by an independent prescriber

Transcribed items should be checked and authorised by an independent prescriber within a designated time period (eg 24 hours or next working day). The original source of information must be used to confirm that the transcription is correct. The independent prescriber must then countersign all the transcribed items to indicate their authorisation.

Verbal orders

In healthcare, verbal orders are usually used in exceptional circumstances where a practitioner may need to remotely prescribe for a child a previously unprescribed medication or request that a dose be adjusted to effectively manage symptoms, when a delay in administration to obtain a written prescription would compromise patient care. Whilst the use of verbal orders are not underpinned by legislation, the institution within which they are used must have appropriate governance and policy detailing the safe and effective use of verbal orders and be risk assessed to ensure appropriateness of the use of verbal orders.

Verbal orders must only be given by a practitioner who is a prescriber. The nurse must ensure that the prescriber has all the relevant information. Prescribers must not prescribe for a patient they have not assessed. Email, text or fax may be used to confirm the prescription before administration and should be verified by a second nurse.

Policies must ensure that child confidentiality is protected and that there is adequate documentation. This should include the message in full, the telephone number it was sent from, the time sent, any response given, the date and the signature of the nurse receiving the text. Text messages must be read by a second person and the documentation signed to confirm that they agree with the text message. The text message must be documented as a child contact. Text messages should then be deleted to ensure confidentiality.

Prescribers must provide a prescription or amend the MAR chart as soon as possible (ideally within 24 hours) but if unable to do this, changes must be communicated by an appropriately secure electronic method.

For hospitals there is rarely ever a need to use verbal orders, especially with the introduction of e-Prescribing systems to allow safer prescribing. However, in institutions, such as hospices where there may not be medical or prescriber availability 24 hours a day, 7 days a week, verbal orders are still utilised. The use and implementation of verbal orders, MUST however be accompanied by the appropriate governance, risk assessment and policy to ensure their safe and effective use. Royal Pharmaceutical Society Guidance suggests that any medicine other than a schedule 2 CD may be requested via a verbal order.

Monitoring and audit

Children's hospices/palliative care services should have a specific category for transcription errors in their medication incident reporting procedures, so that practice can be monitored and reviewed. Services that routinely use transcribing on admission should regularly audit this practice. This audit approach has been advocated by NICE.



Case for discussion

The homecare team go out to visit L, a 13 year old girl with a brain stem glioma who is receiving end of life care. L is being looked after jointly by the local hospital's paediatric palliative care team, the children's hospice homecare team and her GP.

Overnight, L's GP had been out on a home visit at the request of the hospital team. L's pain had not been well controlled overnight. She had required five breakthrough doses of oral morphine in the night and had become increasingly agitated. Following discussions with the palliative care team, the GP gave L's mum written instructions to increase L's MST Continus[®] suspension dose from 8mg twice daily to 12mg twice daily, and to increase her breakthrough Oramorph[®] dose from 2.5mg to 4mg when required up to hourly. It had also been recommended that L's mum could use the 'just in case' ampoules of midazolam 10mg/2mL injection via the buccal route if L became severely agitated. L has not had a benzodiazepine before and her mum is very concerned about overly sedating L, so it had been suggested that the midazolam should be given at a dose of 2mg for agitation to start with.

The GP had not realised that there was an NHS chart in L's home for the nurses to administer against. When the hospice homecare nurse arrives at the home, L's mum informs her that the GP has been out overnight and some changes had been made to L's medications. She had forgotten to ask him to update the chart but instead he had written down instructions on a piece of paper.

The homecare nurse uses the GP's handwritten note to transcribe the new instructions onto the medication chart. The doctor's handwriting is not very clear, but the nurse thinks she can make out the dose. There is not another nurse at the home, so the nurse asks the hospice support worker who is also present to check it with her. After reviewing the note, the staff between them are confident that they have been able to identify the doses.

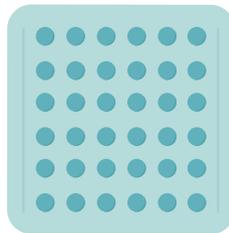
A little while later L becomes agitated and the homecare nurse decides to give her a 4mg breakthrough dose of Oramorph[®], which does not satisfactorily control her agitation so then the nurse decides to administer a dose of midazolam and gives L the 7mg dose that she transcribed onto the chart. L becomes increasingly drowsy and her respiratory rate slows. Mum seems quite concerned that she is so sedated and comments to the nurse "the doctor said that a 2mg dose was only a very low dose – surely she shouldn't be this drowsy?". At this point the homecare nurse realises that she has transcribed the dose incorrectly and contacts the GP to clarify the correct dose which was 2mg and arranges for L to be urgently assessed.

- Is this a scenario that could happen in your organisation?
- How could this have been avoided?
- What should the homecare nurse have done differently?



Knowledge bite

- Transcribing should always take place from an approved, reliable source of information and be verified with another independent source.
- Never undertake transcribing if you are unsure of any information relating to the medication. Always double check and verify medicines information to avoid any harm to the child.
- Transcribing should always be double checked by another healthcare professional before any administration of medication takes place.
- All transcribed items should be signed off by an independent prescriber within a designated time period at the next earliest opportunity. This should be clearly stated within the hospice's transcribing policy.
- Most pADEs (Potential Adverse Drug Events) are caused by prescribing or transcribing errors.



Goals for notable practice

As with any potential change in practice, indicators need to be used to identify whether the changes that are being made to the service are necessarily an improvement. Indicators therefore need to be more than the collection of process data, but also an assessment of the impact that the improved service is making for children or young people in hospice or homecare. Not only will this give hospices information they need to support their ongoing efforts to improve, it will also provide the information they need to make informed decisions about the safety, quality and value of their services.

- The profile of medicines reconciliation and safe transcribing practice must continue to remain high on the clinical governance agenda of any hospice. Quality improvement leads, prescribing leads and clinical governance teams at all hospices should be involved in ensuring medicines reconciliation and safe transcribing practice are firmly embedded into routine practice and audited regularly to ensure adherence.
- Specify standardised systems for collecting and documenting information about current medications relating to either inpatient hospice stay or if the child is being cared for at home.
- Ensure the responsibilities of staff in the medicines reconciliation/transcribing process are clearly defined. Hospices should have written policies and procedures endorsed by a multidisciplinary committee and senior management team for medicines reconciliation and transcribing not only for an inpatient hospice setting but also if homecare is being provided.
- Strategies are incorporated into medication reconciliation policy that detail how to obtain information about medicines for children with communication difficulties.
- Systems that are designed for medicine reconciliation and transcribing should focus on improving the safety and clinical outcomes of the child whether this is in an inpatient or homecare capacity, thus not exposing them to harm related to ineffective medicines management policies. Hospices should consistently monitor and audit how effectively they transfer information about medicines.
- Notable and less notable practice in regards to medicine reconciliation and transcribing should be shared with other hospices to improve systems and encourage a learning culture.
- Incorporate medicines reconciliation and transcribing into the training and development of healthcare professionals and support staff that are involved in the care of a child or young person.



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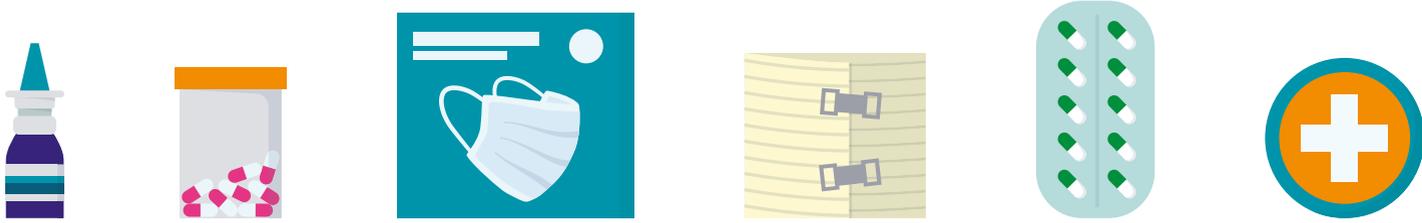
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Chapter 6: Non-medical prescribing and advanced clinical practice

By Michael Tatterton



Interest in non-medical prescribing continues to grow as the number of non-medical prescribers within children’s hospices and children’s palliative care services increases. This chapter focuses on issues relating to non-medical prescribing and provides a resource for existing and trainee prescribers, as well as those services considering the introduction of non-medical prescribing.

This chapter covers:

- What non-medical prescribing in a children’s hospice looks like
- Maintaining clinical competency
- Monitoring prescribing practice
- Non-medical prescribing and demonstrating CQC compliance

Although this chapter has been written with the four countries of the UK in mind, it is important to consider any country-specific and profession-specific guidelines, as set out in figures 1 and 2.

Figure 1: Country-specific governments and regulators

	Government	Care regulators
England	www.gov.uk	www.cqc.org.uk
Northern Ireland	www.northernireland.gov.uk	www.rqia.org.uk
Scotland	www.gov.scot	www.careinspectorate.com
Wales	https://gov.wales	https://careinspectorate.wales

Figure 2: Professional regulators of non-medical prescriber

	Professional regulator
Allied Health Professionals’	www.hcpc-uk.org/standards/standards-relevant-to-education-and-training/standards-for-prescribing
Nursing	www.nmc.org.uk/standards/standards-for-post-registration/standards-for-prescribers
Pharmacists	www.pharmacyregulation.org/education/pharmacist-independent-prescriber





Non-medical prescribing in children's palliative care

In recent years, as the number of prescribers has increased, there has been disagreement about exactly how to refer to those who are not doctors (Nuttall and Rutt-Howard, 2020). Professional regulators continue to define prescribers by specific profession, using terms such as 'nurse prescriber' (Nursing and Midwifery Council, 2018a), 'pharmacist prescriber' (General Pharmaceutical Society, 2018) and 'allied health professional prescriber' (Health and Care Professions Council, 2016). However, there is a broader range of literature using the collective term of 'non-medical prescribers' (All Wales Medicines Strategy Group, 2017; Department of Health Northern Ireland, 2020; NHS England, 2020; Scottish Government, 2020), highlighting the multidisciplinary nature of current prescribing practices across the UK, and the shared responsibility of prescribers for assuring safe and effective practice. Within this chapter, we refer to prescribers collectively, as non-medical prescribers (NMPs).

In developing this resource, NMPs and medical staff working across the children's palliative care sector shared their thoughts and experiences. Examples of notable practice have been gathered from existing prescribers based within children's hospices and the wider children's palliative care workforce, shown as 'practitioner perspectives'.

Children's hospices remain predominantly nurse and therapist-led services, with many examples of innovative approaches taken by organisations to meet the needs of the children and families who rely on their care. Non-medical prescribing is a good example of this. Drivers for non-medical prescribing (Kroezen et al, 2011) include:

- timely and more efficient access to medicines
- making better use of the skills of health professionals
- contributing to more flexible team working
- the development of advanced-level clinical roles

This chapter has been updated to reflect the findings of new children's hospice-specific research around non-medical prescribing (Tatterton, 2017), as well as other recent developments in prescribing practice, sector-specific guidelines (CQC, 2018a), the National Institute of Health and Care Excellence (NICE) guidelines for end of life care for infants, children and young people (NICE, 2016) and the Royal Pharmaceutical Society (RPS) Competency Framework for all Prescribers (RPS, 2016).

Previously this chapter focused on supporting organisations to consider and implement non-medical prescribing, highlighting the governance and support needed to ensure safe practice. With more NMPs now working within children's hospices and the wider children's palliative care sector, this new edition focuses on supporting prescribers themselves to think about the context of their prescribing, and the specific challenges they may face within children's palliative care. These include defining the scope and the clinical skills that surround prescribing, clinical assessment and decision-making, the benefits of continuing professional development including the Competency Framework for all Prescribers (RPS, 2016), and the importance of peer support and supervision. This chapter includes examples from practice as well as practitioner perspectives, sharing the thoughts of individuals from hospices and the broader palliative care workforce.

There is now a space on the Together for Short Lives website specifically for non-medical prescribers to discuss issues relating to safe use of medicines, enabling NMPs and other practitioners to share best practice and resources between organisations, and to provide opportunities for peer support. You can access this page [here](#).



What does prescribing in a children's hospice look like?

Prescribing practice varies significantly in hospices around the UK. There are variations in the volume and frequency of prescribing, classification of medicines being prescribed and the perceived benefits and barriers of prescribing practice within children's hospice care. A research study conducted with 20 children's hospices (Tatterton, 2017) identified 39 NMPs. More recent research (Tatterton & Walker, 2019) identified 69 NMPs working in children's hospices, almost a doubling of the numbers in just three years. In the 2017 study, a range of medications were being prescribed, most frequently to enable continued supply of an existing prescription (50% of respondents). Prescribing largely surrounded symptom management, with pain, constipation, anxiety and nausea being the most frequently cited symptoms requiring a prescription.

Prescribers and their managers described a number of benefits to children and young people, their families and the organisation, and to the prescribers themselves. These are shown in figure 6 overleaf.

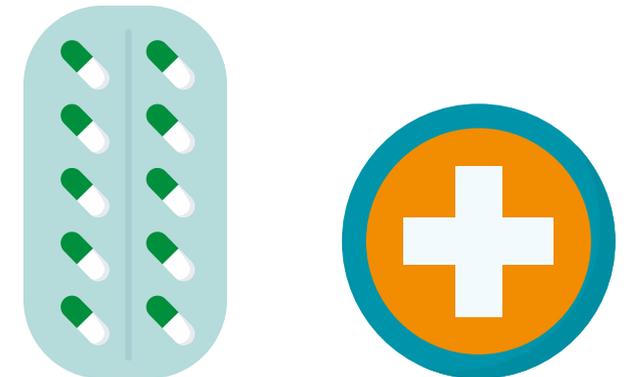


Figure 3: Benefits of non-medical prescribing in a children's hospice

Children and young people	Parents and families
<p>Timely access to medicines and efficiency in care provision.</p> <ul style="list-style-type: none">• more efficient access to medicines and reviews• increased efficiency and accuracy in the admissions process and medicines reconciliation• improved holistic care provision• improved symptom control• an increased ability to offer choice in the place of hospice care	<p>Increased ability for prescribers to provide support, advice and reassurance, not only about medicines and symptom control, but wider aspects of care.</p> <ul style="list-style-type: none">• increased ability to provide medicine advice and support• timely access to care and advice• the ability to reassure families around symptom control care issues• improvements in the provision of medicines-related education and health promotion• improved continuity of care

Practitioner perspective:

Helen Storton, Clinical Nurse Specialist in Children's Palliative Care, Martin House

Helen qualified as a non-medical prescriber last year. Below, she reflects on her role as a community nurse in the hospice setting, the difference that prescribing makes to the children and families in her care, and the importance of peer-support.

'Prior to working in the hospice, I was a community-based palliative care CNS in the NHS. I knew that being able to prescribe would make a difference to children and families in my care, enabling me to be reactive to needs, treating and managing symptoms quickly and efficiently.'

Prior to being able to prescribe I had relied on other NMPs, relaying my assessment of the child and requesting that they prescribe the medications that the child required.

During the prescribing course I became more aware of the responsibility around prescribing which helps to remind us that we should always be working with our own scope of clinical practice and to prescribe only when we are confident to do so.

As a prescriber, particularly when working in isolating roles such as in the community, support from peers is really important. Within Martin House there are a number of prescribers who offer support and guidance. The team is extremely supportive and inclusive – one where nurses and doctors work very closely in an environment which feels safe to learn and share knowledge. This has been vital, allowing me and my colleagues to build confidence, gain new skills and consolidate learning and experience.

Being a prescriber means that I can provide holistic, individualised care to children and young people, providing families with real choices in terms of the place of care and place of death. This will expand the support that families can receive if they choose to have their child's palliative care outside of the hospice setting.

From a personal perspective, being a prescriber has led to a sense of increased job satisfaction. I now have the skills and qualification to enable me to build on my clinical assessment skills, providing effective symptom management. It's really helped me feel like I am making a difference'

Introducing NMPs to a hospice workforce is not without its challenges. Both managers and prescribers highlighted the need to develop confidence in this area, due to the relatively low numbers of prescribers within individual hospices. Defining scope was a challenge, due to the breadth of conditions that affect babies, children and young people with life-limiting conditions. Time constraints, and the ability to prescribe within an already-established role was discussed, suggesting that time needs to be allocated to allow NMPs to assess, diagnose and prescribe when necessary. A lack of continuing professional development opportunities was also highlighted, where prescribers were unable to access suitable training to maintain or extend their scope. These challenges can of course be overcome.

A case study of the approach taken by Martin House Children's Hospice is highlighted opposite.



