Medicines Management in Hospices policy

Version 3.2

Audience
Hospice staff and volunteers who prescribe, handle, supply, store, assist or administer medicines.
Summary This policy provides an overview of legislation, regulation and national guidance relating to Medicines Management. It provides detailed guidance to ensure safe and effective management of medicines within Marie Curie (MC).

Date of first issue	**Date of last revision**	**Next planned review**
January 2013	October 2018	October 2021

Supporting documents

Waste Management policy

Health & Safety policy

Incident Management policy

Drug and Alcohol –guidance

Non-medical prescribing policy

Local Standard Operating Procedures

Clinical Records Policy
Central Alert Policy

Consent policy

Safeguarding policy (England, Northern Ireland & Wales)

Safeguarding policy (Scotland)

Sharps policy

1. Objective

This policy is designed to:

- Ensure all aspects of medicines management medicines comply with current legislation.
- Ensure the safety of all patients, visitors and staff.
- Promote the safe, secure and effective handling of all medicines.
- Define the standards for the development of local Standard Operating Procedures for medicine management.
- Ensure all elements of the medicine trail (ordering - administration - disposal) are linked by defined controlled processes making it possible to audit the safe and secure handling of medicines.

This policy covers professional accountability of the multidisciplinary groups involved in medicine management and applies to all healthcare workers who prescribe, handle, supply, store, assist with or administer medicines in the course of their duties. This includes but is not exclusive to, doctors,

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pharmacists, nurses, pharmacy technicians/assistant technical officers, healthcare care assistants, and delivery drivers.

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2. Glossary of Terms

Administering medicines: Preparing, giving, and evaluating the effectiveness of prescribed medication

Assisting with medication: Physically helping a patient with the self-administration of routine, regularly prescribed medications that are intended to be self-administered. The patient must have mental capacity and the ability to tell the healthcare assistant (HCA) or nurse what they require e.g. opening a medication container or removing tablets from a blister pack.

Authorised practitioners: Include RNs, pharmacists, doctors and other allied healthcare professionals including pharmacy technicians.

Authorised witness: An appropriately trained person authorised by the Accountable Officer Controlled Drugs (AOCD) to witness denaturing of schedule 2 controlled drugs that must be independent from the day-to-day management, administration or supply process of CDs. They are required to remain subject to a professional code of ethics or are the subject of a satisfactory standard-level Disclosure and Barring Service (DBS), or equivalent, check at intervals not exceeding two years. They should be appropriately trained and be fully aware of local CD SOP.

Controlled Drugs (CD) - Schedule 2, 3, 4, 5: Controlled drugs are defined and governed by the Misuse of Drugs Act (MDA) 1971 and associated regulations (Misuse of Drugs Regulations [MDR] 2001) which fall within the remit of the Home Office. The Health Act 2006 and its associated regulations (Controlled Drugs -Supervision Management and Use) Regulations 2006, set out requirements for the governance and monitoring of CDs. The schedule in which a controlled drug is placed is legislated and depends upon its medicinal or therapeutic benefit balanced against its harm when misused.

Controlled Stationery: Controlled Drug requisition pads, prescriptions and registers which, in the wrong hands, could be open to abuse such as fraudulently obtaining CDs.

Cytotoxic and cytostatic medicines: Cytotoxic medicines cause disturbance to cellular structure or function often leading to cell death. Cytostatic medicines work by stopping the cancer cells from multiplying and growing e.g. hormone therapies used to treat breast cancer, which block particular receptors of the cancer cells.

Exceptional circumstances: The healthcare professional bodies (e.g. GPhC , NMC) have been reluctant to clarify their understanding of ‘exceptional circumstances’ however for the purposes of this document they pertain to events that are neither planned or predicted by service providers or commissioners.

Medicine reconciliation: Defined by the Institute of Healthcare Improvement (I.H.I.)2 as being the process of identifying the most accurate list of a patient’s current medicines — including the name, dosage, frequency, and route — and comparing them to the current list you are working from. This enables any discrepancies to be recognised and changes documented, thereby resulting in a complete list of medications, accurately communicated. Medicines reconciliation can be undertaken by anyone competent to do it (pharmacists, nurses, doctors or technicians) it is important to establish who has responsibility for the process locally. It is an ongoing process and involves review at discharge and transfer of information to other care settings at this point.

Multidisciplinary Patient Record (MDPR): A paper or electronic patient record maintained for the purpose of managing patient healthcare which may include care plans, MPAR, medical, nursing and allied health professionals’ records, district team records, laboratory and other results. There is currently no standard MC MDPR and each hospice and MCNS may use MDHRs aligned to local PCOs or Trusts. These MDPR may be called care plans, kardex, community patient held record etc.

Patient-specific direction (PSD): A written instruction from a qualified and registered prescriber for a medicine including the dose, route and frequency or appliance to be supplied or administered to a named patient. Examples may include instructions on an Inpatient medicine prescription / administration records (MPAR); Infusion therapy charts, pre-printed therapy specific charts e.g. care pathway, IV heparin or insulin; Day Care record sheets; patient's medicines administration chart.

Prescription: A prescription is an order for the dispensing of a medicinal product. The order is presented to a professional who is legally authorised to dispense, in writing, in a legally prescribed format and signed by the person authorised by law to prescribe.

Primary Healthcare Organisation (PCO) a generic term used to refer to a Health and Social Care Trust, Clinical Commissioning Group, NHS Board or Local Health Board

Safety Critical Drugs are those that include a higher risk of harm, and could include warfarin, insulin, methotrexate, digoxin, lithium and opioids, as well as off label and recently issued black triangle medications, which require monitoring for adverse effects

Transcribing: The action of copying details of prescribed medication from a prescription originally written by an independent prescriber, a record provided by the patient's GP, or the pharmacy label on the medicine container onto a healthcare organisation 's PSD/ MPAR.

3. Responsibilities

All responsibilities are detailed in the MC policy for the development and management of clinical policy, standards, procedure and guidelines

The Accountable Officer Controlled Drugs (AOCD): Each MC hospice must have a designated AOCD responsible for the safe management and use of CDs, in most cases this is the hospice manager. Responsibilities are detailed in appendix 1.

Nursing associates: Nursing associates must have an individual scope of practice (appendix 2) that clearly details the responsibilities and activities that he / she is expected to perform in the execution of their duties with regards to medicines management. The scope of practice must name and provide parameters for any safety critical medicines. The nursing associate must work within the parameters of their scope of practice and the requirements of this policy. A copy of the scope must be retained by the Nursing Associate and Line Manager in the HR file.

Student Nurses: Students must be given opportunities to participate in the administration of medication but this must always be under direct supervision. They should have an assigned mentor to assess proficiency in the administration of medicines in accordance with the expectations in their Assessment of Practice Portfolio and should work in a supernumerary capacity 'shadowing' an MC Nurse.

4. Prescribing

All prescribers must be qualified as prescribers with a recognised regulatory body and must complete local induction programs. They should have access to the current British National Formulary (BNF), electronic and /or paper version, and local Health Board, NHS Trust, network and/or local area formularies. All medicines, including medical gases, must be prescribed.

Prescription writing requirements

Prescribers must comply with current prescribing legislation and are accountable for their practice.

Prescribing Controlled Drugs (CDs)

The requirements of the Misuse of Drugs Act 1971 and the Medicines Act 1968 must be satisfied for all controlled drug prescriptions. Full guidance is available in the British National Formulary (BNF). CD Prescriptions no longer need to be hand written however the signature must be hand written.

Self-Prescribing

In line with the General Medical Council (GMC) and other professional bodies MC does not support self-prescribing.

