Liverpool Heart and Chest Hospital NHS
NHS Foundation Trust

**Reference Number:** FOI202324/351
**From:** Other

**Date:** 31 October 2023

**Subject:** Medicines Checking and Trust Policies

Q1 All Trust policies that include information on the checking of medicines when they are being administered to patients, and any associated documents e.g. medicines policy, specific medicine/ clinical area policies, codes, appendices to the relevant policies etc.

We are a research team carrying out research that makes care safer. We are aware that policy and practice relating to the checking process when administering medicines varies considerably across NHS Trusts in England. As part of an ongoing project, we are requesting policies from all acute NHS Trusts in England that relate to the administration of medicines. We are trying to gain a national picture of the extent to which second (or double)-checking is required in policies, for which patient groups, which medicines and in which clinical areas; we are not trying to highlight any concerns with regards to individual Trusts. We will be using the policies for research purposes only.

A1 In response to your request, please find attached the following LHCH Policies:
Medicines Administration
Administration of Discretionary Medicines
Patient Group Directions
Safe Management of Controlled Drugs
Medicines

# Administration of discretionary medicines

## Policy

| For completion by Author | | | |
|---|---|---|---|
| Author(s) Name and Title: | Rebecca Renfrew, Senior Clinical Pharmacist | | |
| Scope: | Trust Wide | Classification: | Clinical |
| Version Number: | 3.1 | Review Date: | 22/03/2025 |
| Replaces: | 3.0 | | |
| To be read in conjunction with the following documents: | PGD protocol, Medicines Policy, Medicines Administration Policy | | |
| Document for public display: | | | |
| Executive Lead | Dr Perry | | |

| For completion by Approving Committee | | | |
|---|---|---|---|
| Equality Impact Analysis Completed: | | No | |
| Endorsement Completed: | Yes | Record of Changes | Yes |
| Authorised by: | Drugs and Therapeutics Committee | Authorisation date: | 18/10/2023 |

| For completion by Document Control | | | | | |
|---|---|---|---|---|---|
| Unique ID No: | T19DC015 | Issue Status: | Approved | Issue Date: | 24/10/2023 |
| After this document is withdrawn from use it must be kept in archive for the lifetime of the Trust, plus 6 years. | | | | | |
| Archive: | Document Control | | Date Added to Archive: | | |
| Officer responsible for Archive: | IG and Document Control Facilitator | | | | |

# Contents

# Document Statement

Medicines that are classified as Pharmacy (P) or General Sales List (GSL) medicines can be administered without the need for a Patient Group Direction (PGD) or a Patient Specific Direction (PSD) from a prescriber. This policy defines which medicines may be administered by band 4 smoke free advisors, band 5 or above nurses at the Liverpool Heart Chest Hospital; the circumstances in which they may be given and the maximum number of doses that can be given without the need for a Patient Specific Direction from a prescriber or a Patient Group Direction.

# 1. Roles and Responsibilities

The Patient Group Direction (PGD) pharmacist is responsible for updating this protocol, providing training and coordinating audit of use every 2 years. Nursing staff band 5 and above are responsible for ensuring that they have attended training and only administer medicines without a PSD or a PGD listed in Appendix 1 and in accordance with each individual protocol. Band 4 smoke free advisor can administer NRT products after successful completion of the Knowsley Smoking Cessation Level 2 training and the Trust smoking cessation lead is responsible for their training. The Drug and Therapeutics Committee is responsible for approving this policy.

# 2. Policy

a) Medicines that may administered in accordance with Appendix 1

Treatment with medicines specified in Appendix 1 may be administered by Liverpool Heart and Chest nurses band 5 or above and band 4 smoke free advisors without the authorisation of a prescriber or a Patient Group Direction provided:

- The individual protocol in Appendix 1 is followed.
- The treatment is recorded on the appropriate section of EPR to show administration (as appropriate)
- The treatment is documented in EPR nursing records/EMIS patient records
- The nurse has completed training on ESR /Band 4 smoking advisor completed Knowsley level 2 training

Medication initiated by a registered nurse shall be restricted to the maximum number of doses listed in each individual protocol and must be reported to the prescriber when he/she next visits the ward or earlier if indicated by the condition of the patient. If the patient's condition does not respond to this treatment the prescriber must be notified immediately.

b) Topicals that may be administered without the need for an administration order record on EPR

The following topical medicines may be applied without the authorisation of a prescriber or a PGD

- Aqueous cream – moisturiser/soap substitute
- Lubricating Jelly – dry lips or nasal passages in patients on Oxygen
- White soft paraffin/yellow soft paraffin for patients with dry/chapped lips not on Oxygen

The nurse should make a record in their nursing notes of this administration but a record on the patient's medication chart is not required

c) Wound Care that may be administered to adult patients at the discretion of a Registered Nurse

- See First Dressing Scheme policy

# 3. Policy Implementation Plan

All band 5 and above staff and band 4 smoke free advisors are required to complete Administration of Discretionary Medicines training on ESR. Staff will need to successfully pass the assessment before being given access to the discretionary medicines listed in Appendix 1 on EPR.

# 4. Monitoring of Compliance

An audit will be completed every 2 years to check compliance with the medicines listed in Appendix 1.

# 5. References

When PGDs are not required: Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines. https://www.sps.nhs.uk/wp-content/uploads/2019/03/SPS-When-PGDs-should-not-be-used-V1.3-March-21.pdf Accessed 2nd September 2021.

# 6. Appendices

## Appendix 1

**Protocol for the administration of paracetamol**

| 1. Staff competencies | |
|---|---|
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Mild to moderate pain |
| **Patients included** | All patients with mild to moderate pain who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Patients who are prescribed or have taken paracetamol contain product within the last 4 hours.<br>Patients with renal impairment or active liver disease<br>Patients with known allergy/hypersensitivity to paracetamol or its excipients. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Paracetamol 500mg tablets/ dispersible tablets/suppositories |
| **Dose schedule including maximum dosage** | 1g every four to six hours |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | One dose |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

## Protocol for the administration of Gaviscon advance liquid

| 1. Staff competencies | |
|---|---|
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Indigestion/heartburn |
| **Patients included** | All patients with indigestion/heartburn who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Patients with known allergy/hypersensitivity to Gaviscon advance or its excipients. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Gaviscon advance liquid |
| **Dose schedule including maximum dosage** | FIVE mL (5 mL) to be given initially after meals and/or at bedtime, if no relief of symptoms within 30 minutes a further FIVE mL (5 mL) can be given. |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | One dose (10ml) |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

**Protocol for the administration of simple linctus**

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | cough |
| **Patients included** | All patients with cough who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Allergy/hypersensitivity to any excipients of Simple Linctus. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Simple linctus |
| **Dose schedule including maximum dosage** | 5ml up to four times a day |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | Four doses |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

**Protocol for the administration of senna**

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Occasional constipation |
| **Patients included** | All patients with occasional constipation who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Patients with known allergy/hypersensitivity to senna or its excipients.<br>Cases of intestinal obstructions (e.g. DIOS) and stenosis, atony, appendicitis, inflammatory bowel diseases (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion<br>Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Senna 7.5mg tablet or 7.5mg in 5ml liquid |
| **Dose schedule including maximum dosage** | Two tablets or 10ml (15mg) |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | One dose |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

**Protocol for the administration of Strepsils Honey and lemon**

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Sore throat |
| **Patients included** | All patients with sore throat who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Known allergy/hypersensitivity to Strepsils honey and lemon lozenges or any of the excipients. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Strepsils Lozenges (1.2mg 2,4-Dichlorobenyl alcohol and 0.6mg Amylmetacresol) |
| **Dose schedule including maximum dosage** | One lozenge up to four times a day |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | Four doses |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

## Protocol for the administration of chlorphenamine

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Symptomatic relief of allergy |
| **Patients included** | All patients requiring relief of allergy who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Known allergy/hypersensitivity to chlorphenamine tablets or any excipients.<br>Patients who have been treated with MAOIs within the last fourteen days |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Chlorphenamine 4mg tablets |
| **Dose schedule including maximum dosage** | One 4mg tablet |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | One dose |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice.<br>• If given for suspected drug allergy seek medical advice in a timely manner. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

**Protocol for the administration of glyceryl trinitrate (GTN) 500microgram tablets or 400microgram spray**

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Nurses band 5 and above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR. |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Symptomatic relief of angina |
| **Patients included** | All patients requiring relief of angina who are not excluded below |
| **Patients excluded** | Patients under the age of 16 years of age<br>Patients who are pregnant or breast-feeding<br>Allergy/hypersensitivity to GTN tablets or spray or any excipients.<br>Patients with systolic blood pressure lower than 90mm Hg, hypotensive shock, severe anaemia, constrictive pericarditis, extreme bradycardia, Glucose-6-phosphate-Dehydrogenase-deficiency, cerebral haemorrhage and brain trauma, aortic and/or mitral stenosis and angina caused by hypertrophic obstructive cardiomyopathy.<br>Patients with circulatory collapse, cardiogenic shock and toxic pulmonary oedema.<br>Patients taking concurrent phosphodiesterase inhibitors such as Sildenafil, Tadalafil or Vardenafil or concomitant use with the soluble guanylate cyclase stimulator riociguat. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to prescriber and record in EPR notes |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Glyceryl Trinitrate (GTN) 500micrgram tablets or 400microgram spray |
| **Dose schedule including maximum dosage** | One dose (Two sprays or one tablet) initially under the tongue. If no relief of symptoms within five minutes a further dose can be given. |
| **Maximum number of doses which can be administered under protocol for before review by a prescriber** | One dose |
| **Follow up/Patient advice** | Advise patient to close their mouth after administration<br>Inform that a headache may develop following administration which may be relieved by paracetamol.<br>Inform patient of medicine being administered and rationale.<br>If administered seek medical advice in a timely manner. |

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|---|---|
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR |

**Protocol for the administration of Nicotine Replacement Therapies**

| | |
|---|---|
| **1. Staff competencies** | |
| **Authorised staff** | Band 4 Smokefree advisors and Nurses band 5 & above |
| **Additional requirements** | Completion of training on administration of discretionary medicines on ESR.<br>Band 4 smoke free advisor can administer NRT products after successful completion of the Knowsley Smoking Cessation Level 2 training |
| **2. Clinical condition or situation** | |
| **Clinical situation** | All smoking patients admitted in LHCH<br>Any LHCH staff who smoke and wish to quit. |
| **Patients included** | All smoking patients who are not excluded below<br>Any LHCH staff who smoke and wish to quit. |
| **Patients excluded** | Following patients<br>• No valid consent<br>• History of uncontrolled psychiatric illness<br>• History of Seizures<br>• Current use of Bupropion (Zyban)<br>• Current use of Varenicline (Champix)<br>• Previous allergic reaction to an NRT product<br>• Unstable Cardiovascular disease<br>• Creatinine Clearance less than 30ml/min<br>• Moderate to severe hepatic impairment<br>• Stroke in the previous 2 weeks<br>• Uncontrolled hyperthyroidism<br>• chronic generalised skin disease (patches only)<br>• Client undergoing treatment for alcohol dependency (Quickmist only due to ethanol content)<br>• Chronic nasal disorder (nasal spray only)<br>• Phenylketonuria (lozenges only)<br>• History of gastritis, oesophagitis or peptic ulcers (oral therapy only)<br>• Phaeochromocytoma.<br>• People who have been unsuccessful with the service in the last three months, unless deemed ready for another attempt by the Smoking Cessation Adviser<br>• Hypersensitivity to any of the ingredients contained within the product<br>• Under 18 years of age. |
| **Action for patients excluded** | Refer to prescriber |
| **Action if patient declines** | Refer to smokefree advisors |
| **Cautions** | Diabetes |

| | |
|---|---|
| | • Insulin dependent diabetics should be advised to monitor blood sugars more closely during therapy. Catecholamines released by nicotine can affect carbohydrate metabolism leading to hyperglycaemia. As nicotine requirements reduce diabetics may require less insulin. Non-insulin dependent diabetics should be advised about the risk of hyper/hypoglycaemia during nicotine replacement therapy.<br><br>Gastrointestinal disease<br>• Gastrointestinal disease may be exacerbated using oral NRT products and therefore should be avoided. Patients should be informed that other products could rarely exacerbate disease.<br><br>• The pregnant or breastfeeding woman must be referred to her GP or smoking champions in our service.<br><br>Drug interactions:<br>• Smoking cessation may cause alteration to the levels in the patients taking the following drugs. This would not normally be sufficient to cause therapeutic problems, but clients should ensure their GP is aware that they are attempting to quit.<br><br>• Beta agonists<br>• Beta blockers<br>• Alpha blockers<br>• Oxazepam<br>• Furosemide<br>• H2 receptor antagonists<br>• Warfarin<br>• Fluvoxamine<br>• Clomipramine<br>• Imipramine<br>• Flecainide<br>• Pentazocine<br>• Theophylline<br>• Cinacalcet,<br>• Ropinirole<br>• Some antipsychotics (including clozapine, olanzapine, chlorpromazine, and haloperidol)<br><br>• The above list is not exhaustive, please refer to medicines.org.uk/ BNF for complete list |
| **3. Description of treatment** | |
| **Medicine to be administered/supplied** | Initial supply of NRT may be supplied in one or more of the following forms:<br><br>Less then 10cigarettes per day (<10cpd) low nicotine dependency then provide |

| | |
|---|---|
| | Nicotinell TTS 20 14mg/24hours patches , apply one daily<br>OR<br>Nicorette Inhalator 15mg PRN<br>OR<br>Nicotine Quickmist 1mg PRN<br><br>If more than 10 cigarettes per day (>10cpd-- should be offered a combination of a long acting NRT (i.e. patch) and a short acting NRT)<br><br>Nicotinell TTS 30 21mg/24hours patches, apply one daily and<br>Nicorette Inhalator 15mg PRN<br>OR<br>Nicotinell TTS 30 21mg/24hours patches, apply one daily and<br>Nicotine Quickmist 1mg PRN<br><br>Already on Nicotine Patches – weaning to lower dose then issue<br>Nicotinell TTS 10 7mg/24hours patches 1 od |
| **Dose schedule including maximum dosage** | The minimum pack size<br><br>Patches -7 doses<br>Inhalator -20<br>Quickmist spray -13.2ml |
| **Potential adverse reactions See BNF for full list and for a full list, the manufacturers Specification of Product Characteristics (SPC) available at www.emc.medicines.org.uk** | Usually transient and may be due to either the NRT or the cessation of smoking<br>Side effects may include:<br>• With nasal spray: sneezing, epistaxis, watering eyes, ear sensations.<br>• With patches: skin reactions –discontinue if severe, vasculitis reported and changes in blood pressure , sleep disturbances, nightmares, chest pain. .<br>• With inhalator: hiccups, throat irritation<br>• With oromucosal spray: hiccups, oral symptoms such as burning lips or taste disturbance and gastric upset |
| **Follow up/Patient advice** | • Inform patient of medicine being administered and rationale.<br>• If administered monitor patient and use clinical judgement to decide when to seek medical advice. |
| **Record keeping** | Doses must be recorded on EPR in the orders section under the title Nurse discretionary medicines<br>Entry made in nursing notes document on EPR<br>For LHCH staff entry made in EMIS record |

## 7. Endorsed By:

| Name of Lead Clinician / Manager or Committee Chair | Position of Endorser or Name of Endorsing Committee | Date |
|---|---|---|
| Dr Dennis Wat | Drug & Therapeutics Committee | 22/03/2023 |
| Dr Dennis Wat | Drug & Therapeutics Committee | 18/10/2023 |

## 8. Record of Changes

| Section No | Version No | Date of Change | Description of Amendment | Description of Deletion | Description of Addition | Reason |
|---|---|---|---|---|---|---|
| 1 | 2.0 | September 2021 | Change in responsibility of writing policy and audit. | Educational pharmacist | Patient Group Direction Pharmacist | |
| 4 & 7 | 2.0 | September 2021 | Training | Face to Face training | | Update made to reflect that training is via ESR only and not face to face. |
| 1, 2&7 | 3.0 | March 2023 | New staff group, their training and new medication protocol | | Band 4 smoke free advisor can administer NRT protocol | New staff group and new NRT protocol added |
| 2 a) | 3.1 | October 2023 | Added recording for LHCH staff | None | Treatment documented in Emis Patient Record<br><br>Band 4 smoking advisor completed Knowsley level 2 training | New service to LHCH staff |
| 6 (page 13 & 16) | 3.1 | October 2023 | Criteria for LHCH staff | None | Pg 13. Clinical situation: Any LHCH staff who smoke and wish to quit. Patients included: Any LHCH staff who smoke and wish to quit.<br><br>Pg 15. For LHCH staff entry made in Emis record | New service to LHCH staff |

# Medicines Administration

## Procedure

| For completion by Author | | | |
|---|---|---|---|
| Author(s) Name and Title: | D Forrest (Chief Pharmacist), F Altintas (HON Surgery), J Shaw (HON Clinical Services), J Roy (HON Medicine), J Brislen (Deputy Head of Education), Graham Holland (Deputy Chief Pharmacist) | | |
| Scope: | Applies to all staff involved in the administration of medicines | Classification: | Clinical |
| Version Number: | 9.0 | Review Date: | 20/07/2024 |
| Replaces: | 8.0 | | |
| To be read in conjunction with the following documents: | Medicines Policy, Safe Management of Controlled Drugs, Parenteral Therapy Policy, Infection Control Policies concerning hand hygiene and line care, Acute Pain Protocol | | |
| Document for public display: | Yes | | |
| Executive Lead | Dr Raphael Perry | | |

| For completion by Approving Committee | | | | |
|---|---|---|---|---|
| Equality Impact Analysis Completed: | | | No | |
| Endorsement Completed: | | Yes | Record of Changes | Yes |
| Authorised by: | Drug & Therapeutics | | Authorisation date: | 19/07/2023 |

| For completion by Document Control | | | | | |
|---|---|---|---|---|---|
| Unique ID No: | DD02(08) | Issue Status: | Approved | Issue Date: | 25/07/2023 |
| After this document is withdrawn from use it must be kept in archive for the lifetime of the Trust, plus 6 years. | | | | | |
| Archive: | Document Control | | Date Added to Archive: | | |
| Officer responsible for Archive: | IG and Document Control Facilitator | | | | |

# Contents

# Document Statement

This procedure outlines the process to be followed whenever a medicine is to be administered to a patient. It incorporates the standards for medicines management (RPS Professional guidance on the safe and secure handling of medicines 2018, Professional guidance on the administration of Medicines in Healthcare Settings 2019, Advisory guidance on administration of medicines by nursing associates, legislative frameworks (including the Medicines Act 1968 and the Misuse of Drugs Act 1971 as amended), government guidelines and other professional regulations.

No medication should be administered to a patient if a prescription is ambiguous or there is any doubt about appropriateness, safety etc. If the prescription is in any way unclear, illegible, or not complete, as detailed in the Trust's Medicines Policy, the member of staff administering the drug should draw the prescriber's attention to this fact. The prescriber must re-write the prescription. If the prescriber refuses to re-write the prescription, the dose must not be administered and the member of staff administering the medicine should contact his or her manager, or a more senior member of medical staff.

The therapeutic uses of the medicines, its normal dosage, side effects, precautions and contra-indications should be known by the person administering the medicine.

If there is any doubt about the identity or quality of a medicine in a container, a pharmacist should be contacted and the medicine should not be administered.

**DoH Never Events**

The department of health issued a revised list of "never events" for its policy framework 2018. Should a "never event" occur it must be reported via the trust's incident reporting system immediately.

**Potassium Solutions**

For the purposes of administration of a potassium-containing solution, death or severe harm as a result of the maladministration of a potassium-containing solution is considered to be a "never event" and therefore must be reported via the trust's incident reporting system immediately. Maladministration refers to:

- Selection of strong potassium solution instead of intended other medication.

**Administration of medication by the wrong route**

For the purposes of administration of medication by the wrong route, death or severe harm as a result of the following is considered to be a "never event":

- intravenous chemotherapy by the intrathecal route
- Oral / enteral medication or feed / flush by any parenteral route
- Intravenous administration of an epidural medication that was not intended to be administered by the intravenous route.

**Overdose of Insulin due to abbreviations or incorrect device**

For the purposes of administration of insulin, death or severe harm as a result of maladministration of insulin by a health professional is considered to be a "never event" and therefore must be

reported via the trust's incident reporting system immediately. Maladministration as an overdose refers to when a health professional:

- gives a 10-fold or greater overdose of insulin because the words "unit" or "international units" are abbreviated; such an overdose was given in a care setting with an electronic prescribing system
- fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin
- withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.

**Midazolam**

For the purposes of administration of midazolam during conscious sedation, death or severe harm as a result of overdose of midazolam injection following use of high strength midazolam (5mg/mL or 2mg/mL) for conscious sedation is considered to be a "never event" and therefore must be reported via the trust's incident reporting system immediately. This excludes areas where use of high strength midazolam is appropriate, e.g. general anaesthesia, intensive care, or palliative care.

**Methotrexate**

For the purposes of administration of methotrexate, a never event is considered to have occurred, and must be reported, when an overdose (more than the intended weekly dose and when the care setting is using an electronic prescribing system) has occurred by any route, for non-cancer treatment

# 1. Roles and Responsibilities

The Director of Nursing is responsible for the implementation of this procedure.

All administration should be in the patient's best interests and follow professional guidelines.

All references to "signing the prescription" to confirm administration refers to either using a paper chart or using the electronic prescribing system.

a) Registered Nursing staff are responsible for the majority of medicines administration within the Trust, being guided by the RPS, Nursing and Midwifery Council's Standards and the local procedure. To achieve this, nurses must have sound knowledge of the use, action, usual dose and side effects of the medicine being administered. Nursing staff are also responsible for the immediate and honest disclosure if an error should occur (Duty of Candour). Training for nurses on the contents of this procedure will be conducted by nurse trainers and pharmacists on clinical induction. Ward managers are responsible to ensure that the nursing staff, under their direction, are familiar with the contents of this procedure.
b) Pharmacists are responsible for ensuring that medication is prescribed and administered in compliance with all Trust policies and procedures together with current legislation. Pharmacists will take part in training of staff on aspects of this procedure.
c) Operating Department Practitioners, cardiac radiographers (who are studying for, or who have obtained, the gradcert in adult cardiac catheter laboratory practice), cardiac physiologists (who are studying for, or who have obtained, the gradcert in adult cardiac catheter laboratory practice) and Perfusionists, are responsible for administering medicines as required during their roles in compliance with this procedure.

d) Medical Staff may, in the course of their duties, be required to administer medication. This must be done in compliance with this procedure.
e) The Drug and Therapeutics Committee is responsible for the ratification and approval of this procedure.

# 2. Controlled Document Standards

**General Checklist for Medicines Administration (for more detail see section 3)**

**Witnessing the Preparation and Taking of Medicines**

It is the responsibility of the person administering medicines that they are taken as intended. It is not acceptable to store patient's medicines on the patient's locker, table etc.

It is unacceptable to prepare substances for injection in advance of immediate use or to administer medication drawn into a syringe or container by another practitioner when not in their presence, exceptions being infusions in progress or preparations made or supplied by the pharmacy department.

In an emergency, where an individual may be required to prepare substances for injection by a doctor, they should ensure that the person administering the drug has undertaken all the appropriate safety checks as set out within this procedure.

**Knowledge and Understanding of Medicines Being Administered**

In exercising your professional accountability in the administration of medicines and in the best interests of your patient you must:

- Know the therapeutic uses of the medicine, its usual dosage, side effects, precautions and contra-indications.
- Be aware of patient's plan of care.
- Have considered the dosage, method of administration, route and timing of the administration in the context of the condition of the patient and co-existing therapies.
- Contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicines are discovered, where the patient develops a reaction to the medicines (contact the pharmacy department, complete green ADR form and a clinical incident form), or where assessment of the patient indicates that the medicine is no longer suitable.

**Interruptions during Medication Rounds**

Medication should be administered during an uninterrupted medication round by a dedicated nurse. Interruptions during medication administration have been found to significantly increase the risk of medication errors (NPSA 2007). Red bibs should be worn during medication rounds to facilitate this.