Clinical competence and prescribing

Safe and effective clinical decision-making, including prescribing, can only be achieved through proficient assessment, diagnosis and ongoing monitoring. It is therefore essential that prescribers are able to lead a consultation, take a history and have the skills to perform clinical examinations (Duderstadt, 2019). Responsibility around monitoring and assessment continues beyond initial prescribing (Nuttall and Rutt-Howard, 2020). Prescribers are required to monitor the effect of their prescribing decisions (Royal Pharmaceutical Society, 2016). In this section we will explore how prescribers can assure their own competency, define their scope of practice, as well as looking at opportunities to develop and extend their professional scope. Finally, we will look at advanced level practice, and the implications of this on prescribing and caring for children with life-limiting conditions.

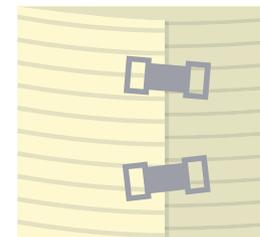
Practitioner perspective:

Angela Hynard, Staff Nurse and independent prescriber at Martin House Children's Hospice

As a staff nurse in a children's hospice, I have experienced the frustration of trying to reconcile medication during the admission process and having to ask parents to administer the medication as a prescriber was not available. I am also aware of the ever-increasing workload on the doctors both internally and externally, therefore non-medical prescribing is advantageous to the children and young people, the doctors and for personal professional development of nurses and allied health professionals.

Children's palliative care is a specialised nursing field which encompasses many sub-specialities. The extensive number of life-limiting conditions that affect children and young people, and the age spectrum – from birth to young adulthood of children that we care for – present a real barrier to prescribing. Trajectories of illness, vast differences in age, numerous conditions, co-morbidities and issues of polypharmacy. I have found this variety daunting as a newly qualified prescriber.

My scope of practice as a clinical nurse differs from my scope of practice as a prescriber and it was important that this was acknowledged by my colleagues, to ensure there were no unrealistic expectations of my prescribing role. The majority of prescribing I have carried out has been during an admission, when a medication dose has been increased by another prescriber and no evidence has been available to confirm this. When making more complicated prescribing decisions I have contacted the doctor on call and explained my rationale, providing reassurance that they agree with my decision. In addition to this, my mentor continues to be supportive and I attend a NMP network where we share knowledge and skills. In the hospice we take opportunities to deliver and attend short teaching sessions during a shift (around 30 minutes) on various subjects which promote CPD. Since qualifying last year, with the support of my peers, I have developed my scope of practice slowly. I am working towards extending my scope of practice to include symptom control at end of life, as I feel that prescribing for all eventualities within the children's palliative care spectrum is unrealistic, as it is so diverse. That's why it's important to be part of a team, to recognise your limitations and to build links with others working in the same field.



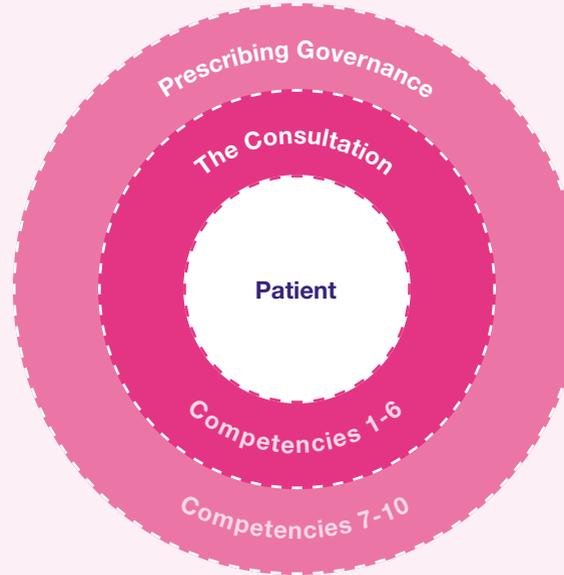


Professional standards

As practitioners registered with either the Nursing and Midwifery Council (NMC), Health and Care Professions Council (HCPC) or the General Pharmaceutical Council (GPhC), prescribers are required to work within their professional codes of conduct (GPhC, 2017; HCPC, 2018; NMC, 2018b). In collaboration with all prescribing professional regulatory bodies across the UK, the Royal Pharmaceutical Society (RPS) has produced a Prescribing Competency Framework for all prescribers which aims to support safe and effective prescribing. The Framework contains ten competencies divided into two domains, enabling prescribers to develop knowledge and skills in prescribing practice. This is shown in figure 4.

Some elements of the framework are explored below, but it is recommended that prescribers follow the full framework www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/DPP%20Framework/DPP%20competency%20framework%20Dec%202019.pdf?ver=2019-12-18-150746-160

Figure 4: The prescribing competency framework (RPS, 2016: 9)



The Consultation	Prescribing Governance
1. Assess the patient	7. Prescribe safely
2. Consider the options	8. Prescribe professionally
3. Reach a shared decision	9. Improve prescribing practice
4. Prescribe	10. Prescribe as part of a team
5. Provide information	
6. Monitor and review	



Clinical essentials: Assessment and history taking

Many practitioners have described their reluctance to prescribe as stemming from an inability to safely and effectively assess the needs of children in their care. Organisations have taken different approaches to addressing this need. This includes supporting staff to undertake training in advanced clinical assessment, applied pathophysiology and clinical decision-making as standalone modules, or combining these along with non-medical prescribing training, following the advanced clinical practitioner pathway (Health Education England, 2017), explored in the section on advanced clinical practice.

In order to make safe decisions around prescribing (including the consideration of non-pharmacological options), practitioners must be able to effectively assess the needs of children and young people in their care. Following clinical assessment, which includes being able to take a comprehensive history, practitioners need to be able to interpret their findings and consider options for the treatment. This requires practitioners to not only understand the presenting condition or symptom, but also the implications of their prescribing decision, which may include issues of polypharmacy.

The ability to take an effective clinical history from a child or family is at the root of all clinical decision-making, indeed the majority of diagnoses are made on the basis of signs and symptoms elicited as part of the history taking process (Moulton, 2016; Foulkes, Trays and Sullivan, 2018; Duderstadt, 2019). Practitioners need to be able to take a robust and comprehensive history that not only explores the child's current needs (presenting complaint) but also their underlying condition and past medical history. There are numerous models, prompts and mnemonics available to practitioners to support practice. The core elements of history taking are included in figure 5 below. We have also included some mnemonics, that can be useful during a consultation in figures 6 and 7.

Figure 5: Core elements of history taking

- Presenting complaint
- History of the presenting complaint
- Past medical history
 - Prenatal/antenatal history
 - Postnatal/neonatal history
 - General past medical history
- Growth and development
- Feeding and nutrition
- Immunisations
- Medication (include prescribed, over the counter, homeopathy and vitamins)
- Allergies
- Family history
- Social history

Figure 6: OLD CART mnemonic

O	Onset	When did the symptom begin?
L	Location	Where is the symptom? Does the location change?
D	Duration	How long has it been a problem? Is it constant or intermittent? How long does it last?
C	Characteristics	What does it feel like?
A	Aggravating factors	What make it worse?
R	Relieving factors	What relieves it?
T	Treatment	What treatments have been tried and for how long? What professionals have already been consulted?

Figure 7: SOCRATES mnemonic

S	Site	Where is the pain? (Localised or diffuse?)
O	Onset	When did it start?
C	Character	What does the pain feel like?
R	Radiation	Does the pain move?
A	Associated symptoms	Any other symptoms?
T	Time/duration	Does the pain follow a pattern?
E	Exacerbating/relieving factors	What makes the pain better or worse? What medicines and interventions have been tried and were they effective?
S	Severity	How bad is the pain, using pain tools?

Case study: Consultation models in practice

Working within a children's hospice means that practitioners often have very different relationships with families under their care, predominantly due to the nature, frequency and duration of contact.

The parents of 'Abi', a child with microlissencephaly and epilepsy, who was known to the hospice, requested a home visit to review her symptoms as her pain continued to be difficult to manage, despite regular analgesia and distraction (strategies that normally work).

There were seven core components to the consultation, with the aim of identifying the needs of Abi and achieving concordance. They were:

- **establishing a relationship with patients:** including both children (regardless of age) and their parent(s)
- **identifying the problem or reason for attendance and parental expectations**
- **examination:** taking an effective history, and physical examination if appropriate
- **discussion of how the problem affects daily living**
- **development of a plan:** negotiated with the child/young person and parent including prescribing of medication, further investigation or referral, recommendation of adjunct, signposting to an appropriate service, or no intervention
- **explanation and summing up:** to ensure shared understanding and agreement
- **arranging next contact, review or discharge**

Central to any consultation, and key to the effectiveness of a consultation are interpersonal and communication skills. It is essential that the prescriber leading a consultation is able to draw out the above points to determine their influence on decision-making and the effectiveness of any prescribing decisions, including decisions not to prescribe.

Using a child-focused, family-centered approach, it was identified that Abi's pain could be more effectively managed using modified release granules of morphine, rather than regular oral solution. Following the framework led to a discussion about parental anxiety around increased pain signifying Abi was nearing end of life – as had been the case for their older child, who died around the same age from the same condition. Disclosure of this meant that their concerns could be addressed, and reassurance provided.



Defining scope

The approach and scope of practice of NMPs in children's palliative care varies significantly around the UK. Challenges in balancing the expectations of service managers and the ability of prescribers to prescribe within their scope of competence and confidence. The role of independent prescribers during the hospice admission process has been discussed frequently, particularly in light of the challenges that surround transcribing (see **Chapter 5**).

Safe prescribing requires more than an independent prescribing qualification. Practitioners must have adequate knowledge and clinical experience, enabling them to take a history, perform appropriate examinations to rule out life-threatening causes and to consider differentials before diagnosing.

The specific challenges to prescribing in children's palliative care services, variance in prescriber confidence and competence and the level of medical support available means that there is not a 'one size fits all' model. Independent prescribers are accountable to their employer and the RPS recommends that employers specify the parameters of their prescribing. Organisations need to be clear about the boundaries between transcribing, medicine reconciliation and when changing medicines and doses etc. become prescribing (van Doormaal et al, 2009). The role and expectations of independent prescribers should be negotiated in each organisation, based on the experience and knowledge of the prescriber as well as the needs of the service. This will inform decision-making about how independent non-medical prescribing will be used on admission, which must be reflected in the organisational policy as well as the job descriptions of those undertaking independent prescribing.

Practitioner perspective:

Katie Rich, Trainee Clinical Nurse Specialist at Martin House Children's Hospice, and student non-medical prescriber

When starting the non-medical prescribing course, defining scope was a major topic discussed both in university and within the hospice setting. Scope is so varied for each individual, and changes throughout your career. Defining my scope was something I worried about. Will I be expected to prescribe the same medicines as all other non-medical prescribers? In practice I've realised that this is not the case. As a non-medical prescriber, scope is personal: Something that I may feel comfortable to prescribe, another in the hospice may not, as they have not had the experience with that symptom or drug. I can see that once I qualify, I will be supported by nursing and medical colleagues who are experienced in prescribing in the hospice setting.

The children on the caseload at Martin House have conditions that require medicines not usually prescribed for or licensed for use in children. This adds extra unease to prescribing – how can I be expected to understand every single medication that is used? Within my role, I have observed my colleagues prescribe medications for pain, constipation and for agitation. I have also observed medications being prescribed in end of life care. Within each of those areas there is a vast and varied array of medicines, some that are unlicensed for children or for a particular symptom, however they are vital. Will I be expected to be comfortable with prescribing these medications? The answer I have found is no. Having the confidence to say that you are not happy to prescribe is fine and is essential to ensure you are a safe practitioner. I now understand that this is not an expectation, and that I was putting myself under pressure to know everything about every medicine! I realise that I am part of a team, who work together to ensure safe and appropriate practice.

My practice and confidence continue to develop. I hope that as my knowledge and experience grows, so will my scope of practice and scope to prescribe. Having a supportive network within your place of work is vital to ensure prescribing is safe and effective. I have also found that being surrounded by colleagues who also prescribe helps me to not feel pressured to prescribe outside of my scope.

I can see that being able to prescribe safely will improve the care I can offer to children and their families, as well as allowing me to develop within my nursing career.



Continuing professional development

Access to continuing professional development (CPD) is essential in order to enable prescribers to prescribe. The availability of CPD, particularly courses that focus on the needs of children and young people, varies significantly. In some places there is no child specific training available.

Traditionally, non-medical prescribing has been studied as a standalone module. Whilst this provides practitioners with knowledge around safe and effective prescribing in terms of the legal and professional context of practice, and pharmacology, it does not equip practitioners with the skills to assess, diagnose and monitor patients. Increasingly, universities require applicants to have completed a module in advanced clinical assessment prior to starting the independent prescribing course, enabling practitioners to confidently and competently make clinical decisions relating to prescribing.

There are a number of professional frameworks (see Figure 8) that can be used by organisations and practitioners to support continuing development, by enabling the identification of learning needs and to aid reflection. These are discussed in **Chapter 3**.

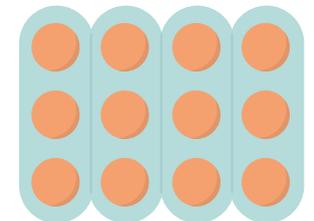


Figure 8: Key development and competency frameworks

Royal Pharmaceutical Society

A Competency Framework for all Prescribers

(Royal Pharmaceutical Society, 2016)

www.rpharms.com/resources/frameworks/prescribers-competency-framework

Multi-professional framework for advanced clinical practice in England

(Health Education England, 2017)

www.hee.nhs.uk/our-work/advanced-clinical-practice/multi-professional-framework

RCN Competencies: Caring for Infants, Children and Young People requiring Palliative Care

(Royal College of Nursing, 2018a)

www.rcn.org.uk/professional-development/publications/pub-007033

Standards for Advanced Level Nursing Practice

(Royal College of Nursing, 2018b)

www.rcn.org.uk/professional-development/publications/pub-007038

Development Needs Analysis Tool

(NHS Education for Scotland, 2011)

www.nes.scot.nhs.uk/our-work/advanced-nursing-practice-anp/

We have highlighted some different approaches taken by organisations to meeting the CPD needs of staff, and the benefits and challenges of these below.

Practitioner perspective:

Hayleigh Short, trainee Advanced Nurse Practitioner, Derian House Children's Hospice

Derian House Children's Hospice is a nurse-led unit supported medically by four local GPs working on a rotational basis to provide routine visits as well as out of hours cover. The implementation of non-medical prescribing and advanced clinical practice was identified as important to enable the team to respond more effectively to the needs of the children and young people who use our service. There was recognition that children using the service were presenting with increasingly complex symptoms and care requirements. Additionally, the nursing workforce within Derian House includes all variants of nursing qualifications: child, adult, mental health and learning disability nurses.

The practitioners who had successfully undertaken the non-medical prescribing qualification had themselves identified knowledge gaps in respect of clinical assessment skills.

Whilst undertaking my NMP module, it soon became apparent that further diagnostic skills would be key, if I was to be confident in my competence to prescribe accurately, appropriately and within my scope of practice.

Clinical assessment is a robust diagnostic tool which facilitates the practitioner in reaching a diagnosis by sifting and sorting the patient's presenting complaints and symptoms. Practitioners undertaking a non-medical prescribing module within the hospice recognise the importance of assessment skills in relation to prescribing decisions.

When prescribing there are elements of clinical reasoning and judgement which help develop your overarching rationale for your prescribing decisions, which I feel would be lost had I not undertaken the clinical assessment module to complement my NMP module.

Additionally, the practitioners also identified the difference between the support available between hospice and acute care.

As an independent prescriber in the hospice setting, I soon understood how non-medical prescribing and clinical assessment go hand in hand. I am acutely aware of how we are quite secluded and are truly making important clinical decisions in isolation. Whereas practitioners in acute care are working alongside other ACP's and medical doctors therefore, having an immediate second opinion available.

Furthermore, due to the advances in medicine, staff within the hospice setting are being repeatedly challenged by the increasing complexity of populations they serve.

Due to the complexity of the patients that use the services provided in the hospice setting, it can be a challenge to establish what is considered 'normal' presentations for these children under our care. Therefore, the module in clinical assessment can facilitate us in developing our clinical reasoning and helping us delineate what we would be satisfied with managing within our individual hospice settings.

Practitioner perspective:

Julie Bayliss, Consultant Nurse, Great Ormond Street Hospital of Children NHS Trust

Since 2012, nurses in the Louis Dundas Centre (LDC) Paediatric Palliative Care Team at Great Ormond Street have been prescribing independently for children and young people with life-threatening and life limiting conditions. We currently employ two levels of nurses who prescribe independently: nurse specialist and advanced nurse practitioners (ANPs).

Independent prescribing was introduced to improve patients' access to treatment, making it easier for parents to get the medicines they need for their child to manage symptoms. The LDC team have invested in training and development of independent prescribers, enabling them to work alongside medical colleagues. The nurses we employ are all experienced palliative care nurses, working for many years in the field of children's palliative care. The training we provide is in addition to the supplementary and independent prescribing module.