Medical Gases

Should be prescribed including details of rate, duration, monitoring and advice. Oxygen can be administered in an emergency situation before a prescription is written.

Antimicrobial Prescribing

When prescribing antimicrobial drugs, the relevant policies, drug therapy guidelines or SOP of a nominated local Primary Care Organisation (PCO) or other agreed trust should be followed. The choice of guidance should be agreed through the Hospice medicines management group. Consideration should be given to review dates and a clear rationale for the route of administration, indication and aims of treatment.

Unlicensed and Off Licence Medicines

An unlicensed medication is a medicine with no marketing authorisation for any indication within the UK. An off licence or off label medicine is a medicine with a product licence but where the product licence does not cover the indication for which the medicine is being prescribed.

Unlicensed medicines should only be used if there is no suitable licensed product. In the first instance a licensed product should be used for its licensed indication; in the second instance for an unlicensed indication, route, dose, group of patients; and lastly an unlicensed product for any indication. In all instances the prescriber should make a judgement about informing the patient and make a record in the MDHR. Local board, Trust, area guidelines should be followed.

Medicines may be prescribed for purposes for which they are not licensed, and 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 patient’s clinical record.

Total Parenteral Nutrition (TPN)

TPN may be prescribed by specialist nutritional support teams on a daily basis for hospice inpatients or outpatients on a specially designed TPN prescription/administration chart. MC Staff should be trained and assessed as being competent in central IV access and TPN administration.

Fluid / Food thickening powder

Fluid / food thickening powder must be prescribed. The patient’s care plan and / or drug chart should be reviewed to ensure it clearly documents the consistencies the patient is able to manage, the directions for use based on the recommended consistency and duration of treatment as

dysphagia can be a temporary condition. This plan should be in line with the International Dysphagia Diet Standardisation Initiative (IDDSI) framework. The patients other medications should be reviewed to ensure they are suitable for a patient with dysphagia, discontinuation, alternative formulations or routes of administration should be considered. Liquid formulations may not appropriate as they may also require thickening to enable the patient to take them
The use of thickening powder to thicken oral liquid products would be an off license use of the medicine, and therefore is not routinely recommended. The decision to administer medicines in this way should be made on an individual patient basis, taking into consideration all therapeutic options. Where it is considered to be absolutely necessary to thicken oral liquid medicines with thickening agents, this must be clearly prescribed and the decision-making process documented in the patients record.

Remote Prescribing (Verbal Orders)

Remote prescriptions (verbal orders) may be accepted:

- In exceptional circumstances, where medication has previously been prescribed and the prescriber is unable to issue a new prescription, but where changes to dose are considered necessary and there is a need to prescribe remotely.
- In exceptional circumstances, a medical practitioner may need to prescribe remotely for a previously un-prescribed medicine.

Where a medication has not been prescribed before, an independent prescriber may not prescribe remotely if they have not assessed the patient, except in life-threatening situations. The prescription must be signed within 24 hours.

Prior to undertaking remote prescribing the prescriber must:

- Be satisfied that he / she can make an adequate assessment, establish a dialogue and obtain the patient's consent (in line with the MC consent policy)
- Only prescribe when he/she has adequate knowledge of the patient's health, and is satisfied that the medicines serve the patient's needs.
- Consider:
    a. the limitations of the medium of communication used
    b. the need for physical examination or other assessments
    c. whether he/she has access to the patient's medical records.
    d. communicate with the patient (or, if that is not practicable, the person caring for them) to make an assessment and to provide the necessary information and advice.

Verbal orders are never permitted for Schedule 1 – 5 CDs.
HCAs should not participate in remote prescribing.
Under no circumstance should a RN, or pharmacist feel obliged to participate in accepting remote prescriptions. If a nurse declines to take a verbal order an incident form (IR1) should be completed and a note made in the MDHR.
Local SOP should define conditions under which hospice RNs and pharmacists may participate in exceptionally accepting verbal orders for non-controlled drugs and make prescription alterations or additions and take into consideration local Health Board, PCT, and NHS Trust guidance.

An IR1 should be completed for all remote prescribing to facilitate monitoring at a local level unless recorded elsewhere.

Stationery

All medicine order and prescription stationery should be securely locked with limited access and an audit trail maintained to ensure appropriate use. A SOP must detail the local procedure for the management and control of prescription forms in line with Counter Fraud Authority guidance (2018)
Loss of this stationery must be reported immediately to the RN in charge/hospice manager, AOCD, pharmacist and police and an IR1 completed.

5. Ordering, Storage, Transport and Security of Medicines Standards for Practice

In general, medical supplies and medicines are obtained from contracted community or NHS Trust pharmacies for MC hospices under Service Level Agreements (SLA).

Requisitions of supplied controlled drugs should be kept by hospices for 2 years from the date on the requisition, records of the destruction of a patient's own controlled drugs for a minimum of 7 years, invoices for controlled drugs for 6 years.

Ordering and Transport of Controlled Drugs

The process for ordering hospice stock CDs should be described in local SOP.

At each point where a scheduled 2, 3 or MC specified controlled drug moves from one authorised possession to another a signature is required for receipt. Local SOP or SLA should define the local carriers authorised by the Hospice Manager / AOCD and local contracted pharmacy.

Local SOP should detail the local process for receiving, checking and securing CD deliveries.

Safe Storage of Medicine

All medicinal products must be stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication, and in accordance with any instruction on the label.

Medicines should be stored in robust, lockable cupboards/refrigerators conforming to BS2881 (1989) used solely for medicines, in areas of restricted public access except in the case of emergency drugs.

Ensure appropriate storage of thickening powder to avoid accidental ingestion, particularly with patients without capacity / adults with incapacity.

Emergency drugs should be accessible to healthcare professionals, yet not obvious to children, vulnerable adults or the general public. Emergency drug boxes should have tamper evident seals applied.

Any unexplained losses of medicines must be reported to the RN in charge /hospice manager/ pharmacist as locally agreed and appropriate. An IR1 form should be completed.

Secure Storage of Schedule 2 Controlled Drugs

Legally schedule 2, CDs (except quinalbarbitone) and some schedule 3 CDS (diethylpropion, buprenorphine and flunitrazepam) require safe custody so must be stored in a locked receptacle conforming to British Standard BS2881 that can only be opened by a person who can legally be in possession, such as an RN in charge, pharmacist, pharmacy technician or a registered person working under their authority. The metal cupboard must be securely attached to an internal wall or floor.

MC requires midazolam, a schedule 3 CD to be treated as schedule 2 CDs i.e. held in safe custody (CD cupboard), balances and each administration recorded in a CD register. Additionally, it may be decided locally that other schedule 3, 4, 5 CDs such as Temazepam or Phenobarbitone should also be treated as schedule 2 drugs. This decision may be influenced by local risks. Local pharmacy requirements and recommendations from LIN. The decision is approved in local governance meetings.

Morphine sulphate 10 mg/5 mL oral solution is legally classed as a Schedule 5 drug and therefore does not require Schedule 2 CD safe custody, and is not require double nurse checking prior to administration, unless locally agreed through governance meetings and detailed in the local SOP

Controlled Access to Medicines

The Hospice Manager is ultimately responsible for maintaining controlled access to medicine stores, cupboards, refrigerators and trolleys. This responsibility is usually delegated to the RN in charge.

Student nurses and HCA's are not permitted to be responsible for any medicine keys.
If a service unit closes overnight, medicine keys should be stored securely, preferably in a manned clinical area or other secure storage area with an authorized signatory list.