**Timing of Medication**

Where possible, all medicines must be administered at the time stated on the prescription. If the person administrating the medicines has concerns around the timing of medications this should be raised at the earliest point possible with the prescriber.

**Delayed/Omitted Medicines**

Following the NPSA alert "reducing harm from omitted and delayed medicines in hospital" issued in February 2010, it was agreed by the Trust that no medicine should be omitted without discussing with a prescriber first.

Nursing staff should ensure the outcome of this discussion is documented in their notes on EPR. The person administering medicines should take the steps outlined in appendix 4 when a medicine is deemed "not available". They should also be familiar with how to reschedule medicines on EPR so that they may be given later in the day, if appropriate.

Special consideration should be given and appropriate action taken for medicines where a delay in administration may cause harm to patients e.g. medicines used to treat Parkinson's disease or Epilepsy, Intravenous antibiotics etc.

**Route of Medication**

All medication must be administered according to the route detailed on the prescription. If this is not appropriate, this must be raised with the prescriber.

# 3. Procedure

**A summarised step by step guide for the process of administering medicines is shown as Appendix 2.**

### 3.1 General Checklist

- Before administration the patients' identity should be confirmed with the patient (if possible), the patient's identity band and then checked against the prescription (worklist manager).
- Read the name of the medicine on worklist manager and obtain the required drug either from the patient's locked bed-side medication cabinet, or from stock.
- Ensure the medicine is being administered at the correct dose (especially where multiple units are required to provide the dose e.g. two tablets of furosemide 40mg for an 80mg dose), via the correct route.
- Check the time at which the drug is due. If administering a "when required" medicine ensure the drug has not been recently administered, whether as a "regular" medicine or "when required" medicine, or that the maximum dose in 24 hours has been reached.
- Ensure that the patient is not allergic to the medicine before administration (by checking EPR and red wrist band).
- Know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications.
- The name, strength and expiry date of the medicine (where available), dose to be given, route and time of administration should be checked (compare the name as written on the worklist manager against the name on the label or outer box of the medicine (if stock there won't be a label), together with the strength and name on the actual medication "foil" itself

prior to “popping” the tablet or capsule from the foil pack (however, not all medicines appear in foil packing).
- You must be aware of the patient’s plan of care (care plan / pathway)
- Check that the prescription or the label on the medicine (if individually dispensed for the patient) is clear and unambiguous.
- Consider whether the medicine should be administered or withheld in the context of the patient’s condition (e.g. digoxin not usually administered if pulse is below 60 bpm).
- The dose should then be administered, and the prescription should be completed accurately and immediately (using the codes listed within the dropdown menu for any omissions).
- The EPR KBMA (Knowledge-Based Medicines Administration or ‘closed loop’) module should be utilised to support accurate medicines administration where available. This includes scanning the patient wristband to confirm identity and scanning medication to verify correct drug, dose and schedule.
- For administration of medicines by students, see appendix 1. All student signatures must be countersigned by the person responsible for supervising the student during the administration of the medication, as a witness. Student passwords to the electronic prescribing system force the need for a witness. Currently, the EPR system does not facilitate this, therefore the mentor must log-on and sign for medicines when supervising a student.
- Medicines should not be left on patient’s lockers.
- All intravenous injections must be administered separately from the routine oral medicine round.
- Medication orders, generated on the EPR system, which do not require the actual administration of a medicines but which serve as a “reminder” for a task, e.g. the anticoagulation order set reminder which appears on the worklist manager when a patient is on warfarin to remind staff to prescribe a daily dose, NEED TO BE ACKNOWLEDGED as though they were a real medicine. Therefore, once the “task” has been completed e.g. a dose of warfarin has been prescribed, the “order” would be acknowledged as having been “done” to remove the item from the worklist manager

If a dose of a medicine is not given then the doctor responsible for the patient MUST BE INFORMED and the prescription annotated accordingly.

### 3.2 Variable Dose Prescriptions

Where medication had been prescribed within a range of dosages it is acceptable for practitioners to titrate the dose according to the patient’s response and symptoms within the prescribed range. The accurate interpretation of test results may be necessary to adjust the dose administered to the patient appropriately. It is essential that administration of variable dose drugs should be carried out by practitioners who are competent to interpret such tests e.g. blood results for heparin dosing, glucose levels for insulin regimens. The dose administered must be recorded.

### 3.3 Availability of Medication (see Appendix 4)

Where drugs are not available on the ward it may be necessary to:
- Request a supply of the drug from the ward pharmacist or by phoning the pharmacy department (during opening hours).
- Use the pharmacy Emergency Cupboard (out of pharmacy opening hours).
- Borrow the medicine from another ward (out of pharmacy opening hours).

- Contact the on-call pharmacist for supplies (out of pharmacy opening hours).

Whenever a pharmacist has seen a prescription, and verified it, a small green clipboard will appear on the drug line (on the orders tab view) and the pharmacists name will appear under the drug name. If a patient is likely to require this medicine on discharge, a labelled supply will be made from pharmacy (unless the patient has a supply of their own). For all other medicines, stock should be used.

### 3.4 Requirement of a Second Checker

In most circumstances medicines may be administered without the need for a second check. However this does not apply to:-

- Controlled drugs (please refer to Trust policy on Safe Management of Controlled Drugs)
- Where the dose has to be calculated
- Where the dose is weight related e.g. mg/kg or obtained from a weight / dosing chart
- Subcutaneous insulin (Exception- nursing staff caring for patients who are self-medicating insulin do not need to obtain a second nurse signature for administration. The patient will provide this check.
- All intravenous medication (including bolus or infusion)

In these circumstances both the **preparation** and the **prescription** must be checked by a second practitioner (refer to the Trust procedure on Medicines Administration). An exception to this is where the medicine has been prepared (including dose and weight calculations) in the pharmacy department, for example, iron infusions).
In addition, the second checker must witness the actual **administration** of controlled drugs and intravenous infusions that require the use of an infusion pump.
In certain wards and departments, Assistant practitioners, will be trained and competency assessed to act in the capacity of a second checker for intravenous medication. Training will be provided by Learning & Development and competency assessed annually by their manager. This function will not incorporate the checking of controlled drugs or complex intravenous medication nor the administration of the medication. (Assistant practitioners have completed a 2 year foundation degree)

Anaesthetists can administer certain medicines without the need for a second check. This does not apply to controlled drugs.

**Amendment to process during COVID**
In order to minimise cross contamination of drugs and reduce excessive use of PPE, the above process has been modified in **certain circumstances** for suspected or positive COVID patients **only**. See Appendix 5 (non CDs) and Appendix 6 (CDs)

Please see Appendix 1 for administration of medicines by student nurses/nursing associates.

### 3.5 Oral Medication (also see Appendix 2)

#### 3.5.1 Crushing Medication

The mechanics of crushing medicines may alter their therapeutic properties rendering them ineffective and not covered by their product licence. Medicinal products should not routinely be

crushed unless a pharmacist advises that the medication is not compromised by crushing and crushing has been determined to be within the patient's best interest.

### 3.5.2 Enteral Feeding Tubes

For details of using an enteral feeding tube and the administration of medicines via such a route, see the LHCH Enteral Feeding Policy.

### 3.6 Controlled Drugs

See Appendix 6 for modified process in certain circumstances in COVID/suspected COVID patients

There must be two members of staff involved in the administration of a controlled drug, one of whom must be a registered healthcare professional

The second person i.e. the checker can be an RGN, doctor, pharmacist or registered Operating Department Practitioners (ODP). In addition other healthcare personnel who have received training and have been assessed as competent to check controlled drugs can perform the second check (see Medicines Policy). Controlled drugs (CDs) should be administered in a timely manner. The process should follow that outlined in the standard operating procedure (see Safe Management of CD policy):

- An appropriately registered practitioner should take the prescription to the CD cupboard (using an EPR trolley, the PC in the treatment room near the CD cupboard or a handheld device).
- Obtain keys and ensure another appropriate practitioner is available to provide a second check / witness signature.
- Read the prescription independently and one person should remove the required quantity of the required drug from the cupboard.
- This drug should be shown to the witness who confirms that this is consistent with the prescription.
- Both practitioners should confirm the remaining balance of the drug left in the CD cupboard.
- Both practitioners should confirm that the medication to be administered is in date, and if labelled individually, bears the patient's name.
- The administering practitioner should open the CD register at the correct page and complete the entry, witnessed by their colleague. Both should confirm the remaining balance.
- Lock the CD cupboard / fridge.
- Both practitioners should return to the patient and confirm the identity of the patient.
- Administer the medication and both practitioners must sign the prescription and the entry in the CD register.

### 3.7 Injectable Medicines (also see Appendix 2)

Medication for injection must not be prepared in advance of their immediate use. Medication prepared by another practitioner when not in their presence should not be administered. Exceptions to this are when there is an already established infusion which has been instigated by another practitioner or when medication has been prepared or supplied by the pharmacy department.

Injectable medicines must be administered separately from oral medication and by dedicated, trained practitioners.

### 3.7.1 Subcutaneous method

Follow the process in Appendix 2 for selection of correct drug etc. Ensure the patient is lying or sitting appropriately then remove appropriate garments to expose the chosen site (ensure patient's modesty is maintained by use of curtains etc). Choose the correct needle size to minimize the risk of missing the subcutaneous tissue, clean the site with isopropyl alcohol 70% and pinch the skin into a fold. Insert the needle into the skin at an angle of $45^{O}$ and release the skin (unless insulin is being administered when an angle of $90^{O}$ should be used). Inject the drug slowly then withdraw the needle rapidly and apply pressure to the administration site.

### 3.7.2 Intramuscular method

Follow the process in Appendix 2 for selection of correct drug etc. Ensure the patient is lying or sitting appropriately then remove appropriate garments to expose the chosen site (ensure patient's modesty is maintained by use of curtains etc). Clean the chosen site with a swab saturated with isopropryl alcohol 70% for 30 seconds and allow to dry. Stretch the skin around the chosen site and hold the needle at an angle of $90^{O}$ quickly plunge it into the skin. Pull back the plunger and, if no blood is aspirated, depress the plunger at approximately 1 mL every 10 seconds. If blood appears, withdraw the needle completely and start again. Wait 10 seconds before withdrawing the needle then withdraw rapidly and apply pressure.

### 3.7.3 Intravenous method

Method guidelines are shown in Appendix 2. Two practitioners should check medication that is to be administered intravenously, one of whom should then administer the medication (see section 3.4 for exceptions). Method for preparation and appropriate diluents can be found within the parenteral therapy guide for LHCH or by contacting the pharmacy department. Any dose calculation should be checked independently to ensure correct volume or quantity of medication. Whenever an infusion is to be administered the patient and infusion device should be checked regularly.

## 3.8 Other Routes of Administration

There are many other routes of administration.

- Epidural and paravertebral routes are covered in the pain management procedure.
- Rectal drugs can be in the form of enemas, some of which require retention by the patient for a period time, or suppositories. Administration of these should take place as shown in Appendix 2.
- Eye drops and ointments should be administered as shown in Appendix 2.
- Nasal drops should be administered by first cleaning the patient's nasal passages with tissues then hyperextending the patient's neck (unless contra-indicated). Avoid touching the external nares with the dropper then administer the required number of drops and ask the patient to maintain this position for one or two minutes.
- Ear drops should be administered by asking the patient to lie on his / her side with the ear to be treated uppermost. Warm the drops to body temperature if allowed then pull the cartilaginous part of the pinna backwards and upwards. Allow the drop(s) to fall in direction of the external canal then request the patient to remain in position for 1 or two minutes.

- Topical skin patches should be placed in clean skin, free from hair and the site should be rotated when the patch is changed. Remove semisolid or stiff preparations from their containers with a gloved hand. If the medication is to be rubbed into the skin, the preparation should be placed on a sterile topical swab. The wearing of gloves may be necessary.
- Sublingual administration requires the medicine to be place under the tongue of the patient.
- Buccal administration requires the drug to be placed in the pouch of the cheek.
- Nebulised inhalations should be measured using a syringe and any equipment should be cleaned afterwards, see Trust's nebulisation guidelines for more details.

There are various other routes of injectable medicines; e.g. intercameral, intraocular, intra articular, however, these are used rarely at LHCH. If, however, information is required please contact your pharmacist.

### 3.9 Administration of Medicines Without A Prescription

No medication should be administered to a patient in the absence of a valid written prescription. There are currently some exceptions:

a) Patient Group Directions – Certain named healthcare professionals, following training, may administer medicines under group protocols which have been approved by the Drug and Therapeutics Committee.
b) In an emergency, a drug may be given on the verbal instruction from the doctor, provided that the name, dose and route of the drug are recorded on the nursing care plan by the nursing staff, and the doctor prescribes on the electronic prescribing system within 24 hours. The doctor must subsequently ensure that this drug, which has already been administered, is not administered for a second time by mistake.
c) During certain procedures e.g. PCI, EPS, or device implantation / explanation, drugs may be given on the verbal instruction from the doctor, (in an emergency situation not planned treatment) provided that the name, route and dose are recorded either on the drug treatment section of the integrated care pathway, or on the prescription and, in both cases, signed by the doctor at the end of the procedure. The likely regular medicines must be prescribed before the case is commenced.

### 3.10 Self-Administration (except insulin)

Patients who fulfil the criteria may be allowed to self-administer their own medication, or medication supplied from pharmacy for this purpose. Currently self-administration schemes are available on Birch Ward, Maple Suite and Cherry Ward.

An exception to this is for patients taking medicines for parkinsons disease. These are time critical medicines and therefore to assist in avoiding delayed/missed doses, staff may apply the standard risk assessment used for the above patients for any patient in the Trust

When patients are self-administering continual assessment must be undertaken to recognise and act upon any changes in the patient's condition which may affect their ability to self-medicate. For assessment criteria and forms, refer to the Trust's Medicines Policy. The nurse must check each drug individually with the patient before annotating the administration record.

### 3.11 Self-Administration (insulin only)

Patients who fulfil the criteria (refer to Medicines policy) may be allowed to self-administer their own insulin. Currently self-administration schemes are available to all patients except those on Critical care, CCU, HDU and those on intravenous insulin.

### 3.12 Relabelling of Medicines

The instructions on the medicine label must always correspond to the dose and frequency prescribed on the in-patient prescription and TTO. When a dose is altered, a new supply will be issued or the original supply will be returned to pharmacy and relabeled, if the original supply has not been re-used, the old pack should be returned to pharmacy for destruction. Medicines issued by the hospital during the current admission may be relabelled in pharmacy. Patient's own drugs will not normally be relabelled, unless the pharmacy is unable to obtain a supply, and then only at the discretion of the ward pharmacist. When this occurs, a label will be attached to the original container (allowing the original dispenser's name and address to remain visible), bearing the words 'Patient's own supply relabelled'.

### 3.13 Management of Adverse Events

If an error is made the individual practitioner must take any action to prevent any potential harm to the patient and report as soon as possible to the prescriber, line manager according to ward policy. All actions should be documented and Trust incident forms completed.

### 3.14 Clarifying Identity

Where there are difficulties in clarifying an individual's identity refer to the trust's policy regarding patient's identification for guidance, which currently states the following:
*Before any patient intervention or treatment the following mechanism of identification must be followed to ensure the correct patient is receiving the prescribed treatment or care.*

- *By asking the patient to tell you their forename, surname and date of birth.*
- *Check this is compatible with the identity band*
- *If the patient is unable to tell you their name, refer to the identity band and, if possible, verify the information by asking the family, relatives or another member of the clinical staff who knows the patient*
- *By asking that the relatives identify the patient by name and date of birth if applicable*
- *By the hospital unit number. (NHS number will be used when more widely available)*

### 3.15 Take-Home Medication

When discharging a patient the following process must be used (there is a video available on the intranet which outlines this process). It is suggested that the first three steps below should be completed away from the patient's bedside to avoid interruptions and confusion to the patient

1. The TTO **MUST** be verified by a pharmacist first. If it has not been verified, a warning will appear at the top of the printed TTO copy stating "TTO NOT VERIFIED BY A PHARMACIST".
2. Check the patient's name on the TTO and compare the in-patient prescription, using the ORDERS TAB within EPR, with the printed TTO copy. The current in-patient medicines ON THE ORDERS TAB must match the printed TTO copy (discretion should be exercised for those medicines that are clearly not for discharge. If there is any doubt advice should be

sought from the prescriber or pharmacy). Caution should be exercised to ensure all regular and "when required" medicines appropriate for discharge are included on the TTO – PRESCRIBERS MAY HAVE ADDED AN IN-PATIENT MEDICINES BUT OMITTED TO ADD IT TO THE TTO. (*Medicines included on the TTO will carry a "thumbs up" sign on EPR, those just for in-pt use don't have a "thumbs up", however, if a prescriber has added a new medicine as an in-pt but omitted to add this to the TTO, please check with the prescriber whether the patient should be taking the item on discharge and ask for it to be added to the TTO.*

3. Ensure all drugs already on the ward labelled for the patient to take home, together with those supplied with the TTO paperwork, are present. Ensure all drugs are labelled with the correct name for the patient being discharged, ensure directions on the TTO match those on the label for all drugs. It is probably best to complete this process methodically, line by line. Compare the EPR orders tab – check an in-pt line and a TTO (thumbs up) line for the first drug, check the dose and frequency, then ensure there is a matching medicine, labeled correctly with the correct strength and dose and frequency and that this matches the contents of the box or bottle (i.e. a box labeled aspirin 75mg tablets should contain strips of aspirin 75mg). Then move on to line two.
4. Check the patient's name on the TTO with the patient (verbal check and their wrist band).
5. Explain to the patient or carer what each drug is for and when it should be taken (using teach-back technique), i.e. follow the discharge drug information algorithm closely (attached as appendix 3). Complement the verbal instructions with a Trust drug information leaflet, if available, directing the patient to the side effect information for each drug.
6. Give the patient a copy of the TTO and file the 'notes' copy in the patient's notes (i.e. for scanning onto EPR).
7. Any drugs remaining on the ward which belong to the patient, but which are no longer required, should be sent to pharmacy for destruction. However, if the patient insists on taking them home, the nurse must emphasize to the patient that they are no longer prescribed them. The nurse must ensure that the patient understands that these medicines are not part of their current treatment.
8. Document the discharge in the nursing notes by stating that the TTO has been explained.
9. If Controlled Drugs are part of the TTO, obtain a signature in the "patient's own" CD register from the patient, or their representative, when handing over the CDs. Countersign this record yourself.

### 3.16 Training

All clinical staff during induction will be made aware of the existence of the Medicines Policy and Medicines Administration Procedure.

### Registered nurses/ODP/Radiographer/Nursing Associates

All nursing staff are required to complete the Medicines Management e-learning and competency assessment for oral/topical/nebulized/PR/PV/SC/IM non-controlled drugs, controlled drugs, KBMA and TTO. Competency assessments must be completed in practice and signed off by a suitably qualified member of staff (minimum of Band 6). The Medicines Management e-learning and competency assessments should be completed every 2/3 years

Newly qualified registered nursing staff and nursing associates- will receive a full day Medicines Management training as part of their Preceptorship programme.

Intravenous medicines – newly qualified nursing staff, ODP and radiographers must attend an 'Injectable Medicines Workshop' and undertake competency assessment as part of the preceptorship programme. For nursing/ODP/radiographer new to Trust who are experienced in administration of injectable medicines must complete 'Injectable Medicines Update' (E-learning package) and undertake competency assessment. Competency assessments must be completed in practice and signed off by a suitably qualified member of staff (minimum of Band 6). 'Injectable Medicines Update' (E-learning package) should be completed every 2/3 years.

In order to administer discretionary medicines (previously Patient Group Directives) an e-learning package must be completed.

**Non-medical prescribers**

Non-medical prescribers – please refer to the Non-Medical Prescribing Policy. Must have completed a recognised supplementary prescribing course and attend EPR prescribing session.

**Pharmacy staff**

All Pharmacy staff undertake mandatory training including an e-Learning package on the safe use of insulins.
All staff read the appropriate SOPs relating to their role. SOPs include information on the safe clinical checking and supply of medications.
All Pharmacy staff are invited to monthly CPD journal club sessions to help ensure knowledge is up to date.
All Pharmacy staff attend trust induction and in-house Pharmacy induction where they are informed of where to find Policies and Procedures. They are asked to read several of these during induction.
Pharmacists and Pharmacy technicians undertake dispensing and checking logs to ensure they are working safely and as per SOPs.
Pharmacists and Pharmacy technicians undertake anticoagulation counselling training, over the Counter medications training and Medicines Reconciliation Training.

**Medical Staff**

All medical staff receive training on induction.
All trainee medical staff demonstrate competence on IV administration on induction.
Medical Staff will receive training on various aspects of the policy during weekly training sessions provided by the training pharmacist.

**Staff not achieving competence/failing e-learning**

If there are any concerns regarding competence of a member of staff to safely prescribe, dispense or administer medicines this should be discussed with their manager to determine appropriate development plan. The member of staff should not undertake medicines prescribing/dispensing or administration until competency has been achieved. The competency assessments and e-learning may be accessed at any time if further training is required.

# 4. Policy Implementation Plan

This procedure will be distributed to all wards and departments. Nurse trainers and ward managers will be responsible for ensuring that the procedure is implemented fully within the Trust. All staff currently employed by the Trust will be expected to read this procedure and sign a record to indicate that they have understood its contents and will endeavour to comply with it at all times.

# 5. Monitoring of Compliance

Incidents involving medication administration will be reviewed at the medication error review committee. This committee will report via “hot topics” to the Patient Safety Committee. Missed doses reports are available on EPR for each ward manager to assess whether their patients are receiving medicines in a timely and accurate manner.