To enable ANPs to prescribe safely, they have undergone a model in physical assessment. They are supported with a period of supervised practice during the course and for a period of time after the course. On completion, nurses will need to have a recordable qualification with the NMC as an independent and supplementary prescriber (V300). All practicing independent prescribers on the team keep their knowledge and skills up to date. To maintain competency, they are expected to practice clinically, attend regular training, and have an annual update.

Independent prescribers on the LDC team can prescribe any medicines within their scope of practice. There is a local operating guideline where some medicines need to be prescribed by a doctor in palliative medicine such as patient-controlled analgesia (PCA) and methadone, although with training and supervised practice this may change in time.

Our independent prescribers in the LDC team do not prescribe on FP10 pads. Prescriptions are generated through the electronic prescribing system (EPIC) for all patients using Great Ormond Street Hospital. The introduction of the specialist children's palliative care pharmacist to the team provides independent prescribers with a safety check for all prescriptions generated.

Independent prescribers consult with medical colleagues, discuss patients in multidisciplinary meetings and conduct joint consultations to make joint decisions about what to prescribe. They are encouraged to refer back to senior nurses or a doctor if they feel that it is appropriate at any point. This may be because the child's condition is outside their scope of practice or because they do not feel that they have the necessary skills or experience to recommend a change to a child's treatment.

In summary the patients, families and team benefit from a workforce of independent prescribers. The ambition of the LDC team is to have at least 50% of the nursing workforce with the advanced physical assessment and independent prescribing qualification over the next five years.

Some NMPs have found it difficult to meet their CPD needs and to access continuing education as prescribers (Courtenay, Carey and Burke, 2007; Latter et al, 2007). CPD for NMPs can be sought from a number of sources: conferences, formal taught sessions, support groups and reflective clinical supervision, as well as the use of frameworks discussed in **Chapter 3**. Resources are also available online via NICE and the Royal Pharmaceutical Society and from websites including Together for Short Lives (www.togetherforshortlives.org.uk/?s=prescribing) and the International Children's Palliative Care Network (www.icpcn.org).



Maintaining competency

Prescribing for babies, children and young people with life-limiting and life-threatening conditions is a complex and often daunting task, and not one that should be undertaken lightly (Tatterton, 2018). As has already been stated, children with palliative care needs frequently present with comorbidities and polypharmacy (Mtunzi and Baba, 2019), highlighting the need for precise and methodical medication review, enhanced clinical assessment and a critical awareness of the risks associated with polypharmacy including drug interactions and compatibility which increase the risk of adverse drug reactions (ADR) (Smyth et al, 2012).

Prescribing resources

In addition to the BNF, BNFC and Palliative Care Formulary (PCF), there are a number of useful resources written specifically for use in children's palliative care. These resources are updated frequently and so are best accessed electronically to ensure that the most up to date edition is being used. Links to the key electronic resources are below:

- **British National Formulary (BNF)**
(<https://bnf.nice.org.uk>)
- **BNF for Children**
(<https://bnfc.nice.org.uk>)
- **Association of Paediatric Palliative Medicine (APPM) Master Formulary**
(<https://www.appm.org.uk/guidelines-resources/appm-master-formulary>)
- **Handbook of Drug Administration via Enteral Feeding Tubes**
(White and Bradnam, 2015)
- **The Syringe Driver: Continuous Subcutaneous Infusions in Palliative Care**
(Dickman and Schneider, 2016)

In addition to the websites above, the BNF and BNFC are available as free smartphone apps. There is also the **Palliative Care Formulary 7th Edition**. We are also aware of some organisation-specific formularies that reflect local practices. If there are any resources you think would be of benefit to other organisations and prescribers, please share them on our **Digital Care Forum**.

Advanced clinical practice

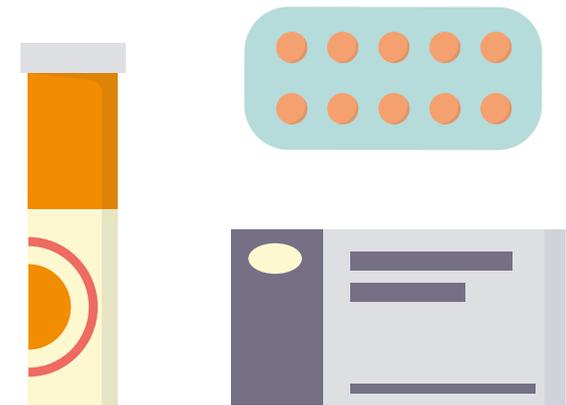
In recent years, there has been greater attention paid to specialist and advanced level practice, as the scope of nurses and allied health professionals evolves in response to the changing needs of those in our care, and the context of the wider healthcare workforce.

Specialist nursing roles within children's hospices and palliative care are not uncommon, however there are currently very few registrants working at either advanced or consultant level around the UK. Advanced clinical practice can be defined as:

'Advanced clinical practice is delivered by experienced, registered health and care practitioners. It is a level of practice characterised by a high degree of autonomy and complex decision making. This is underpinned by a master's level award or equivalent that encompasses the four pillars of clinical practice, leadership and management, education and research, with demonstration of core capabilities and area specific clinical competence.'

'Advanced clinical practice embodies the ability to manage clinical care in partnership with individuals, families and carers. It includes the analysis and synthesis of complex problems across a range of settings, enabling innovative solutions to enhance people's experience and improve outcomes.'
(Health Education England, 2017)

Due to the changing needs of children, young people and their families who rely on palliative care services, some organisations have made the move to recruiting advanced clinical practitioners. Below are two similar case studies, one from a hospital Trust, where nurse specialists and Advanced nurse practitioner (ANP) work together, and a second from an ANP working in a community children's nursing team.



Practitioner perspective:

The role of specialist nurses and ANPs in the Louis Dundas Centre, at Great Ormond Street Hospital of Children NHS Trust

The role of the advanced nurse practitioner (ANP) in children's palliative care is evolving and developing across the multiple paradigms of clinical practice, within tertiary hospitals, hospices and community nursing teams. The development of such roles in palliative care have been less forthcoming compared to colleagues working in acute, hospital-based specialities. We feel that there are a number of advantages to utilising the skills of ANPs within our palliative care team, illustrated in the below example.

'Jack' is a 6-year-old boy with a progressive brain tumour, who had completed radiotherapy and was on a weaning dose of steroid. An ANP accompanied a nurse specialist who knew Jack to undertake a routine review. The ANP and nurse specialist agreed that the nurse specialist would lead on the discussion with Jack and his parents and the ANP would support and undertake a clinical examination if necessary.

The benefits of the joint review from a parent perspective were the availability of an advanced assessment at home, conducted whilst playing with Jack, putting him and his parents at ease. Jack's parents felt reassured when the discussion was held separately with them by a person that they knew, having already built up trust and an effective therapeutic relationship.

Jack and his parents gave their consent to undertake a neurological examination. During the examination, Jack did not complain of pain, nausea or vomiting, but had signs of increased ataxia, increased bulbar weakness with slurred speech. The ANP reviewed the steroid weaning plan, and concluded that the dose decrease was too rapid, advising parents to prolong the next dose wean, with a plan for the on-call palliative care team to review at 48 hours prior to the next wean. This clinical decision also included liaison with the tertiary oncology team and informing the local team.

Aside from supporting the nurse specialist, this intervention also benefited Jack by improving his symptom control. His parents, although realistic about their child's prognosis, were relieved that the increased symptoms were manageable and improved. The example demonstrates the ANP role extends across teams and places of care, forging and maintaining partnership working with the child, their parents and clinical teams involved in the child's care. It emphasises that prescribing medications is not the only answer to a problem in palliative care; a conclusion reached through expert communication with the child, parents and professionals and advanced clinical assessment skills.

Practitioner perspective:

Dave Owen, Advanced Nurse Practitioner, formerly of Community Children's Nursing Team, Isle of Wight NHS Trust

This example shows the considerable advantages of being an NMP as a Community Children's Nurse (CCN)

Glen is an 8 year old with an inoperable brain tumour. He has received palliative radiotherapy and chemotherapy. Glen's last CT scan showed increased disease progression; no further cancer treatment can be offered and his oncologist has introduced the palliative care consultant. An advance care plan (ACP) has been written with the family including symptom management advice. His prognosis has been measured in months.

Glen is prone to chest infections. His family's wish is for him to be cared for at home and avoid hospital because Glen dislikes hospital admissions. His ACP states that he should be treated for reversible causes, and a specific plan is in place for lower respiratory tract infections (LRTI), with oral amoxicillin as first line antimicrobial treatment.

One morning, I visited Glen at home to perform routine central line cares. On arrival, his mother appeared very anxious, stating that she has needed 'to suction all night' and that Glen has just recorded a fever. I take a full history and examine Glen to confirm he has a likely LRTI but that he is well enough to remain at home.

I collected a sputum sample and prescribed a five day course of oral amoxicillin. I dropped the prescription into the local pharmacist, and they arranged delivery to Glen's home during the afternoon. Three days later I checked the sputum sample (streptococcus pneumoniae – sensitive to amoxicillin) and revisited Glen at home. He had clinically improved so I advised that Glen should complete the course of antibiotics and that I will review him again on his weekly central line visit.

One of the key benefits of non-medical prescribing is the improvement of patient experience (HEE, 2020), as illustrated in the above example. Glen was clinically assessed, diagnosed and a prescription prepared in a timely fashion, whilst avoiding hospital admission, as per his advance care plan. Glen's experience mirrors CCN philosophy of care (DH, 2011).

Although there are considerable advantages to enabling independent prescribing within community nursing teams, it is not without its challenges. Potential barriers include colleagues' perceptions of NMP roles and responsibilities (eg scope to prescribe controlled drugs) and these need to be clearly articulated and agreed to be acceptable to all parties. For example, during my practice I agreed with the Paediatricians that they would prescribe on the syringe driver administration chart (ie a range of dosage) and initial "to take out" (TTOs) supply, whilst I would arrange and prescribe supplemental TTO supply. This avoids the CCN prescribing and administering in the same episode of care, and therefore minimises 'risks to patients by using or developing processes that support safe prescribing particularly in areas of high risk' (RPS, 2016: 13).



Good governance

Individual prescribers and the organisations that employ them are accountable for the standards of care they deliver. Professional codes of conduct provide a regulatory framework for prescribers and organisations to follow, ensuring that services are of high quality, safeguard the public and have professional credibility (Nuttall and Rutt-Howard, 2020), and are safe, effective, caring, responsive and well-led (Care Quality Commission, 2018b). Clinical governance provides a framework through which organisations can continuously monitor and develop the quality of care provision. Governance and regulatory compliance is explored in more detail in **Chapter 2**. Examples of prescriber-specific governance issues are included below.



Monitoring prescribing practice

Good practice suggests that services and practitioners should monitor prescribing activities in order to assure safe, effective and appropriate practice. There are a number of ways this can be achieved, and may include the use of the Competency Framework for all Prescribers (RPhS, 2016), the Hospice UK audit tools, discussed below, or ePACT2 data, available through the NHS Business Services Authority (NHSBSA). ePACT2 is an online application which gives authorised users access to analyses of prescribing data held by NHS Prescription Services. This only applies to practitioners who prescribe on FP10s (NHSBSA, 2019). More information on ePACT2 can be found here:

www.nhsbsa.nhs.uk/epact2

A tool specifically designed to audit medicines in children's hospices, which includes a specific chapter on non-medical prescribing is available from Hospice UK National Audit Tools Group, and can be found here: www.hospiceuk.org/what-we-offer/clinical-and-care-support/quality-assurance/tools-for-measuring-quality

We are keen to learn from individual organisations about the approaches taken to monitoring and quality assurance in prescribing. We're inviting prescribers and organisations to share tools, models and approaches to prescribing governance on our Digital Care Forum which can be found [here](#).



Care Quality Commission

The implementation of non-medical prescribing in a children's hospice can help organisations to demonstrate compliance with the CQC's key line of enquiry (KLOE) (CQC, 2018b). The brackets at the end of each point relate to the KLOE in the sector specific guidelines (CQC, 2018a)

Safe

- Increased availability of prescribers who have a robust understanding of pharmacology in relation to polypharmacy and comorbidity (S4).
- Increased awareness of the proper and safe use of medicines (S4).
- Assurance of medicine records (S4).
- Appropriate prescribing, administration and supply of medicines (S4.2).
- Provision of individualised advice about medicines (S4.3).
- Communication of prescription changes when children access more than one service* (S4.5).
- Timely medicines reconciliation (S4.5).
- Increased capacity to perform medicines reviews, including the use of 'as required' medicines (S4.7).

Effective

- Appropriate use of anticipatory prescribing (E1).
- Timely monitoring of treatment outcomes in relation to prescribed medicines (E2).
- Availability of enhanced, high quality education for the care team, provided by prescribers (E3).
- Effective, cross-agency communication around medicines changes (E4).

Caring

- Compassionate, timely and appropriate care when people experience physical pain, discomfort or emotional distress? (C3.2).

Responsive

- Provision of services that reflect the needs of the caseload, and that ensures flexibility, choice and continuity of care (R1.1).
- Services are delivered, coordinated, accessible and responsive to children and young people with complex health needs (R2.2).
- Support of families to make informed choices where children approach the end of life (R2.9).
- Helping families to access care and treatment in a timely way (R3).

Well-led

- Understand the importance of quality and sustainability, taking actions to address them (W1.2).
- Assuring that services delivered focus on the needs and experience of people who use them (W3.2).



Enabling prescribing

Following the publication of the previous version of this toolkit, we have gathered a number of insights that may help organisations to think about how to implement, support and enable NMPs to work effectively. The key points of the paper are included below.

Non-medical prescribing training on its own is not enough to enable prescribers to prescribe. Practitioners from hospices across the UK felt they needed access to the following to allow them to practice confidently and competently:

Continuing professional development opportunities should include:

- Training that focuses on advanced clinical assessment, at postgraduate level
- Prescribing practice updates
- Peer support and supervision: where this is not possible within an organisation, partnerships may be achievable locally with other children's hospices in the region, adult hospices or prescribers working in the NHS.
- Clinical supervision

Hospices that have successfully implemented non-medical prescribing suggest that the following points have helped to assure safe and effective prescribing:

- Shared learning between medical and non-medical prescribers.
- Meetings between service managers and practitioners to enable discussion of prescribing scope, and an opportunity to agree training or development needs required to enable the practitioner to safely and effectively prescribe.

- Introduction of NMPs alongside doctors has led to being enhanced, providing wider and more timely access to medicines and medicine reviews.
- Workforce planning to allow prescribers to have time for discussion, consultation and assessment with the child, in addition to the administrative tasks of medicines reconciliation.

Services that have struggled to introduce non-medical prescribing did not allow practitioners the additional time required to prescribe, or trained a number of prescribers at once, preventing practitioners from consolidating and maintaining competence and confidence in independent prescribing.



Closing thoughts

Non-medical prescribing has been an undoubted success across the UK, with more professionals than ever before prescribing with equal effectiveness as medical prescribers (Weeks et al, 2016). As discussed throughout the chapter, there has been growth in both the number of NMPs and scope of practice of prescribers within the children's palliative care sector.

In the near future, changes to the training of professional registrants, particularly nurse education, means that more practitioners than ever before will be eligible to prescribe, both within and allied to the children's palliative care sector. Changes to the workforce, coupled with the fact that children are living longer with more complex conditions mean that organisations need to be ready to meet the changing needs of those who are cared for, and employed by palliative care services.



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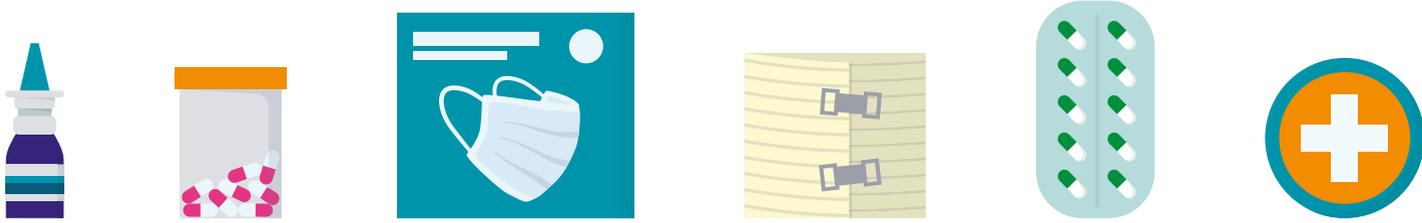
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Chapter 7: Controlled drugs

By Kate McCusker and Bhumik Patel



Due to the desirability of controlled drugs and their potential for harm, controlled drug (CD) use is restricted and highly regulated. The Misuse of Drugs Act 1971 outlines those restrictions, but also aims to ensure that health care professionals are not prevented from treating patients appropriately.

This chapter covers:

This chapter provides legal, best practice and governance information to support the safe management and use of controlled drugs (CDs) and draws on UK wide legislation and guidance. The following topics are described:

- Legislation
- CD best practice resources
- National Inquiries
- Responsibilities of CD accountable officer and Local Intelligence Network
- CD Classification
- CD medicine management processes
- Cannabis based medicinal products



Legislation

The principle legislations applicable to controlled drugs are summarised in the table opposite.