Temperature Control of Medicine Refrigerators

Hospice refrigerators should be locked and fitted with periodically calibrated maximum/minimum thermometers. Temperatures should be maintained above +2.0°C and below +8.0°C, checked and recorded daily. If the refrigerator temperature has deviated from the above range, and potentially medicines have been stored incorrectly, an IR1 should be completed and the RN in charge and pharmacist are contacted. If the medicine has been administered to a patient, the prescriber should be informed immediately.

Transport and Delivery of Medicines

All transactions should be initiated through a tracking documentation system in which all orders, dispatches and receipts are recorded to maintain an audit trail. Signatures are recorded by suppliers and recipients as evidence of delivery. All medicines transported between the contracting pharmacy and the hospice should be transported using tamper evident sealable containers by locally approved transporters / operators identified in an SLA.

The contracted pharmacy retains responsibility for the CDs until receipt is signed for at departmental level. The courier/driver acts as the messenger. The RN, pharmacist or pharmacy technician who signs for receipt assumes responsibility until they are signed into the CD register and secured in the CD cupboard.

Day Care/Outpatients should collect or receive CDs in person or authorise a representative to collect them. In exceptional circumstances, MC staff may be authorised to collect CDs prescribed for named patients under local SOP.

Use of Patients' Own Drugs (PODs)

POD's may be used in combination with MC stock medicines during an episode of care within a hospice. PODs remain the personal property of the patient. Patient permission is required to remove and dispose of unwanted items. Disposal must be documented.

Patient's own Drugs should never be used to treat another patient or used as ward stock and must be kept separately from ward stock, securely in the department CD cupboard or in approved bedside medicine/CD lockers. Local SOP should define standards and process for use of ward CD stock and patients' own CDs.

Security of Controlled Drugs and Controlled Stationery

CD cupboard keys should be held by the RN in charge who is responsible for controlling access to the CD keys and cupboards in that clinical area for that shift or kept in a keysafe with restricted access.

CD key holding may be delegated to another RN (preferably a permanent member of staff), doctor, pharmacist or pharmacy technician.

If the CD keys are noted to be missing, urgent efforts should be made to locate them (e.g. by contacting relevant staff who have gone off duty). The RN in charge must be contacted and the AOCD notified in a timely fashion. If wrong doing is suspected the AOCD may decide to involve the police.

Controlled Drugs Requisitions and Registers

The local process for security of controlled stationery should be detailed in local SOP.
If a CD requisition or register is suspected missing, the RN in charge, AOCD and contracted pharmacy should be informed immediately. A stop will be placed on the requisitions to prevent any unauthorised ordering, interim arrangements are agreed and an IR1 is completed.

Any suspected misuse of CD order or record books (e.g. unauthorised amendments, ripped pages, suspected theft) should be reported immediately to the AOCD and the police. An IR1 is completed.

Recording of Controlled Drugs Transferred or Used in another Department

The transfer of CD stocks between hospice departments should only occur in exceptional circumstances where otherwise unacceptable delays to medicines administration would result. The transfer of stock CDs from one department to another could be interpreted as the RN in charge supplying CD stock. Evidence of a local SOP and a robust audit trail must be in place for such transactions.

Storage and supply of reversal agents

A readily accessible supply of opiate reversal agent, naloxone, and benzodiazepine reversal agent, flumazenil must be available in all clinical locations where such medicines are administered. The rational for using, and outcome of the use, of a reversal agent should be recorded in the patients notes and an IR1 completed

6. Dispensing

Dispensing from Hospice Stock

Only in exceptional circumstances, when all other measures are impracticable, may a doctor or pharmacist dispense from hospice stock providing all the legal stipulations are fulfilled. A local SOP should be in place.

Issuing Hospice Discharge Medicines/To Take Out (TTOs) Packs

Discharge medication /TTO's should only be issued against a legal prescription written and signed by an authorised prescriber, OR under a valid Patient Group Direction (PGD). Dispensing of discharge medicines should be carried out by the contracted pharmacy or patient's community pharmacy. Issuing of the pre-packed labelled medicines is carried out by registered practitioners. Discharge medicines should not be sourced from hospice stock.

If a dispensing error occurs (whether a dose has been administered or not), an adverse Incident Report (IR1) is completed, the error is reported to the pharmacy manager or line manager.

7. Administration of Medicines

Safe Administration of Medicines

Unless specifically required by MC or local requirements to undertake a double nurse checking procedure, appropriately trained staff may administer, with a single signature: any prescription only medicine (POM); general sales list (GSL); or pharmacy (P) medication in accordance with the following conditions:

- May only administer medicines to MC patients with valid PSD.
- May not administer medicines to staff, family or visitors except in emergency situations.
- Should have access to appropriate reference sources to support safe administration, including local pharmacists, doctors, the BNF (available via MC library URL, http://www.bnf.org/bnf/,) Palliative Care Formulary Symptom Management in Advanced Cancer Care, Oxford Handbook of Palliative Care; NEWT guidelines (where appropriate), syringe driver handbook, the Marsden Manual and package inserts.

In addition, staff should ensure the following when administering medication:

- The PSD is legal, valid, legible, unambiguous, complete and signed/dated by an authorised prescriber.
- The PSD is clinically appropriate in the current patient circumstances.
- Be certain of the identity of the patient.
- Clarify that the patient is not allergic to the medication before administration.
- Know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions, route and contra-indications
- Consider the dosage, weight where appropriate, method of administration, route and timing
- Administer or withhold in the context of the patient's condition and co-existing therapies.
- Ensure that devices for the administration of infusions/ feeds / insulin / oral medications are available.
- Seek pharmaceutical advice before crushing, dissolving or mixing any product as this may alter the effect of the medication.
- Obtain the patient's full participation and cooperation. See below for covert administration.
- Maintain a record of administration at all times on the PSD /MPAR. Where medication is not given, the reason for not doing so must be recorded.
- Monitor response to medication administered following administration. Recording all adverse reactions, allergies, hypersensitivity or anaphylactic responses, and inform the prescriber. Complete a yellow card is if a reaction may be related to a medicine.

If any of these conditions cannot be met the prescriber or RN in charge are informed. If the healthcare professional has any concerns regarding the clinical appropriateness of any prescription with due regard to the patient's condition, advice should be sought from the prescriber or RN in charge without delay before administering the medication.

Medicines to Be Checked by Two Practitioners Prior to Administration

MC has identified the following procedures as requiring double checking during preparation and administration by two practitioners (two RN or one RN and one other practitioner):

- Intravenous medicines (including infusion, pump and syringe set up).
- All epidural and intrathecal medicine preparations.
- Oncologist/haematologist prescribed cancer chemotherapy except prednisolone and dexamethasone.
- Injectable insulin.

Registered nurses who have completed the relevant competency may administer schedule 2 CDs in line with local standard operating procedures. This includes the disposal of any wasted or part used medication e.g. part ampoule, tablet or transdermal patch. For RN's who have not completed the relevant competency schedule 2CD's are subject to double checking.
Hospices should adhere to the principles in appendix 3

All staff should ask for advice, help or a second check if they do not feel entirely confident about the administration of any medication.

Recording Controlled Drugs Administration and Balances

Balances should be checked and recorded in the CD register as each dose is removed from the controlled drugs cupboard. Administration is recorded on the PSD/MPAR and in the appropriate CD register.

Each service unit that holds schedule 2, 3 CDs keeps a record of stock CDs received, disposed of or administered in both the stock and patients' own CD registers. The RN in charge is responsible for maintaining the CD registers current and in good order.