# 6. References

RPS Professional guidance on the safe and secure handling of medicines 2018

Professional guidance on the administration of Medicines in Healthcare Settings 2019

Advisory guidance on administration of medicines by nursing associates

DoH Never Events list 2018

NPSA – Interruptions of Medicines Rounds 2007

# 7. Appendices

## Appendix 1

### MEDICATION ADMINISTRATION AND STUDENT NURSES

See Section 3.4. LHCH follows single nurse administration except for Controlled Drugs, where the dose has to be calculated or where the dose is weight related.

| ROUTE / CLASS / ACTIVITY | YEAR 1 | YEAR 2 | YEAR 3 |
|---|---|---|---|
| **Single nurse medication administration** | No | No | No |
| Oral excluding Controlled Drugs (CDs) | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse |
| Intravenous medication preparation and administration and flushing cannulae | Can observe only | Can observe only | Can observe only |
| Subcutaneous / intramuscular medication preparation and administration | Can prepare and administer under DIRECT supervision of Registered Nurse | Can prepare and administer under DIRECT supervision of Registered Nurse | Can prepare and administer under DIRECT supervision of Registered Nurse |
| Rectal and vaginal administration | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse |
| Inhaled therapy | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse |
| Topical therapy | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse |
| Controlled Drugs administration | Can observe administration of CDs | Can act in role of 3rd checker | Can act in role of 3rd checker |
| Via nasogastric tube or percutaneous endoscopic gastrostomy | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse |
| Blood products | Can observe only | Can observe only | Can observe only |

**MEDICATION ADMINISTRATION AND TRAINEE NURSING ASSOCIATES**

| | |
|---|---|
| Single trainee associate administration | No |
| Oral medication excluding Controlled Drugs (CD's) and cytotoxic medications | Can administer under the direct supervision of a Registered Nurse. |
| Controlled drugs administration (CDs) | Can act in role as 3rd checker. |
| Intravenous (IV) medication preparation | Not part of training |
| Intravenous (IV) medication administration | Not part of training |
| Subcutaneous (SC) Preparation and administration | Can prepare and administer under direct supervision of a Registered Nurse |
| Intramuscular (IM) Preparation and administration | Can prepare and administer under the direct supervision of a Registered Nurse |
| Per Rectum (PR) | Can administer suppositories and enemas under the direct supervision of a Registered Nurse |
| Per vagina (PV) | Not part of training |
| Inhaled therapy / Oxygen | Can administer under the direct supervision of a Registered Nurse |
| Topical | Can apply under the direct supervision of a Registered Nurse |
| Nasogastric (NG) /Percutanous Endoscopic Gastrostomy (PEG) | Can administer under the direct supervision of a Registered Nurse |

**MEDICATION ADMINISTRATION AND QUALIFIED NURSING ASSOCIATES**

Registered nursing associates are staff registered with the Nursing and Midwifery Council as Nursing Associates. In order to undertake unsupervised administration of medicines the Nursing Associate must have completed LHCH training in medicines management. Registered Nursing Associates can hold the medication keys (BUT not the Controlled Drug keys). Registered Nursing Associates must not supervise Nursing or Nursing Associate students.

| | |
|---|---|
| Oral medication **excluding Controlled Drugs (CD's) and cytotoxic medications** | Can administer oral medications with the exception of Controlled Drugs and cytotoxic agents. |
| Controlled Drugs | Cannot initiate the administration of a Controlled Drug but can be the second checker.<br>Can check and sign the entry in the Controlled Drug Register and the patient's own Controlled Drug Register.<br>Can be the second checker for the Controlled Drug daily reconciliation.<br>Cannot order Controlled Drugs from pharmacy or sign for delivery in the Controlled Drug order book. |
| Intravenous (IV) medication | Cannot be involved in the administration or second check of IVs |
| Subcutaneous (SC) and Intramuscular (IM) injections | Can administer. **Excludes Controlled Drugs, cytotoxic medication and vaccines.**<br><br>Insulin doses must be double checked by registered nurse as per Trust policy.<br>Any manipulations of volumes from a syringe or vial must be double checked by a registered nurse<br><br>To administer Insulin – must have undertaken eLearning, session and associated training |
| Per rectum (PR) | Can administer. |
| Per Vagina (PV) | **Cannot** administer |
| Inhaled therapy / Oxygen | Can administer.<br>**Excluding inhaled antibiotics and inhaled Controlled Drugs** |
| Tropical creams/gels/ lotions & washes | Can administer. |
| Eye drops or ointment, ear drops or sprays, nasal drops, sprays or ointments | Can administer |
| Nasogastric (NG) / Percutaneous Endoscopic Gastrostomy (PEG) | Can administer once attended NG tube training. |
| Blood / Blood products | Cannot administer or act as a 2nd checker for blood or blood products. |
| Cytotoxic medications | **MUST NOT** administer<br>Examples of cytotoxic agents include methotrexate, cyclophosphamide. |
| Unlicensed medications | **MUST NOT** administer |

| | |
|---|---|
| Patient Group Directives (PGD) | **MUST NOT** supply and/or administer medicines even under direct supervision if the medicines are supplied / administered under a Patient Group Directive (PGD). |

**Appendix 2**

## ADMINISTRATION OF MEDICINES CHECKLIST

### Guidelines for Oral Administration

1. Wash hands with bactericidal soap and water or bactericidal alcohol handrub.

2. Before administering any prescribed drug, check that it is due and has not already been given. Check that the information contained on the prescription is complete, correct and legible.

3. Before administering any prescribed drug, consult the patient's prescription and ascertain the following:

- Drug
- Dose
- Date and time of administration
- Diluent as appropriate
- Validity of prescription
- Name of doctor
- The prescription is legible (applicable to paper charts where these are in use).
- If working in an area that has adopted the EPR KBMA module, these workflows should be used to verify correct drug, dose, and schedule.

4. Select the required medication and check the expiry date, ensure the medicine within the container matches the label on the outside.

5. Empty the required dose into a medicine container. Avoid touching the preparation.

6. Take the medication and the prescription to the patient. Check the patient's identity by asking the patient to state their full name and date of birth. If the patient is unable to confirm details then check the patient identity band against the prescription. If working in an area that has adopted the EPR KBMA module, the patient's wristband should be scanned to confirm identity.

7. Evaluate the patient's knowledge of the medication being offered. If this knowledge appears faulty or incorrect, offer an explanation of the use, action, dose and potential side-effects of the drug or drugs involved.

8. Administer the drug as prescribed.

9. Offer a glass of water, if allowed.

10. Record the dose given electronically and / or in any other place made necessary by legal requirement or policy.

11. Administer medicines appropriately according to meal times (i.e. certain medicines are irritant unless given after food, some medicines interact with food).

12. Do not break a tablet unless it is scored and appropriate to do so. Break scored tablets with a tablet cutter. Wash cutter after use.

13. Do not interfere with time-release capsules and enteric coated tablets. Ask patients to swallow these whole and not to chew them.

## Guidelines for the Administration of Injections

1. Collect and check all equipment:

- Clean tray or receiver in which to place drug and equipment
- 21 G needle(s) to ease reconstitution and drawing up, 23 G if from a glass ampoule
- 21, 23 or 25 G needle, size dependent on rout of administration
- Syringe(s) of appropriate size for amount of drug to be given
- Swabs saturated with isopropyl alcohol 70%
- Sterile topical swab, if drug is presented in ampoule form
- Drug(s) to be administered
- Patient's prescription, to check dose, route etc
- Recording sheet or book as required by trust policy or law
- Any protective clothing required by policy

2. Check that the packaging of all equipment is intact.

3. Wash hands with bactericidal soap and water or bactericidal alcohol handrub.

4. Prepare needle(s), syringe(s) etc. on a tray or receiver.

5. Inspect all equipment.

6. Consult the patient's prescription and ascertain the following:

- Drug
- Dose
- Date and time of administration
- Route and method of administration
- Diluent as appropriate
- Validity of prescription
- Name of doctor

7. Check all details with another nurse.

8. Select the drug in the appropriate volume, dilution or dosage and check the expiry.

9. Proceed with the preparation of the drug, using protective clothing if advisable (see below for individual types of vials).

10. Evaluate the patient's knowledge of the medication being offered. If this knowledge appears to be faulty or incorrect, offer an explanation of the use, action, dose and potential side-effects of the drug or drugs involved.

11. Administer the drug as prescribed.

12. Record the administration on EPR.

***Single-dose ampoules***

As above but for preparation of the ampoule:

- Inspect the solution for cloudiness or particulate matter. If this is present, discard.
- Tap the neck of the ampoule gently.
- Snap the ampoule open. If there is any difficulty a file may be required.
- Inspect the solution for glass fragments; if present, discard.
- Withdraw the required amount of solution, tilting the ampoule if necessary.
- Replace the sheath on the needle and tap the syringe to dislodge any air bubbles. Expel air. (Replacing the sheath should not be confused with resheathing used needles, alternatively to expel the air use the ampoule or vial to receive any air).
- Change the needle, and discard used needle into appropriate sharps container.

***Single-dose ampoules: powder***

As above but for preparation of the ampoule:

- Tap the neck of the ampoule gently.
- Snap the ampoule open. If there is any difficulty a file may be required.
- Inject the correct diluent slowly into the powder within the ampoule.
- Agitate the ampoule.
- Inspect the contents.
- When the solution is clear withdraw the prescribed amount, tilting the ampoule if necessary.
- Replace the sheath on the needle and tap the syringe to dislodge any air bubbles. Expel air.
- Change the needle, discard the used needle into appropriate sharps container.

***Multi-dose vial – powder***

As above but for preparation of the ampoule:

- Clean the rubber cap with the chosen antiseptic and let it dry.
- Insert a 21 G needle into the cap to vent the bottle.
- Inject the correct diluent slowly into the powder within the ampoule.
- Remove the needle and the syringe.
- Place a sterile topical swab over the venting needle and shake to dissolve the powder.
- Inspect the solution for cloudiness or particulate matter. If this is present, discard.
- Clean the rubber cap with an appropriate antiseptic and let it dry.
- Withdraw the prescribed amount of solution, and inspect for pieces of rubber which may have “cored out” of the cap.
- Remove air from the syringe.
- Change the needle.
- Check the expiry date and storage instruction once reconstituted and annotate the ampoule accordingly.

***Multi-dose vial – liquid***

As above but for preparation of the ampoule:

- Clean the rubber cap with the chosen antiseptic and let it dry.
- Withdraw the prescribed amount of solution and inspect for pieces of rubber which may have “cored out” of the cap.
- Change the needle.

## Guidelines for the Administration of Intravenous Drugs by Intermittent Infusion

1. Obtain the following equipment:
   - Clean receiver or tray containing the prescribed drug to be administered
   - Patient’s prescription
   - Recording chart or book as required by policy, protective clothing
   - Container of appropriate intravenous infusion fluid
   - Swab saturated with isopropyl alcohol 70%
   - Drug additive label
   - Intravenous administration set and infusion stand
   - Clean dressing trolley and clean receiver or tray
   - Sterile needles and syringes
   - 20mL for injection of a compatible flush solution plus heparin if required
   - Sterile dressing pack and hypoallergenic tape

2. Before administering any prescribed drug, check that it is due and has not been given already. Check that the information contained on the prescription is complete, correct and legible.

3. Before administering any prescribed drug, check the following: drug, dose, date and time of administration, route and method of administration, diluent as appropriate, validity of prescription, name of doctor.

4. Wash hands with bactericidal soap and water or bactericidal hand rub.

5. Prepare the drug for administration as described above.

6. Check the name, strength and volume of intravenous fluid against the prescription.

7. Check the expiry date of the fluid.

8. Check that the packaging is intact and inspect the container and contents in a good light for cracks, puncture, air bubbles and check the fluid for discoloration, haziness and crystalline or particulate matter.

9. Check the identity and amount of drug to be added, consider: compatibility of fluid and additive, stability of mixture over the prescription time, any special directions for dilution e.g. pH, optimum concentration (refer to Parenteral Therapy Guide), sensitivity to external factors such as light, any anticipated allergic reactions. Obtain a second check if required.

10. Any additions must be made immediately before use.

11. Place infusion bag on flat surface and remove any seal present, cleaning the site with the swab and allowing it to dry.

12. Inject the drug using a new sterile needle into the bag, using a 23 G or 25 G needle.

13. Invert the container several times to ensure thorough mixing.

14. Check for haziness, discoloration and particles.

15. Complete the drug additive label and fix to the bag.

16. Place the container in a clean receptacle, wash hands and proceed to the patient.

17. Identify the patient as before, recheck the prescription and infusion bag, obtain a second check if required.

18. Check that the contents of the previous container have been delivered. Switch off the infusion and disconnect the empty infusion bag.

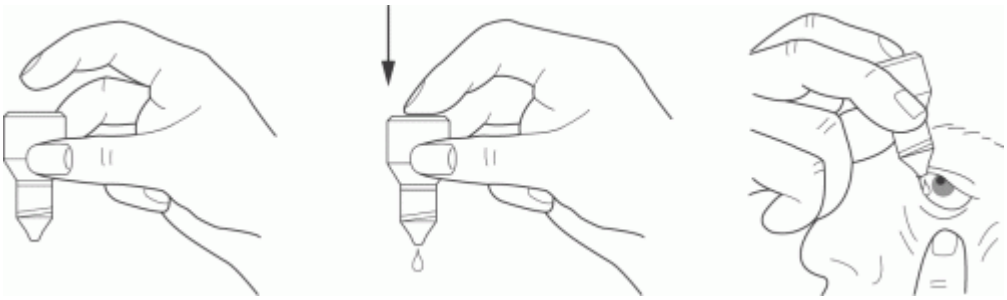
19. Spike the new bag without touching the spike and hang the bag on the infusion stand. Restart the infusion and adjust the flow rate if required. This should be checked by a second practitioner.

## Administration of Eye Drops and Ointment

Most types of drops are instilled into the upper rim of the inferior fornix (i.e. just inside the lower eyelid) (see Figure 1), as the conjunctiva in this area is less sensitive than that overlying the cornea. Also, the drops will run into the pocket of the inferior fornix preventing immediate loss of the drops into the nasolacrimal drainage system. Exceptions to this instillation technique are as follows:

- *Drugs used to lubricate the cornea*: oil-based drops produce less corneal reaction than aqueous ones as they do not feel as cold to the cornea when administered. They may therefore be instilled directly into the inferior fornix.
- *Anaesthetic drops:* the first drop should be instilled into the inferior fornix for absorption and then directly onto the cornea one drop at a time until the patient is no longer able to feel the drops.
- *Drops used to treat the nasal passages*: these drops should be instilled into the eye at the nasal canthus (nearest the nose) end of the eye.

**Figure 1** How to instil eye drops.



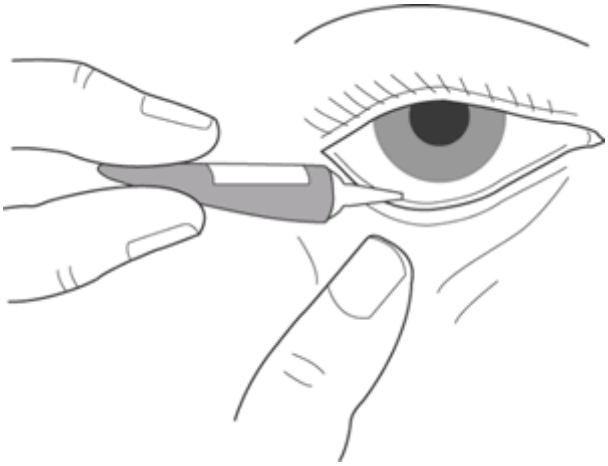
The number of drops instilled depends on the type of solution used and its purpose. Usually, one drop only is ordered and will be sufficient if it is instilled in the correct manner. The exceptions to the 'one-drop' rule are:

- *Oil-based solutions*: these are used for lubricating the eyeball. Usually one drop is instilled and repeated as required.
- *Anaesthetic drops*: it is usual to instil two or three drops at a time. This is repeated until the drop cannot be felt on the eye.

The dropper should be held as close to the eye as possible without touching either the lids or the cornea. This will avoid corneal damage and reduce the risk of cross-infection. If the drop falls from too great a height it is difficult to control and will also be uncomfortable for the patient. The eye should be closed for as long as possible after application, preferably for 1–2 minutes.

**Ointments** are also applied to the upper rim of the inferior fornix (i.e. just inside the lower eyelid) using a similar technique to eye drops (see Figure 2). A 2 cm line of ointment should be applied from the nasal canthus (nearest the nose) outwards. Similarly to the instillation of eye drops, the nozzle should be held approximately 2.5 cm above the eye to avoid contact with the cornea and eyelids.

**Figure 2** How to instil eye ointment.



## Administration of Enemas and Suppositories

Explain the procedure to the patient and gain their verbal consent. During either the administration of an enema or a suppository the patient's perianal region should be checked for abnormalities (including blood or pain) or for faecal loading.

### For Enemas

1. Obtain the following equipment: disposable incontinence pad, disposable gloves, topical swabs, lubricating jelly, enema and tube (usually contained within pack), bath thermometer.

2. Ensure privacy, allow patient to empty bladder if necessary and ensure that a bedpan, commode or toilet is available.

3. Warm the enema to the required temperature by immersing in a jug of hot water, testing with a bath thermometer (e.g. 40 to 43$^{O}$C is recommended).

4. Assist the patient to lie in the required position, i.e. on the left side with knees well flexed, the upper higher than the lower and with the buttocks near the edge of the bed.

5. Place a disposable incontinence pad beneath the patient's hips and buttocks.

6. Wash hands with bactericidal soap and water or bactericidal alcohol handrub, and put on disposable gloves.

7. Place some lubricating jelly on a topical swab and lubricate the nozzle of the enema or rectal tube.

8. Expel excessive air and introduce the nozzle or tube slowly into the anal canal while separating the buttocks. Slowly introduce the tube or nozzle to a depth of 10 to 12.5 cm.

9. If a retention enema is used introduce the fluid slowly and leave the patient in bed with the foot of the bed elevated by 45$^{O}$ for as long as prescribed. If an evacuant enema is used introduce the fluid slowly by rolling the pack from the bottom to the top to prevent backflow, until the pack is empty or the solution is completely finished.

10. Slowly withdraw the tube or nozzle. Clean and dry the patient's perianal area with a gauze swab.

11. Ask the patient to retain the enema for 10 to 15 minutes before evacuating the bowel.

12. Ensure that the patient has access to the nurse call system, is near to the bedpan, commode or toilet, and has adequate toilet paper.

13. Remove and dispose of equipment and wash hands.

**For Suppositories**

1. Obtain the following equipment: disposable incontinence pad, disposable gloves, topical swabs or tissues, lubricating jelly, suppository(ies).

2. If you are administering a medicated suppository, it is best to do so after the patient has emptied his / her bowels.

3. Ensure privacy and that a bed pan, commode or toilet is readily available.

4. Assist the patient to lie in the required position, i.e. on the left side with the knees flexed, the upper higher than the lower one, with the buttocks near the edge of the bed.

5. Place a disposable incontinence pad beneath the patient's hips and buttocks.

6. Wash hands with bactericidal soap and water or bactericidal alcohol handrub and put on gloves.

7. Place some lubricating jelly on the topical swab and lubricate the blunt end of the suppository (having removed it from its packet). Separate the patient's buttocks and insert the suppository blunt end first, advancing it for 2 to 4 cm. (Certain suppositories should be inserted pointed end first, check with the patient information leaflet contained with the suppositories). Repeat this procedure if a second suppository is to be inserted.

8. Once the suppository(ies) has been inserted, clean any excess lubricating jelly from the patient's perianal area.

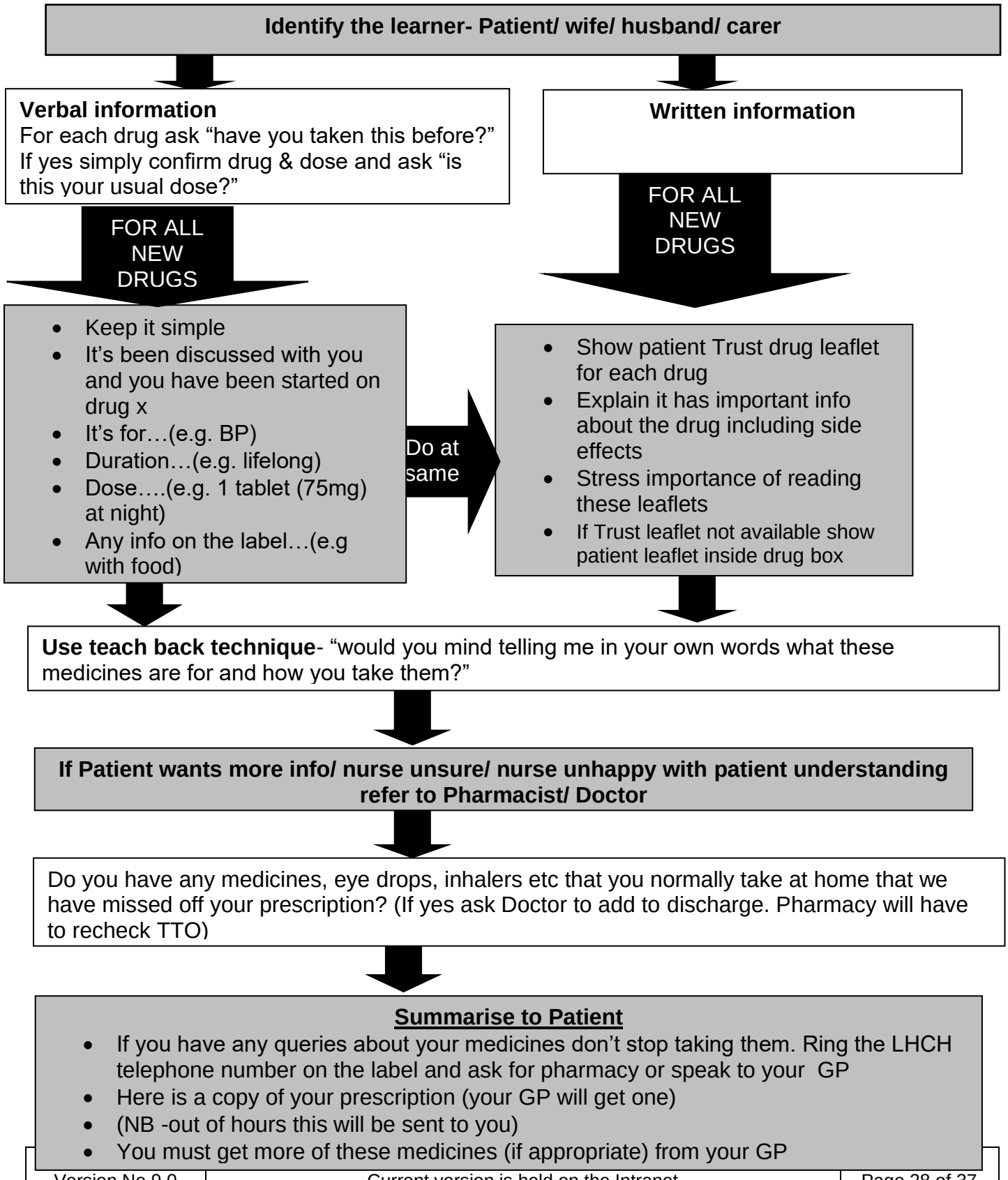
9. Ask the patient to retain the suppository for 20 minutes, or until he or she is no longer able to do so. If medicated suppository given remind the patient that its aim is not to stimulate evacuation and to retain suppository for at least 20 minutes or as long as possible.

Remove and dispose of equipment. Wash hands.

**Appendix 3**

**Discharge Drug Information Algorithm**

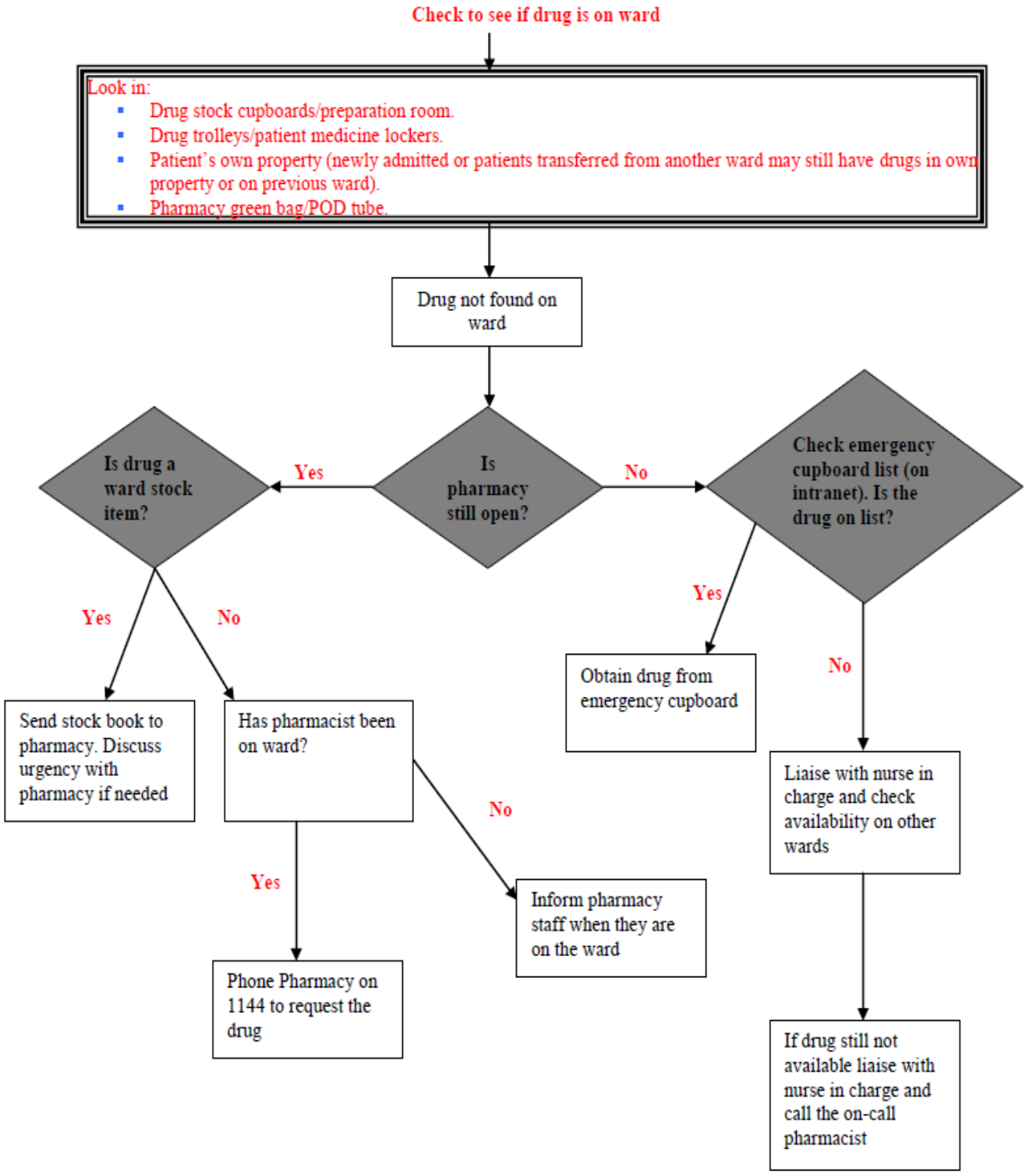
**NB** Any patient without support who appears confused or has other likely compliance problems should be referred to a pharmacist (within working hours)



## Appendix 4

### Action for the Apparent Non-availability of a Medication on the Ward

Before documenting that a drug is not available use the following protocol:



**Appendix 5**

**Process to administer medicines (except CDs) requiring a second (independent) check to suspected or positive COVID patients**

In order to minimise impact on nursing time and reduce excessive use of certain types of PPE, the following process should be followed when administering medicines (except CDs) requiring a second (independent) to a patient in a yellow or red area **AND** where FFP3 masks and full length arm gowns are required.