Key Legislation	
Act and dates	Summary
Misuse of Drugs Act 1971	Provides the statutory framework for the regulation of CDs. The Act imposes prohibitions on the possession, supply, manufacture, import and export of CDs – except where permitted by the 2001 regulations or under license from the Secretary of State.
Misuse of Drugs (Safe Custody) Regulations 1973	Imposes controls on the storage and safe custody of CDs. The degree of control depends on the CD classification.
Misuse of Drugs Regulations 2001 And Misuse of Drugs Regulations Northern Ireland 2002	These regulations impose controls on the storage of CDs. The degree of control depends on the premises where the drugs are stored. All Schedule 2 and some Schedule 3 CDs should be stored securely in accordance with the safe custody regulations. These regulations state that such CDs must be stored in a cabinet or safe, locked with a key. It should be made from metal, with suitable hinges and fixed to a wall or floor with rag bolts that are not accessible from outside the cabinet.
Health Act 2006	Introduces the concept of ‘Accountable Officers’ and sets out their roles and responsibilities as to controlled drugs. Principles regarding use and management of CDs including co-operation between responsible bodies and powers of entry and inspection are described.
The Controlled Drugs (Supervision of Management and Use) Regulations <ul style="list-style-type: none"> • Scotland and England, 2006 (update 2013) • Wales 2008 • N. Ireland 2009 	The Shipman Inquiry exposed a number of loopholes in the management of CDs, and these regulations form part of the action programme set out in Safer management of controlled drugs, the Government’s response to the Fourth Report of the Shipman Inquiry . These Regulations make the first use of powers in the Health Act 2006 relating to CDs.

Controlled drug best practice resources

The following guidance on best practice comes from the NHS and Government departments.

- **Department of Health (National Archives)**
Safer management of Controlled drugs: a guide to good practice in secondary care (England). October 2007.
- **Department of Health**
Controlled Drugs (Supervision of management and use) Regulations, February 2013.
- **National Prescribing Centre**
A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England) 3rd edition 2009.
- **National Prescribing Centre**
Handbook for controlled drugs: Accountable Officers in England. First Edition March 2011.
- **The Scottish Government**
Safer Management of Controlled Drugs: A guide to good practice in Secondary Care (Scotland). February 2008.
- **NHS Scotland**
Management of controlled drugs: A guide to the good management of Controlled drugs in primary care (Version 2). September 2014.
- **Care Quality Commission**
Controlled Drugs governance self-assessment tools (for primary care and secondary care).
- **Care Quality Commission**
The safer management of Controlled Drugs annual report.
- **National Institute for Health and Care Excellence**
Controlled drugs: safe use and management. NICE guideline. 2016.
- **Department of Health (N Ireland)**
Guidance on the safe management and use of controlled drugs.
- **Home Office.** Guidance for the safe custody Controlled Drugs and drug precursors in transit. September 2013.



National inquiries

There have been two notable national inquiries that demonstrate the necessity for CDs to be highly regulated: the Shipman Inquiry (2005) and the Gosport Inquiry (2018). Indeed, it was the Shipman enquiry that led to the establishment of CD accountable officers as set out in the Health Act 2006 and the Controlled Drugs (Supervision and management of Use) Regulations 2006 and 2013.

Shipman Inquiry

Harold Shipman, a GP from Greater Manchester, was convicted in January 2000 of the murder of 15 of his patients, and of forging the will of one. He murdered his patients by administering lethal doses of opioids, some of which he obtained personally from a local community pharmacy.

In February of the same year the Secretary of State for Health announced that an independent inquiry would take place to establish the extent of Shipman's activities, the activities of the statutory authorities and other organisations involved and what system changes should take place to safeguard patients. The Inquiry published a total of **six reports**, the first published in July 2002 and the last in January 2005. It was the fourth report, *The Regulation of Controlled Drugs in the Community (July 2004)*, that made recommendations to strengthen and improve systems for the management and use of CDs. The UK Government then translated these recommendations into an action plan as set out in **Safer management of controlled drugs, the Government's response to the Fourth Report of the Shipman Inquiry** and changes to legislation to enact the action plan followed (refer to legislation section).

Gosport Inquiry

The **Gosport Independent Panel Report** concluded that 450 patients had their lives shortened while in Gosport War Memorial Hospital (GWMH) by the unnecessary prescribing and administering of “dangerous doses” of opioids. Furthermore, the report highlighted a number of institutions that failed to safeguard patients and relatives, including the senior management team of the hospital, healthcare organisations, Hampshire Constabulary, local politicians, the coronial system, the Crown Prosecution Service, the GMC and the NMC.

In November 2018, the UK Government responded with **The Gosport Independent Panel: Government Response**. The poor use of CDs and a blanket approach to prescribing end of life medicines, irrespective of the circumstances of individual patients, were identified as central to the failures in care in GMWH. The Government’s response report goes on to state that, since the period analysed by the report, there have been significant changes in the governance arrangements for the use and management of CDs, many instigated as part of the Government’s response to the Shipman Inquiry’s Fourth Report. The measures that have been put in place mean that the inappropriate use of CDs can be detected more quickly, so that poor or inappropriate practice is less likely to continue unchecked.

Learnings from GWMH are ongoing. The most recent report from the **Care Quality Commission: The Safer Management of Controlled Drugs** criticised the blanket ‘one size fits all,’ approach to prescribing end of life medicines that routinely, and inappropriately, occurred in GWMH. Instead, the report recommends that decisions around end of life care should be patient-centered and states that the needs and wishes of patients and carers must be considered.



Governance and monitoring

CD Accountable Officers

Organisations providing healthcare who have been assigned “**designated body**” status and involved in the use and management of CDs must appoint a CD Accountable Officer (CDAO). The CDAO must have regard to best practice in relation to the use of CDs. **The Health Act 2006** and **The Controlled Drugs (Supervision of Management and Use) Regulations 2006** outlines the responsibilities of the CDAO as follows:

- Ensure safe management and use of CDs.
- Monitor and audit the management and use of CDs.
- Ensure relevant individuals receive appropriate training and that their training needs are regularly reviewed.
- Monitor and assess the performance of such individuals in connection with the management or use of such drugs.
- Make periodic inspections of premises used in connection with the management or use of such drugs.
- Record, assess and investigate concerns expressed about incidents that may have involved improper management or use of such drugs.
- Ensure appropriate action is taken in cases where such concerns appear to be well-founded.
- Establish arrangements for sharing information.
- Establish and maintain appropriate arrangements to comply with Misuse of Drugs legislation.
- Ensure adequate and up-to-date standard operating procedures are in place in relation to the management of CDs.

- Ensure adequate destruction and disposal arrangements for CDs.
- Establish and/or participate in Local Intelligence Networks (LIN).

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (updated 2013) also provides governance arrangements for the appointment, support and removal of CD accountable officers. Healthcare regulators for **Scotland, England, Wales** and **N. Ireland** must be informed of the appointment, removal or change of CDAO. Published lists of CDAOs are also available from these organisations. Information on organisations who are exempt from appointing a CDAO can be found [here](#). Nevertheless, it is good practice for those organisations to appoint a ‘nominated person’ to undertake key CD governance functions and ensure the safe use and management of CD in their organisation.



Local Intelligence Networks (LINs)

There is a legal requirement for CDAOs to share information and concerns regarding the management and use of CDs with other designated and responsible bodies. As a consequence, LIN have been established to provide a forum for information sharing. The membership of LIN can vary but typically consist of: health board and independent hospital/hospice CDAO; nominated person where organisations are exempt from appointing a CDAO; police; social services; relevant inspectorates; counter fraud services; healthcare regulators including the General Pharmaceutical Council. The network enables agencies that have cause for concern about the activities of healthcare organisations, professionals or individuals, to share them as soon as possible with other local agencies that may be affected or that may have complementary information.



Standard Operating Procedures

It is a legal requirement that all organisations involved in the management of CDs have Standard Operating Procedures (SOPs) in place. However, the 2013 regulations do not stipulate a minimum list of SOPs that organisations must have. Instead, the regulations allow flexibility for this to be determined locally at the discretion of CDAOs or 'nominated person' provided that the requirements of 2013 Regulations are fulfilled.

Notable practice point

The NICE guideline 'Controlled drugs: safe use and management (2016)' describes the overarching themes that should be contained within CD SOP(s) to fulfill the 2013 regulations and those themes are summarised as follows:

- Prescribing, supplying, administration and clinical monitoring of those prescribed CDs.
- Storage and access to CDs.
- Record keeping.
- CD stock checks and auditing.
- Managing discrepancies.
- Transporting.
- Destruction and disposal.
- Awareness and dissemination of patient safety alerts.

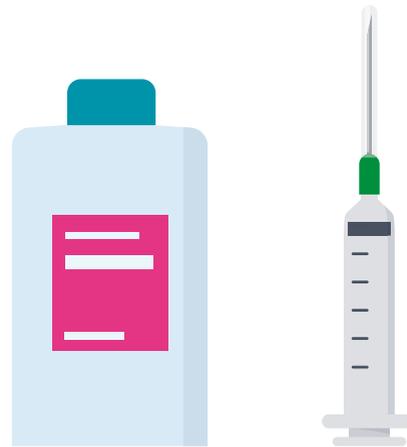
Good practice point

SOPs must be unambiguous, roles and responsibilities for every stage of practice or use of CDs should be clear with processes for review and update of SOPs (normally every two years or sooner if necessary). There should be processes in place where staff are informed of new or updated SOPs and that they should be adhered to. Evidence that staff have read and understood the SOPs is desirable.



Auditing and CD checks

The CDAO or 'nominated person' is required to ensure their organisation establishes and operates appropriate arrangements to monitor the management and use of CDs through processes such as adverse event analysis, CD checks and audit.



Good practice point: Audit

A regular, well-constructed, audit program with CD balance checks can help determine the effectiveness of processes and minimise the risks associated with CDs. Good practice would suggest the following key areas should be audited:

- CD requisitions eg appropriately completed, signed on receipt, all requisitions reconciled against CD register.
- Correct completion of CD registers eg receipt, return, administration, destruction and balance transfer entries.
- Safe storage and security of CDs maintained eg stock segregation maintained as per local policy, access to cabinet is controlled.
- CD balance checks are conducted eg ensure evidence of checks is available and frequency is appropriate.
- Dealing with discrepancies or concerns eg discrepancies in the CD register have been appropriately investigated.
- Check staff understanding of CD management processes.

Results from audits should be analysed to identify any areas where systems could be improved and better coordinated. Audit results should be published within the organisation for wider awareness and learning.

Good practice point: CD checks

In line with Royal Pharmaceutical Society (RPS) **Safe and Secure Handling of Medicine** guidance, the balance of all entries in the CD register should be checked and reconciled with stock amounts in the CD cabinets. It is also good practice for expiry dates to be checked at this time. Ideally, CD checks should be carried out at each staff changeover, although this may not always be practical. The frequency of such checks can be determined locally by risk assessment, although it is good practice to have weekly checks as a minimum. Two people should carry out stock checks if possible and both should sign the appropriate documentation. (This could be an entry in the CD register to say a check has been carried out and the balance is correct or a separate CD check recording form). Refer to the discrepancy section for steps to take when there is a CD balance discrepancy.



The **NICE guideline 'Controlled drugs: safe use and management (2016)** provides a baseline **audit tool** to assess whether organisations have appropriate CD medicines management processes in place.



Inspections

The CDAO must undertake (or delegate to an appropriate person) periodic inspections of their organisation with regard to the use and management of CDs. Those inspections can be unannounced and records of the inspections must be kept. For those organisations without a CDAO it is good practice for their 'nominated person,' to undertake such inspections.

Most organisations providing healthcare care are inspected by professional and/or regulatory bodies (eg Health Care Improvement Scotland, Care Quality Commission) and those inspections, either announced or unannounced, can include a review of CD management processes. The 2013 CD Regulations maintains the 'powers of entry and Inspection,' to relevant premises without a CDAO or those premises not subject to inspection by professional and/or regulatory bodies.

Notable practice point

Other agencies and professionals such as, local pharmacy personnel, person's qualified to conduct mock inspections, peers in similar organisations (eg CDAO from other children's hospices) or the Police Officer from CD LIN can be invited to organisations to inspect the use and management of CDs. This can be particularly helpful if organisations work in isolation for a long time, as that isolation may increase the risk of new innovations or best practice being missed. External checks can enable confidence that processes and practice are safe and current.



Raising concerns

In addition to concerns arising from routine analysis of adverse events, audit and inspection, concerns may be raised by individual staff members. The CDAO or 'nominated person' should ensure that robust systems are in place to:

- Enable concerns to be raised about CDs, individuals or processes and that those concerns are logged.
- Alert relevant individuals of these concerns, including the CDAO or 'nominated person'.
- Allow an investigation to be initiated.

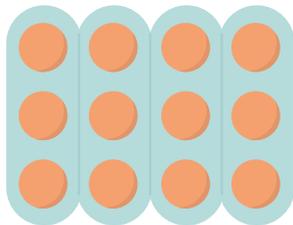
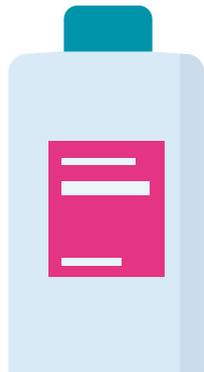
Electronic adverse events reporting systems could be constructed to facilitate the above requirements.



CD classification

The Misuse of Drugs Act 1971 divides CDs into three classes – Classes A, B and C. The class of a drug reflects its potential for harm to an individual and to society when misused, in a descending order of severity, from A to C. The Act specifies those CDs that fall into all three classes as well as the maximum penalties for offences of possession and supply of those CDs.

Misuse of Drugs Regulations 2001 classifies CDs into five schedules according to the different levels of control attributed. The table opposite provides a description of each class and examples.



CD classification		
Schedules	Description	Examples
Schedule 1 CD Lic POM	Most have no therapeutic use, a license is required for their production, possession or supply.	LSD, ecstasy, raw opium, cannabis.
Schedule 2 CD POM	Persons named in the 2001 regulations have authority to possess, supply and procure.	Diamorphine, morphine, ketamine, fentanyl, alfentanil, oxycodone, nabilone, methadone.
Schedule 3 CD No Reg POM	Minor stimulations less likely to be misused, and less harmful if misused than those in schedule 2.	Buprenorphine, temazepam, midazolam, phenobarbital, gabapentinoids (gabapentin, pregabalin)
Schedule 4 CD Benz POM or CD Anab POM	Part 1, CD Benz POM: Most benzodiazepines, except those in Schedule 3, hypnotics and Sativex. Part 2, CD Anab POM: most anabolic steroids and androgenic steroids, clenbuterol (an adrenoceptor stimulate) and growth hormones.	Diazepam, zopiclone, Sativex (a cannabinoid)
Schedule 5 CD INV POM or CD INV P	CDs exempt from full controls due to low strength.	Codeine, pholcodein, low strength morphine (10mg/5mL), epidyolex (pure cannabidiol [CBD] with negligible tetrahydrocannabinol [THC])

The table below gives a summary of some useful information regarding CDs relevant to practice.

	Schedule 2	Schedule 3	Schedule 4 Part I and II	Schedule 5
Prescription requirements*	Yes	Yes	No	No
Prescription valid for	28 days	28 days	28 days	6 months
CD Requisition necessary	Yes	Yes	No	No
Safe storage in CD cabinet	Yes	Yes, some exemptions**	No	No
Recording in CD register	Yes	No	No, except Sativex****	No
Destruction using CD denaturing kit	Yes	Yes	Yes (part 1)	No
BNF-C symbol			 	

* Refer to Medicine Management section for prescription requirements.

** Common Schedule 3 CDs which require safe storage include temazepam and buprenorphine. Exemptions to safe storage include phenobarbital, midazolam, tramadol and gabapentinoids.

**** The Home Office strongly recommend the use of a CD register for making records relating to Sativex.

The British National Formulary (BNF) also provides information under the 'Controlled Drug and Dependence,' section regarding CD classification, CD prescription requirements as well as information for patients and carers regarding travelling abroad with CDs. In addition, preparations in CD Schedules are identified throughout the BNF and BNF *for children* with a CD symbol (within drug monographs, under 'medicinal forms' section, next to the preparation) as per the table opposite.



Knowledge bite

Travelling abroad with CDs

If a person travelling is carrying less than three months' supply of CDs (Schedule 2, 3 4) or traveling for less than 3 months then a UK Home Office License **is not required** for entering or exiting the UK. However, a covering letter signed by the prescriber must be obtained prior to travel to confirm the name of the patient, travel plans, name of the prescribed CDs, total quantities and dose. It is also advisable to contact the destination countries UK Embassy or Consulate in case further controls are required in the destination country.