Patient Self-administration of Medicines for Immediate Access

Patients wanting to self-administer medications for immediate release e.g. salbutamol inhaler, glyceryl trinitrate should have a valid prescription and an accessible storage place should be identified which does not present a hazard to other patients and visitors. An assessment of the patient's understanding of the purpose of the medication, their ability to use the medicine appropriately and their willingness to inform staff or record doses taken should be completed.

Covert Administration of Medicine

All patients have the right to refuse to take their medication and to covertly administer medication may amount to a deprivation of their liberty, dependent on the medication being covertly administered. A clear distinction should always be made between those patients who have capacity to refuse medication and whose refusal should be respected and those who lack capacity. The covert administration of medicines is only likely to be necessary or appropriate in the case of patients or clients who actively refuse medication but who are judged not to have the capacity to understand the consequences of their refusal. The covert administration of medicines should only be used in exceptional circumstances when such a means of administration is judged necessary, in accordance with the Mental Capacity Act 2005. (NICE 2015)

A decision to covertly administer a medicine should only be made following an assessment of the capacity of the patient to make a decision regarding their medicines and a best interests meeting. A plan of care should be agreed that includes how the medicine can be covertly administered, whether it is safe to do so. There must be a regular review of the plan and the need for continued covert administration. Medicines should not be administered covertly until after a best interests meeting has been held. If the situation is urgent, a discussion should take place between the nursing staff, prescriber and family (or advocate) to make an urgent decision. A formal meeting should be arranged as soon as possible.

Staff involved in decisions relating to administration of medicines in this way must act within his / her professional code. A decision to undertake covert administration should not be made in isolation and should be discussed and agreed with the wider MDT, referring to local and national policies and applying the requirements of the law, particularly in relation to capacity. Consideration also needs to be given to the potential that covert administration may have on the therapeutic properties of the medication which may render them ineffective and not covered by their product licence. This should be discussed with the pharmacist as part of the decision-making process.

Recording Administration of Medicine

MC PSDs (medicine instructions) should be recorded on an approved medicine instruction / administration record (PSD /MPAR). There are no standardised MC PSD /MPAR available currently.

Records must be retained for 8 years after admission or death and 25 years for a child and archived according to the MC Records Management Policy. MCNS record on local PCO documents.

Timeliness of Medicine Administration and Missed Doses

If a dose is missed or refused the dose administration field on the PSD/MPAR is filled with an appropriate code/ code number (code/ code numbers may differ according to the local PSD/MPAR in use).

An IR1 should be completed for all unintentionally omitted medicine doses where no reason for omission is recorded on the PSD/MPAR and for all medicines administered outside the following timeframes:

Emergency – must be administered immediately parenterally in line with resuscitation policy:

- Adrenaline
- Chlorphenamine
- Flumazenil
- Glucagon
- Hydrocortisone
- Quick acting carbohydrate e.g. hypostop
- Naloxone
- Procyclidine
- Midazolam for seizures

Critical - must be administered between half an hour before or after prescribed time. The MC list of 'critical' medicines includes:

- Medications with a dosing schedule more frequent than every 4 hours
- Scheduled (not prn) opioids
- Immunosuppressive agents
- Medications that must be administered apart from other medications (e.g., antacids).
- Medications that require administration within a specified period of time before, after, or with meals - for example, rapid-, short-, or ultra-short-acting insulins, certain oral antidiabetic agents. These should be detailed on the PSD/MPAR by the prescriber or pharmacist.
- Glyceryl trinitrate sub-lingual
- Anti-Parkinsonian medicines

The list is not exhaustive and a clinical decision should be made on the potential harm, to a patient, if any medication is omitted or delayed. If in doubt, a pharmacist or doctor should be contacted for advice.

Medications administered more frequently than daily but not more frequently than every 4 hours - Administer these medications within 1 hour before or after the prescribed time.

Daily, weekly, or monthly medications - administer these medications within 2 hours before or after the scheduled time.

Missed doses should be reported to the nurse in charge, and escalated to a senior manager and doctor if harm to the patient or if controlled drugs are involved and medical advice sought on when to give the next dose. An IR1 should be completed

Administering Medicines Previously Checked by Other Practitioners

Nurses may assume responsibility for care for the administration of medicines previously checked by other practitioners such as medicines mixed in syringe pumps and IV fluids already in progress when the patient's care is transferred to them at a shift change or on admission.

The receiving RN must be satisfied that an established intravenous, subcutaneous infusion is 'in-situ' if required and a valid prescription exists. The label, signed by a registered healthcare professional, should clearly state the contents and an expiry date.

Emergency administration

In an emergency medication may be administered before the PSD is written. The PSD must be completed as soon as the emergency is over. See also section on remote prescribing.

Homely remedy (symptomatic relief) protocols

Homely remedy protocols are not PSD's but protocols to enable administration of general sales list (GSL) and pharmacy only (P) listed medicines. Homely remedy protocols cannot be used for prescription only medicines or controlled drugs which must be supplied and administered under a prescription.

Local medicine management groups should decide whether to approve homely remedy protocols at each of the hospices and which range of medicines to approve. A local SOP should clearly define this process and assign responsibilities.

Personal use of medication

MC hospice staff are not permitted to use or take hospice or patient stock medication for their own personal use or to give it to another person or member of staff. This constitutes theft and can lead to disciplinary and/or legal action being taken.

Patient wristbands

Identification wrist bands and allergy wrist bands or allergy wrist bands (patients should have one or the other and not both) should be applied as soon as possible for all in-patients. The wristbands must include: last name, first name, date of birth, NHS number and in Wales the first line of address. Only use a white wristband with black text. If a patient has a known risk (or example, an allergy or where a patient does not want to receive blood or blood products), the wristband should be red with patient identifiers in black text on a white panel on the wristband.

8. Disposal of Medicinal Waste

Staff must ensure medicines are disposed of safely in line with waste and CoSHH regulations and that the Marie Curie waste policy is followed at all times.

Disposal is licensable and only undertaken by authorised contractors under SLA. Local SOP should clearly describe the management and processes for disposal of medicines and CDs and identify local staff and contractors responsible and take local NHS Trust or PCO guidelines into consideration.

Disposal of Stock Hospice Medicines

Stock supplies of medicines that have passed their expiry date or are no longer required should be disposed of by the local authorised waste contractors as defined in local SOP. Unwanted and unused medicines originally dispensed by an NHS Trust or contracted community pharmacy should preferably be returned to that pharmacy for destruction. Contracted pharmacies usually have arrangements with contractors licensed for disposal of medicines. Each hospice should have

a method of recording medicines ready for disposal, which should clearly state the drug name, form, strength and quantity to be returned alongside the date of disposal and signature of disposer. It is the responsibility of the Hospice manager to maintain this.

Disposal of Patients' Medicines

All medicines prescribed and dispensed for a person are the property of that individual.

- If the person leaves the service, their medicines should be given to them unless they give consent for their safe disposal.
- Following the death of a patient where a delay in obtaining a death certificate can be anticipated (unexpected death; suspicious circumstances; coroner or the police involvement) all medicines including partly used syringe pumps should be retained until such time as a death certificate is issued. If the death is expected and verification of death is completed, medicines can be discontinued, denatured and disposed of as described above

Disposal of Controlled Drugs

All Schedule 2, 3, and 4 Part 1 CDs must be denatured before being placed into waste containers for disposal. There is no legal requirement, however, for CDs other than Schedule 2 to be denatured in the presence of an authorised witness. The local process for disposal of schedule 2 CDs should be detailed in local SOP.

Disposal of Unwanted and Expired Schedule 2, 3, 4 CDs

A local SOP should detail the process for disposal of stock or patient's own CDs that become unwanted or expired and require denaturing and disposal. A T28 exemption is required for any hospice that denatures any amount of CD's on site.