If the medicine stock is sited **within** the yellow or red area, follow normal Trust policy for administration.

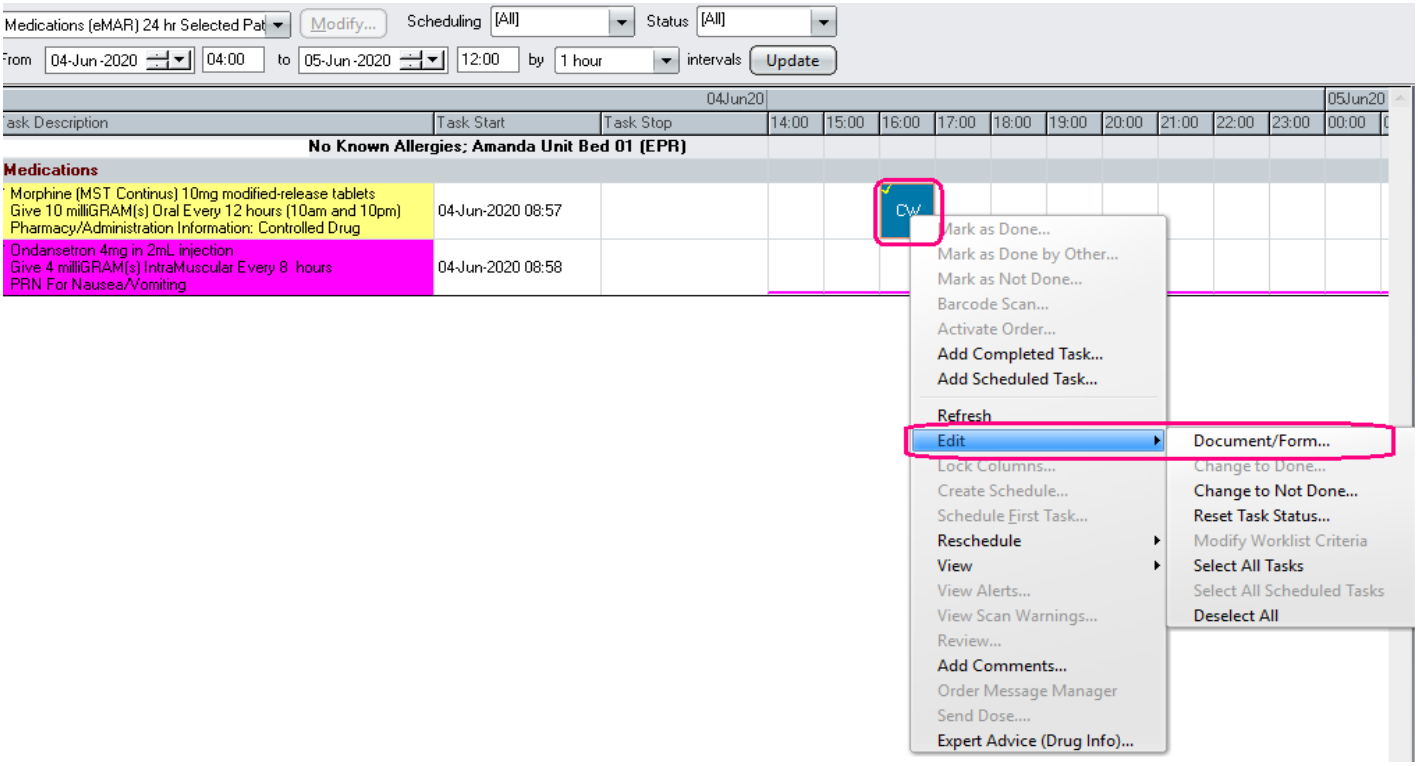
If the medicine stock is **not** sited within the yellow or red area the following procedure should be followed.

1. Nurse in infected area needs to administer a medicine (Nurse No1)
2. Nurse No1 phones colleague outside the area (Nurse No2) to request.
3. Nurse No2 reviews EPR work list manager and prepares/labels medicine.
4. Nurse No2 takes prepared medicine, together with any empty containers, to boundary of yellow or red area. Nurse No2 enables Nurse No1 to clearly identify prepared medicine and expiry date.
5. Nurse No1 takes medicine and administers to patient as per normal process. If working in a bay it is essential to remember to take the mobile cart to the bedside to ensure correct administration. If Nurse No1 **has another colleague** present in the yellow or red area, this person will provide the second signature on work list manager for administration if required i.e. pump requires to be programmed.
   If Nurse No1 is **working alone*** - they may sign work list manager for administration without the need for a second signature. In the second signature box they should enter the ward specific COVID username and password given by the EPR team.
   ****Extra care should be taken if the medicine requires a pump to be programmed as there will be no independent check performed**.**
6. Nurse No2 (who has prepared the medicine) must add a comment on worklist manager where nurse No1 has signed for the medicine (see screen shot below).
7. If Nurse No1 needs to administer a medicine that requires a second check that is **already** in the infected area e.g. insulin pen, the preparation should be checked by Nurse No2 at the yellow/red boundary

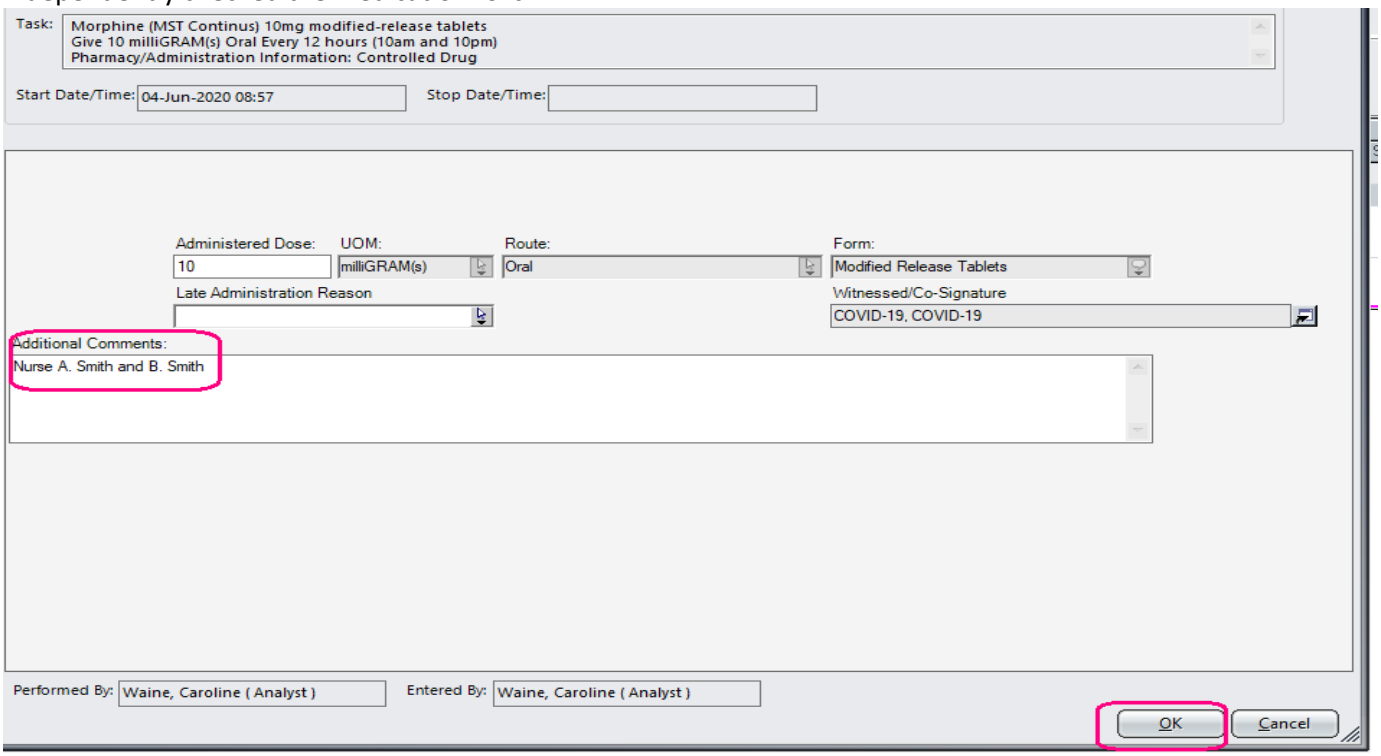
*Only applicable for areas requiring FFP3 mask/full gown.

How to add a comment on worklist manager for the above situation

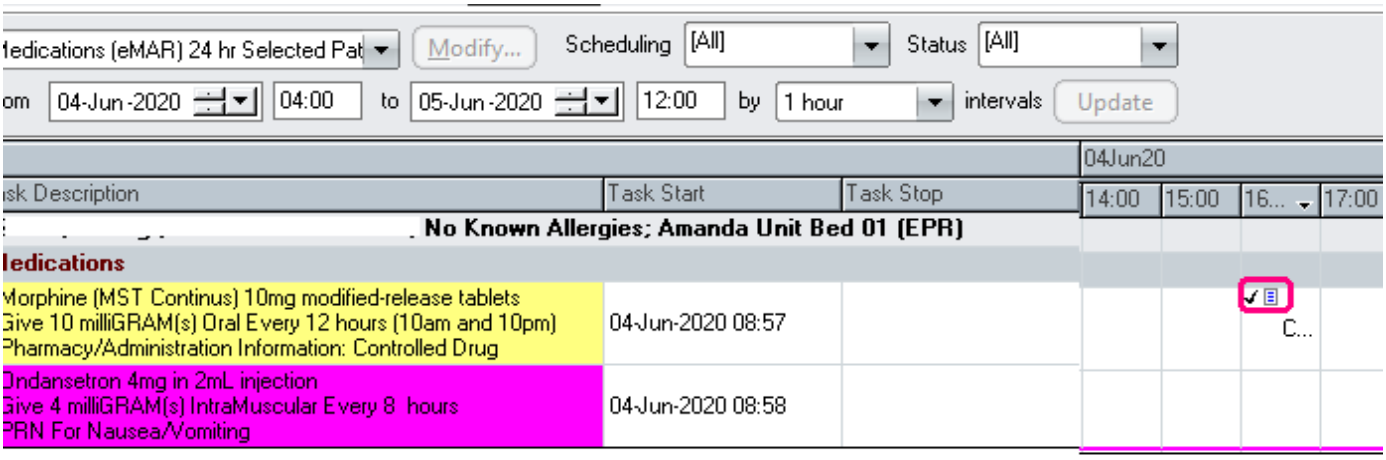
Right click on administered medication signature on Worklist Manager>Edit>Document/Form



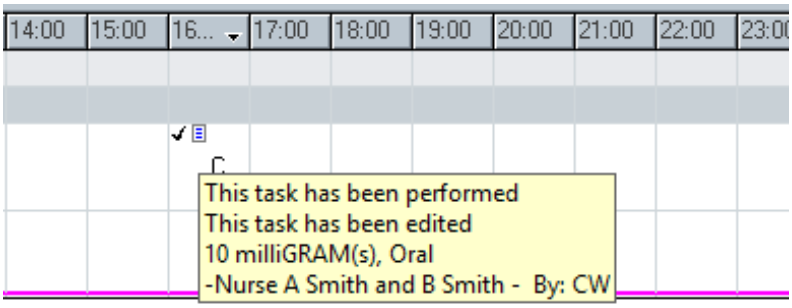

This will open the task form. In the additional comments field, enter the 2 nurses names that have checked and independently checked the medication>Click




A comments icon will now appear on the Worklist




By hovering over the icon, you will be able to see the information entered into the comments field:



**Appendix 6**

**Process to administer CDs to suspected or positive COVID patients**

In order to minimise impact on nursing time and reduce excessive use of certain types of PPE, the following process should be followed when administering CDs to a patient in a yellow or red area **AND** where FFP3 masks and full length arm gowns are required.

If the CD cupboard is sited **within** the yellow or red area, follow normal Trust policy for CD administration.

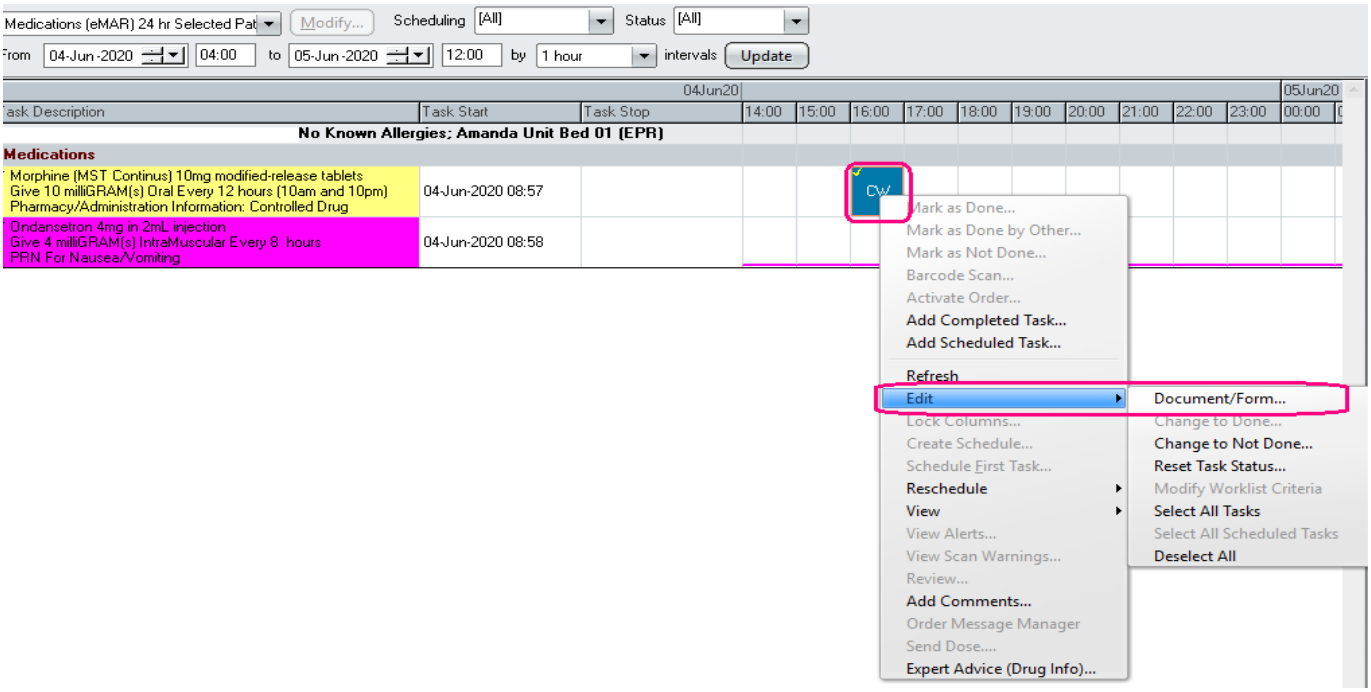
If the CD cupboard is **not** sited within the yellow or red area the following procedure should be followed.

1. Nurse in infected area needs to administer a CD (Nurse No1)
2. Nurse No1 phones colleague outside the area (Nurse No2) to request.
3. Nurse No2 reviews EPR work list manager alongside another colleague (nurse No3).
4. Nurses No2 and No3 follow standard process for removal of required CD from cupboard and register entry and balance checks.
5. Nurses No2 and No3 take register, CD and residual stock box to boundary of yellow or red area. Nurse No2 enables Nurse No1 to clearly identify CD to be administered and shows Nurse No1 register entry and residual stock remaining. Nurse No1 does not touch register or stock box.
6. Nurse No1 takes CD and administers to patient as per normal process.
   If Nurse No1 **has another colleague** present in the yellow or red area, this person will provide the second signature on work list manager for administration.
   If Nurse No1 is **working alone***- they may sign work list manager for administration without the need for a second signature. In the second signature box they should enter the ward specific COVID username and password given by the EPR team.
   ****Extra care should be taken if the medicine requires a pump to be programmed as there will be no independent check performed****.
7. Nurse No2 (who has prepared the medicine) must add a comment on worklist manager where nurse No1 has signed for the medicine (see screen shot below).
8. Nurses No2&3 take register and remaining CD stock back and secure as normal.
9. Nurse No1 **must** sign CD register as normal for any CDs administered during their shift when they exit the area at the next available opportunity (e.g. for a break)

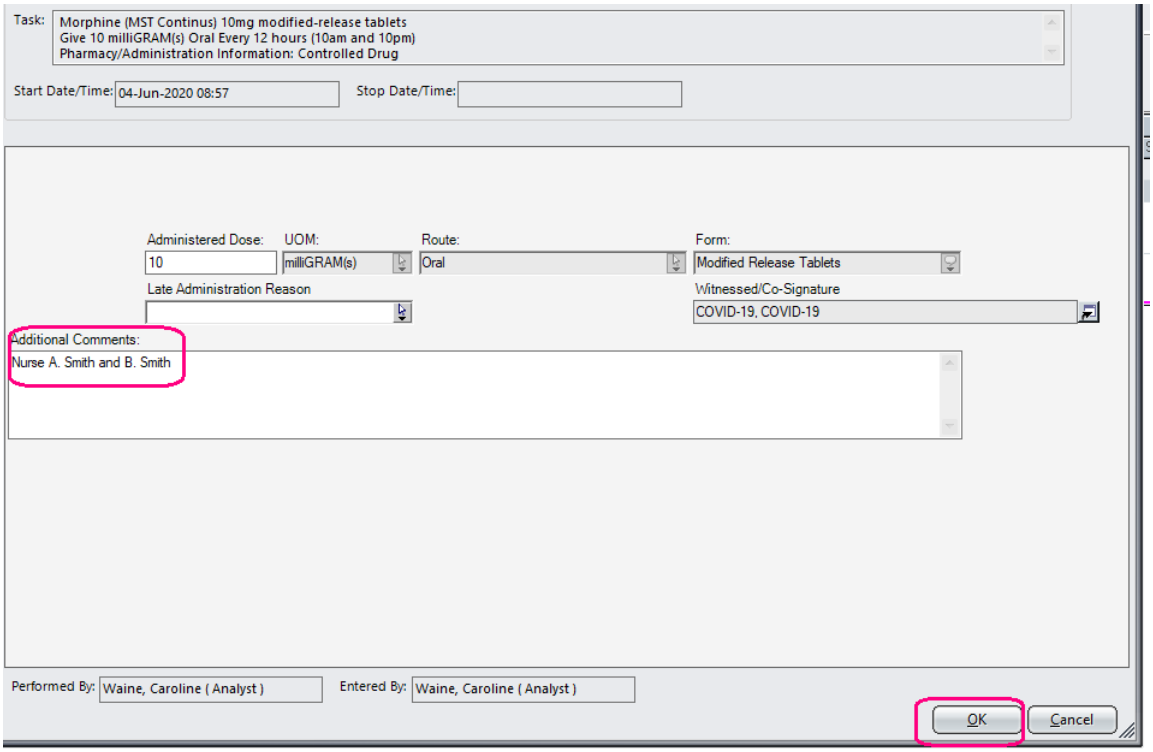
*Only applicable for areas requiring FFP3 mask/full gown.

How to add a comment on worklist manager for the above situation

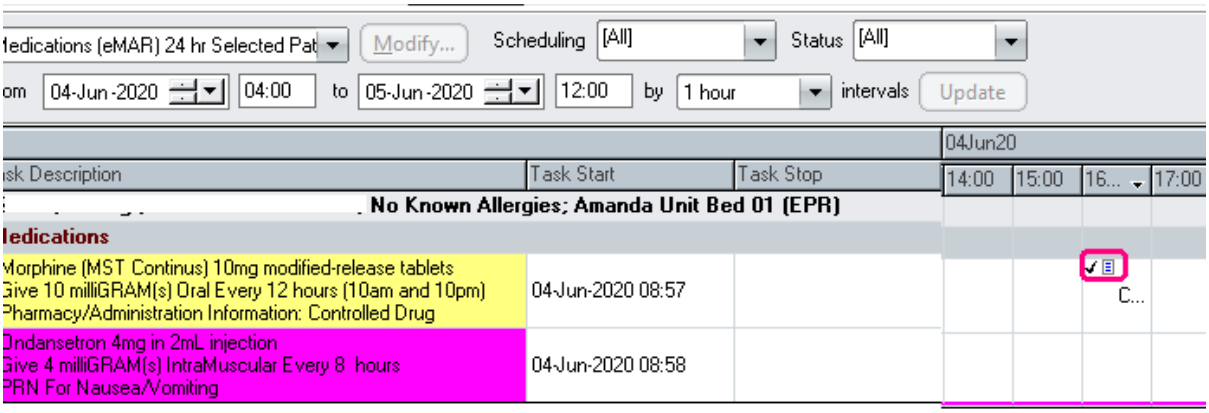
Right click on administered medication signature on Worklist Manager>Edit>Document/Form



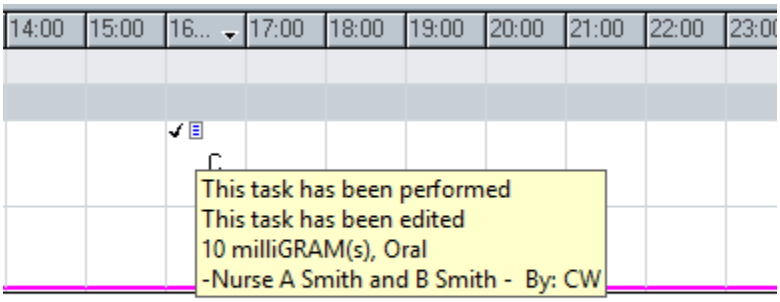

This will open the task form. In the additional comments field, enter the 2 nurses names that have checked and independently checked the medication>Click



A comments icon will now appear on the Worklist




By hovering over the icon, you will be able to see the information entered into the comments field:



## 8. Endorsed By:

| Name of Lead Clinician / Manager or Committee Chair | Position of Endorser or Name of Endorsing Committee | Date |
|---|---|---|
| Dr Nigel Scawn | Drug & Therapeutics Committee | 17/11/2021 |
| Dr Dennis Watt | Drug & Therapeutics Committee | 19/7/2023 |

## 9. Record of Changes

| Section No | Version No | Date of Change | Description of Amendment | Description of Deletion | Description of Addition | Reason |
|---|---|---|---|---|---|---|
| 3.1 | 7.0 | Nov 2021 | | | Reference to new KBMA (‘closed loop’) workflows | New process |
| 3.16 | 7.0 | Nov 2021 | | | Reference to new KBMA (‘closed loop’) workflows | New process |
| Appendix 2 | 7.0 | Nov 2021 | | | Reference to new KBMA (‘closed loop’) workflows | New process |

# Medicines

## Policy

| For completion by Author | | | |
|---|---|---|---|
| Author(s) Name and Title: | Danny Forrest, Chief Pharmacist | | |
| Scope: | Trust Wide | Classification: | Clinical |
| Version Number: | 20.1 | Original Review Date:<br>Extended Review Date: | 30/09/2023<br>30/09/2024 |
| Replaces: | V20.0 | | |
| To be read in conjunction with the following documents: | Safe Management of Controlled Drugs, Parenteral Therapy Policy, Medicines Administration Procedure, Non-Medical Prescribing Policy, Patient Group Directions Protocol, Antimicrobial Prescribing Policy, Anticoagulation Policy, Waste Disposal Policy, Enteral Feeding Policy and the LHCH Drug Formulary. | | |
| Document for public display: | Yes | | |
| Executive Lead | Dr Raph Perry, Medical Director | | |

| For completion by Approving Committee | | | |
|---|---|---|---|
| Equality Impact Analysis Completed: | | No | |
| Endorsement Completed: | Yes | Record of Changes | No |
| Authorised by: | Drug & Therapeutics Committee | Authorisation Date:<br>Extension Authorisation Date: | 16/11/2022<br>20/09/2023 |

| For completion by Document Control | | | | | |
|---|---|---|---|---|---|
| Unique ID No: | TC03(08) | Issue Status: | Approved | Issue Date: | 25/09/2023 |
| After this document is withdrawn from use it must be kept in archive for the lifetime of the Trust, plus 6 years. | | | | | |
| Archive: | Document Control | | Date Added to Archive: | | |

| | |
|---|---|
| Officer responsible for Archive: | Document Control Administrator |

**TABLE OF CONTENTS**

## INTRODUCTION

This Medicines Policy intended to be read by all individuals who deal with medicines within the Trust. The policy provides guidance on all aspects of medicines handling, including prescribing, ordering, storage and administration and, as such, constitutes an important element of the Trust's risk management strategy.