If a person travelling is carrying more than three months' supply of CDs or travelling for more than three months then a **UK Home Office License** is required.



CD medicine management processes

Prescribing of controlled drugs

Prescription requirements

In addition to the normal prescription requirements for prescription only medicines, prescriptions for Schedule 2 and 3 Controlled Drugs must satisfy other legal requirements as detailed below (1 to 8):

1. Dose: The dose does not need to be in words and figures however it has to be legally acceptable. The table below describes examples of doses that are acceptable and examples that are not.

Not legally acceptable	Legally acceptable
As directed	Give one as directed
When required	Give two when required
PRN	Give one prn
To be used in a continuous subcutaneous infusion	Give three ampoules via continuous subcutaneous infusion over 24 hours
Twice a day	Give one twice a day

2. Formulation: The form of the prescribed CD must be written on the prescription eg tablet, capsules etc. The form must be stated regardless of whether there is only one form available or if the form is implied from the name ie MST Continus. When a preparation has different release characteristics, it should be clearly written on the prescription eg monitored-release or immediate release.

3. Strength: The strength needs to be written on the prescription if there is more than one strength available. When more than one strength of CD is required to achieve the desired dose eg MST Continus 25mg, each strength should be prescribed separately (MST Continus 15mg, with separate dose, form total quantity etc. and MST Continus 10mg, with separate dose, form total quantity etc.).

4. Total quantity: The **total** quantity required must be written on the prescription in both words and figures. The quantity should be expressed as follows:

- For liquids state the total volume in both words and figures ie 100mL (one hundred mL)
- For tablets, capsules, ampoules, vials and patches, state the total number of dosage units in both words and figures eg 10mg x 10 (ten) or total quantity of drug as milligrams eg 100 (one hundred) mg. **The former is recommended by the RPS due to risk of arithmetic errors with the latter.**

5. Quantity prescribed: It is recommended by The Department of Health and the Scottish Government that the maximum quantity of Schedule 2, 3, or 4 CDs prescribed should not exceed 30 days. This is not a legal requirement and there may be a genuine clinical need for prescription quantities to exceed 30 days. In these exceptional circumstances, it is good practice for prescribers to record the reasons for supplying more than 30 days of CDs in the patients notes.

6. Prescribing more than one drug: Medicines that are not controlled drugs should not be written on the same prescriptions as Schedule 2 or 3 CDs. Schedule 2 and 3 controlled drugs can however be written on the same prescription.

7. Validity: Prescriptions for CDs (Schedules 2, 3 and 4) are valid for 28 days from an appropriate date specified on the prescription. This date may be the date the prescription was signed or a forward date specified by the prescriber in the body of the prescription (whichever is later). Schedule 5 prescriptions are valid for six months from the appropriate date.

8. Signature: Prescriptions should be signed in ink by the prescriber. It is worth noting that **NHS Digital** is rolling out an **Electronic Prescription Service** which includes Schedule 2 and 3 CDs. More information can be found **here**. It will be interesting to see how this digital service may be utilised by hospice services in the future or how this technology may be integrated with hospital electronic prescribing systems.

Refer to local protocols for the standards required for 'direction to administer' entries on inpatient medication charts.

Hospice case study

A hospice prescriber sent the below prescription to the local community pharmacy. There was no corresponding entry in the child's notes. The prescription was returned because it did not meet the legal requirements for a CD prescription.

- What is legally wrong with this prescription (think about the strength of morphine requested, the form, are the words and figures correct?)
- Is the number of days of treatment legal?
- What should the prescriber have documented in the child's notes?
- What could be done to prevent these prescribing errors from occurring again?

FORM HBP (5) NATIONAL HEALTH SERVICE (SCOTLAND)

Name: **Minnie Mouse**
Address: **c/o Hospice House
Lovely Town**
Age if under 12 yrs: **10y**
Yrs / Mths:
Postcode:
Pharmacy stamp:
No. of Days Treatment: **90** CHI No.
Dispensing Endorsements:
Pack size Numbers only:
Pack size Numbers only:
Pack size Numbers only:
Pack size Numbers only:
Date:
Signature of Prescriber: **Dr Joe Bloggs** Date: **1/2/2021**
J. Bloggs
Hospital or Clinic: **Hospice House Children's Hospice,
Avenue Road, Lovely Town, LT00 ILU**
01/13 00620062

Morphine sulfate monitored-release 25mg (twenty five mg)
Give 25mg every 12 hours

SCOTLAND



Making and recording prescribing decision

Prescribing CDs must be safe and appropriate. The table below provides some information for healthcare professionals to consider before, during and after prescribing CDs and includes a summary of recommendations from **NICE guideline 'Controlled drugs: safe use and management (2016)**.

Considerations	Actions
Prescribing decisions	<ul style="list-style-type: none"> • Review benefits of treatment versus risks (side-effects, toxicity, dependency, diversion). • Ask about past and present CD use. • Check interactions or contra-indications with other prescribed medicines. • Specifically ask about complementary or herbal medicine including those purchased abroad (eg cannabis-based products). • Check evidence-based sources for prescribing decisions eg APPM Master Formulary, BNF-C etc. • Involve patient/carer in the decision-making process.
Prescribing and recording prescribing decisions	<ul style="list-style-type: none"> • Document the indication and clear instructions for when and how to take/give the CD in the patients notes. • Prescriptions must satisfy all legal requirements and provide clear directions on how to take/give the CD so that the directions can be included on the prescription label when dispensed. • In-patient 'direction to administer' must be clear and unambiguous and provide all the information required for safe and appropriate administration. • Discuss with patient, carer or and/or other healthcare professionals that may continue care, the arrangement for reviewing and monitoring treatment.
Reviewing or changing	<ul style="list-style-type: none"> • Determine an appropriate timeframe for review based on individual patient circumstances. • Review effectiveness and appropriateness of route, dose, frequency and formulation. • Use recognised symptom control tools to review effectiveness, side-effects or toxicity. • Check patient has been taking/given their CDs as prescribed (for in-patients check with nursing teams) including any prn use before considering increasing/decreasing doses or switching a CD. • Use a recognised opioid conversion guide when changing an opioid and ensure the total opioid load is considered (appropriate PRN use should be included in the total opioid load). • Use locally agreed processes for reviewing anticipatory prescribing in primary care; include review of on-going clinical need, CD stock monitoring and expiry date checks.

Considerations	Actions
Providing patient/carer information	<ul style="list-style-type: none"> • Inform the patient/carer: <ul style="list-style-type: none"> – What the CD had been prescribed for. – How long the patient may need to use the CD. – How long it will take to work. – How to use the CD eg when monitored-release and immediate release formulations are prescribed together or how to administer and change patches (check understanding). – Possible side-effects and what to do. – Provide medicine literature if available eg medicine leaflet from Medicine for Children website. – To be used only by the patient it is prescribed for. – May need to show identification when collecting CD from a community pharmacy. – Usually only one month at a time will be supplied. – Return expired CDs or those CDs no longer needed to a community pharmacy. • Record the information given to patients/carers in the patients' notes.
Information sharing	<ul style="list-style-type: none"> • Inform GP of all prescribing decisions so the patients care record can be updated. • Have knowledge of local information governance policies and procedures and ensure they are followed when informing GP and wider healthcare teams about prescribing decisions. • Share anonymised information when it is for the benefit of the community eg teaching. • Consider an individual's right to object to the sharing of information.

The following guidance can be used by organisations to develop local policies and procedures and risk assessments for remote prescribing/ transcribing and subsequent administration of CDs:

- **General Medical Council: Good practice in managing and prescribing medicines and devices.**
- **Specialist Pharmacy Service: Direction to Administer forms – in response to Covid-19.**
- **RPS/RCN: Professional guidance on the administration of medicines in a healthcare setting (paragraph 31).**



Good practice point: Carmel Caldicott, Acorns Children's Hospices

"I invite other agencies such as, the local pharmacy, the CCG's pharmacist, other children's hospices and the police officer from CDLin (Controlled Drugs Local Intelligence Network) to come into our treatment/medicines room and audit annually. I am aware that we often work in isolation for a long time and can miss new innovations, best or current practice occurring outside of the hospice. This has enabled us to feel confident we are working up to standard and not missing anything."

Administering controlled drugs

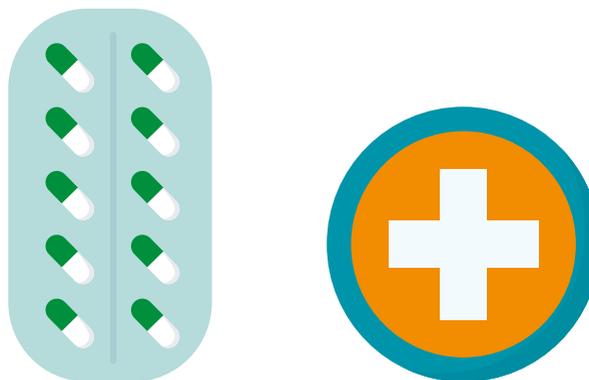
As for prescription only medicines, administration of CDs in a healthcare setting must be done in accordance with a prescription, a Patient Specific Direction or a Patient Group Direction (PGD). Information on who can supply and administer CDs under a Patient Group Direction can be found [here](#). It is important to note that under any PGD it is not possible for healthcare professionals to delegate responsibilities.

Health care professionals administering CDs must follow the relevant standards set by their professional regulators for medicine administration. The RPS and Royal College of Nursing (RCN) have co-produced **Professional Guidance on the Administration of Medicine in a Healthcare Setting**.

Healthcare professionals administering CDs should check with a prescriber about any safety concerns such as those described in the **NICE guideline 'Controlled drugs: safe use and management (2016)** eg is the dose safe, is the formulation appropriate, have past or previous doses been taken into consideration, is the dose safe in the context of all other prescribed medication for that patient.

Patients/carers should be supported to self-administer CDs if they wish to do so as long as there is local policy, SOP(s) and risk assessment to support this practice.

For safety reasons, the person who is prescribing the CD should not normally undertake the preparation and administration of the CD. In exceptional circumstances for example, during a home care visit, separation of prescribing and administration tasks may not be possible and organisations should ensure there is appropriate risk assessment and SOPs in place to support this eventuality if appropriate. The RCN, RPS and the Specialist Pharmacy Service have provided a **position statement** regarding the practice of prescribing alongside the dispensing/supply/administration of medicines by the same health care professional.



Records of administration

As detailed within **NICE guideline 'Controlled drugs: safe use and management (2016)**, records for the administration of CDs should include:

- Name/DOB/CHI of patient having the dose administered.
- Date and time of dose administered.
- Name, formulation, strength and dose of CD administered.
- Name and signature or initials of the person administering the dose.
- Name and signature or initials of any witness to administration.

Witness for administration

It is good practice for the whole process of preparation and administration of Schedule 2 to be witnessed and for the witness to act as a second signatory on the record of administration. The witness should preferably be a registered healthcare professional (nurse, doctor, pharmacist) or another competent healthcare practitioner depending on the setting and in-line with local policies or SOPs.

In the home setting, a parent/carer/family member could be asked to act as a second signatory for the administration of controlled drugs and this should be clearly laid out in local policy and SOPs. In those exceptional circumstances where there is not a witness available in the home setting, a risk assessment must be undertaken to ensure that it is safe for healthcare professionals to administer CDs (refer to Good Practice Point on page 106).

Hospice case study

A hospice was developing a hospice at home service. The new home service was required to develop policy and procedure for the administration of medicines. Existing hospice policy was adapted to ensure the safe administration of medicines in the home setting including CDs. It was identified early on in development of the service that administration of CDs by two nurses, which was standard hospice policy, would not always be practical and could lead to unnecessary delay and subsequent patient harm.

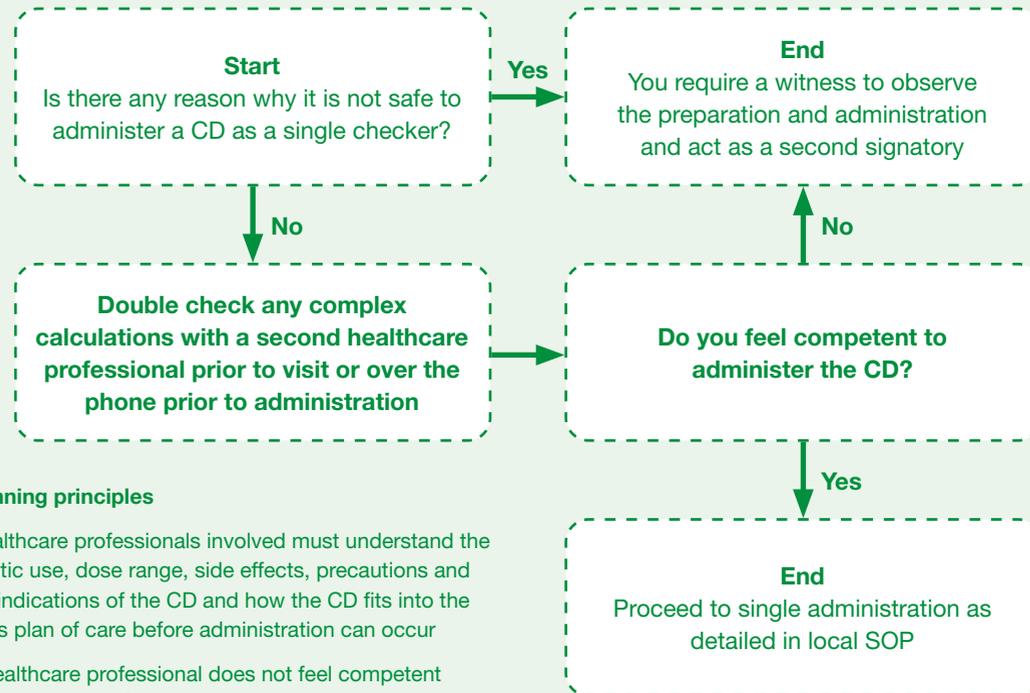
The lead for medicine management developed training for hospice home care support workers (HCSW) to act as CD witnesses for the administration of CDs in the home setting when a second registered nurse was not available. The training comprised a mixture of online training with 'test your learning' questions as well as practical based assessment, and a requirement for annual re-validation.

In the absence of a HCSW parents can act as witnesses as they are generally very familiar with their child's medicine regime. However, one of the benefits of a home care service is to release parents from care duties and provide respite. To this end, the lead for medicines management developed a risk assessment that underpinned the single nurse-administration of CDs if needed (refer to Good Practice Point).

Administration of medicine by HCSW, parents or a single nurse was also incorporated in policy and SOP(s).

Good practice point

Below is an example of a risk assessment flow chart, developed by Kate McCusker for CHAS, for use in the home setting to decide whether it is safe to administer CDs without the presence of a witness. Organisations should design their own risk assessments based on local policy, level of service and associated risks.



Underpinning principles

- The healthcare professionals involved must understand the therapeutic use, dose range, side effects, precautions and contra-indications of the CD and how the CD fits into the patient's plan of care before administration can occur
- If the healthcare professional does not feel competent to single administer CDs, then learning needs should be discussed with their line manager

CD Register and other record keeping

The register

Healthcare professionals are legally required to record Schedule 2 CDs in a controlled drug register (CDR). A separate CD register must be kept for each of the premises of an organisation where CDs in Schedule 2 are stored. A separate CD register can be kept for patient's own CDs if they are being used for administration within the premises.

A record of all receipts and supplies of Schedule 2 CDs must be made in the CDR at the time of the transaction or as soon as possible but no later than the following day. Some organisations also choose to record Schedule 3 CDs that require safe storage in the CDR, although there is not a legal requirement to do so (refer to Storage and handling section for risk assessment guidance). It is worth noting that the Home Office strongly recommends the use of a CDR for making records relating to Sativex. All transactions in the CD register should be observed and signed by a second witness.

The register must be a bound book unless an electronic CDR is maintained. Electronic CDRs must have safeguards built into the software to ensure entries are attributable, cannot be altered and can be audited.

Access to archived CDRs, and other appropriate documentation (eg requisitions, invoices, CD checks etc.) should be made available to authorised persons upon request, for example during a CDAO inspection.

The table opposite describes the required layout of a CD register based on legislation and good practice.

Page layout	Receipt/return entries	Running balance
Drug name, strength and form specified at the head of each page.	Date of transaction.	Maintain for receipt, supply, return, administration and destruction entries.
Entries made in respect of drugs received and drugs supplied/returned may be made on the same page or separate pages.	Quantity, name, form and strength.	For solid dosage forms the quantity should be counted at receipt, supply, return and destruction.
Separate page for each strength and form of each drug.	It is good practice to write quantity received and supplied in both words and figures to prevent errors in running balances.	For liquid dosage forms the volume should be measured at receipt and return. For administration entries the volume can be visually confirmed against the running balance – this is to prevent mechanical loss of liquid due to handling.
Entries should be chronological, in ink or indelible and unaltered.	Name and address of the supplier (eg wholesaler, pharmacy) or recipient.	Balance discrepancies must be investigated. Guidance on acceptable loss of CD liquids can be found here .
Original erroneous entries must remain unaltered (ie must not be scored through or obliterated by pen) and a correct entry made and signed.		Maintaining a running balance and dealing with any discrepancies lies with the health care professional in charge and not with the person to whom they may delegate day-to-day responsibility under defined SOPs.
An index should be maintained.		CDs awaiting destruction must remain in the CD cabinet and included in the running balance until they are destroyed.