Disposal of Broken Controlled Drugs Ampoules

When accidental breakage of ampoules or spills occur, the drug can be discarded and safely disposed of in the department in the presence of another healthcare professional (RN, pharmacist, pharmacy technician) and recorded as wastage.

9. Risk Management

Medicines management groups

Each hospice should have a medicines management group to oversee the safe management of medicines within the hospice. Representation should include, but not be limited to; the AO, pharmacist, medical consultant, facilities manager and lead nurse. The terms of reference for the group should include the oversight and appropriate escalation of:

- Medicines management audits including the completion of action plans
- Medicines management Incidents; trends, risk assessment, review of learning, sharing of learning
- Monitoring of prescribing trends and the reasons for high / low prescribing of CD's
- Medicines management training
- Impact analysis of relevant new or reviewed guidance or products

Medication Incidents

Medication incidents should be managed in line with the MC incidents management policy. An MC Incident Reporting Form (IR1) should be completed and guidance regarding the process of investigation, escalation and involvement of senior managers and the Quality Assurance

Department followed in line with the policy. A guide to grading of severity of medicine incidents is attached in the Appendix 4.

As soon as it is realised that an adverse incident involving any element of the medicine management process has occurred, the patient's condition should be assessed and any necessary action/ monitoring taken immediately. Appropriate medical advice (doctor in charge or on call), should be sought and the correct clinical counter-measures taken, under medical guidance.

Requirements for Controlled Drugs

In the hospice the RN in charge is responsible for ensuring regular balance checks are made for all CDs.

Two registered nurses, midwives or registered health professionals should check the physical quantity of all CD stocks present against the balances in the CD Register at least once per day. Where possible the staff undertaking this check should be rotated periodically. The frequency can be increased at the discretion of the AOCD or RN in charge depending on perceived or actual risk.

A pharmacist or authorised pharmacy technician should make an independent check of CD stocks held in each department at least once every 3 months and may include a check of requisitions, quality of record keeping, accuracy of the list of authorised signatories, exceptional or unusual usage and physical security arrangements.

Dealing with CD Stock Discrepancies

There should be no unexplained gaps in the running balance. If any discrepancy is detected every possible step should be taken immediately to identify the cause of the loss and correct the errors/omission(s) in the CD Register. If the balance is adjusted, this should be made as a separate entry. An IR1 should be completed.

If the discrepancy cannot be resolved and corrected during the shift having performed a preliminary investigation, the RN in charge and senior manager should be informed. Out of hours the RN in charge should be contacted. An IR1 is completed and the matter reported to the AOCD /Hospice Manager or on-call manager no later than the next working day. The RN in charge should investigate the discrepancy.

The AOCD/ Hospice Manager should be kept informed in the case of all major incidents or those where there is suspicion of wider fraud/misuse and make a decision when to inform the police.

Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. Any discrepancy should be reported to the accountable officer who should investigate the frequency and significance of discrepancies. Further action should be considered if more than one discrepancy has occurred within a short period of time or if the volume is considered to be significant. An IR1 should be competed in these situations.

Adverse Drug Reaction (ADR) Reporting

A 'yellow card' should be completed for adverse drug reaction. Available online at https://yellowcard.mhra.gov.uk/. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800 731 6789

- by electronic download through the Yellow Card section of the MHRA website https://yellowcard.mhra.gov.uk/downloadable-information/
- smartphone app. https://www.gov.uk/drug-safety-update/new-yellow-card-app-for-reporting-suspected-side-effects

When reporting, as much information as possible should be detailed, including information about medical history, any concomitant medication, onset and treatment dates. They may be submitted by a doctor, pharmacist, nurse or patient. An Incident Reporting Form (IR1) should also be completed.

Safety Guidance
National medicines safety guidance, such as patient safety alerts, should be addressed in line with the MC Central Alert Policy

Defective Product Reporting

All defective or suspected defective products (medicinal products, devices, medical gases, clinical disposables) should be removed from service and retained with any other device attached to them and the batch /serial number and expiry dates noted where applicable. If a medicinal product the pharmacist should alert drug company The Hospice Manager should inform users of any defective infusion device or disposable or product recall, in accordance with local procedures and they should follow the guidance and instructions given out by the alerting system which includes the degree of urgency. If a defective (or suspected defective) product affects a patient or member of staff, it should be reported to the RN in charge of the department and an Incident Reporting Form (IR1) completed.

Control of Substances Hazardous to Health Regulations (COSHH)

Some medications can pose a risk to people dispensing, administering, disposing and destroying them, examples include Cytotoxic medicines. Where this is the case, then a risk assessment aimed at reducing the risk to relevant parties is required to be carried out under the Control of Substances Hazardous to Health Regulations (COSHH). This can take the form of a general risk assessment or the Marie Curie COSHH assessment form can be used.

Drug Abuse Vigilance

Each hospice should have a robust process for monitoring ordering patterns in particular the monitoring of ‘desirable’ medication
All staff should be alert to the possibility of drug abuse in any of their colleagues. They should look out for signs and patterns of unusual behaviour that may point to possible drug abuse. These may include: actual physical symptoms; changes in a person’s mood or personality; unusual tiredness or irritability, suspicious absences from their usual working area and suspicious patterns of absence. They should also be alert for clues that could indicate the possibility of theft of drugs, for example changes in ordering patterns or in usage of certain medicines. In such cases, staff should approach a MC colleague (preferably their line manager) and discuss the matter in confidence. The priority of managers will be the welfare and support of their staff.

10. Clinical Trials

Any proposed clinical research involving medicinal products, medical devices or dressings will need approval from the MC Research Department and the local Trust, PCO to ensure compliance with regulatory requirements and good clinical practice for clinical trials. The trial protocol is agreed by the Research Department and the clinical team involved and all staff involved should have completed GCP training (Good Clinical Practice).

11. Guidance for Persons Travelling Overseas or into the UK Carrying CDs

Patients travelling abroad for a period of over three months will need to have a personal licence for carrying controlled drugs.

For further information and enquiries contact the Home Office, Drugs Branch (telephone number: 020 7035 4848, or visit https://www.gov.uk/travelling-controlled-drugs.

12. Dealing with the Suspected Possession of Illegal Substances by Patients/Family

It is not acceptable for illicit substances to be kept or used by patients. If there is any doubt as to the legality of the substance it should be treated as if it were illegal.

Suspicion of possession of illegal substances for personal use

The RN in charge, AOCD/hospice manager and patient's consultant should be informed. Consent should be obtained from the patient and the substance confiscated, packaged securely and marked as "suspected illegal substance" and secured in the CD cupboard until removal plans are made. A separate entry should be made in the CD Record Book. Record the patient's name, the date and time, description of the substance, amount and two witnessing staff signatures. If the patient refuses to surrender the substance this should be documented in the patient's record. If the suspected illicit substance is in a syringe, with or without a needle attached, it should be placed in the appropriate clinical waste bin immediately. There is no need to record this in the CD register.

Do not attempt to remove an item by force. Do not attempt to search the person or their property. Any suspected illegal substances should not be returned to a patient on discharge as this would be committing an offence of unlawful supply of a CD under current law.

When considering whether to report illegal substances likely to be for personal use to the police, the duty of confidentiality will often outweigh the misdemeanour of possession. If this decision is unclear then advice should be sought from the local CD liaison officer.

Suspicion of possession of illegal substances with the intent to supply

Do not approach without the support of a security or the police. The RN in charge/hospice manager must inform the police as this is a criminal offence that warrants over-riding the patient's confidentiality in the public interest. A police incident number should be obtained and recorded. The patient should not be informed about the action taken. If the police are called in, they usually accept responsibility for the illegal substance and any subsequent action. A record should be made in the patient's notes. Police officers would only be expected to remove substances where they have an incident number.