This policy applies to all staff who are required to prescribe or administer medicines in the course of their work, who are registered with a recognised professional body and/or where the prescribing or administration of medicines is within their agreed scope of practice (including temporary staff). These groups of staff include Nurses, Doctors, Dentists, Operating Department Assistants and Operating Department Practitioners, Dietitians, Occupational Therapists, Pharmacists, Physiotherapists, Podiatrists, Cardiac Radiographers, Cardiac Physiologists, Radiographers.. Medicines Management Training will be provided by pharmacy and nursing personnel to all groups of staff involved in the process. Compliance with various aspects of this policy will be audited according to an annual work-plan (see section 14).

This policy will be subject to annual revision and may be modified by local protocols which must be agreed by the Drug and Therapeutics Committee. Comments and suggestions should be directed to the Chief Pharmacist who is responsible for all aspects of Medicines Management within the Trust including statutory responsibility for ensuring compliance with current legislation.

## POLICY STATEMENT

All staff will follow the standard protocols and procedures detailed in this policy when dealing with medicines in order to ensure patient safety; providing a standard for the handling of medicines which can be audited. Prescribing and / or medicines administration may utilise a paper chart or the electronic system. The same standards apply to both systems.

NHS Improvement issued a revised list of "never events" in 2018, some of which involve medicines. Should a "never event" occur it must be reported via the trust's incident reporting system immediately. More detail is contained in Section 2.12.

### ROLES AND RESPONSIBILITIES

**The Medical Director** is accountable to the Trust board for the implementation of this policy.

**The Chief Pharmacist** is responsible for ensuring that the contents of the policy comply with current legislation.

**The Director of Nursing** is responsible for ensuring nurses are trained in the contents of this policy and demonstrate competencies in the fulfilment of their duties.

**All prescribing staff** (all grades of medical staff, non-medical prescribers and dietitians) must carry out their duties in line with the prescribing responsibilities section. For the purposes of this policy the term prescriber refers to Doctors, Dentists, Dietitians (although prescribing authorisation is limited to dietetic products only)., Non Medical Prescribers and Supplementary Prescribers (see separate policy relating to non-medical prescribing). Pharmacists who are not NMPs but hold a post grad diploma are authorised to transcribe discharge prescriptions (TTOs) as part of a multi-disciplinary team.
Medical students and unregistered locums do not have authority to prescribe. Registered prescribers can prescribe medicines, in accordance with the Medicines Act 1968, and controlled drugs, in accordance with the Misuse of Drugs Act 1971 and subsequent legislation (refer to Trust CD policy), but may not prescribe cocaine or diamorphine for addicts, unless licensed to do so. If addiction to controlled drugs is suspected, doctors are legally obliged to notify the Chief Medical Officer at the Home Office.

**Dietitians working within LHCH** are authorised to prescribe sip feeds, nasogastric feeds and dietary supplements (refer to the Enteral Administration of Nutritional feed and Medicine Policy).

**Nursing staff and other staff involved in the administration of medicines** must do so in accordance with the contents of this policy and the medicines administration procedure (see section 5).

**Ward Managers** are responsible for those duties detailed in section 4.1.

**Pharmacists** are responsible for those duties detailed in section 3.3.

All staff involved with medicines should report any incidents relating to prescribing, administration, dispensing, storage, theft etc via the Trusts datix system. These will be reviewed by the Safe Medicines Practice Committee.

## 1. PRESCRIBING STANDARDS

All prescribers are expected to adhere to the following minimum requirements when prescribing within LHCH. These requirements apply to both paper prescriptions (e.g. CD discharge prescriptions) and to electronic prescriptions. Specific requirements applicable to out-patient prescriptions are referred to in section 2.7

1.1 Medicines may be prescribed for patients using: -

Electronic Prescribing system (in EPR)
Out-patient prescriptions
Pathways in cath lab / theatre
CD Discharge prescriptions
Haemofiltration charts
Enteral feeding prescriptions
Private Prescriptions (OPD white prescriptions marked with “Private Prescription” in the top corner (for use during private consultations)

1.2 The patient’s name, address, date of birth, hospital number (or NHS number), ward (for in-patients) and the name of the consultant must be entered on the prescription. Once medication has been prescribed no alterations or additions to the patients’ details should occur unless to clarify details of the patient after discussion with the prescriber.. The patient’s allergy status, their weight and their height should also be entered within the electronic prescribing system or on the in-patient chart.

1.3 The name of the medicine (approved name) should be written legibly using block capitals (if written in ink). The approved name should be used wherever possible to avoid confusion, unless the product is a multi-ingredient preparation or where the proprietary name defines a specific formulation (e.g. diltiazem preparations or theophylline preparations).

1.4 The DATE on which treatment is to commence must be entered on the prescription, unless an outpatient prescription is being written, in which case the date of signing must be entered (out-patient prescriptions cannot be dispensed prior to this date, but a prescription can be POST dated if this is the intention).

1.5 The DOSE must be expressed in S.I. units. Quantities less than 1 gram must be written as e.g. milligrams and not as a proportion of a gram, for example 500mg not 0.5g so as to avoid confusion. Whenever a decimal point is necessary, great care must be exercised by both the prescriber and the individual administering the drug. The terms MICROGRAM, NANOGRAM and UNITS must not be abbreviated but must be printed in full.

1.6 Only the following abbreviations are acceptable:-

- mg - milligram
- g - gram
- kg - kilogram
- L - litre
- mL - millilitre
- mmol – millimole

1.7 ROUTE OF ADMINISTRATION
Only the following abbreviations are acceptable:

I.M. for intramuscular
INH. for inhalation

| | |
|---|---|
| I.V. | for intravenous |
| NEB. | for nebulised |
| P.O. | for oral |
| P.R. | for rectal |
| P.V. | for vaginal |
| S.C. | for subcutaneous |
| S.L. | for sublingual |
| TOP. | for topical |
| N.G. | for nasogastric |
| P.E.G. | for percutaneous endoscopic gastrostomy |
| N.J. | for nasojejunal |

Other routes of administration must be written in full.

1.8 DOSAGE FREQUENCY

For “as required” medicines the frequency of administration must be written by the prescriber. A maximum dose in 24 hours should be stated.

Pre-medication (before surgical procedures) should be given in accordance with consultant anaesthetist instructions and prescribed accordingly.

For “regular medicines” prescribing times should be in accordance with regular medicine rounds wherever possible. E.g. a 7 a.m. or midnight dose should only be ordered if there is a justifiable reason.

1.9 PRESCRIBER’S SIGNATURE

For electronic prescriptions the prescribers details will automatically appear. For OPD and CD prescriptions a full signature must be used and the prescribers name must also be printed.

1.10 DISCONTINUING MEDICINES (electronically)

Medicines must be discontinued by using the “discontinue order/ cancel” function on EPR

1.11 ALL MEDICINES must be written on the electronic prescription, including details of oxygen therapy Cross reference must be made to other charts in use e.g.

Dialysis fluid chart
Enteral feeding chart
Haemofiltration chart

1.12 PRESCRIBING BY TELEPHONE

In the interests of patient safety, prescriptions must not be given or accepted over the telephone, except in an emergency (since EPMA is accessible remotely). Two members of staff must hear the verbal order. The name/dose/route of drug and name of the witness must be recorded in an EPR nursing note by the member of staff administering the drug. The prescriber must prescribe the drug within 24 hours. The prescriber must subsequently ensure that the drug is not mistakenly administered for a second time.

Any emergency supply of drugs by pharmacy required in this scenario will be issued as a temporary stock.

1.13 VALIDITY OF PRESCRIPTIONS

Unless the course of treatment is clearly specified, the prescription will be considered valid until cancelled by the prescriber (see also Section 1.16).

For electronically prescribed antibiotics a stop date, or a review date, should be entered and a note added to the system that includes details of the infection, including specified duration or review date. . Infusions which are intended to be used within critical care areas only , must be discontinued when the patient leaves the critical care area

Prescriptions must be re-written if the patient is re-admitted or transferred from another hospital.

Prescriptions are only valid at the base hospital where originally written.

Prescriptions for controlled drugs should be reviewed regularly

1.14 PHARMACIST PRESCRIPTION AMENDMENT PROTOCOL (“PHARMACIST AMENDMENT PRESCRIBING”)

Pharmacists (with or without NMP status) may amend prescriptions in accordance with the protocol shown in Appendix 11 which has been approved by the Drug and Therapeutics Committee and all three divisional governance committees. It provides clear guidance as to the amendments that can be made to a prescription

without being an independent prescriber. This includes inpatient, outpatient and discharge prescriptions. It also aims to clarify, for other healthcare professionals, what is permitted practice for pharmacists within this Trust.

1.15 PRESCRIBING BY STAFF FOR THEMSELVES AND THEIR FAMILIES

- Medical prescribers should follow current GMC guidance*. Currently this is; Drs must avoid prescribing wherever possible for themselves or anyone with whom they have a close personal relationship. NMPs are not authorised to prescribe for themselves.
- Staff should attend Occupational Health or the Accident and Emergency Department of the Liverpool University Hospitals NHS Trust or refer to GMC guidance below. The current prescription charge will be payable if a prescription is issued. Alternatively, if deemed more appropriate, a consultant may prescribe an acute medicine for another member of staff to keep them in work e.g. salbutamol inhaler. Prescribing for chronic conditions should be avoided. This should be manage by a more appropriate prescriber e.g. GP.

*Current GMC guidance describes circumstances where there is exceptionality. This describes urgent situations and subsequent requirements for adequate documentation and communication.
https://www.gmc-uk.org/-/media/documents/Prescribing_guidance.pdf_59055247.pdf

1.16 RE-WRITING OF PRESCRIPTIONS
If a change in dose, frequency or route of administration is required, the whole prescription (for the drug affected) must be re-written and the original entry discontinued.

1.17 OTHER ENTRIES
Any information relating to drug hypersensitivity should be recorded by the prescriber in the allergies section of EPR. Information relating to renal or liver impairment, pregnancy or special diet should be recorded by the prescriber in the relevant section of the EPR record.

1.18 LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST FORMULARY
LHCH Drug Formularyis the approved list of medicines for use within the Trust. Products are approved by the Drug and Therapeutics Committee. . Any newly prescribed medicines, for which continuity of supply is required by GPs, will also align to Pan Mersey formulary recommendations. Medicines which are not listed in the Formulary may not be routinely available.

When prescribing medication, prescribers should refer to the Trust Formulary to determine appropriate selection of drugs. Newly prescribed items which are not included in the formulary will need a Consultant application and subsequent D&T approval before they can be used. New product request forms are available from the pharmacy department (see Appendix ONE).

If a patient is admitted on a non-formulary preparation which is not stocked by pharmacy, and if the patient's medication is not being altered and the treatment is appropriate, the pharmacy department will order a small supply to cover the requirements of that particular patient once their own supply is exhausted.

1.19 STORAGE OF PRESCRIPTIONS
Following discharge, the patient's electronic prescription record will be stored as part of the EPR system. Paper prescriptions e.g. CD discharge prescriptions will be scanned into EPR using the EDMS tab. A paper copy of dispensed prescriptions (TTOs, TTO CDs and OPD) will be held in pharmacy for the required length of time.

All controlled stationary will be held securely within pharmacy until required and ordered as per pharmacy SOP. This includes FP10, OPD and EPR BCP inpatient charts. In use pads will be kept secured in relevant locations e.g. OPD.

1.20 PRESCRIBING ERRORS
Prescribing errors should be reported via the trust's incident reporting system, regardless of whether the prescriber is a member of medical, nursing or pharmacy staff. All errors involving medicines (prescribing,

dispensing, administration or miscellaneous) reported via the Trust's datix system are reviewed at the Safe Medication Practice committee.

## 2. ORDERING AND SUPPLY OF MEDICINES

### 2.1 PURCHASING, STORAGE AND DISTRIBUTION OF MEDICINES

Medicines are unlike any other items of commerce and for this reason the purchase, storage and distribution should be under the control of a pharmacist. The Trust Standing Financial Instructions delegates the financial responsibility, within pre-set limits, for tenders and the signing of orders for medicines to the Chief Pharmacist who has procedures to ensure that legal and ethical requirements are met. Medical, nursing and other staff are not permitted to undertake contracting or tendering for, or purchasing of, medicinal products intended for administration to patients within the Trust. It is also unacceptable practice for representatives of pharmaceutical manufacturing companies to supply "samples" of medicines, dressings or devices to practitioners or leave such samples on wards / departments. All such requests or offers should be referred to the pharmacy department. Pharmaceutical Representatives within the trust must adhere to the code of practice stipulated by the Association of British Pharmaceutical Industry (ABPI) and must not make claims or suggestions to Trust staff without reference to a standing committee. Similarly promotion literature must not be provided by companies at sponsored events or to ward / department staff. New medicines must only be used within the Trust when purchased in the manner described above and when approved by the Trust's Drug and Therapeutic committee.

### 2.2 QUALITY OF PURCHASED MEDICINES

In NHS hospitals substitution of branded products with generic equivalent products, where available, is standard practice. The quality of medicines is of prime importance and is strictly controlled through the pharmaceutical drug contracts and purchasing procedures. New generic drugs are checked for quality prior to contract award and existing drugs are monitored throughout the period of contract, so that staff and patients can have complete confidence in their use. However if a problem arises as a result of poor quality it must be reported promptly to the pharmacy so that corrective action can be taken. A national pharmacy network exists for reporting and disseminating drug defects to ensure patient safety (see Section 2.12).

### 2.3 IN-PATIENT SUPPLY AND TRANSFERRING MEDICINES

Ward pharmacists will review inpatients on all wards at least once a day each week day. The ward pharmacist will be responsible for checking patients' prescriptions and arranging supplies of medicines for in-patient and take-home use. Supply will only be made against a valid prescription except in emergencies. The pharmacist will verify the medicine with their name and date indicating that they have professionally checked the prescription.

On the electronic system a dispensing note will be added to the drug indicating whether the patient has their own supply or whether a supply has been made from pharmacy. The electronic prescribing system ensures that information highlighted within their electronic record, regarding their drugs, stays with the patient's record on transfer to another clinical area and therefore is available for the new nursing staff and medical staff in the new clinical area.

Patients' own drugs may be used in hospital, but they must first be inspected by a pharmacist, pharmacy technician, nurse or member of the medical staff (see Section 8). Electronically, pharmacists will indicate if the patient has their own supply and this information will be visible on the electronic administration record (worklist manager).

All dispensed medicines will be labelled with the approved name of the preparation. Proprietary names will only be used when the proprietary name defines a specific formulation or combination (e.g. slow-release theophylline preparations).

When a patient is transferred, ALL their individually dispensed medication must be taken to the new ward i.e. all medicines labelled with the patient's name (whether dispensed at LHCH, a transferring hospital or the patient's community pharmacy). Medicines must be placed in a green plastic "patient's own medicines" bag. For patients going to theatre, the "patient's own medicines" bag must be sent with the patient to theatre so that their medicines arrive on the ward with the patient.

**In order to minimise cross contamination of drugs, the above process has been modified for suspected or positive COVID patients only. Refer to Appendix 12 for details.**

2.3.1 DAY WARD (Holly Suite

When a medicine needs to be administered to a patient, an electronic prescription should be completed for the patient in the usual manner. If the patient does not have their own supply a supply should be requested from pharmacy. Any Day Ward patient that requires their usual medicines during their visit may self-administer without the need for the usual consent process (Appendix 7)

New medicines for day ward patients to go home with will be prescribed using an Outpatient Prescription which should be sent down to pharmacy. An exception to this is for Day Ward acute coronary syndrome patients (ACS). These patients will have an electronic prescription and TTO completed in the usual manner.

2.3.2 DISCONTINUED MEDICINES

The ward pharmacist, nurse or pharmacy technician must remove patients' medication no longer required.from the patient's medicine locker/medicine trolley.

All medication should be returned to the pharmacy for destruction or reuse. Discontinued patient's own drugs, will be destroyed, once the patient has given consent (see Appendix SEVEN).

Hospital issued medication cannot be returned to stock if it has been taken outside the hospital.

Secure green bins are available on each ward. Unwanted medicines should be placed into these bins. Pharmacy staff will regularly empty these and return medicines to the pharmacy for either destruction or reuse.

**Amendment to process during COVID**

**In order to minimise cross contamination of drugs, the above process has been modified for suspected or positive COVID patients only. Refer to Appendix 12 for details.**

**Any medication returned to pharmacy from non COVID areas is quarantined for a period of 5 days in pharmacy before either being destroyed or returned to stock.**

2.3.3 RELABELLING OF MEDICINES

The instructions on the medicine label must always correspond to the dose and frequency prescribed on the drug chart and TTO. When a dose is altered, a new supply will be issued or the original supply will be relabelled by pharmacy

Patient's own drugs maybe relabelled as per pharmacy SOP. When this occurs, a label will be attached to the original container (allowing the original dispenser's name and address to remain visible), bearing the words 'Patient's own supply relabelled'.

2.4 TAKE-HOME MEDICINES (TTO)

Prescribers are responsible for ensuring that TTO prescriptions are prescribed, and the pharmacy department informed of such, in sufficient time for them to be dispensed and returned to the ward prior to the patient's discharge. This should ideally be 24 hours prior to discharge. The prescriber should ensure that all the medication that the patient is taking is included on the TTO and not just those required to be dispensed. The pharmacy team will annotate the TTO whether the item requires supply, has already been supplied to the ward or if the patient's own medicines are to be returned to the patient. A TTO for every inpatient discharged from LHCH should be seen by a pharmacist whether supplies of medication are required or not. This enables a professional check to take place and also completes the patient's medication history while an in-patient. A complete medication history enables queries from GPs following discharge to be handled efficiently. On the electronic prescribing system, information will automatically transfer onto the TTO if the prescriber or pharmacist,(during the prescribing or verification process), has indicated that a patient was admitted on a therapy which subsequently has been altered. Each patient will normally receive 28 days supply from pharmacy as an in-patient, ensuring a minimum of 14 days supply at discharge. Medicines should never be "dispensed" by nursing staff from stock supply for patients going home (see Section 2.4.1).

Medicines belonging to a patient (patients own) must never be shared with another patient. On no account must any item be added or any changes made to a TTO once it has been verified unless a pharmacist is informed. If any additions are made to the TTO then the pharmacy must be contacted to verify the amended

TTO. It is the responsibility of the prescriber to ensure all such alterations are communicated to the nursing team to ensure they do not discharge the patient with an older out of date TTO. This is particularly important when “last minute” changes are made to TTOs and nursing staff may have completed their “teachback” handover of the medicines to the patient. TTOs written outside pharmacy opening hours should still be verified by a pharmacist. TTOs which have not been verified by a pharmacist must not be printed.. TTOs may be transcribed by an appropriate pharmacist ( usually the transcription will take place as part of a multi-disciplinary ward round). For those patients who need to stay overnight but for whom there have been no changes to their medication (and no supply made from the Trust), a discharge summary stating “no change to medication” can be prepared. In order for this information to be shared electronically with the GP, a pharmacist will still need to verify this discharge summary.

Day case patients

These patients are not entitled to a TTO. Such patients should have a “day case summary document” completed. Any newly prescribed medicines requiring supply should be written on an OPD prescription as described previously.

Patients self-discharging or unwilling to wait for TTOs

It is essential for patients self-discharging against medical advice or unwilling to wait for TTO medication to still have a TTO completed so that the patient’s GP is fully informed. This will include any relevant medical, nursing and pharmacy information relating to the patient, with particular emphasis on any associated risk and need for follow up, where possible.

Any medication required should be provided where possible. If the pharmacist has any concern regarding the safe supply of any particular medicines this should be discussed with the prescriber for further review. If the patient refuses to wait for TTO medication then all reasonable steps must be taken to ensure the patient receives it e.g. relatives or patient may return later in the day/following day to collect. In order to facilitate this scenario, staff should seek to administer medication due later in the day earlier than prescribed, if safe to do so.

Out of hours, the on call pharmacist should use their discretion regarding having to come into the hospital to supply medicines. Generally, this should be minimal since the pharmacy “labels for discharge” on wards and also has a number of commonly used medicines available as TTO packs. If this is not possible, further supplies of any non critical medicines should be obtained from the patient’s GP/chemist.

The pharmacist should ensure any critical medicines (anticoagulants, antiplatelets, medicines for epilepsy/parkinsons disease, antibiotics etc) are either supplied by themselves on the TTO or an arrangement is made so that the patient will not miss any doses (e.g. patient/relative to collect TTO later or assurance patient can obtain supplies from GP without delay)

All staff should ensure appropriate documentation within EPR

2.4.1 PRE-PACKAGED MEDICATION

Certain Pre-packed medicines are available which are over-labelled with directions for discharge e.g. Nystatin mouthwash (30mL), Salbutamol inhalers and Glyceryl Trinitrate sprays.. Pre-packed medicines are available in the Emergency Cupboard and on authorised Ward areas. In all cases a registered nurse must check the TTO against the label ensuring all details match and any blank dose instructions are completed where required including the patient’s details and date of issue. Standard operating procedures are in place where ward TTO cupboards are in operation. When issued to a patient the pre-pack must be recorded in the pre-pack issue record form and the details completed by an authorised individual issuing the pre-pack. A second authorised individual must witness issue of a pre-pack and sign the record form accordingly. These pre-packs may then be issued to the patient against a completed Prescription.

2.5 USE OF UNLICENSED MEDICINES (see Appendix SIX)

Prescribers should always prescribe licensed products with licensed indications wherever possible. However, this may not always be possible if such a product is not available in the UK (either permanently or temporarily).

Therefore, a consultant may authorise the prescribing of an unlicensed drug.. To commence prescribing of a new unlicensed medicine within the Trust, an unlicensed medicine request form should be completed which is available from the pharmacy department (see Appendix SIX). This will subsequently be reviewed by D&T Committee for approval. A record of receipt and quality control of such medication will be kept in the pharmacy department. These medicines, and their usage figures, will be reviewed annually by the Drug and Therapeutics Committee.