Balance discrepancies

SOPs should clearly define the action to be taken if a CD balance discrepancy arises. Once resolved, a note should be made in the CD register to correct the discrepancy in the balance. The record should clearly state the reason for the entry, the date of the error or omission and the signature of the person making the entry and a witness. It is also advisable to keep appropriate records of the investigation and action taken when discrepancies arise. If the source of the discrepancy cannot be identified, then a formal internal investigation should be undertaken and the CDAO or 'nominated person' informed. If the discrepancy is resolved but a cause for concern, the CDAO or 'nominated person' should also be informed. All CD discrepancies, whether resolved or not should be reported as an adverse event through usual adverse event procedures. Consideration must be given to whether the adverse event should be reported to governing bodies such as Healthcare Improvement Scotland or the Care Quality Commission. If criminality is suspected, the police should be informed.

Retention of records

As per **NICE guideline 'Controlled drugs: safe use and management (2016)**, CD registers must be kept for a minimum of 2 years from the date of the last transaction, and if they contain records of the destruction then they must be kept for a minimum of 7 years. Requisitions for CDs should be kept for two years from the last requisition date and invoices for 6 years. **NHS digital** are currently reviewing the *Record Management Code of Practice for Health and Social Care 2016* and have prepared **new draft guidance**. It is worthy to note that retention Schedules for CD records may change based on responses from this new draft guidance.

Storage and handling

Storage

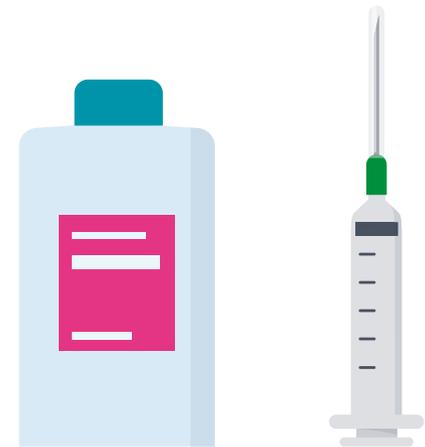
The Misuse of Drugs (Safe Custody) Regulations 1973 impose controls on the storage of Schedule 2 and 3 CDs, unless exempt under the regulations. In April 2013, gabapentin and pregabalin were rescheduled as Schedule 3 CDs and are exempt from safe custody requirements. Common Schedule 3 CDs that do require safe storage include temazepam and buprenorphine.

Healthcare organisations must comply with the requirements for safe custody. They must ensure that the relevant CDs are kept in a locked cabinet or room as detailed with the Misuse of Drugs (Safe Custody) Regulations 1973. This requirement does not apply to CDs under the direct personal supervision of a healthcare profession, eg nurse administering CDs. Those CDs requiring safe storage and no longer needed (eg expired) must be kept in a CD cabinet until they can be denatured. The requirement for safe custody for CDs also applies to those dispensed in a compliance aid.

Some organisations may carry out a risk assessment to determine the need for storage and recording of Schedule 3 CDs in the same way as Schedule 2 CDs. **NICE guideline 'Controlled drugs: safe use and management (2016)** provides advice on what could be included in such risk assessments. Those Schedule 3 CDs risk assessed as requiring safe storage and recording should be included in relevant policy and SOPs.

Good practice point

- Keep stock to a minimum but adequate to provide the desired service.
- Do not store anything other than the CDs, the CD register or CD requisition stationery in the CD cabinet.
- Segregate and clearly mark patients' own CDs and CDs awaiting destruction, from stock CDs.
- Segregate similar CDs or high and lower strength opioids to reduce the risk of mis-selection.
- Do not display anything on the outside of the cabinet or room to indicate that CDs are being stored.



Access to CDs

Organisational SOP(s) should contain relevant information to ensure there is monitored access to the CD cabinet or room, as well as steps to take if there has been a security breach (eg missing CD keys or unauthorised access).

Appropriate access should include the following:

- One designated person within the premises should take overall responsibility for the keys or codes for digital keypads.
- The number of sets of keys to the cabinet, and who holds them, or who has access codes, must be known at all times by the designated person.
- The keys should always be kept separate from the cabinet and all other keys and should never be accessible to unauthorised persons.
- The CD cabinet should only be opened by the designated person or by a person authorised by them, eg nurse undertaking CD administration.
- The area where the CD cabinet is situated and keys required for access should not normally be accessible to patients or service users.
- Patients, workmen, drivers or users of the service who do have to enter the area where CDs are stored, should be continuously supervised.
- Security breaches should be reported to the CDAO or 'nominated person' and possibly the police as determined by the CDAO.

Destruction

Where there is a requirement to make a CDR entry for a CD, a witness is required to observe destruction and act as a second signatory in the CDR. The CDAO has the authority to appoint CD destruction witnesses. Those witnesses are usually senior members of staff who are not involved in the day-to-day management or use of CDS. The CDAO cannot act as a witness.

The Home Office advises that all CDs in Schedule 2, 3 and 4 should be denatured before use. Denature kits are available from community pharmacies and should be used in accordance with manufacturer's instructions. Generic advice for destruction includes:

- Tablets and capsules can be disposed of whole without crushing or opening.
- Vials/ampoules should be opened and added to kits without the need to withdraw the liquid.
- Liquids can be added directly to kits, including bottle washings.
- Patches should be opened and folded in half before disposal.
- Denature kits should be disposed of in appropriate pharmaceutical/sharps waste containers for incineration.

Destruction processes involving CDs usually require an appropriate license. However, there are exemptions to obtaining a license for some organisations where destruction is deemed a low-risk activity. Information regarding disposal and licenses can be found as detailed below:

- England/Wales, www.gov.uk/waste-exemption-t28-sort-and-denature-controlled-drugs-for-disposal
- Scotland, www.sepa.org.uk/waste/waste_regulation/application_forms/exempt_activities.aspx

Reporting incidents/adverse events

All CD incidents and adverse events should follow usual organisational incident reporting processes and include details of any immediate actions taken to reduce harm to patients as well as action taken to prevent recurrence of the incident. In addition, the CDAO or 'nominated person' must be notified of any significant incident or adverse event as soon as possible and ideally within 48 hours, this includes:

- Losses/discrepancies in CD registers against actual stock in the CD cabinet.
- Discrepancy in CD stock which, although resolved, raises concerns.
- Prescribing, administration, supply, dispensing or destruction of CDs, including near misses.
- Complaints from patients/carers/service users relating to CDs.
- Concerns raised about professional practice or behaviour of staff in relation to CDs.
- Loss of CD register or prescription stationery including CD requisition stationery.

The CDAO can advise whether the CD incident or adverse event should be reported to governing bodies (eg Healthcare Improvement Scotland, Care Quality Commission) or the police if criminality is suspected.



Cannabis-based products

The use of cannabis-based products has garnered significant attention nationally and internationally. Many parents/carers of children with life-limiting conditions, that are life limiting, seek to explore the use of these medicines either for control of symptomology or for curative intent or a combination of symptom management and intent to cure. The conversations that relate to the use of cannabis-based products can often be very difficult, involving emotional, professional and occasionally legal challenges that need negotiating to ensure the safety of the child or young person, as well allow for the safe practice of professionals involved. This section lays out the current government guidance for use of cannabis-based products as well as aiming to help clarify the current complexity and ambiguity surrounding cannabis-based products.

The cannabis plant is extremely chemically diverse, containing over 500 compounds that may demonstrate activity on biological receptor systems in animals. Of these there are over 100 different cannabinoids, all thought to exert various effects in the body once ingest. The focus on this section will be on tetrahydrocannabinol (THC) and Cannabidiol (CBD), the two most commonly discussed cannabinoids, in an effort to simplify the discussion and reduce confusion.

Key support documentation	
Guidance and Dates	Summary
Cannabis Based products for Medicinal Use (October 2018)	Aims to set out the expectations for the prescribing of cannabis-based medicines to patients, providing support and guidance to clinicians. The document was produced in response to parliamentary rescheduling of certain cannabis-based products for medicinal use.
Cannabis-based products for medicinal use: Frequently Asked Questions	A set of FAQ's to further support prescribers of cannabis-based products.
Barriers to accessing cannabis-based products for medicinal use on NHS prescription. Findings and Recommendation. NHSE/I (August 2019)	Provides a review of the barriers to patients accessing cannabis-based products for medicinal use within the NHS and where use is thought to be clinically appropriate, seeks to provide solutions to overcome these barriers.
Additional Guidance to clinicians: Cannabis-based products for medicinal use (November 2018)	Provides further supplementary advice to prescribers to clarify previous guidance.
Guidance to clinicians: The Process for prescribing Cannabis-based products for medicinal use (December 2019)	Provides guidance to clinicians for the prescribing of cannabis-based products for medicinal use. Also provides links to training resources to up-skill clinicians in the safe prescribing and reference the NICE TA.
Cannabis-Based Medication: An Interim Desktop Guide (RCGP) (November 2018)	A reference guide to support general practitioners, relating to the use and prescribing of cannabis-based products for medicinal use.
NICE Guideline: Cannabis-Based Medicinal Products (NG144) (November 2019)	National guideline covering the prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

Whilst the guidance published would suggest the area of cannabis-based medicine is clearly defined and well governed, unfortunately the current situation is extremely complex and confusing, not just for professionals but also for families. The key(s) to managing a patient taking or contemplating using cannabis-based products are (1) questioning and (2) understanding.

“Cannabis-based products for medicinal use” is a heterogeneous term used to describe a vast spectrum of products that families/patients can access to use with a therapeutic intent. A family’s understanding of this term can differ greatly from that of the healthcare professional and from current legislation and regulation.

What does a healthcare professional understand by the term cannabis-based medicinal product?

The key here is the use of the medicinal product. When a healthcare professional discusses medicinal products, we describe a ‘drug’ or pharmaceutically produced product made by a company producing medicines under the auspices and direction of the Medicines Health Regulatory Authority, who define the quality and safety of the medicine produced before it can be used in humans with a therapeutic intent.

When a family member or patient discusses medicinal products they are describing any product that is available that could provide a therapeutic intent, whether this is a drug, a natural product, complementary therapy or homeopathic remedy.

What cannabis-based products are currently available?

Healthcare professional

Currently Licensed Pharmaceutical Medicines in UK:

- Epidiolex (Cannabidiol (CBD)) for intractable/resistant seizures in Lennox-Gaustat or Dravets Syndrome in children.
- Sativex (Nabiximol – mix of tetra-hydrocannabinol (THC) and CBD) for spasticity in MS.
- Nabilone – (synthetic THC analogue) for chemotherapy induced nausea and vomiting in adults.

In addition the MHRA have granted additional ‘specials’ licenses to companies manufacturing natural/synthetic cannabis-based medicines for use in patients who have been prescribed these products by a clinician who has been trained as a specialist in cannabis-based medicine and appears on the GMC register as such. Usually these products are CBD based.

Internationally, Marinol (dronabinol (THC) is available as a licensed medicine in Europe and the US but not readily available at present in the UK.

Family/carer/patient

Any cannabis-based product, whether the manufacturer or product has a license for use or not can and will include those sold and marketed as health food supplements, or complementary natural therapies. Currently in the UK, CBD (with no THC or THC less than legal limits) and whole cannabis-plant extracts (again with no THC or THC less than legal limits) can be sold to the general public without prescription. These products however can NOT be sold with the intent of treating medically diagnosable conditions, they can only be sold as a health food supplement.

What about THC?

THC remains illegal in the UK unless prescribed by a clinician with a specialist registration. Where the medication itself is produced under a specials licence, the company supplying the product MUST seek a special Home Office license allowing for the compounding, sale and distribution of a Class B drug.

What is the role of the healthcare professional, when a family is using or wants to use cannabis-based products for medicinal purposes?

Engagement and especially early engagement is key and the healthcare professional may need to raise a safeguarding concern or involve the police.

Role of Social Care

Where available, early discussion and engagement with local social care workers is key. Discussions should not be about referral and implementation of child protection measures, but to ensure all relevant local services are aware that the family may use cannabis-based products, in order to prevent unfortunate rapid escalation as natural deteriorations may occur. Families should always be kept informed of discussion and reasons to ensure that working relationships remain intact and that they feel fully supported in difficult decision-making.



Role of the Healthcare Professional

This should not change, regardless of the setting of care or the role of the professional care provider (doctor, nurse, pharmacist etc.). Healthcare professionals should seek to actively engage families in discussions about cannabis-based products, if the families wish to investigate this as a potential treatment path. Healthcare professional should ask:

1. What current knowledge the patient or family has?
2. What their aim is for using cannabis-based therapy (curative intent Vs symptom control).
3. Type of product (CBD/THC/Whole plant extract).
4. Sourcing of cannabis-based products (Prescribed Vs Self-purchased, including sources).

The answers provided to the above will help guide further discussions. Whenever use of un-prescribed THC is disclosed, there should be an escalation as per local policy for the use of illicit substances, to avoid the healthcare professional being deemed complicit in illegal activity and intoxication of a minor. It is the remit of local judiciary and social services to determine what approach and response is required, not the remit of the healthcare professional, regardless of the circumstances.

Where possible (and available) the healthcare professional should try and seek or direct the patient/family to a specialist in cannabis-based medicine or to encourage them to seek a GMC registered clinician specialising in cannabis-based medicine so that a prescribeable cannabis-based product can be used.

What is the harm in a family/patient sourcing and using non-prescribed cannabis-based medicine?

THC remains a class B drug, thus illegal.

CBD may be legally bought and sold, however only for health food use. Companies that sell CBD in this way need only ensure that the product is fit for human consumption as determined by the food safety agency (FSA). All chemical compounds will undergo some form of degradation pathway in response to heat, light or air exposure. Pharmaceutically produced products must demonstrate that at the end of a designated shelf life they remain within 5% of the stated content at manufacture (ie if 5% at manufacture and shelf life of two years, at the end of two years the content of the product must remain within 5% of this initial content).

Products produced under the proviso of being health food supplements need not demonstrate this degradation profile, but need to prove that at time of manufacture contained the content as stated on the label. Studies have demonstrated that of those products sold under general sale as CBD for health use, more than 70% contained a CBD content difference of more than 10% to that stated on the label. In addition, there can be significant batch to batch variation, resulting in erratic effects (efficacy and toxicity) from similar dosing of similar brand or variances in effective of different brands.

It must also be remembered that both THC and CBD, regardless of legality and method of procurement, interact with normal biological cellular pathways in the body to produce an effect. Whilst some of these are desired, others may not be (side-effects). At present it is unclear what dose levels (especially in children) produce a desired effect vs a side effect. As with other chemical compounds CBD and THC once ingested are subject to breakdown in the body to ensure they are effectively removed and the effects can be terminated. THC and CBD are cleared by the liver by cytochrome P450 system.

THC and CBD as well as being substrates Cytochrome P450 3A4 for its own breakdown also inhibit this enzyme. This can mean that there is a delay in an individual being able to clear other drugs that need this enzyme for their own breakdown, in particular opioids and anticonvulsant drugs used in palliative care. The potential for drug interaction is especially difficult to predict where there is a lack of uniformity in the content of CBD/THC in the formulation being used, if bought and not prescribed.

It should also be noted that there are now synthetic CBD variants available ('Spice' or 'Black Mamba'), which whilst not illegal have been associated with significant harm and death.

If a family brings a cannabis-based product for medicinal use into a healthcare institution, what should be done?

This is a problem that healthcare providers are becoming increasingly aware of and familiar with. Many children and young people's healthcare institutions have already developed policies to manage families who bring in cannabis-based products that have been sourced externally to that care-provider. If these policies exist then this should be the first point of reference, and local policy followed. Where there are no local policies in place, the healthcare professional should first ascertain the nature and source of the product. There should be two types:

1. Prescribed cannabis-based products
2. Procured cannabis-based products

Prescribed cannabis-based products

- The healthcare professional should seek advice from the prescriber and request that they provide written information relating to dose information, indication etc.
- Where this information is provided, the healthcare provider must ensure they are aware of the legal classification of the product before them, to ensure that the product is stored correctly.
 - CBD (Epidiolex only) – schedule 5, no requirement for logging in a register with no requirement for safe custody. Can be stored in a normal medicine cupboard or patient’s own drug locker.
 - CBD (manufactured specials) – currently unclear about the legal classification, safe practice would be to treat as a schedule 2 and observe safe custody when admitted for inpatient care.
 - THC products (inc. more 1mg containing products and synthetic products eg Nabilone and all manufactured specials) – Schedule 2, requires safe custody and logging in a CD register when admitted for inpatient care.
- The healthcare provider should be explicit to the family/carer/patient that the current care provider cannot be party to further provision of the prescribed cannabis-based medicine. It is the responsibility of the patient or their family carer to ensure supply is maintained and that requests for repeat prescription are obtained in a timely manner for both use during inpatient stay as well as for use at home post discharge. Further supplies cannot be supplied from the current care provider on discharge, when transitioning back to home.