To maintain the continuity of evidence, staff may be asked to make witness statements.

13. Controlled Drugs Standard Operating Procedure (SOP)

The AOCD must ensure the hospice has adequate and up-to-date CD SOPs for management and handling of CDs, which are monitored as part of strengthened governance arrangements for CDs. All staff should be familiar with local SOPs.

- SOP describe the details of current agreed local working practice, including responsibilities, procedures and audit, necessary to safely and accountably manage CDs.

- SOP should cover the full CD process (ordering, receipt, administration, prescribing, documentation, responsibilities, storage, access and destruction).
- The overall purpose of the SOPs is to improve governance of CDs and ensure an audit trail is maintained.
    - Provide clarity and consistency for all staff handling CDs.
    - Define local accountability and responsibilities and clarify delegated responsibilities.
    - Ensure practice is in line with the regulatory frameworks.
    - Act as a training and reference tool for new and existing staff.
- Local SOPs are approved at local hospice governance structures.
- A list of required SOPs is contained in the appendix 5.

14. Access, dissemination, implementation

This policy and procedure will be stored on the Marie Curie intranet. It is expected that line managers will ensure that all new employees or volunteers working with medicines are made aware of this policy and procedure during their induction.

15. Training

All healthcare professionals, including Medical staff, Registered Nurses, Nursing Associates, Pharmacists and maintenance staff who are involved in any part of the medicines management process are responsible for demonstrating and maintaining their competence. All staff should adhere to the MC requirements for induction and mandatory training in respect to medicines management. Competence frameworks may be determined at local Hospice level through local governance groups.

16. References and related documents

- Acute care Guidelines for the Timely administration of scheduled medicines 2011 Institute for safe medication practices. Available from: https://www.ismp.org/Tools/guidelines/acutecare/tasm.pdf Accessed 05.07.18
- British National Formulary (BNF) Available from https://www.bnf.org/products/bnf-online/ Accessed 17/08/18Controlled Drugs (Supervision and Management and Use) Regulations 2013 Department of Health Available from: https://www.legislation.gov.uk/uksi/2013/373/contents/made Accessed 17/08/18
- Counter Fraud Authority (2018) Management and control of prescription forms A guide for prescribers and health organisations Available from: https://cfa.nhs.uk/fraud-prevention/fraud-guidance Accessed 24/08/18
- Department of health; Northern Ireland medicines management guidance and resources. Available from: https://www.health-ni.gov.uk/articles/medicines-management Accessed 17/08/18
- Health and Social Care Act. 2012. Explained. http://www.dh.gov.uk/health/2012/06/act-explained/ Accessed 05.07.18
- Healthcare Improvement Scotland (no date) Safe Management of Controlled Drugs Available from: http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/controlled_drugs.aspx Accessed 17/07/18
- Heath Education England (2017) Advisory Guidance, Administration of Medicines by Nursing Associates. Available from: https://www.hee.nhs.uk/sites/default/files/documents/Advisory%20guidance%20-%20administration%20of%20medicines%20by%20nursing%20associates.pdf Accessed 23.05.19
- International Dysphagia Diet Standardisation Initiative (IDDSI) framework, Information and resources available from: https://improvement.nhs.uk/resources/transition-to-iddsi-framework/ Accessed 17/08/18

- General Medical Council (no date) Remote prescribing via telephone, video-link or online Available from: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/remote-prescribing-via-telephone-video-link-or-online Accessed 17/08/18
- Managing the use of medicines in hospitals a follow-up review. 2009. Audit Scotland. http://www.audit-scotland.gov.uk/docs/health/2009/nr_090416_managing_meds.pdf Accessed 05.07.18
- Misuse of Drugs (safe custody) Regulations. 1973. Legislation.gov.uk. http://www.legislation.gov.uk/uksi/1973/798/made Accessed 05.07.18
- Misuse of Drugs Act, 1971. Legislation.gov.uk. http://www.legislation.gov.uk/ukpga/1971/38/pdfs/ukpga_19710038_en.pdf Accessed 05.07.18
- Misuse of Drugs Regulations, 2001 Legislation.gov.uk. http://www.legislation.gov.uk/uksi/2001/3998/contents/made Accessed 05.07.18
- NPSA (2007) Safer Practice Notice 'Standardising wrist bands improves patients' safety'
- NICE (2015) Quality Statement 6 Covert medicines Administration Available from: https://www.nice.org.uk/guidance/qs85/chapter/quality-statement-6-covert-medicines-administration Accessed 17/08/18
- NICE (2016) Controlled Drugs safe use and management. Available from: https://www.nice.org.uk/guidance/ng46/resources/controlled-drugs-safe-use-and-management-pdf-1837456188613 Accessed 17/08/18
- NHS England Patient Safety Alert (2015) – Risk of death from asphyxiation by accidental ingestion of fluid/food thickening powder: https://www.england.nhs.uk/wp-content/uploads/2015/02/psa-thickening-agents.pdf Accessed 05.07.18
- NHS Scotland (2014) A guide to good practice in the management of controlled drugs in primary care – Scotland Available from: https://hub.careinspectorate.com/media/115219/a-guide-to-good-practice-in-the-management-of-controlled-drugs-in-primary-care.pdf Accessed 17/08/18
- NMC (2010) Nurse and Midwife independent prescribing of unlicensed medicines Circular 04/2010. http://www.nmc-uk.org/Documents/Circulars/2010circulars/NMCcircular04_2010.pdf Accessed 05.07.18
- Royal Marsden: Manual of Clinical Nursing Procedures, ninth edition. Dougherty L, Lister S (eds).2015. Wiley-Blackwell available on MC L & D site. Accessed 05.07.18
- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- Safe Management of Healthcare Waste V2.0. DOH. April 2012. http://www.srcl.com/wp-content/uploads/2011/11/Safe_Management_of_Healthcare_Waste_v2.0_April_2012.pdf Accessed 05.07.18
- Safer Management of Controlled Drugs A Guide to Strengthened Governance Arrangements in Northern Ireland dhsspni.gov.uk https://www.health-ni.gov.uk/publications/safer-management-controlled-drugs-guide-strengthened-governance-arrangements-northern Accessed 05.07.18
- Standards for medicines management. NMC. 2007. http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf Accessed 05.07.18

17. Governance

Consultation MC Hospice Pharmacists, Hospice Managers, Medical Directors, Lead Nurses, Director of Nursing, Head of Clinical Quality, members of the Clinical Reference Group, Health and Safety Manager, Practice Development Facilitators, Head of L+D

Monitoring

Adherence to the MC medicines management policy will be monitored in line with responsibilities stipulated in this policy.

Applicable legislation

Health and Social Care Act 2012.
Misuse of Drugs (safe custody) Regulations 1973.
Misuse of Drugs Act 1971.
Misuse of Drugs Regulations 2001.

Controlled Drugs (Supervision and Management and Use) Regulations 2006.