2.5.1 USE OF LICENSED MEDICINES FOR UNLICENSED INDICATIONS ("off label")
When a licensed medicine is prescribed for an unlicensed indication, the prescriber is professionally accountable for his/her judgement in so doing and he/she may be called upon to justify his/her actions e.g. it may be appropriate to prescribe off label because a particular licensed route of administration is unavailable.

2.6 CONTAINERS
Pharmacy does not re-use plastic or glass bottles. When empty, plastic bottles may be disposed of in black rubbish bags. Liquids may be returned to pharmacy. Glass bottles, when empty, may be disposed of in the grey sacks in glass bins. Child-resistant containers (CRCs) are used routinely on discharge items for any medicines not prepacked into blisters.. If a member of staff feels that CRCs would be difficult for the patient to open, plain tops will be fitted at the pharmacists discretion. The likelihood of children coming into contact with the medicines should be considered.

2.7 OUT-PATIENT PRESCRIPTIONS
The requirements for out-patient prescriptions are generally the same as in section 1 – Prescribing. A minimum of 28 days' supply will be dispensed unless circumstances dictate that a larger supply is necessary. Exceptions include:

- Hospital only medicines – these cannot be prescribed by General Practitioners
- Clinical trial medicines
- Pulsed / cyclical treatment
- Reducing doses of drugs e.g. steroids
- Drugs for tuberculosis treatment, cystic fibrosis and oncology
- Courses of antibiotics

2.8 DELIVERY OF DRUGS
Pharmacy Assistants will deliver medicines to wards and departments at specified times throughout the day in sealed bags and boxes which should be emptied completely **in a timely fashion** and the medicines stored securely and appropriately on the ward as soon as possible after receipt.

2.9 TOPPING-UP MEDICINES
Many medicines will be held as stock on the wards. A master ward stock list is held on the intranet (see under pharmacy green cross). Ward/Department managers may request changes at any time following consultation with the ward/department pharmacist or technician.
Technicians (or Pharmacy Assistants for stock items) visit wards and departments weekly to top-up stock items and named patient individual items. It will be necessary for ward staff to put stock and non-stock items away in the appropriate place. Named patient individual items should be carefully checked before being placed in individual patients' lockers/ward trolleys.

2.10 MEDICINES REQUIRED OUT OF HOURS
Out of hours, medicines may be obtained from the Pharmacy Emergency Cupboard, located outside the pharmacy entrance (see Appendix TWO).
A copy of the Emergency Cupboard stock list is available on the intranet (see under pharmacy green cross). If a product is unavailable from the Emergency Cupboard it may be borrowed from another ward (see under pharmacy green cross on intranet for stock available on wards). If still unavailable, the doctor or nurse in charge should contact the on-call pharmacist via switchboard.

2.11 DRUG INCIDENTS OR ERRORS
A drug incident is typically defined as any incident involving medicines that has caused or may cause harm (generally this includes prescribing, dispensing, administration but may include others). Other incidents may include breach of Trust policy/procedure e.g. safe storage, breach of legislation e.g. CDs, device failure (e.g. syringe pumps) etc.. The Trust's Incident Monitoring System should be used to report any drug errors or

incidents involving medication. If a drug incident occurs the following people should be informed as soon as possible:

a) The ward manager or nurse in charge of the ward or department,
b) The doctor concerned if inappropriate administration or prescribing of a drug has occurred,
c) The senior nursing officer on duty or on-call (if deemed serious e.g. major patient harm/CD theft),
d) The ward pharmacist
e) The on-call pharmacist (if deemed serious and cannot wait until next working day).
f) The Chief pharmacist or deputy pharmacist (if deemed serious e.g. major patient harm/CD theft)

NHS improvement issued a revised list of "never events" for 2018. Should a "never event" occur it must be reported via the trust's incident reporting system immediately. The "never events" involving medicines have been incorporated into the relevant clinical policies, which are detailed below:

- Mis-selection of a strong potassium containing solution, for example, when a patient intravenously receives a strong potassium solution rather than intended different medication (Parenteral therapy policy)
- Wrong route administration of medication , for example, the patient receives one of the following:
  oral / enteral medication, or feed / flush, administered via the parenteral route(Medicines policy),Intravenous administration of an epidural medicine not intended to be administered by the IV route( the acute pain policy and sedation policy and parenteral therapy policy),
  i/v chemotherapy via the intrathecal route
- Overdose of insulin due to abbreviations or incorrect device – (the insulin / diabetes policy)
- Mis-selection of strength midazolam during conscious sedation – (the sedation policy)
- Unintentional connection of a patient requiring oxygen to an air flowmeter

Overdose of methotrexate for non cancer treatment- patient is given a dose, by any route, for non cancer treatment that is more than the intended weekly dose.

2.12 DRUG DEFECT REPORTING PROCEDURE

Health Service Guidelines HSG (93) 13 requires Chief Executives to ensure prompt reporting of adverse incidents, reactions and defective products relating to medical products. In response to these guidelines Regional Quality Control has developed an efficient system for the dissemination of hazard / recall notices issued by the Medicines and Healthcare products Regulatory Agency (MHRA) and a procedure for assessment of defects arising in hospitals. The pharmacy department maintains an up to date copy of the procedure. All drug defects should be reported, as soon as practicable, to the Pharmacy Department.

2.13 SEPSIS PACKS

Sepsis packs are kept on wards and when used must be returned to pharmacy. The pharmacy department will replenish the packs. Extra packs are stored in the emergency cupboard.

2.14 EXTRAVASATION KITS

Extravasation kits are available in the emergency cupboard. The extravasation kit may be used in accordance with the parenteral therapy policy.

2.15 ANAPHYLAXIS KITS

Anaphylaxis kits are available within cardiac arrest boxes (or separately in critical care areas)

2.16 EMERGENCY CPR BOXES (RESUS BOXES)

When opened, emergency boxes should be returned to pharmacy as soon as possible and a replacement obtained. Out of hours, replacements are available from the Emergency Cupboard located adjacent to the pharmacy department.

The number of emergency boxes and secondary boxes available in each area is at the discretion of the Ward/Department Manager and the Resuscitation Training Officer by prior agreement with pharmacy.

## 3. PHARMACY SERVICES

The pharmacy department at LHCH aims to provide a comprehensive, cost-effective and high quality service ensuring that all patients receive the correct drug at the correct dose at the correct time. The department

maintains standards by ensuring its internal standard operating procedures are adhered to at all times and are updated and audited regularly.

3.1 PHARMACY SERVICE

The pharmacy department is open from 9.00 a.m. until 5.00 p.m. on weekdays and from 9.00 a.m. until 2 p.m. Saturdays. Advice on any aspect of pharmacy services, medication policy or medicine use can be obtained during working hours from either the dispensary or from ward pharmacists. Outside these hours an on-call pharmacist is available at all times via switchboard.

3.2 GRADES OF PHARMACY STAFF WORKING ON WARDS

Pharmacists complete an honours degree course or a masters degree course plus a one year period of pre-registration experience before they qualify and register as Members of the General Pharmaceutical Council of Great Britain (GPhC). Pharmacists may also be members of the Royal Pharmaceutical Society of Great Britain and are therefore entitled to use the post-nominals MRPharmS. In addition, many pharmacists have, or are studying towards, further qualifications such as MSc or Diploma in Clinical Pharmacy.

Pharmacy technicians complete a two-year BTEC and NVQ level 3 course before they qualify.
Pharmacy Assistants are required by the Royal Pharmaceutical Society of Great Britain / General Pharmaceutical Council to complete an NVQ level two qualification.

3.3 CLINICAL SERVICES (PHARMACY PROCESS)

- Pharmacists visit all wards within LHCH at least once every week day.. Apart from ordering new non-stock items and checking patients' own medicines they monitor prescriptions for safety, appropriateness and compliance with the formulary.
  Dispensary based pharmacists will carry out a clinical check prior to supply of any items which are requested by wards during pharmacy opening hours. Pharmacists will provide medicines information if needed and will advise on all aspects of medicine use, supply and storage on the wards.
- Drug Information; a limited service is provided on site however more extensive queries can be referred by the pharmacists to the Regional Drug Information Service. The department should be contacted with any Drug Information enquiries.
- Poisoning; these queries should be referred immediately to the poisons centres listed in the BNF, e.g. Birmingham.
- Adverse Drug Reaction Monitoring (yellow card reporting); The yellow card scheme is the UK system for collecting and monitoring information on safety concerns involving medicines or devices. It is controlled by the MHRA. Any health care professional can complete a yellow card. This can be done via paper (back of BNF) or more commonly on line- see intranet pharmacy/green cross /www.mhra.gov.uk/yellow card.
- Aseptic preparation and Parenteral Nutrition (see Section 7).
- Cytotoxic Drugs; cytotoxic drugs for use within LHCH are currently prepared at LUHFT under strict aseptic conditions. Cytotoxic drugs may present a hazard to the person handling them.
  Guidelines for the safe handling of cytotoxic drugs are located in the COSHH file in the relevant wards or departments (see Section 11 and appendix 10). Patients requiring cytotoxic therapy are usually re-patriated to their referring hospital to have their therapy administered.
- Wound Management; contact the Tissue Viability Nurse (available wound management products are listed within the drug formulary).
- Therapeutic Drug Level Monitoring; if help or advice is needed with the monitoring and dosing of drugs such as gentamicin, theophylline or digoxin contact the ward pharmacist.
- Patient Counselling and Education; patients' understanding of the drugs they are given should be checked prior to discharge. Pharmacists may be requested to counsel patients which may highlight any potential problems and may improve compliance. Several devices are available in pharmacy which may aid compliance.
- All patients newly commenced on anticoagulation for discharge will be counselled by a pharmacist or technician.
- Identification of Medicines; Pharmacists are available to identify medicines brought in to hospital by patients if there is any doubt as to their composition. Formulary; the Trust's formulary is available on the intranet. This should be referred to when commencing new therapy.
- Clinical Trials; the medication aspects of clinical trials are managed within pharmacy, all trials involving drugs must be discussed with pharmacy prior to initiation.
- Use of unlicensed medicines (see Appendix SIX)
- Pharmacist clinical interventions are audited monthly via pharmacy EPR documents.

- A limited number of pharmacists are authorised to undertake a medicine transcribing role to produce discharge prescriptions (TTOs – to take out) as part of a multi-disciplinary team
- A number of pharmacists hold NMP status and will prescribe new therapy for patients or continuation prescribing (mainly correcting prescribing omissions/errors on admission).

3.4 DISPENSING ERRORS

Dispensing errors should be reported via the trust's incident reporting system. In addition, dispensing and checking errors are also captured as "near misses" and reported i.e. at the pharmacy checking stage before they leave the department. All errors involving medicines (prescribing, dispensing, administration or miscellaneous) reported via the Trust's incident reporting mechanisms are reviewed at the weekly MDT and the monthly safe medication practice committee.

## 4. STORAGE OF MEDICINES ON WARDS AND NURSE RESPONSIBILITIES

4.1 RESPONSIBILITIES OF WARD MANAGERS

The ward manager is responsible for ensuring that all medicines are stored securely and that only authorised staff have access to them and that keys are passed only to authorised staff as appropriate. Particular attention should be paid to medicines stored on resuscitation trolleys and in treatment rooms. The keys to the cupboard(s), fridge(s), trolley(s) etc. are to be held by a registered nurse on each ward. The controlled drugs key should be kept on a separate bunch. Whilst a nurse is in charge of a ward or department he or she is responsible for all the medicines on the ward. In the event of any discrepancies or apparent loss, a pharmacist should be informed. If a nurse takes a key home, every effort must be made to retrieve it as soon as possible. If a master key or drug trolley key cannot be found, all cabinet locks or trolley locks must be changed. The ward staff together with the estates department will arrange the procurement of the locks and installation. This cost will be borne by the ward, unless a member of the pharmacy staff is involved with the loss of the key, in which case the cost will be borne by the pharmacy. If an individual cabinet key is lost, then only that lock need be changed. Medicines should be stored securely in the appropriate location on wards. These cupboards should only be used for the storage of medicines and for no other purpose. All storage areas should be locked/secured appropriately.The Emergency Drugs (CPR) box should be accessible at all times for quick retrieval.

4.2 SELF-ADMINISTRATION CABINETS AND LOCKABLE DRAWER TROLLEYS

On wards, medicine supplies for patients will be kept in locked medication cabinets next to the patient's bed. All medication cabinets will be attached to the wall. Each cabinet will have an individual key and a master key. A maximum of 4 master keys will be available per ward. This will enable different nursing teams to administer drugs concurrently. Where practical, the ward pharmacist will possess a master key. Master keys must be accounted for at the beginning of each shift. Individual cabinet keys, if not in use, can be kept inside the appropriate key cabinet.

Stock medicine supplies for patients will be kept either in main store cabinets or mobile carts/trolleys. These will be attached to the wall at all times other than drug administration rounds. Each cart/trolley will have an individual key or electronic locking code.

4.3 CONTROLLED DRUG STORAGE

At quarterly intervals the pharmacists are required to check on the storage, security and records for any controlled drugs kept at ward level (see section 6.6). Storage of Controlled Drugs is covered in detail in the Safe Management of controlled Drugs Policy.

4.4 MEDICINES REFRIGERATOR

Medicines marked "Store in Refrigerator" must be stored between 2-8$^{o}$C. The fridge should be defrosted regularly, kept locked and reported to the estates department if the temperature indicates a fault. No food or drink (other than TPN) should be stored in the medicines fridge. A daily temperature log is maintained for each ward remotely within the pharmacy department (the system records the temperature of fridges and ambulatory storage areas). Deviations are reported to the ward manager and ward pharmacist at the earliest opportunity. Vaccines requiring refrigeration must be kept under strict temperature control. Only authorised personnel within the Trust may store vaccines, the pharmacy department's standard operating procedure for vaccines is available with more details. Any temperature deviation outside of 2-8 $^{o}$C may have an impact on

the quality of medicines depending on the drug, degree of excursion and length of time. Pharmacy advice must be sought before use in such circumstances.

4.5 EPIDURAL INFUSIONS
Epidural infusions must be stored separately from other medication. If the epidural is a controlled drug then this must be stored in a controlled drug cupboard or fridge which does not contain other controlled drug infusions (see section 6.6).

**5. ADMINISTRATION OF MEDICINES (also refer to Medicines Administration Procedure)**

5.1 PRESCRIPTION CLARITY
No medication should be administered to a patient if a prescription is ambiguous or there is any doubt about appropriateness, safety etc. If the prescription is in any way unclear, illegible, or not complete as detailed in this policy, the member of staff administering the drug should draw the prescriber's attention to this fact. who should re-write the prescription or administer the medicine personally. If the prescriber refuses to re-write the prescription, the dose must not be administered and the member of staff administering the medicine should contact his or her manager, or a more senior member of medical staff. The therapeutic uses of the medicines, its normal dosage, side effects, precautions and contra-indications should be known by the person administering the medicine.

5.2 INDIVIDUAL PATIENTS' MEDICINES
All medicines for individual patients are labelled by the pharmacy department (unless brought in from home-patient's own drugs). . If there is any doubt about the identity or quality of a medicine in a container, a pharmacist should be contacted and the medicine should not be administered. Never add extra tablets to a bottle or box to "tidy up", keep in the original container.

5.3 ADMINISTRATION PROCESS (this section is expanded upon within the medicines administration procedure ).
Before administration the patients' identity and allergy status should be confirmed with the patient's identity and allergy band and then checked against the prescription. Ensure that the patient is not allergic to the medicines before administration. Any concerns should be highlighted to a prescriber in a timely manner. The name, strength and expiry date of the medicine (where available), dose to be given, route and time of administration should be checked. The dose should then be administered, and the electronic medication administration record (worklist manager) should be completed accurately and immediately.

5.4 Medicines should not be left on patient's lockers.

5.5 All intravenous injections must be administered separately from the routine oral medicine round (refer to parenteral therapy policy and below)

5.6 NON-ADMINISTRATION
If any doses of a medicine are not given then the prescriber responsible for the patient must be informed and EPR annotated accordingly. Where drugs are not available on the ward it may be necessary to:

- Inform pharmacy, during pharmacy opening hours, and ask for a supply to be made
- Use the pharmacy emergency cupboard (outside of pharmacy opening hours)
- Borrow the medicine from another ward (outside of pharmacy opening hours)

- Contact the on-call pharmacist for supplies (outside of pharmacy opening hours).

This process is summarised as Appendix Nine, a laminated version of which is available on every ward in their treatment room.
Any medicine at LHCH may be considered to be essential dependent upon the circumstances and condition of the patient, therefore it is imperative that action is taken to avoid omitting any medicine. A member of the medical team should be informed if administration is not possible to discuss what steps should be taken to obtain the drug or whether an alternative should be prescribed instead.

Special consideration should be given to and appropriate action taken for medicines where a delay in administration may cause harm to patients e.g. medicines used to treat Parkinson's disease or Epilepsy, Intravenous antibiotics etc.

5.7 SINGLE-PRACTITIONER ADMINISTRATION AND MEDICINES REQUIRING AN INDEPENDENT CHECK (refer to medicines administration policy for details)
In most circumstances medicines may be administered without the need for an independent check. However this does not apply to:-

- Controlled drugs (please refer to Trust policy on Safe Management of Controlled Drugs)
- Where the dose has to be calculated
- Where the dose is weight related e.g. mg/kg or obtained from a weight / dosing chart
- Subcutaneous insulin (Exception- nursing staff caring for patients self-medicating insulin (see appendix 7c) do not need to obtain a second nurse signature for administration. The patient will provide this check.
- All intravenous medication (including bolus or infusion) unless being administered by the prescriber

In these circumstances both the **preparation** and the **prescription** must be checked by a second practitioner (refer to the Trust procedure on Medicines Administration). In addition, the independent checker must witness the actual **administration** of controlled drugs and programming of pumps for intravenous infusions that require the use of an infusion pump.

**Amendment to process during COVID**

**In order to minimise cross contamination of drugs and reduce excessive use of PPE, the above process has been modified for suspected or positive COVID patients only. Refer to medicines administration policy for details.**

Defining the independent second checking process:

The primary administrator and the second checker should clearly understand their remit in the process. The two roles assume equal responsibility for the preparation and administration, but the primary administrator is responsible for checking the clinical appropriateness of the medicine.
The second person i.e. the checker can be an RGN, doctor, pharmacist or registered Operating Department Practitioners (ODP). In addition other healthcare personnel who have received training and have been assessed as competent to check controlled drugs can perform the second check

The additional benefits of a second checker are only evident if the check is **independent.** This means:

- The second member of staff checks **all** of the particulars relating to preparation and administration themselves.
  -Is the prescription for the correct patient?
  -Does the product match the prescription?
  -Is the product being administered to the correct patient?
- **None of the particulars are verbalised**. Being asked to check an infusion of X increases the likelihood of the second staff member seeing X when it is actually Y
- The second staff member is responsible for witnessing the correct preparation and administration to the correct patient (see medicines administration policy)

Both the initial checker and the independent checker should confirm that they have selected the:

- Right patient (confirm allergy status)
- Right medicine and formulation
- Right dose (all calculation should be checked independently)
- Right route
- Right time

See Appendix EIGHT for administration of medicines by student nurses/other staff.

5.8 ADMINISTRATION OF MEDICINES WITHOUT A PRESCRIPTION
Under normal circumstances medication should not be administered to a patient in the absence of a valid written prescription. There are currently some exceptions:

a) Patient Group Directions – Certain named healthcare professionals, following training, may administer medicines under group protocols which have been approved by the Drug and Therapeutics Committee (see Appendix THREE and the patient group direction protocol)
b) In an emergency, a drug may be given on the verbal instruction from the prescriber (see section 1.12),
c) During certain procedures e.g. PCI, EPS, or device implantation / explanation, drugs may be given on the verbal instruction from the doctor (in an emergency situation not planned treatment) provided that the name, route and dose are recorded either on the drug treatment section of the integrated care pathway, or on the prescription and, in both cases, signed by the doctor at the end of the procedure.
d) While in theatre under the care of an anaesthetist, medication to maintain anaesthesia may be recorded on the anaesthetic chart which should then be scanned into EPR as a permanent record.

5.9 RECORDING OF MEDICINES' ADMINISTRATION
After the medicine has been administered the person administering the medicine must record this in the administration section of EPR. If for any reason the medicine has not been administered the appropriate entry should be made on EPR. The prescriber should be informed that the patient has not received their medication and a note to this effect added to the electronic record (see 5.06).

5.10 SELF-ADMINISTRATION
Patients who fulfil the criteria may be allowed to self-administer their own medication, or medication supplied from pharmacy for this purpose. Currently self-administration schemes are available on Birch Ward, Maple Suite and the Cherry Ward (see Appendix SEVEN). In addition, any patient in LHCH may self-administer insulin or parkinsons disease medicines if assessed as safe and appropriate to do so.

5.11 ADMINISTRATION OF MEDICINES TO PATIENTS UNABLE TO TAKE SOLID DOSAGE FORMS, OR HAVING DIFFICULTY SWALLOWING
Nursing staff should liaise with pharmacy regarding administration of medicines to any patient unable to swallow solid dosage forms of medicines.

A pharmacist will advise on:
- Availability of liquid preparations
- Medicines that are suitable for crushing
- Necessary formulation, dose or medicine changes where there is no alternative.

All medicines administered in liquid form (including crushed tablets dissolved in water) must be given using a 5mL spoon, graduated medicines pot or an enteral syringe. Syringes for parenteral use (i.e. male luer lock) should NEVER be used for the oral or enteral administration of medicines. Purple coloured enteral syringes (with female luer locks) or bladder tips (available from Medicina) have been designed to fit enteral feeding administration systems for patients requiring enteral (NG, NJ, PEG) administration. If the administration set does not contain a male port then a purple enteral feeding adaptor must be attached to render the port compatible with enteral syringes. For further advice consult the Enteral Feeding Policy on the Intranet.

Where the liquid form of a drug is only available in a glass ampoule, a 5 micron disk filter (B Braun) and medicine straw should be used to extract the medicine from the ampoule. Where the only available form of the medicine is an injection vial with a rubber bung then the contents of the vial should be reconstituted (if applicable) using a luer lock syringe and needle. The needle should then be discarded and the syringe attached to an enteral syringe and the contents expelled into the enteral syringe. The contents of the enteral syringe should then be administered to the patient orally or enterally.

5.12 COVERT ADMINISTRATION OF MEDICINES
This section has been taken from the Royal Pharmaceutical Society (RPS) published guidance, this can be reviewed in full at
https://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

The best interests of the patient or client are paramount. The interests of the registrant, team, or organisation should not determine any decision to administer medicines. Open multi-professional discussion should take place prior to implementing covert administration and this meeting should be documented in the patient's care plan. By disguising medication in food or drink, the patient is being led to believe that they are not receiving medication, when in fact they are. The registrant will need to be sure that what they are doing is in the best interests of the patient and be accountable for this decision. Every registrant involved in this practise

should reflect on the treatment aims of disguising medication and such treatment must be necessary in order to save life or to prevent deterioration or ensure an improvement in the patient's physical or mental health. If consent to receive medication cannot be obtained by a patient, the multidisciplinary team may seek permission from a court of law.

5.13 MEDICINES ADMINISTRATION ERRORS (see also 2.11)
Administration errors should be reported via the trust's incident reporting system, regardless of whether the medicine has been administered by a member of medical, nursing or pharmacy staff. All errors involving medicines (prescribing, dispensing, administration or miscellaneous) reported via the Trust's incident reporting mechanisms are reviewed at the Safe Medication Practice Committee.

## 6. CONTROLLED DRUGS (See also policy for Safe Management of Controlled Drugs Policy)

6.1 PRESCRIBING OF CONTROLLED DRUGS
All medical staff (except students and unregistered locums) and certain NMPs may prescribe controlled drugs, but may NOT prescribe diamorphine or cocaine for addicts unless licensed to do so. Supplementary prescribers may also prescribe controlled drugs where they are listed in the Clinical Management plan (refer to 3.1.5 of the safe management of CDs policy). Controlled drugs prescriptions for out-patients or discharges frequently present problems due to non-compliance with the regulations. Prescribers should ensure that all legal requirements are fulfilled. Methadone should NOT normally be prescribed for discharge where an addict has a registered pick-up point. If it is not possible to make arrangements for a pick-up soon after discharge then the minimum quantity required should be prescribed, taking in to account previous supplies (check with usual supply point).