Procured cannabis-based products

- The healthcare professional must determine the content of the product brought in and whether there are any legal implications eg THC content. The healthcare professional may take label contents at face value, unless concerns are raised upon questioning the patient or family as part of standard medicines reconciliation.
- The patient or family should be encouraged to take procured cannabis-based products home and not to administer during the stay. Where this request is refused, then it is advised that this is escalated to a senior manager and a local risk assessment conducted.
- Where it is decided, following risk assessment to allow continued use during the stay, it should be made clear that healthcare professionals will not be responsible for administration of the procured cannabis-based product.
 - This is because there is no way of verifying the dose that the child or young person should be on or what would constitute a safe dose, with significant potential for inter-batch variation in content.
 - Where it is decided that continued administration is not permitted during a stay it should be noted that there is a minimal risk of withdrawal occurring, including following chronic use. This is because the time that cannabis-based products remain in the body is extremely long and they will slowly wash out of the body following acute and even chronic ingestion.

Goals for notable practice

Professionals should adhere to the following:

- Have an awareness of the law underpinning medicines management, the professional standards you should meet when managing medicines and the standards expected by the Care Quality Commission.
- Have an understanding and awareness of local policy and standard operating procedures, and work within them.
- Only administer medicines that have been prescribed by an appropriately qualified practitioner, from a patient group direction or from a homely remedy protocol.
- Ensure that children and parents are given information about their medicines and that it is at an appropriate level to ensure their understanding of the treatment. Parents and children should be involved in decision-making about medicines management and supported to take their medicines as prescribed.
- Be aware of controlled drugs policy and standard operating procedures and ensure these are implemented.
- Be aware of your responsibility and accountability in medicines management, particularly when delegating tasks.
- When delegating tasks to healthcare assistants or when supporting children and parents to self-administer, ensure that an assessment of their competence has been undertaken, documented and reassessed as necessary.
- Remember that you work as part of a team; all medicines management activities should be clearly documented to reduce risk and promote continuity of care.



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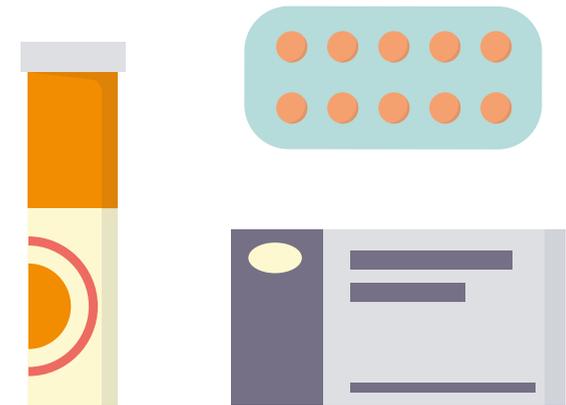
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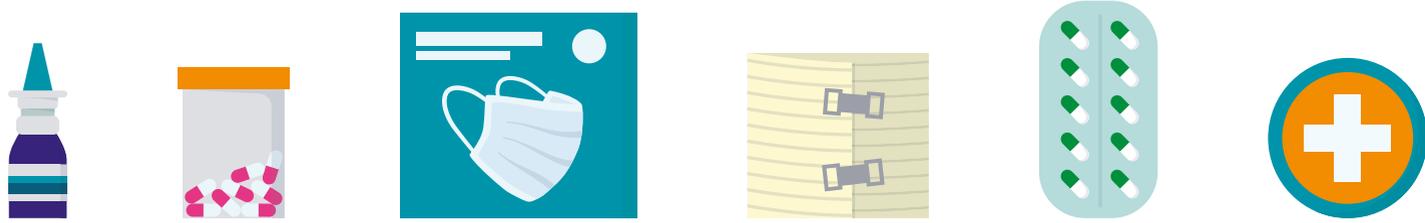
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Appendices



Appendix 1: Medicine reconciliation modules

This appendix includes a series of modules that have been developed as support tools for organisations to use in a number of ways:

- to train staff
- to audit current practice
- to develop policy
- to audit practice in accordance with policy

The modules are a guide and it is not intended to be fully exhaustive. Organisations must use relevant new guidance alongside these modules, as well as referring to the other documents we have recommended.

Each question within the modules 1-5 is of immediate priority. Module six is a more long-term goal.



Module 1: Collecting information

This module involves the collection of medication history and other relevant data. This could be from a variety of sources, where some are more reliable than others.

Question 1.1

Have the child's/young person's details been documented for this admission? (ensure dated and signed, with name and profession of person recording)

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes		
<input type="checkbox"/> Yes, partially		
<input type="checkbox"/> No (explain why not)		

Details include:

- date of admission
- child/young person's full name, date of birth, address, NHS number (CHI in Scotland)
- registered GP name, address and telephone/fax number
- next of kin name and contact details
- reason for admission
- active conditions and child/young person's last consultation
- family history
- weight of child

Question 1.2

Does the child/young person have any known adverse drug reactions or allergies?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record response to adverse drug reaction/allergy and date when last experienced.
- Healthcare professional asking and recording must sign, date and state profession.
- Document the source of information used to ascertain drug allergy status.

Question 1.3

Are you able to use a reliable source of information to collect medication history? (record the date, source name and profession of person recording.)

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

Not all sources are reliable – establish if the child/young person is able to provide a good source of information. If the child/young person is confused or too ill they should not be approached. Some examples of sources of information include:

- verbal information from the child/young person, their family, carer or ambulance staff, etc. Document name of source. Care must be taken to ensure that the patient is taking the medication as prescribed
- computer print-out or fax from a GP records system. Treat with caution, as this may not include hospital-only, or other specialist medicines
- GP referral letter
- medicines brought in by the family. Occasionally these will be brought in without labelled directions
- medical notes or discharge summary from a child/young person's previous recent admission
- medical notes transferred from another unit or ward
- medication administration record (MAR) sheet
- medication reminder card or record card from a community pharmacy
- tear-off side of a child/young person's repeat prescription. Check to see the date medicine was last issued
- Emergency Care Summaries (ECS)

When using sources, ensure that they are for the individual child/young person and they are current. Record sources of information used; a range of sources should be used.



Question 1.4

Is the source reliable?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Ensure that the most reliable source has been used. Some sources are not reliable.
- If unreliable, use another source and document the reasons for doing so.
- Obtain faxes from GP surgeries or community pharmacy/chemist of current medicines.

Question 1.5

Is the source current/recent?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record date of source used.

Question 1.6

Does the child/young person have any communication barriers?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- if the child/young person uses a hearing aid, is it turned on or charged? Write notes for the child
- if the child/young person is visually impaired, talk to them. Ensure they are wearing their reading glasses if used
- if the child/young person has learning difficulties, confused, agitated or is under 16, use information from their family, carers, or friends
- if the child/young person cannot speak English, consider a translator if necessary, or use their family, carers or friends

Good practice point

Training in the basics of interpreting should be given to those who regularly act as interpreters, to promote best practice.

Question 1.7

Is support needed to manage medicines appropriately in the home?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record how medicines are administered.
- Do carers administer medicines?
- Any compliance aids used?
- Which community pharmacy fills it? Document the details of the pharmacy that supplies the medicines in a compliance aid.
- Does anyone help you with your medicines at home?
- If so, who?
- What do they do?
- Do you have problems reading the labels?
- Some people forget to take their medicines from time to time. Do you?
- What do you do to help you remember?



Module 2: Documenting of medication history

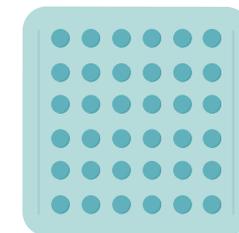
This module aims to establish what the child/young person is currently taking, and also to tell you about recent changes that may not be on the GP's records.

Question 2.1

Has the child/young person brought in their own medicines?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record all information of medicines brought in.
- Record drug name, form, route, dose, frequency, course length (where appropriate) and date when last issued (these should be stated on labels from community pharmacy/chemist) on appropriate documentation.
- If the child/young person has not brought any of their medicines, use one of the sources stated in Module 1.3 and record on appropriate documentation.



Question 2.2

Have you used further prompts to ensure that all medicines have been recorded with required information?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Use simple vocabulary to ensure the patient will understand.
- If eye/ear/nasal preparations have been used, establish if left, right or both sites.
- Details of insulin preparations must include strengths and presentation, brand, administration device (cartridges or pre-filled pens) and dose.
- Site of any topical preparations.
- State day of any once-weekly medicines such as methotrexate; you should confirm the number of tablets taken weekly and the day. On the medicines chart, cross off the remaining six days the medicine is not taken.
- Indications and durations to be stated for antibiotics.
- State strength and type of device for inhalers.
- If patches are used, state when the last patch was used, how often it should be replaced and most importantly where the patch should be applied.
- Are any nebulisers or oxygen therapy used?
- Is the young person taking any oral contraceptives?
- Is the child/young person taking any steroids? Ask about any recent courses (within last six months). If so, what was the dose and duration of the course (was it a short course or reducing dose?). Document on the medicines chart if on long term steroids to ensure the steroids are not abruptly stopped.
- Is the child/young person taking any opioid medications? Confirm the brand, strength, dose, frequency of use and any recent dose changes that have happened.

Question 2.3

Have any of the child's/young person's medicines been stopped or doses changed prior to admission?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Has the child/young person discontinued any medicines prescribed by the prescriber?
- Indicate reason why medicine has been stopped or changed.
- Have any medicines been stopped recently in the past six months?
- Any recent dose changes?

Question 2.4

Have any of the child's/young person's medicines been stopped or doses changed at the point of admission?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

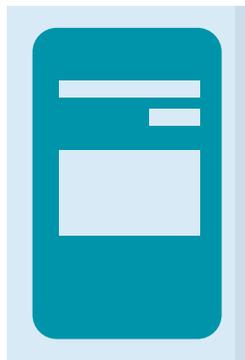
- Indicate clinical reason why medicine has been stopped or choice/doses changed
- Has the hospice doctor signed and dated the change to the patient's treatment?

Question 2.5

Does the child/young person take any medicines with specialist requirements/monitoring, anticoagulants or opioids (eg controlled drugs)?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record drug name, form, dose, frequency, course lengths and date when last used.
- Contact specialist to confirm drug particulars, course lengths and intervals of medications as appropriate, before transcribing.
- Please refer to hospice policy on handling and storage of these medicines.



Question 2.6

Does the child/young person take any additional medicines, eg over-the-counter, homeopathic or herbal, vitamins or supplements?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Record drug name, form, dose, frequency, course length (where appropriate) and date when last used.
- Is the prescriber aware of these medicines?
- Record if the above medicines have been recently stopped/doses changed and reason.

Question 2.7

Any issues of concern with drug therapy that require further intervention?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- State issues and inform hospice doctor/pharmacist/nurse (as appropriate).



Module 3: Verifying information

This module ensures that the original list is verified and that any discrepancies are accounted for and actioned appropriately.

Question 3.1

Have you been able to conduct medicines reconciliation within 24 hours of admission, checking with an alternative source to confirm history obtained?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- The history should be checked with other sources within 24 hours of admission.
- Information may be checked with prescribers (eg GP surgery, hospital specialist, community prescriber) within 72 hours, for admissions over the weekend.
- Refer to 1.3 for examples of sources of information. Note: Local risk assessment should determine the checks for appropriateness. From a regulatory point of view, there would be a need to verify the information.

Good practice point

Medicines reconciliation should be conducted as soon as possible within 24 hours of admission.

Question 3.2

Have discrepancies been noted and accounted for?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- It is important that any intentional changes made by the hospice doctor have been documented in the child/young person's medical notes, signed and dated.
- Any discrepancies established by the nurse must be reported to the hospice doctor and dealt with accordingly. Serious discrepancies must be dealt with by speaking with the doctor and rectified as soon as possible.
- Does a prescriber need to be contacted? Refer to hospice procedures and nurse manager.

Good practice point

As recommended by NICE/NPSA1, pharmacists/prescribers should be involved in medicines reconciliation, as soon as possible after admission.





Module 4: Communicating

This module looks to ensure that any changes, omissions and discrepancies related to medicines are communicated through appropriate documentation to the place where the child/young person's care is transferred.

Question 4.1

Is there clear documentation in discharge summaries and the child/young person's medical notes of discrepancies, omissions or changes?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Discrepancies must be acted upon and resolved.
- State reason why and when medication was stopped/started, detailing route, frequency or formulation change.
- Any actions must be signed, dated and recorded in the child/young person's medical notes or discharge summaries.
- Does a prescriber need to be contacted? Refer to hospice procedures and nurse manager.

Question 4.2

Are discharge summaries up to date?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Signed copies must be placed in child/young person's medical notes and sent to where the child/young person is being transferred, eg GP.
- Copies to be given to the parent, guardian or carer.





Module 5: Defining roles and responsibilities for key healthcare professionals

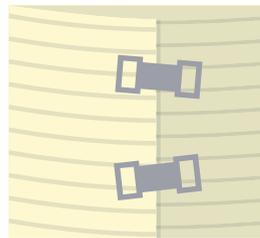
This module looks at the roles and responsibilities that affect key healthcare professionals in the medicines reconciliation process.

Question 5.1

Has the doctor/nurse checked the child/young person?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Ensure the child/young person has been admitted and history documented in their medical notes.



Question 5.2

Has the doctor/nurse obtained a medication history?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Refer to modules 1 and 2.
- Ensure that child/young person's medication history has been documented.
- Healthcare professional has signed, dated and stated source in child/young person's medical notes.

Question 5.3

Has prescriber documented, signed and dated any intentional changes to child's/young person's medication record?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- All changes to be signed and dated (and reasons given) in the child/young person's medical notes.

Question 5.4

Has doctor/nurse verified first history taking with alternative source, within 24 hours of admission, as stated in Module 3?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Doctor/nurse to document second source within 24 hours, unless admitted over a weekend, hence 72 hours.
- Refer to Module 2 to obtain comprehensive medication history.
- Has the nurse identified any support/compliance aid required/side-effects for adherence to medicines?

Question 5.5

Has the nurse notified the doctor of any discrepancies as appropriate?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Serious discrepancies must be dealt with as soon as possible.

Question 5.6

Has the hospice doctor/prescriber dealt with discrepancies?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Ensure that identified discrepancies are resolved before child/young person's care is transferred, as appropriate.

Question 5.7

Has a prescriber/nurse/pharmacist been involved in the medicines reconciliation process?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Pharmacist/prescriber should be involved as soon as possible after admission.

Question 5.8

Has the doctor/nurse completed the discharge summary for the child/young person?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Refer to Module 4.

Question 5.9

Has the doctor/nurse transferred the discharge summary?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Refer to Module 4.



Module 6: Monitoring and audit

An audit is a process for checking that procedures are in place to assure quality, integrity or standards of provision and outcomes. Audits should be conducted annually. The objective of the audit in this case is to measure current practice in medicines reconciliation on admission of a child/young person to a children's hospice. Monitoring requires you to standardise data collection and repeat the process to help support continuous improvement.

Good practice point

It is important to monitor the implementation of policy, ensuring that annual audits are undertaken and patient safety incident reports are reviewed. An audit tool is available from the NICE website.

Question 6.1

Has an audit been conducted to assess medicines reconciliation, as outlined by NICE?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Follow audit tool set by NICE – refer to www.nice.org.uk. An audit should identify any areas of weakness to meet the required standards. This enables the organisation to put its principles and policies into practice.



Action plan worksheet for modules

Priority and action plan required	
Resources required	
Achievement indicators	
Timescales	
Staff lead	

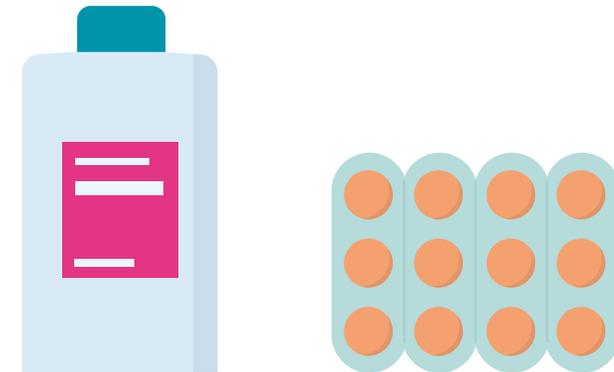


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Appendix 2: Modules for transcribing medication



Module 1: Transcribing and collecting information

This module ensures that all particulars relating to transcribing are met.