Version history

V 1.1 August 2013 - Frequency for medical practitioners to complete the opioid test has been changed from one to three years; Wording in section 7.2 'Prescription writing requirements' amended by D Oxenham'; Wording changes in relation to discontinuing or retaining medicine running added to correspond with the recently ratified VOED policy.
V1.2 July 2014 - Removal of Liverpool Care Pathway references; All PCO replaced Clinical Lead Nurse replaced with Clinical Nurse Manager.
V2 Nov 2015 - Reviewed by Head of Clinical Effectiveness and procedure sections removed.
V2.1 March 2016 – Updated Job Titled for Assistant Director of Hospices and Clinical Quality Governance Director
V2.2 April 2016 – Amended to change requirement for medicines management group TOR approval from central to local governance.
V2.3 August 2106 – Updated to include guidance regarding thickening agents and holding of CD cupboard keys
V2.4 October 2016 – updated to include guidance on thickening oral medications
V2.5 November 2016 – updated to include guidance on patient wrist bands
V2.6 March 2017 – updated to remove requirement for 10% discrepancies to be reported
V2.7 June 2017 – updated to clarify IR1 reporting for liquid CD discrepancies
V2.8 January 2018 – updated to clarify changes to double checking of CD's and complex calculations
V3 November 2018 Complete review incorporating NICE guidance
V3.1 May 2019 – This has been amended to include a link to the MC Cannabinoid Guidance.
V3.2 July 2019 - Updated to include requirements for Nursing Associates

18. Support

If you have questions about the application of this policy contact your line manager, or a member of the Quality Assurance Team.

19. Equality Impact Assessment

This policy has been assessed using an equality impact assessment initial screening template and is deemed to meet current equality requirements.

Date undertaken: 17/08/18

		Y/N	Comment
1	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	Race	N	
	Ethnic origins (including gypsies and travellers)	N	
	Nationality	N	
	Gender	N	
	Culture	N	
	Religion or belief	N	
	Sexual orientation including lesbian, gay and bisexual people	N	
	Age	N	
	Disability - learning, physical, sensory impairment and mental health problems	N	
2.	Is there any evidence that some groups are affected differently?	N	
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4	Is the impact of the policy/guidance likely to be negative?	N	
5	If so can the impact be avoided?	N/A	
6	What alternatives are there to achieving the policy/ guidance without the impact?	N/A	
7	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Head of Clinical Policies and Standards together with any suggestions as to the action required to avoid/reduce this impact.

Author	Head of Clinical Effectiveness	June 2015
Reviewed by	Head of Quality Improvement	August 2018
Approved by	Clinical Reference Group	October 2018
Ratified by	Clinical Governance Executive Committee	November 2018
Document owner	Director of Nursing, Allied Health Professionals and Quality	

20. Appendix 1: Responsibilities of the Accountable Officer Controlled Drugs (AOCD)

The AOCD must not be routinely involved in the prescribing, dispensing or administration of controlled drugs and is registered with the Care Quality Commission in England, the Scottish Commission for the Regulation of Social Care in Scotland, the Health Inspectorate for Wales and the Regulation and Quality Improvement Authority in Northern Ireland.

The AOCD Is responsible for ensuring that:

- Every aspect of the journey of controlled drugs (CDs) is defined within current policy.
- Adequate and up-to-date CD management SOP are in place
- Practice complies with current legislation.
- Adequate CD records are maintained to ensure an audit trail is maintained.
- Use of CDs is monitored through routine processes such as data analysis, audit and clinical governance, as an integral part of normal governance arrangements.
- Adequate arrangements exist for destruction and disposal of CDs.
- Effective communication with the Local Intelligence Network (LIN) is maintained.
- Effective positive engagement with the local LIN to ensure all local procedures and can demonstrate the required assurances that the hospice procedures are safe and meet requirements of the local LIN.
- Management and use information of CDs is shared with other responsible bodies.
- A nominated deputy takes on the responsibility in their absence and planned or unplanned absence for four or more weeks is notified to the regulatory body.
- Quarterly audit of CD registers are done and reported at the local medicine management group.

Have regard to best practice in relation to management of CDs and ensure:

- Ensure all personnel involved in each stage of the handling of controlled drugs have been trained and/or are qualified for the tasks undertaken
- Appropriate action is taken if well founded concerns occur.
- A record of concerns regarding relevant individuals is maintained.
- Effective assessment and investigation of concerns and effective sharing information takes place.
- Quarterly reports of controlled drug occurrences are submitted to the Director of Caring Services & Partnership, Clinical Quality Governance Director and the local District services and LIN as appropriate.
- Assurances are provided to the LIN that CD management meets regulatory requirements.
- Procedures are in place for raising concerns about ‘wrongdoing’ in the workplace
- Where required locally a declaration is completed every two years on hospice stocks, prescribing and administering activity. Documentation is provided by the local LIN to be returned to the relevant regulatory authority.
- The Hospice UK Audit Tools, Management of Controlled Drugs and Self- Assessment for the Accountable Officer are completed annually.
- Action plans and implementation strategies are developed for any areas of deficiency and overseen through local governance groups.
- The hospice has established and operates appropriate arrangements for securing the safe destruction of schedule 2, 3 and 4 controlled drugs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2013

21. Appendix 2: Nursing Associate Medicines Management Scope of Practice Statement

This scope of practice statement should be completed for all Registered Nursing Associates. Undertaking medicines management

- For governance purposes to monitor against your standards of practice and records
- To be used during your appraisal as a tool to plan your development in medicines management
- To provide assurance to the organisation that you have attained the necessary competencies

Please complete this form (including the table listing areas of practice), and sign/date in the space below. You are only permitted to undertake medicine management practice in line with the parameters agreed with your line manager in this document.

Once completed one copy of the completed form should be retained by the Nursing Associate. This agreement must be updated annually as part of the appraisal process or when the Nursing Associate scope of practice changes.

Name:	**Professional Registration (PIN)**
Work Base:	**Telephone No:**

My intended scope of practice and prescribing parameters have been discussed with my manager

	Name	**Signature**	**Date**
Nursing Associate			
Line Manager			
Accountable Officer (if the scope of practice includes controlled drugs)			

Scope of medicine management practice:

Practice Area	**Competence achieved Yes/No**	**Parameters for practice**
Ordering medicines		
Receiving medicines		
Safe Storage of medicines		
Disposal of medicines		

Scope of practice administration parameters

Route of Administration	Competence achieved Yes/No	Parameters for practice
Oral		
Topical		
Subcutaneous		
Per rectum		
Inhaled		
Other		

Name any safely critical medications that may carry a higher risk of harm, Examples of these medicines include methotrexate, insulin, digoxin, lithium and opioids; medicines used outside of their licensed indication (off-label), and recently licensed Black triangle medications.			
Name of drug/group of drugs	**Within scope of practice Yes/No**	**Name of drug/group of drugs**	**Within scope of practice Yes/No**

22. Appendix 3: Guidance on information sharing with Local Intelligence Networks

(LIN)Regulations place a statutory duty of co-operation on MC to share information about concerns with respect to the management of CDs. Responsibility for establishing Local Intelligence Networks (LIN) lies with NHS England and Scotland but each organisation is separately accountable for action within its own remit. The LIN network facilitates sharing of concerns related to CD use / abuse with other local agencies who may be affected or who may have complementary information.

The controlled drug regulations place a statutory duty of collaboration on healthcare organisations, police services, social service authorities, and the relevant inspection and regulatory bodies to share information about controlled drugs offences and potential or actual system failures.