Controlled drugs prescriptions for outpatients and TTOs must have the:

a) full name and address of the patient
b) full name of the controlled drug (not the Trade Name)
c) form of the drug e.g. tablets, slow release tablets etc.
d) strength of the preparation to be supplied, if several exist
e) dose and frequency
f) total quantity of the preparation, or the total number of dose units, in both words and figures
   none of the above need be in the prescriber's own handwriting, however, if an addressograph label is used for the patient's name and unit number, the label must be signed by the prescriber in ink, and, in addition,
g) the prescription must be signed and dated by the prescriber in ink and in the prescribers own handwriting.

It is illegal for the pharmacy staff to dispense an incorrectly written prescription for controlled drugs. Omissions in CD prescriptions or take home prescriptions will lead to delays in patients' discharge.

6.2 ORDERING CONTROLLED DRUGS FOR IN-PATIENTS
Refer to safe management of CDs policy for more details

6.3 OBTAINING CONTROLLED DRUGS IN AN EMERGENCY OUT-OF-HOURS
Refer to safe management of CDs policy for more details

6.4 DELIVERY OR COLLECTION OF CDS FROM PHARMACY
Refer to safe management of CDs policy for more details

6.5 RECEIPT OF CONTROLLED DRUGS ON WARDS OR DEPARTMENTS
Refer to safe management of CDs policy for more details

6.6 STORAGE OF CONTROLLED DRUGS
Medicines designated as Controlled Drugs by the Misuse of Drugs Act 1971 must be stored in a locked cupboard, or a CD fridge, which must be attached to the wall and comply with the CD regulations. Access and keys should be restricted to persons authorised under the Act, i.e. the ward manager or person in charge of the ward.

Epidural infusions must be stored in a separate cupboard therefore any epidurals containing CDs must be stored in a CD cupboard or fridge not containing other CDs (Refer to safe management of CDs policy for more details)

6.7 STOCK LEVELS OF CONTROLLED DRUGS

Refer to safe management of CDs policy for more details

6.8 ADMINISTRATION OF CONTROLLED DRUGS

Refer to safe management of CDs policy for more details

6.9 ADMINISTRATION OF CDS WITHOUT A PRESCRIPTION

Refer to safe management of CDs policy for more details

6.10 PATIENTS' OWN CONTROLLED DRUGS

As with other types of medicines, these remain the patients' own property and should preferably be given back to relatives. If this does not happen then they should be placed in the Controlled Drugs cupboard and an entry made in the "patient's own" CD record book supplied for this purpose. Patients' own CDs should NOT be given to any other patient and they must NOT be added to ward stock. On discharge they should be returned to the patient if still appropriate, in which case the items must be signed out of the register by a nurse and a signature of the patient, or their representative, must be obtained.

TTOs received on a ward, which require locking in the CD cupboard (i.e. they are not being given directly to the patient who is being discharged immediately upon their receipt) must also be entered into the "patients own" CD register.

On discharge, the drugs should be given to the patient and signed out of the register as above, the nurse must sign together with the patient or their representative.

Patient's own controlled drugs should not be routinely used. Ward stock should be used whenever possible. Patient's own controlled drugs may be used if the pharmacy department does not stock the drug or if there is likely to be a prolonged delay in obtaining the drug e.g. out of hours. Entries should be made in the patient's own controlled drug register in the usual manner.

Refer to safe management of CDs policy for more details

6.11 DESTRUCTION / RETURN OF CONTROLLED DRUGS

Nurses and medical staff must not return any controlled drugs to pharmacy. Unwanted or outdated (expired) controlled drugs must be retained in the controlled drugs cupboard and the ward pharmacist should be informed. Unwanted stocks should be booked out by the pharmacist for return to pharmacy and the pharmacist will complete a form for this purpose. Patient's own can also be destroyed at ward level rather than returned to pharmacy. Both the register and the form must be countersigned by a witness on the ward. Used CD patches should be treated as clinical waste and disposed of on the ward.

Refer to safe management of CDs policy for more details

**7. INTRAVENOUS DRUGS, ASEPTIC SERVICES AND PARENTERAL NUTRITION** (**See Parenteral Therapy Policy and Appendix 4 – Trust policy for the Aseptic Preparation of Medicines)**

In the absence of a full central intravenous additive service (CIVAS) it will be necessary for medical staff or nurses with the required training to add drugs to fluids in non-aseptic conditions. These bags or syringes:

a) have a twenty-four hour expiry unless otherwise advised
b) MUST be initiated within ONE hour of preparation, not put aside for later use.

7.1 PARENTERAL NUTRITION

All Total Parenteral Nutrition (TPN) should be prepared in the aseptic unit in the pharmacy department. All TPN should be requested on a TPN requisition form and prescribed on EPR. Changes to regimens may be made Monday to Friday, by consultation with the pharmacist. Changes may be made in person or by telephone. A copy of the regimen details will be sent to the ward each time a change is made.

7.2 ADMINISTRATION OF INTRAVENOUS DOSES BY STAFF

All staff who have satisfactorily demonstrated competence in intravenous drug administration may administer intravenous drugs, please see the Parenteral Therapy Policy and the Medicines Administration Procedure. The Parenteral Therapy Policy should be followed for the flushing of intravenous lines and cannulae.

7.3 DISPOSAL OF SHARPS
Sharps must only be disposed of safely in the accepted receptacles, refer to Waste Disposal Policy. A needle stick injury policy is available on the intranet.

## 8. PATIENTS' OWN DRUGS (See APPENDIX 7)

8.1 Patients should be encouraged to bring all current medication into hospital on admission or first out-patient appointment. This medication remains the property of the patient and should be returned to the patient (or relatives) to take home if the patient does not wish them to be used. Before use within LHCH all medicines should be examined by a pharmacist or technician (the "own medication" box ticked on the electronic prescribing system indicates that this check has been completed), unless the pharmacy is closed (or pharmacy staff are not present at the time of drug administration) in which case a doctor or nurse can authorise suitability.
Patient's consent must be obtained before use (see Appendix 7). These medicines cannot be administered legally to any other patient.

8.2 It is the responsibility of the Ward Manager or Nurse-in-Charge to ensure that patients are made aware on admission of the importance of not taking any medicines without the knowledge of hospital staff. Medicines, even those supplied for self administration, should be kept locked. If a patient refuses to hand over their medicines then this should be brought to the attention of the consultant, ward pharmacist and senior nurse manager.

8.3 Medicines supplied for patients who have died or been discharged and not returned to patients (except for controlled drugs) should be removed from the trolley or locker as soon as possible and returned to pharmacy in the pharmacy green bin for safe destruction. Discontinued medicines should not be given back to a patient but returned to pharmacy for destruction once patient's permission has been obtained (see Appendix SEVEN).

Medicines supplied to the patient, or those brought in by the patient (i.e. those medicines which are labelled with the individual patient's name) must be transferred with the patient whenever they are moved from one area of the hospital to another e.g. from critical care to a ward (wards have "green" medicine bags available for this purpose), also see section 2.3.

## 9. ADVERSE DRUG REACTIONS

All suspected and confirmed adverse reactions to medicines including contrast media should be reported to the MHRAusing the yellow cards which are available in the back of the BNF or online at www.mhra.gov.uk/yellowcard.. ADRs and allergies should be documented on the electronic prescribing system in a timely manner. Anaphylaxis due to a medicine requires additional reporting steps to be followed (Refer to anaphylaxis policy)

## 10. CLINICAL TRIALS

In addition to the need to follow all the procedures in this policy, attention is drawn to the need to observe special additional requirements when medicines are administered in connection with a clinical trial. Clinical trials are only undertaken after careful consideration by the local ethics committee and by the Research and Development committee. Patients must always give informed consent, in line with the Patients' Charter rights. Supplies are issued by pharmacy only as agreed in the trial protocol and pharmacists continue to supervise the use of medicines in the trial. See appendix 5 for the process to follow in the event of a patient being admitted to LHCH while undergoing a clinical trial conducted either by LHCH or by another hospital. The storage and documentation of clinical trial drugs (whether investigational, unlicensed or commonly-used licensed medicines) is controlled tightly by European legislation.

## 11. CYTOTOXIC DRUGS

Currently at LHCH the only parenteral cytotoxic drug occasionally administered is Cyclophosphamamide for vasculitis (see Appendix 10). This drug is obtained from the Liverpool University Foundation Trust pharmacy department and requires special care for use and disposal.

Under no circumstances should parenteral cytotoxic therapy, other than Cyclophosphamide, be administered to any of LHCH's patients without having first discussed the case with the following:

a) pharmacy – in order to arrange supply and preparation from an appropriate source,
b) the risk management department – to ensure that all necessary steps have been taken to ensure the safety of the patient and staff involved,
c) the physicians involved with the prescribing of the chemotherapy regimen,
d) chemotherapy specialist nurses who must be available on site at LHCH to perform the administration via the correct route.

Alternatives to the administration of chemotherapy on the LHCH site must be sought, and if possible, the patient should be transferred back to their referring hospital for treatment.
The Department of Health and the National Patients Safety Agency recommend that chemotherapy is administered in specialist centres at all times, unless under extreme emergency situations. For the safety of patients and staff at LHCH the information contained within appendix 10 has been prepared, however, the default should be that no chemotherapeutic intravenous medication is administered at LHCH.

## 12. TRAINING REQUIREMENTS

All clinical staff during induction will be made aware of the existence of the Medicines Policy and Medicines Administration Procedure. Medical Staff will receive training on various aspects of the policy provided by the training pharmacist. All prescribers receive EPR training and assessment on induction. Nursing staff, ODPs and all staff groups involved in the administration of medicines will receive training from the training pharmacist and clinical nurse training facilitators. Specific training on the use of patient group directions will be given to the staff groups involved in the individual PGD.

For further details on training for all relevant staff see Medicines Administration Procedure available on the intranet.

## 13. IMPLEMENTATION PLAN

The Medicines Policy is updated annually, or whenever required by changes in legislation or practise. When significant updates have been approved, all relevant staff will be informed via e bulletins and through the safety huddle. Significant changes may be accompanied by specific training sessions at ward level; for example, the changes to enteral administration of medicines following the NPSA alert.

## 14. MONITORING AND COMPLIANCE

Aspects of the policy are audited or monitored regularly as follows:

- Formulary – sections of the drug formulary are audited regularly, as a minimum two sections annually, according to a workplan produced by the Drug and Therapeutics Committee. Adherence reports are presented to the Drug and Therapeutics Committee and included within the annual report presented to the QPFEC
- Unlicensed Medicines – an annual report of their usage produced by pharmacy is included in the Drug and Therapeutics Committee annual report.
- Discharge prescription audits, quality of in-patient prescribing audits and administration of medicines audits are conducted periodically and the results presented to the Drug and Therapeutics Committee.
- MHRA alert dissemination is audited by Regional QC annually
- Quality of aseptic services are audited annually and the report included as part of the annual Drug and Therapeutics report, the action plan produced as a result of this audit is also presented to the Clinical Services Divisional Governance Meeting.
- Controlled Drug stock level audit – these are performed every three months by the ward pharmacists and their accuracy reported annually to Drug and Therapeutics Committee.

- Various other aspects of prescribing practise are audited as required by national bodies, e.g. the NPSA, NICE. Results are discussed at the Drug and Therapeutics Committee and at QSEC or Divisional Governance Committee dependent upon the nature of the audit.
- Self administration processes (appendix 7) are audited annually and the results are presented to the Drug and Therapeutics committee.
- Records of training (see section 12) received under the trust's mandatory training is held by the Human Resource Department.
- Pharmacists carry out an audit of their clinical interventions monthly, a summary of which is reported to the Drug and Therapeutics Committee on a quarterly basis. . An annual report from the Safe Medication Practice committee is produced and presented to Drug and Therapeutics Committee.
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**Appendix 1**

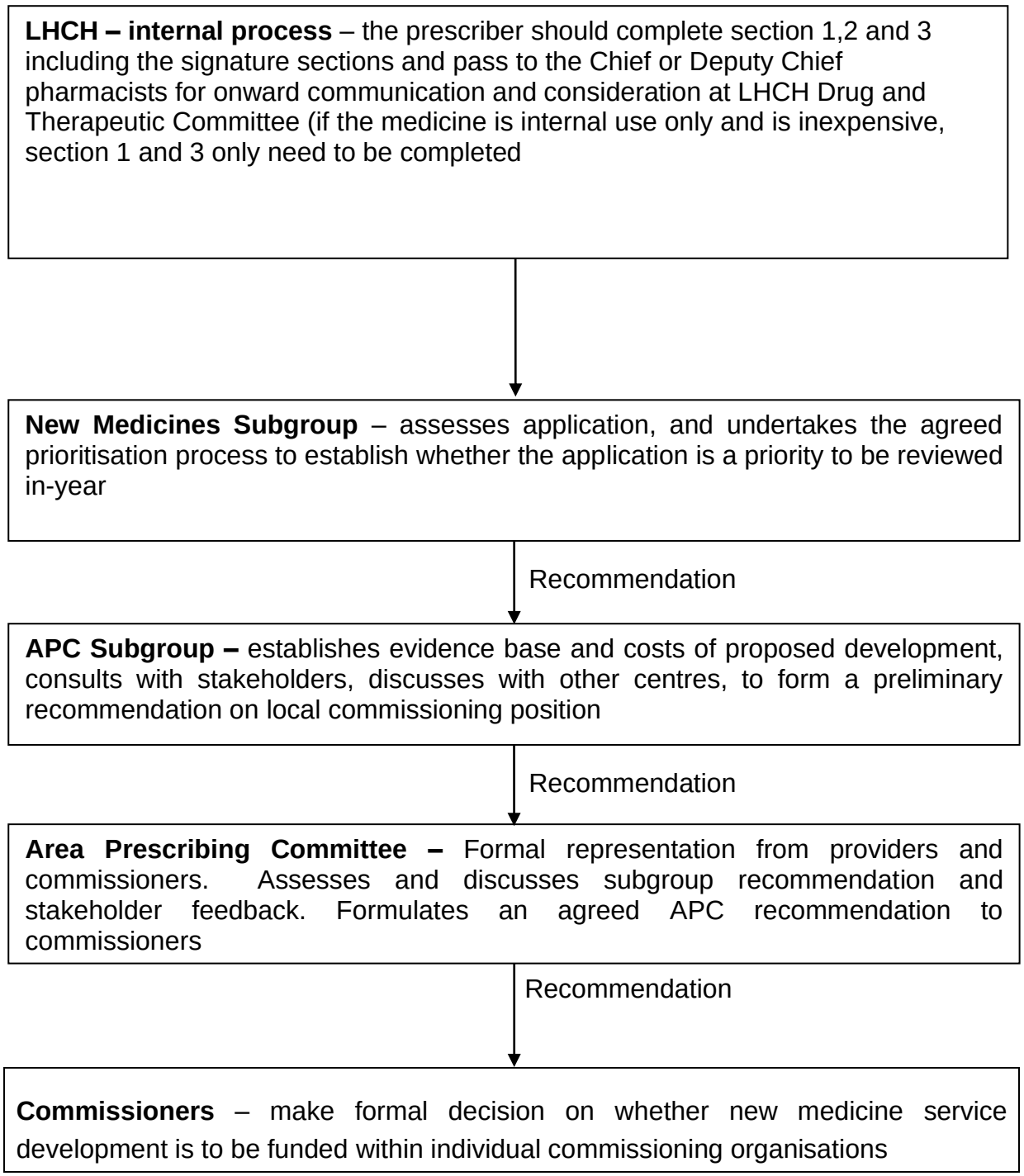
## Merseyside and Warrington Medicines Management Subgroups

# Application and Case for Introduction of New Medicines

**Purpose of this form:** for providers to apply to commissioners for in-year funding of any new drug or extended use of an existing drug (e.g. new indication, new patient group) that will impact on prescribing costs in primary care. This includes where the prescribing will be passed on to primary care prescribers or where the drug is prescribed in hospital but generates additional PBR costs or is excluded from the Payment by Results Tariff and costs are passed on to commissioners. The annual horizon scanning process should be used as the preferred route to identify the majority of new developments, and any in-year funding applications will be subject to a prioritisation process to establish whether it is a local priority to review within the current financial year. Applicants are advised that prioritisation for review does not guarantee a positive commissioning recommendation outcome. **This form will also be used for internal LHCH applications, however, unlicensed drug applications should be completed on the usual unlicensed request different form.**

**This form is not to be used for Individual Funding Requests (IFR).** These are considered where the individual or treatment is exceptional; i.e. where the treatment can be described as exceptional by virtue of the rarity of the condition or the difference of the individual from the generality of similar patients. Separate IFR documentation is available. Sometimes new, innovative treatment options are presented as exceptional: in this case every effort is made to direct the clinical team to the commissioning decision route, via this service development application, although the first few requests via the exceptional treatment route may be considered so as to offer benefit to patients where this is likely.

**Process:**


**LHCH – internal process** – the prescriber should complete section 1,2 and 3 including the signature sections and pass to the Chief or Deputy Chief pharmacists for onward communication and consideration at LHCH Drug and Therapeutic Committee (if the medicine is internal use only and is inexpensive, section 1 and 3 only need to be completed
**New Medicines Subgroup** – assesses application, and undertakes the agreed prioritisation process to establish whether the application is a priority to be reviewed in-year
Recommendation
**APC Subgroup –** establishes evidence base and costs of proposed development, consults with stakeholders, discusses with other centres, to form a preliminary recommendation on local commissioning position
Recommendation
**Area Prescribing Committee –** Formal representation from providers and commissioners. Assesses and discusses subgroup recommendation and stakeholder feedback. Formulates an agreed APC recommendation to commissioners
Recommendation
**Commissioners** – make formal decision on whether new medicine service development is to be funded within individual commissioning organisations

**Please complete this form as fully as possible.** Please complete all relevant sections legibly. Any missing or illegible information will delay the application. You must discuss this application with the relevant Pharmacy Dept. / Medicines Management team within your organisation and obtain organisational support and sign-off for the application before it is submitted. Applications completed by pharmaceutical companies are not acceptable

## Section 1 Clinical information

| | |
|---|---|
| Name of medicine<br>(generic and brand name): | |
| Strength(s) and form(s) of preparation:<br>Dose and schedule of administration: | |
| Licensed indication(s): | |
| Proposed Indication (if different from or in addition to the above): | |
| Is this treatment instead of or in addition to any current treatment?<br>Please give details: | |
| Reason for proposed change.<br>If replacing current treatment please state how it compares regarding efficacy and safety / tolerability | |
| Proposed place in therapy relative to other therapies (include protocol for use if available) | |
| Predicted clinical impact on Primary Care<br>e.g. will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Will it require shared care?<br>Please describe: | |

| | |
|---|---|
| Monitoring requirements<br>(e.g. for efficacy, side-effects) – if any?<br>Do these differ from current situation? | |
| Brief summary of evidence in support of requested medicine / additional use.<br>Meta-analyses, systematic reviews, double-blind randomised controlled trials in peer-reviewed journals.<br>Ensure that evidence to support advantages / benefits of the new medicine over existing treatments is included where appropriate, including criteria for treatment success.<br>Include any relevant morbidity, mortality, health economic and quality of life benefits. | |
| References<br>Please list and include copies or internet liks with the application | |

## Section 2 Financial information

| | |
|---|---|
| Costs: (excluding VAT)<br>Cost per patient per year of medicine:<br><br>Number of patients per year to be treated for the whole organisation:<br>*Where possible / applicable, include assessment of patient numbers across Pan Mersey area.*<br><br>Additional costs e.g. day case tariff, tests per patient per year:<br><br>Any impact on PBR activity? Please give details:<br><br>Overall financial impact: | |
| Current treatment(s) usually used (if any):<br><br>Cost per patient per year currently treated (excluding VAT):<br><br>Number of patients per year currently treated:<br><br>Current additional costs e.g. day case tariff, tests per patient per year: | |
| Predicted financial impact on Primary Care.<br>e.g. Is the medicine hospital only but PBR excluded, will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Please describe: | |

## Section 3 Conflicts of Interest

| | |
|---|---|
| Please state any potential conflicts of interest e.g. funding of research, equipment, consulting or speaking fees, other personal or non-personal or family interest etc. in relation to this request: | |

Name of Applicant Signature of Applicant

Role

Organisation name

**I confirm I have sent a copy of this form to my organisations Drug & Therapeutics Committee / Medicines Management Committee or equivalent, and it has been approved following the appropriate procedure within my organisation.**

Name of Associate Medical Director / CCG Prescribing Lead

Signature Associate Medical Director / Prescribing Lead

Name of Chief Pharmacist / Head of Medicines Management

Signature of Chief Pharmacist / Head of Medicines Management

Name of Divisional Head of Operations

Signature of Divisional Head of Operations

**APPENDIX 2**

## EMERGENCY CUPBOARD PROCEDURE

### HOW TO ACCESS THE EMERGENCY CUPBOARD

When the pharmacy is closed and you need a drug that is not kept as a stock item or has not been supplied to the patient, you may need to access the Emergency Cupboard.

The emergency cupboard list is available on the intranet (under pharmacy green cross). Check the list to see if the drug required is kept in the Emergency Cupboard. If so, you will need to go to switchboard and ask for the key and swipe card to access the Cupboard. If the drug is not available, stock can be taken from other wards (ward stock list also available on the intranet under pharmacy green cross)

The Emergency Cupboard is situated just inside the pharmacy staff entrance to the department (door labelled “Authorised Staff Only”), inside this vestibule the Emergency Cupboard is on the right. The pharmacy department is located on the corridor in between the new main entrance and the Out Patient Department.

When using the Emergency Cupboard you must write down the following on the pad in the Cupboard:

- Name and strength of drug taken,
- Name of patient(s) who is (are) receiving the drug,
- Name of the ward and consultant for the patient.

Always take the full container of tablets / injection / liquid to reduce the risks of unidentifiable medicines on wards and to aid pharmacy when replacing the item.

**APPENDIX 3**

**PHARMACEUTICAL SERVICE**

| **PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF ENTER DETAILS HERE** | |
|---|---|
| Version Number | Enter date |

**Statement:**
The staff indicated in 'Staff Group' may administer, without medical prescriptions, **enter name of drug** in the manner detailed below.

**Staff Group:**
**Individual/professional group and grade (where appropriate),** working in **is/are (delete as appropriate)** entitled to **administer/supply (delete as appropriate)** medicines without medical prescription under this Patient Group Direction if they have:

- The professional qualifications **enter details**
- Attended ENTER DETAILS OF THE TRAINING
- Completed a training record form relating to this PGD within the last 2 years
- Had their names added to the Electronic PGD training record

***Clinical condition to be treated and Criteria under which a Patient shall be Eligible:***
**Enter details of clinical condition, patients to be treated and where necessary evidence based protocols. If use is 'off license' justification for use must be detailed here**

**Exclusion criteria:**
**Enter any individual patient exclusion criteria for this PGD. All core PGDs must include this statement 'Patients who are pregnant/breast-feeding are excluded from this PGD and must be referred to the appropriate medical officer**

Unless otherwise indicated, patients under the age of 16 years of age are excluded from treatment within this PGD
If the patient is receiving any concomitant medication or treatment it is the responsibility of the healthcare professional identified in **'Staff group'** to ensure that treatment with the drug detailed in this PGD is appropriate. In case of any doubt further advice must be sought from the appropriate healthcare professional and recorded as having been sought before the drug is given.