Question 1.1

Are you transcribing from an approved source? (ensure dated and signed, with name and profession of person recording.)

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

Record source of information used. Approved sources include:

- medication record or prescription already written and signed by an independent prescriber
- medication reminder card or record card from a community pharmacy
- GP/hospital letter
- patient's own drugs in original labelled containers can be used, providing that the instructions on the label are up to date. However, medicines which have been decanted by family members cannot be used as an approved source of information

Question 1.2

Are you transcribing from an approved source? (ensure dated and signed, with name and profession of person recording)

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Use black indelible ink.
- Write clearly and legibly.



Question 1.3

Have you documented the patient's details on the front of the medication record?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

Write in BLOCK CAPITALS:

- name of hospice
- date of admission
- patient's name and address
- patient's weight and date of birth
- consultant, unit name and hospice record number
- any known allergies and details/dates

Question 1.4

Is this a re-written chart?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Once complete ensure that a diagonal line is placed on the old record, state re-written and sign and date.





Module 2: Guidance notes on transcribing medicines

This module aims to ensure that all medication information is ascertained to ensure accurate transcribing.

Question 2.1

Have you ensured that all the details for the medicines have been recorded?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

The following must be stated:

- approved name for the drug (exceptions include lithium, theophylline and some anti-epileptics where brand names are required)
- form of the drug (eg tablet, capsule, liquid, type of inhaler or insulin device)
- preparation (eg slow release)
- strength – write drug strengths in full where doses are below 1mg (eg micrograms) or doses are expressed in other ways (eg units). Exceptions are:
 - g: gram
 - mg: milligram
 - ml: millilitres
- dose for liquid preparations should include the dose in mg and ml. Avoid using decimal points where possible

- frequency and time for administering each dose especially if a liquid has been diluted
- route. All should be written in full, except for the following accepted abbreviations:

- IV: Intravenous
- PEG: Percutaneous Endoscopic Gastrostomy tube
- IM: Intramuscular
- INH: Inhale
- SC: Subcutaneously
- Top: Topical
- PO: by mouth
- LE: Left eye
- PR: Per rectum
- RE: Right eye
- NG: Nasogastric

- start date of medication
- any additional information, eg one hour before food
- refer to the latest edition of the BNF for transcribing

Question 2.2

Is the patient on a Schedule 2 or 3 controlled drug?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- BNF should be used to see which schedule the drug falls under (covers some opioids, barbiturates, amphetamines and benzodiazepines such as temazepam/midazolam). The BNF has a box symbol indicating which schedule the drug belongs to (ie CD 2 means it is a schedule 2 CD).

Question 2.3

Have any of the patient's medicines been stopped or doses changed prior to admission?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Has the patient discontinued any medicines prescribed by the GP?
- Indicate reason in patient's medical notes why medicine has been stopped or changed. Inform doctor as soon as possible.
- Do not transcribe medication onto hospice record.
- Do not amend or initiate any medication, unless authorised prescriber.

Question 2.4

Any issues of concern with drug therapy that require further intervention?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- Issues stated and hospice doctor/pharmacist/senior nurse informed as soon as possible (as appropriate).

Question 2.5

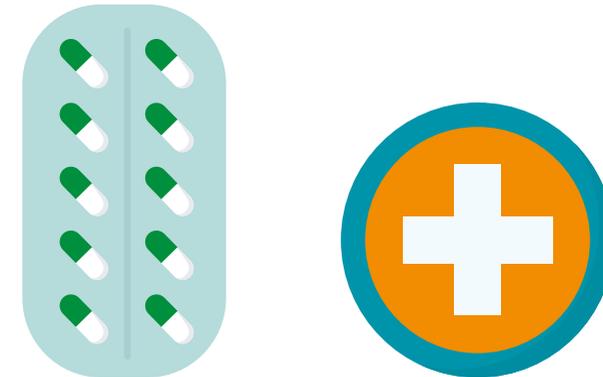
Has the patient more than one medication record?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- This should be clearly stated on the front of the medication record chart (eg 'This is one of two').
- It would also be good practice to keep enteral and parenteral medicines on separate drug charts to minimise risk of drug administration via the wrong route.

Good practice point

Sign and date each transcription on completion.





Module 3: Verifying transcribing

This module aims to ensure that the transcription is double-checked to maintain patient safety.

Question 3.1

Has the transcription been checked?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- All transcribing is checked by another registered nurse, pharmacist or doctor, before medicines are administered.
- All transcriptions and checks have been signed and dated in the relevant section.
- Some medicines may be administered via a patient group direction, if in existence.
- Transcribing should be signed off by a registered prescriber within an agreed time period (ie 24 hours).



Module 4: Authorisation and responsibilities for transcribing by healthcare professionals

This module looks to ensure that healthcare professionals involved in the medicines transcribing process are competent and authorised. They should also be aware of their responsibilities.

Question 4.1

Have you been authorised to perform medication transcribing?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- I am a registered healthcare professional
- I have received training
- My line manager has deemed me competent
- I have completed and signed the authorisation form. A signed copy has been placed in my personal file
- My authorisation to transcribe is reviewed annually

Question 4.2

Are you held responsible for any transcribing errors/omissions, and is adequate support provided?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

- the authorised healthcare professional transcribing is held accountable for any transcription errors/omissions
- the person transcribing a medication record is responsible for each transcription
- support is provided to staff as appropriate
- transcribing errors must be reported as medication incidents
- your medication incident log should have a specific category for transcribing errors so that practice can be monitored and reviewed



Module 5: Monitoring and audit

An audit is a process for checking that procedures are in place to assure quality and integrity in the provision of services. In the case of transcribing practice in children's hospice services, such audits should be conducted annually.

The objective of the audit is to measure current practice in the transcribing of medicines by authorised healthcare professionals, to detect any errors and highlight good practice.

Errors can occur at different stages, including transcribing on to a hospice record.

Good practice point

To monitor implementation of policy, you should ensure that annual audits are undertaken. You should also ensure that patient complaints and adverse incident reporting data are reviewed.

Question 5.1

Has an audit been conducted to assess medication transcribing?

Response	Evidence and supporting information	Follow-up action required
<input type="checkbox"/> Yes <input type="checkbox"/> Yes, partially <input type="checkbox"/> No (explain why not)		

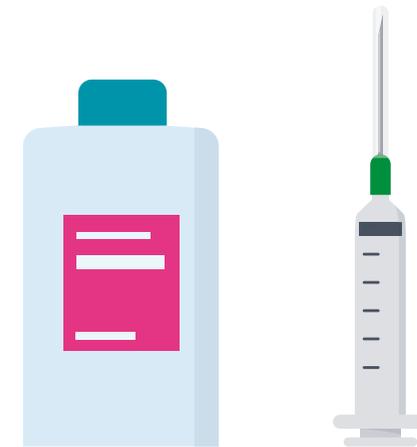
- any adverse incident reporting data have been collected
- an audit has identified any areas of weakness in pursuit of the required standards
- current practice in medical transcribing enables the organisation to put its principles and policies into practice





Transcribing action plan

Priority and action plan required	
Resources required	
Achievement indicators	
Timescales	
Staff lead	



Appendix 3: Medicines management – example of a competency framework

This has been developed by Children’s Hospice Association Scotland and adapted from a framework developed by Naomi House and Jack’s Place Children’s Hospices

Verification of your competence is achieved by assessment against the statements below, which describe the skills, knowledge and attitudes that contribute to this competence area. You must be able to respond positively to all the statements before considering yourself to be competent. If you are not able to verify competence you need to discuss this with your line manager. Resources and training are available to support individual competencies.

Assess your competence against the following statements		Signature and date	
		Nurse:	Verifier:
1.	I have completed a programme of learning delivered by a recognised competent practitioner in medicines management.		
2.	I understand my accountability within the ‘The Code: Standards of conduct, performance and ethics for nurses and midwives’ (NMC 2008. Revised in 2015) and/or my responsibility within the law.		
3.	I can locate the CHAS policies, operating procedures, information or guidelines that relate to medicines management and state the key components of these.		
4.	I can give examples of all the information required on a completed medicine chart.		
5.	I understand that I must be certain of the identity of the child/young person to whom the medicine is to be administered and I can explain/demonstrate how I would ensure this.		
6.	I can explain the importance of having an accurate recent weight and how to record this using CHAScare.		
7.	I know the importance of knowing the method of administration, route, timing and the expiry date of the drug stating the ‘5 rights’.		
8.	I can discuss the importance of understanding the therapeutic uses of the medication to be administered, normal dosage, side effects, precautions and contra-indications. eg paracetamol.		

Assess your competence against the following statements		Signature and date	
		Nurse:	Verifier:
9.	I can describe the meaning of the term 'half-life of a medication'.		
10.	I am aware of and can discuss the importance of checking that the prescription and the label on the medication are clearly written, unambiguous and signed by a doctor.		
11.	I have fulfilled the criteria for single checking and have been assessed in practice by a recognised competent practitioner.		
12.	I can explain/demonstrate when to administer or withhold medication in the context of the child/young person's condition.		
13.	I can explain/demonstrate the importance of hand hygiene and infection control in relation to medicines management.		
14.	I know and can explain rationale of how many times a purple enteral syringe can be used.		
15.	I can explain and give examples of when, in exceptional circumstances, medication may be administered without a written prescription.		
16.	I can explain/demonstrate the procedure to follow if a child/young person refuses to take their medication.		
17.	I can explain/demonstrate the procedure to follow should a drug error occur.		
18.	I can explain/demonstrate the procedure to follow should a child/young person have an adverse drug reaction.		
19.	I can discuss use of the British National Formulary yellow card system and how to report an adverse drug reaction using it.		
20.	When medication has been prescribed within a range of doses I can explain the need to titrate doses according to patient response and symptom management.		
21.	I can discuss my role as a registered nurse in that I am responsible and accountable for the delegation of any aspect of the administration of medicinal products.		

Assess your competence against the following statements		Signature and date	
		Nurse:	Verifier:
22.	I can demonstrate a knowledge of the NMC standards stating that student nurses, and non-single checking nurses must never administer or supply medication without the direct supervision of a registered nurse.		
23.	When supervising a student nurse or non-single checking nurse in the administration of medicines I can discuss my understanding of why I must clearly countersign the signature of the student.		
24.	I can discuss the rationale for using preparations that are unlicensed.		
25.	I can explain what medication off label means and can give an example.		
26.	I can explain the role of the Accountable Officer and know who the Accountable Officer for CHAS is.		
27.	I can explain the procedure for requesting and collecting medication and controlled drugs from pharmacy.		
28.	I can discuss/demonstrate how controlled drugs are stored in accordance with the Misuse of Drugs Act (Safe Custody) Regulations (1973) and the Health Act (2006).		
29.	I can discuss/demonstrate the procedure for administration of controlled drugs.		
30.	I can explain/demonstrate the procedure to follow if there is a discrepancy regarding a controlled drug.		
31.	I can explain/demonstrate how to safely dispose of medicinal products including controlled drugs.		
32.	I can describe how I would review and update the care plan and where I would record my observations and care on CHASCare.		
33.	I can explain how to report an error or clinical incident in relation to medicines management.		
34.	I acknowledge the importance of maintaining an open culture in order to encourage the immediate reporting of errors or incidents relating to medicines management.		

Statement of Competence – Medicines Management

I certify that I am aware of my professional responsibility for continuing professional development and that I am accountable for my actions. I am competent and confident in the practice of medicines management, and can accurately and timeously document the care delivered or actions taken relating to this competency area.

I confirm that my current level of competence is (please tick as appropriate):

- Level 1, **Competent**;
- Level 2, **Highly Developed**;
- Level 3, **Expert**

Signature:

Date:

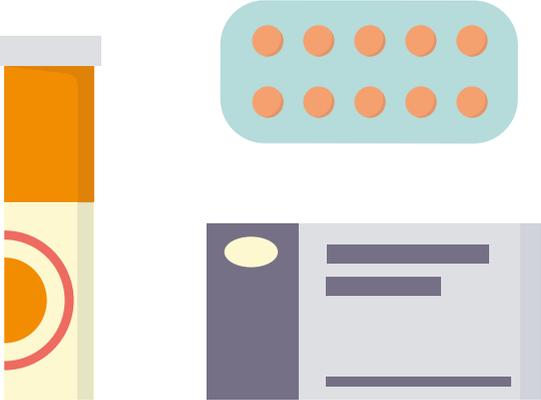
Verified by:

Signature:

Designation:

Date:

Competence must be verified by a recognised competent practitioner.



Appendix 4: Example of a flow chart for decision making



Appendix 5: Example of documentation from EACH regarding syringe driver use

Each prescription must include:

- date
- drug (generic name)
- dose or range to be used
- diluent
- route and duration
- special instructions to include a direction for mixing of drugs as necessary
- discontinue/review date
- prescriber's signature

The registered nurse setting up the infusion must check:

- the prescription is correct
- compatibility of medicines prescribed
- diluent is suitable
- infusion volume required
- size of syringe required
- appearance of solution in the syringe (eg clear not cloudy) and prepare again if required

The registered nurse must record:

- date and time of set up
- dose
- their initials

After daily medication set up the following must be recorded by the doctor/registered nurse preparing the infusion:

- date and time of preparation
- flow rate in mls/hr
- battery life of driver (if under 40%, new batteries required)
- diluent and batch number
- drug name (generic) and batch number
- total volume in syringe
- confirm labels are completed and correct
- site used, device type (eg neria TM soft) and insertion date
- syringe make and size
- any surplus disposed of from previously used infusion

When completing the medicine balance record the RN must record the:

- date and time
- if just in case medicines, clearly record “just in Case Medicines” or “JIC medicines”
- balance on arrival (No of ampoules)
- supply received (ampoules)
- amount used (ampoules)
- amount discarded (strength and volume)
- batch No
- expiry date
- end balance (ampoules)
- signature
- supply ordered
- replace all medicines in the Anticipatory Medicine Box, together with the list, if available, and reseal or relock the box (as applicable)
- ensure that any missing or expired medicines are replaced at the earliest opportunity



Appendix 6: Glossary

Care pathway/journey

Together for Short Lives' description of a 'care pathway' approach to working with children who have life-limiting or life-threatening conditions is a way of engaging with a child and their family's needs, which can be used to ensure that everything is in place so that families have access to the appropriate support at the appropriate time.

Children's palliative care

Palliative care for children and young people with life-limiting conditions is an active and total approach to care, from the point of diagnosis or recognition, embracing physical, emotional, social and spiritual elements through to death and beyond. It focuses on enhancement of quality of life for the child/young person and support for the family and includes the management of distressing symptoms, provision of short breaks and care through death and bereavement.

Children's hospice services

Children's hospice services provide palliative care for children and young people with life-limiting conditions and their families, delivered by a multi-disciplinary team and in partnership with other agencies. Children's hospice care is delivered in the home (commonly termed 'hospice at home service') and/or in a purpose-built building. Children's hospice services aim to meet the physical, emotional, social and spiritual needs of both child and family – through a range of services. These include:

- 24-hour end of life care
- support for the entire family (including siblings, grandparents and the extended family)
- bereavement support

- 24-hour access to emergency care
- specialist short break care
- 24-hour telephone support
- practical help, advice and information
- provision of specialist therapies, including physiotherapy as well as play and music therapy
- provision of information, support, education and training where needed to carers

Community services

Community services refer to a service that an individual or organisation performs within the local community. This might include community children's nurses (CCNs) who deliver nursing care and support within the local community including visiting a patient's home. Community services may also include some of the services delivered by the local council.

End of life

The end of life phase begins when a judgement is made that death is imminent. It may be the judgement of the health or social care team, but it is often the child/young person or their family who first recognises its beginning.

End of life care

End of life care is care that helps all those with advanced, progressive, incurable illness to live as well as possible until they die. It focuses on preparing for an anticipated death and managing the end stage of a terminal medical condition, this includes care during and around the time of death, and immediately afterwards. It enables the supportive and palliative care needs of both child/young person and their family to be identified and met throughout

the last phase of life and into bereavement. It includes management of pain and other symptoms and provision of psychological, social, spiritual and practical support and support for the family into bereavement. This is not confined to specialist services but includes those services provided by any health or social care professional in any setting.

Family

The term 'family' includes parents, other family members involved in the child's care, or other carers who are acting in the role of parents. Family includes informal carers and all those who matter to the child/young person.

Hospice at home

Hospice at home is a term used to describe a service which brings practitioners from a hospice into the home environment.

Life-limiting/life-shortening conditions

Life-limiting conditions, sometimes known as life-shortening conditions, are those for which there is no reasonable hope of cure and from which children or young people will die. Some of these conditions cause progressive deterioration rendering the child increasingly dependent on parents and carers.

Life-threatening conditions

Life-threatening conditions are those for which curative treatment may be possible but can fail, such as children with cancer. Children in long-term remission or following successful curative treatment are not included.