- Whilst there is a duty of care to co-operate, that duty does not automatically override legislation relating to the control of personal data.
- In order to ensure the safer management of controlled drugs (CDs) in accordance with regulations and best practice, it is necessary to share information, including personal information, with other designated and responsible working within the LIN.
- Where concerns are serious (e.g. if patient safety is at risk or the professional's fitness to practice may be impaired) the concern(s) should be passed on to the appropriate Responsible Body at the earliest opportunity. Where concerns appear to be minor, further local investigation may be appropriate.
- If there is an urgent need to share information prior to the completion of an investigation then it should be classed as a serious untoward incident and the Incident Management and Caring Services & Marie Curie Helper Incident reporting procedure/ flowchart followed.
- Initially it is recommended that the broad nature of the concern is disclosed if there is judged to be sufficient risk to patients. Personal/ confidential information should ideally only be shared with the LIN after an investigation has been completed. The sharing of any information must be within the Marie Curie (MC) Data and Information policy.
- Sharing of information must always be done in confidence and the individual informed of the transfer of any information. However, in some circumstances, even if the information is personal/private, there may be a justification for not informing the individual where it is likely to prejudice the discharge of functions, including those to protect the public against dishonesty, malpractice or other serious improper conduct. If the person is not told that information is being shared the public protection issues must be recorded.
- The Assistant Director for Quality and Quality Assurance is responsible for any information that is shared with any LIN and external agencies. The Assistant Director for Quality and Quality Assurance will ensure an appropriate assessment has taken place before sharing any information.

23. Appendix 4: Principles for undertaking single nurse administration of controlled drugs

Our ambition
Marie Curie is working towards a 100% of our nurses feeling capable and confident to undertake single nurse administration (SNA) of all controlled drugs irrespective of the administration route.

Our underpinning philosophy
SNA promotes person centred practice and will improve the patient experience

Underpinning principles
All nurses will work to The Code and Professional standards of practice and behaviour for nurses and midwives when undertaking SNA in particular each nurse has an individual responsibility to 'maintain the knowledge and skills you need for safe and effective practice'

Training and Support
There is an organisational agreed competency framework. However, training needs will be tailored to individual needs and determined in negotiation with their line manager.

Governance
There is clear local governance of single nurse administration to monitor that will agree the pace and direction of implementation, monitor incidents and disseminate any learning following an incident.

There should be an assessment of the impact for patients and staff and careful monitoring of any unanticipated consequences, from a positive and negative perspective. This should take place through existing medicines management groups, with agreed escalation paths.

Each Hospice should promote a culture where is never wrong to ask for a second check or refresh

24. Appendix 5. MC Guide to Incident Grading

MARIE CURIE GUIDE TO MEDICINE INCIDENT GRADING

All incidents should be graded initially according to the Incident Risk Matrix at the time of the incident and not after interventions have been made.
This guide should be used to assist in deciding the Appropriate level of impact/severity/consequence of medicine incidents for patient, staff and the organisation.

RED	**SI # Death or impaired vital organ function results.** **SI # Any medicine error which requires medical intervention (transfer to higher level of care, resuscitation medication, invasive procedure) to stabilise patient** # Omission or unintentional delay of more than 1 hour (NPSA) on any of the following medicines: any medicine on MC critical timing list. # Wrong medicine given to a patient or medicine given to the wrong patient. # Any medicine administered when known allergy or hypersensitivity exists which requires more than 4 hours increased nursing and medical observation/intervention # Incorrect medicine dose, formulation, rate, route or time which requires more than 4 hours increased nursing and medical observation / intervention # Schedule 2 tablet or injectable controlled drug stock discrepancies not attributed to subtraction error which required investigation (e.g. not recorded) # Second occurrence within 3 months of a schedule 2 liquid controlled drug stock discrepancies in excess of a tolerance of 10% unaccounted loss in volume
AMBER	# Repeated incidents involving the same staff member (prescribing, administration, disposal) indicating a need for retraining # Repeated medicine errors when the same error is repeated over time e.g. wrong or omitted dose on more than one drug round. # Prescription error resulting in wrong dose/route/frequency at administration # Admission medicines reconciliation or transcribing omission # Policy contravention e.g. Verbal orders for CD taken # Schedule 2 liquid controlled drug stock discrepancies in excess of a tolerance of 10% unaccounted loss in volume (1st occurrence within last 6 months) # Any medicine administration error which requires medical notification, antidote, increased nursing monitoring (less than 4 hours) #.Omission or unintentional delay of more than 2 hour on any medicine (excluding those on MCCC critical timing list) and no reason noted on the MPAR. # Recording error or failure to record # Administration error by non-MCNS staff, noted by MCNS and reported to District Nursing Service # Incorrect medicine dose formulation, rate, route or time which requires increased nursing observation for a short period (< 4 hours) # CDs left unprotected/not disposed of /un administered at bedside or in a POD locker
YELLOW	# Un witnessed spillage of liquid schedule 2 controlled drug which is appropriately recorded in the controlled drug register # CD incidents not covered above including errors in subtraction resolved immediately but excluding witnessed spillage of CD's # Ambiguous, illegible, confusing prescription or authorisation to administer which requires prescriber contact and clarification , referral to management centre or requiring GP, OOH, District Nursing service intervention
GREEN	# Witnessed spillage of liquid schedule 2 controlled drug which is appropriately recorded in the controlled drug register # Prescribing error noted and acted upon before administration

ACTIONS	SUI	Red	Amber	Yellow/ Green
Escalate to Exec on call	X			
IR1 completed by person involved & manager before end of shift	X	X	X	X
Statements taken from staff before end of shift	X	X	X	
Upload IR1 onto Sentinel within 24 hours	X	X	X	X
Update Sentinel at least every 48 hours	X	X	X	X
Local resolution				X

25. Appendix 6: List of Recommended and Essential SOPs

The following list of SOPs should be written, if the practice is in place in the Hospice. The SOP's should be ratified and reviewed through the Hospice Medicine Management Group and Local Governance Groups

1. Prescribing
Prescribing medicines (including controlled drugs)
Range of prescribing
Clinical trials
Emergency situations
Unlicensed medicines
Oral and parenteral chemotherapy
Approval of PGDs
Medical gases
Verbal Orders
2. Medicine Reconciliation
3.Ordering
Stock medicines
Schedule 2 stock controlled drugs
Non- stock medicines
Non- stock Schedule 2 controlled drugs
To Take Out (TTO) medicines
Outpatients
Out of hours ordering
Named patient medicines
Compliance aids
4. Dispensing schedule 2 & 3 for MCCC hospice patients under exceptional circumstances
5. Transport and Receipt
Transport of medicines and controlled drugs
Receipt of medicines
6. Storage (including CDs, & emergency drugs)
Stock medicines
Non- stock medicines
TTOs
Patients own medicine
Spare keys
Review of schedule 2 stock list
Monthly expiry date checks
Storage of out-of-date medicines
Action to be taken when storage requirements are breached (security, temperature)
Restricted stationary
Retention of records -Schedule 2 CDs (prescription, order, storage, administration, destruction)
Daily controlled drug audits
3 monthly controlled drug audits
Advice for patients on storage of schedule 2 drugs
7. Administration
Administration of medicines including schedule 2 drugs (checks, documentation, disposal,
Inpatients
Day care patients
Omission of doses
Use of oral syringes
Emergency administration
'when required' doses
Intravenous medicines

Clinical trial medicines
Unlicensed medicines
Use of syringe pumps
Self-administration of medicines
Preparation of medicines
Oral & Parenteral chemotherapy
Spinal and intrathecal medicines
Supply of TTO medicines
Supply of TTO medicines to patients attending appointments away from the hospice
8. Disposal / Destruction
Destruction of waste medicines including schedule 2 CDs
Cytotoxic medicines
Medicines other than schedule 2 controlled and cytotoxic medicines
9. Incidents
Action to be taken when schedule 2 controlled drugs are missing (tablets, vials, liquids)
Monitoring the use of medicines that are not schedule 2 drug
Measures to be taken when these drugs are missing or being ordered excessively
Reporting adverse incidents
Measures to be taken following a medicines recall by MHRA
Advice given to patients on discharge for disposal of unwanted schedule 2 controlled drugs