**Legal Status of Drug:**
**Enter details … POM, P, GSL, etc**

**Dose to be given:**
**Enter details. If a variable dose then indicate criteria for choosing dose**

**Frequency of Administration:**
**Enter details. If a variable dose then indicate criteria for choosing frequency**

**Number of Doses to be given:**
**Enter details**

**Route or Method of Administration:**
**Enter details …**

**Contraindications to use of Drug**
**Enter details as stated in the manufacturer's Summary of Product Characteristics**

**Training requirements;**
**Enter details …**

**Advice to be given to patient**
**Enter details …**

**Follow up arrangements (if applicable)**
**Enter details**

**Documentation**
**Enter details e.g. The nurse administering this drug must record the drug name, the dose, the form, the route and the time of administration in the "once only" section of the prescription chart. "RGN" must be added to the nurse's signature.**

**Protocol prepared by**
**Name of person preparing protocol, job title and signature below**

……
**Protocol approved by**
**Name of Clinical Director / Nominated Lead Clinician, job title and signature below**

……..
**Enter name of Senior Pharmacist, job title and signature below**

……..
**Name of Chair of D & T Committee, title 'Chair of Drug and Therapeutics Committee' and signature below**

……..

**Review**
It is the responsibility of the head of nursing services or the head of any other professional body to whom this PGD applies to action the review process.

This protocol must be reviewed by **Enter date**

If continued use is appropriate this PGD must be submitted to the Chair of the Drug and Therapeutics (D & T) Committee for approval. This PGD will remain valid until the next available meeting of the D & T Committee following the review date at which time a decision will be made regarding its future use.
All PGDs should be subject to regular review in line with changes in clinical practice.

**APPENDIX 4**

# LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST

## POLICY FOR
## THE ASEPTIC PREPARATION OF MEDICINES

1. This policy outlines where aseptic preparation should take place and the shelf life of the final product.

2. The Trust accepts that it is best practice for all sterile medicinal products to be supplied by the Pharmacy to the practitioner in a form ready to administer for their intended purpose. It is recognised that this best practice cannot be achieved at present but is a desirable goal. Procedures for the aseptic preparation of medicines within the aseptic unit of the pharmacy department at the Liverpool Heart and Chest Hospital NHS Trust are complete and audited by Regional Quality Assurance every 12 to 18 months. The Chief Pharmacist is responsible for ensuring adequate resourcing of the aseptic preparation service in order that it can meet defined national standards e.g. adequate staffing, funding for appropriate maintenance of facilities.

3. The following products must be prepared in a pharmacy aseptic unit, or purchased from a licensed unit:

   All cytotoxic injections/irrigations

   All TPN solutions

   All Cardioplegia solutions

   All elastomeric devices

   All eye preparations

   All Epidural/Paravertebral injections with the exception of the first dose prepared by the anaesthetist.

4. Irrigations (excluding ophthalmic) for immediate administration do not need to be prepared in an aseptic unit.

5. Products ready for administration:

   Where products not requiring reconstitution are withdrawn from a unit dose container (e.g. vial or ampoule) or from a licensed multidose vial containing antimicrobial preservative, they do not need to be prepared in an aseptic unit.

6. Provided that chemical stability has been confirmed a dispensed product prepared in the aseptic unit may be given a shelf life of up to seven days.
   Products prepared under the Manufacturer's "Specials" License will have an expiry assigned according to validation in conjunction with Quality Control North West.

7. A product prepared in a clinical area may be given a maximum shelf life of twenty-four hours provided that chemical stability has been confirmed. Administration of a product prepared in a clinical area should be commenced immediately.

8. All staff involved in any activity related to aseptic product preparation must be trained to an appropriate level.

This policy must be adhered to in conjunction with the Parenteral Therapy Policy which defines the responsibilities of each staff group within the Trust more clearly.

**APPENDIX 5**

## PROCEDURE FOR PATIENTS TAKING PART IN CLINICAL TRIALS

1. PATIENTS TAKING PART IN A TRIAL ORGANISED BY THE LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST

These patients will receive information from LHCH regarding their trial medication in both written and verbal forms. This information will request the patients to inform other doctors, nurses or pharmacists about their trial medication.

2. PATIENTS TAKING PART IN A TRIAL ORGANISED BY ANOTHER TRUST

It is important that the consultant involved in the treatment of these patients at LHCH is made aware of the patient's involvement in a drug trial at the earliest opportunity. This will enable the consultant to decide whether the possible medication involved in the trial has implications for the treatment to be undertaken at LHCH. It does not always follow that the code of the trial needs to be broken or that the patient should always stop their trial medication.

A. During normal working hours, Monday to Friday 9.00 to 5.00 p.m.

- Any trial medication brought into the hospital by a patient should be shown to the ward pharmacist by the nurse looking after the patient. This can occur either during the usual ward pharmacy visit or by taking the medication down to the pharmacy department.
- The pharmacist will perform the identification procedure of any trial medication by:
    a) Identifying the hospital involved in the study.
    b) Contacting the study centre pharmacy department or principle investigator, if known, and ascertaining the trial and likely drugs involved.
- The pharmacist will inform the consultant that their patient is on a particular trial and discuss the possible implications (the patient may be in the placebo arm of the study, if applicable).
- The pharmacist will record the details in the patients case notes.
- The trial code may need to be broken, a decision not to be taken lightly and should be taken by the consultant.

B. Outside normal working hours

- Any trial medication brought into the hospital by a patient should be shown to a pharmacist on the next working day. The on-call pharmacist should only be called if identification of the trial is felt to be important on clinical grounds.
- The on-call pharmacist will identify the trial and inform the consultant as outlined above.

**APPENDIX 6**

**The Purchase and Supply of Unlicensed Medicinal Products**

Licensed medicinal products are subject to stringent control by the Medicines and Healthcare Products Regulatory Agency (MHRA). Unlicensed medicinal products may not be subject to these same control measures and therefore neither prescribers nor pharmacists can make the same assumptions on quality, safety and efficacy.. If a licensed medicine is unavailable, for example due to a manufacturer's problem, then the pharmacy department may have no alternative but to purchase an unlicensed product to ensure continuity of patient care. Medicines that usually fall into this category are those which are stocked and used regularly in a number of clinical areas and for which there is no direct substitute for a licensed drug. In this case the pharmacy department will send communication to all potential prescribers informing them of the situation.

### 1. Prescriber request for an Unlicensed Medicine

An unlicensed medicine may only be requested by a consultant in the first instance. The consultant must complete an unlicensed medicine request and risk assessment form which should be sent to the Chief Pharmacist. This request will then be discussed and assessed at the Drug and Therapeutics Committee before being ordered. Urgent requests for unlicensed medicines may be considered by the Chief Pharmacist in conjunction with the chairman of the Drug and Therapeutics Committee. If a blanket request is being made, i.e. a consultant is making a request for an unlicensed drug which may be prescribed by several colleagues, then all potential prescribers/areas of use must be listed on the request form – there is space for this.

### 2. Purchase of Unlicensed Medicines

The patient services pharmacist (senior pharmacist) will be responsible for controlling the procurement and supply of unlicensed medicines. Depending on the particular medicine and its manufacturer, the drug may require quality control testing. If testing is necessary then there will be a delay following receipt of the drug before it will be issued to the patient while QC testing takes place.

### 3. Record Keeping

The pharmacy department will keep a record of batch numbers and expiry dates of all unlicensed medicines purchased. All unlicensed medicines that are dispensed in the pharmacy on receipt of a prescription for an individual patient are entered into the pharmacy stock control system which details the patient's name, consultant, date of dispensing, batch number and number of dose units issued. This record is kept within the pharmacy department and can be called upon in the event of a product recall or adverse reaction, thus ensuring a complete audit trail. . Unlicensed medicines prescribed on the EPMA system will automatically require the batch number to be entered onto the system at the point of administration. This information enables identification of patients in the event of a product recall or adverse reaction.

## Request and Risk Assessment Form for Unlicensed Medicines

### A. Unlicensed Medicine Details

Product Name:…….…….....
(International Non Proprietary Name)

Proprietary Name:……...……
(if known)

Pharmaceutical Form: ……..…….…… ……

Strength:…….…….…….

Manufacturer: (if known)...…….…….…….

Indication: ……..……

Dose: ……..……..…….

Frequency: ……

Route: ……..…. ……..

Duration of Treatment: ..……...……...…..…….

Approx. no. of patients per annum……..

Why is an unlicensed Medicine being considered?

1. Pharmaceutically Equivalent Licensed product temporarily unobtainable*

2. Equivalent UK licensed product unavailable/unsuitable because……..……..……..……...

……

…….…..

3. Other* Give details: ……..……..…..……..

……
*Delete as appropriate
If 1, go to "Procurement Details" section C

**B: Clinical Evidence**

Is there any evidence to support its use for the proposed indication? Yes / No

If not, is there any evidence to support its use for other indications? Yes / No

Is there evidence to support its proposed administration schedule (including dose, duration of treatment, concentration for parenteral products and route)? Yes / No

Is the active drug currently in a licensed product for use via the same route? Yes / No

Is the product licensed for the specified indication in an EU member state? Yes / No / Not known

Is the product licensed for the specified indication in a non-EU member state? Yes / No / Not known

Are other centres using this medicine? Yes / No. If so, name
……..……

Summarise below the supporting evidence, list references and attach copies of references where available.
……
What are the risks to the patient of not using this drug?

……
What side effects or toxic effects have been reported?

Describe……..

Is any monitoring required? Yes / No

If so, describe……..……..…

Are there any significant interactions? Yes / No

If so, describe……..……..……

Is there patient information appropriate for intended use? Yes / No
If so, attach.

Will there be any primary care implications? (e.g. need for a shared care protocol) Yes / No

If so, describe……..……..……

Give details of contraindications and any other risks to the patient……

Precautions in Use:…….…..……...
…….……

Pharmaceutical Precautions: ……..……..……..……

Other Precautions:…….…..…….....

## C: Procurement Details

**1. Is the medicine to be obtained from:**

| | |
|---|---|
| An NHS specials unit **Y/N If yes, specify…….and go to 6.** | |
| A commercial specials manufacturer | Y/N |
| A licensed importer | Y/N |
| A company which already has licensed products of the same active ingredient | Y/N |
| A licensed pharmaceutical wholesaler | Y/N |

**2. Is a specification available?** Yes / No
If yes, attach a copy.
If no, then a full product specification will need to be drawn up in conjunction with Quality Control North West

**3. Is the product available "off the shelf" ?** Yes / No

Manufacturer……

**4. Is the manufacturer on the Manufacturer List given in the Quality Control North West Guidance Document GD 109?** Yes / No

**5. Is the manufacturer in the UK? Yes / No**

If no, complete questions 1 to 13 below:

1. Which country?: ……
2. Is this country within the EU? Yes / No
3. .If no, does this country have a mutual recognition agreement with the UK for the manufacture of medicinal products? Yes / No (If no seek QCNW Advice)
4. Importer : ……
5. Does the importer have a Wholesale Dealer Import Licence? Yes / No
6. What is the quoted importation time? ……
7. What quantity is to be imported? ……...
8. What language is used on the label? ……..
9. If not in English, is a translation available? Yes / No
10. Who will provide the translation? ……..
11. Is an English Translation of the Patient Information Leaflet available? Yes / No
12. Who will provide the translation? ……....
13. Are the English Translations Certified? Yes / No
    If yes, by whom:……

**6. Are there any problems associated with continuity of supply?** Yes / No

If so, describe……

**7. What are the costs involved in obtaining this drug?** ..…….……..…

Issues raised by Quality Control North West …….....

**D: Details of Persons Completing the Form and Outcome of Risk Assessment**

Form Completed by:

Pharmacist Name……..…

Pharmacist Signature:……..… Date: ……..…..……

Prescriber Name: ……Directorate/Speciality: ……

I have read the Trust Policy on the prescribing, use and supply of this unlicensed medicine and accept full responsibility for its use. (*The following sentence can be deleted / crossed through if not applicable) *This medicine will be prescribed widely throughout the Trust by the following staff:.....
.....
.....
.....
.....
.....
.....
.....
.....(
please list all prescribers who will be able to prescribe the drug).

Signed: ……..…… Date: ……..
*(Consultant)*

**Outcome of Risk Assessment**

Drug and Therapeutics Committee Approval for use? Yes / No

If no, give reasons……..…..…….

Is the medicine to be added to the formulary? Yes / No

Are there any restrictions on prescribing and use? Yes/No

If yes, please state:…..……..……..……..……

Review Date: …….(Max 5 years)

Name:……

Signed:……..…… Date: ……..……
*(Chairman of D & T Committee)*

**APPENDIX 7a**

## Use of Patient's Own Drugs

### Introduction

This appendix is intended to provide guidance to enable staff to use patients' own drugs safely, the scheme is applicable to all ward areas in the Trust (including Critical Care).

Generally, patients will be encouraged to bring their own medication into hospital.
Elective admissions will be sent a letter prior to admission requesting that they bring all medication with them. Availability of PODS (patient's Own Medicines) facilitates an accurate medicines reconciliation when patients are admitted to hospital and can reduce the number of delayed or omitted medicine doses.

### A Procedure on admission

If obtaining the patient's own medication is likely to take longer than a few hours* then discuss with the pharmacist the next course of action. Medication (labelled with directions) will be issued if necessary by pharmacy in sufficient quantities (typically 28 days) to cover the anticipated length of stay and discharge. The supply and amount supplied will be left to the discretion of the pharmacist.

*For certain medication, e.g. Seretide inhalers when used in CF and COPD patients, it is acceptable to wait up to 48 hours before asking the pharmacy department to issue a supply; this is to enable patients to obtain and use their own supplies.

### A (i) Consent

Medicines brought into hospital by a patient remain their property and may be retained on the ward for use by that patient only. Verbal consent MUST be obtained by the admitting nurse before a patient's own medication can be used or destroyed. Consent may be given by the patient or patient's representative. If a patient does not consent to entering the scheme, their medication should be sent home with a representative if possible.
Patients should be advised about any medicines that have been discontinued, dosage altered or are unfit for use and an offer to destroy these should be made. If a patient does not consent to using their own drugs, then verbal consent from the patient or their representative must be received before any drugs can be destroyed.

### A (ii) Assessment

A pharmacist or technician will assess the suitability of patient's own drugs for use. They will assess their appropriateness against the current prescription. This will ensure that an accurate drug history is obtained. Where a patient's own drugs have not been assessed by a pharmacist or technician (e.g. out of hours), then a doctor or nurse may make the initial assessment. He / she must be satisfied with their suitability for use (see section A (iii)). In this case a pharmacist or technician must assess the medication and endorse the EPMA system as appropriate on their next ward visit.

### A (iii) Suitability criteria

The following criteria will be used to assess patient's own drugs for suitability for use: -

1. Medication in bottles/boxes must be identifiable as being the same as that marked on the label.
2. Medicines must have been dispensed within the last 6 months, unless an expiry date is visible on the container.
3. Medication must be clearly labelled with:
   Name of patient
   Name and strength of drug
   Dosing instructions same as prescription. (Labelled 'as directed' is acceptable providing the patient understands the dosage regime)
   Date dispensed
   Name and address of supplier
4. Ophthalmic preparations must have been in use for less than 4 weeks.
5. Liquids may only be used if they are in the manufacturers original container.
6. Containers must not hold more than one type of drug.
7. Drugs must be of a suitable quality (e.g. not broken, clean)

8. Patient's own controlled drugs must be stored in the ward controlled drug cupboard (including Temazepam preparations). They may only be used in certain circumstances (see section A (iv)).

Medication should ideally be destroyed by returning to pharmacy in the ward bag if: -

- It is not readily identifiable
- Liquids are not in the manufacturers original container
- The expiry date of the medication has been exceeded
- The medicines are in poor condition
- Medication is not in the originally dispensed container
- Medication that is discontinued during admission

If the patient refuses destruction of their own drugs then they should be returned home with a representative.

Patients own drugs that are not in a labelled container but which are in clearly identifiable blister strips together with a batch number and expiry date may be used if the drug is not available as ward stock, from the emergency cupboard out of hours, or if there is likely to be a delay in obtaining the drug from pharmacy. Blister strips MUST NOT be used by patients who are self medicating for self-administration.

Blister packs / monitored dosage systems (MDS)

Dosette boxes / weekly blister packs containing patient's own drugs MUST NOT be routinely used. Out of hours, ward stock or emergency cupboard drugs must be used. If a drug is unavailable, in exceptional circumstances (e.g. a prolonged delay in obtaining the drug), a drug may be used from a dosette box or weekly blister pack, however, the patient must be able to clearly identify the drug and both the nurse and on-call pharmacist must be satisfied of a genuine need for the drug. The on-call pharmacist must be contacted in these exceptional circumstances.

**A (iv) Patient's own controlled drugs**

**Records**

Controlled drugs brought into hospital by patients should be returned home with a representative if possible. If patient's own controlled drugs remain on the ward, they MUST be locked in the ward controlled drug cupboard in accordance with the trust's policy "Safe Management of Controlled Drugs". An entry must be made in the patient's own controlled drug register. Two nurses should check the entry, which should include the patient's name, drug name, strength and quantity.

**Use**

Patient's own controlled drugs should not be routinely used. Ward stock should be used whenever possible. Patient's own controlled drugs may be used if the pharmacy department does not stock the drug or if there is likely to be a prolonged delay in obtaining the drug e.g. out of hours. Entries should be made in the patient's own controlled drug register in the usual manner.

Patient's own controlled drugs should be returned to the patient or representative on discharge provided the prescription remains unchanged. The drugs must be signed out of the register by a nurse and a signature from the patient, or their representative, must be obtained. If patient's own controlled drugs are transferred from one ward to another with the patient, an entry must be made in the register on both wards and witnessed by 2 nurses dealing with the transfer of the drugs.

**Destruction**

Provided verbal consent has been given by the patient or his/her representative, the drugs may be disposed of as described in section 6.11.

**A (v) Obtaining supplies**

WEEKDAYS DURING PHARMACY OPENING HOURS
9am – 5pm
The ward pharmacist/technician or nurse will assess patient's own drugs and the pharmacist will supply any further medication required during routine visits.
Urgently required items may be ordered from the pharmacy department if needed outside the time of the pharmacist's visit. If discharge medication is required it may be dispensed from the TTO form.

WEEKENDS AND OUT OF HOURS
A nurse can use patient's own drugs for patients admitted out of hours if the patient has given their verbal consent and the drugs are deemed suitable for use (see iv). If a doctor or nurse has assessed patient's own drugs then a pharmacist will reassess the medication on their next ward visit.

**A (vi) POD medicine storage**

Patient safety and safe storage of medicines is of paramount importance to the Trust. Generally, all medicines should be locked away in either individual medicine lockers or drug trolleys / cupboards (controlled drugs must be locked in CD cupboards / fridges). The Trust acknowledges that a small number of "when required" drugs may be exempt from the above in order to facilitate better patient access and enhance the patient's experience.

**Only patients who have been assessed as suitable for self-medicating may store these medicines as stated below:**

Creon (for CF patients)
Lubricant eye drops
Respiratory inhalers
Respiratory nebules
Emollients

These medicines are deemed to be low risk and may be kept **out of sight** by patients in their bedside locker or on their person (patients should be reminded of this responsibility). NB, GTN spray should be locked away as normal. Patients experiencing chest pain should notify nursing / medical staff.

**APPENDIX 7b**

## Self Administration Policy
## (Excluding insulin self-administration – refer to 7c)

**Introduction**

This policy is intended to provide guidance to enable staff to use patient's own medicines and for nurses to administer medicines at the bedside. This policy covers self-administration. Self-administration of medicines by patients in hospital is now commonplace in many NHS trusts.
The aims of a self-medication scheme are: -

- To educate the patient to administer their drugs safely and correctly.
- To improve patient compliance with drug regimes after discharge.
- To emphasise the need for safe storage of drugs both in hospital and at home.
- To increase the patient's knowledge of the drugs they are taking.

To promote self-care and independence.

**Currently within the Trust long stay respiratory patients (e.g. Cystic Fibrosis, bronchiectasis), if deemed suitable, are offered the scheme on the following wards ONLY:**

- **Birch**
- **Cherry Ward**
- **Maple**
- **Cedar (CF patients only)**

**Patients with Parkinsons disease may also wish to self-medicate due to the nature of their drug administration times and to avoid delayed/omitted medicines. If a patient is deemed suitable they must follow the process outlined in this section. This is only for their parkinsons medicines. Other medication should be given by the nurse as normal.**
**Other patients on these wards will not be routinely offered the scheme due to the short length of stay and rapidly changing medications. However, such a patient who expresses a desire to self-medicate and who is assessed as appropriate and competent may do so.**
**Day Case patients may self-administer without the need for formal assessment.**

**Exclusion criteria for self medication**

- **Those deemed unsuitable following assessment on Birch, Maple, Cherry Ward**
- **Surgical patients (exception- see Insulin Self-administration Appendix 9)**
- **Patients using blister packs/dosette boxes**
- **Controlled drugs, stat doses, , anticoagulants (e.g. warfarin, dabigatran, rivaroxaban, apixaban)**

**B (i) Patient admission (general medicines – for insulin self administration – see further)**
On admission, a registered nurse (with responsibility for administering medicines) must establish whether the patient has responsibility for administering his/her own medication in the community. If this is the case, the ability of the patient to safely manage their medicines will be assessed during the in-patient stay and the patient should be considered for inclusion in the self-administration scheme. If the patient meets the necessary criteria, this should be initiated as soon as is reasonably possible. (NB It is important that the nurse assessing the patient is competent and aware of the scheme, for this reason bank personnel are not suitable for assessment of patients for the scheme).

**B (ii) Patient assessment**

Before giving their consent, the patient's suitability for the scheme is formally assessed by the registered nurse in charge of the patient's nursing care and the outcome documented (Forms 1&2).
Following approval to self-administer, an on-going assessment is made of that patient. This is to ensure any clinical deterioration in the patient or patient preference necessitating withdrawal from the scheme can be performed in a timely manner. **A patients suitability to self administer must be informally reassessed at each medicines administration time.**

Patients who do not initially meet the approved criteria may be included, if their individual circumstances change.

The 'Assessment of patients for self-administration of medicines' criteria (Form 1) must be used in conjunction with the 'Guidelines for completion of the assessment of patients for self-administration of medicines' (Form 2). All problems and resolution to these should be documented in EPR. If the patient's assessment requires the professional input of a pharmacist then it is the responsibility of the assessing nurse to inform the pharmacist at the earliest opportunity. The pharmacist must also sign the assessment form before the patient can participate in the scheme.
Should the assessment highlight the need for advice from other members of the multidisciplinary team, the assessing nurse will make appropriate referrals as soon as possible.

Both the assessment and consent forms should be filed in the patient's purple notes for patients who are assessed for self-administration. These will be scanned into EPR post discharge.

**B (iii) Patient consent**

After assessment, appropriate patients should be given verbal and written information about the scheme (Form 3). When the consent form has been signed by the patient and witnessed by a nurse (Form 4), it is filed in their purple notes. Patient participation in this scheme is voluntary. If the patient is offered the scheme but declines, the nurse must sign the relevant section on form 4 and medicines will be administered by nursing staff during the stay in hospital.
A patient can withdraw consent at any time by asking a nurse and signing the withdrawal of consent form (Form 4).

**B (iv) Patient information, teaching and supervision**

The information given and period of supervision should be tailored to each individual patient's needs.
The following information should be provided to patients before they begin self-administering any new drugs:

a) The name of the drug
b) Why they are taking it
c) Dose and frequency
d) Any special instruction
e) Duration of the course if appropriate
f) Possible side-effects

**Storage**

If a patient is suitable for self-administration, his/her medicines will be locked in their medication cabinet and/or stored out of sight (see **Appendix 7** A (vi) PODs- Medicines storage). The patient must be informed of their responsibility to keep medicines secure and out of sight and the reasons for this.
The patient administers his/her own medicines. A key for the patient's cabinet may be kept by the patient. Alternatively, nursing staff may choose not to give a patient their own key, rather the nurse will open the patient's medicine cabinet at relevant medication times so that the patient can self administer while the nurse administers medicines to other patients. The nurse is responsible for ensuring the patient's cabinet is locked afterwards.

**Self-administration of PRN medication**

The Trust acknowledges that a small number of "when required" drugs may be exempt from general storage requirements in order to facilitate better patient access and enhance patient experience. **Only patients who have been assessed as suitable for self-medicating may store these medicines as stated below.**

The following medicines are deemed to be low risk (apart from insulin) and may be kept **out of sight** by patients in their bedside locker (Patients should be reminded of this responsibility);

Creon (for CF patients)
Lubricant eye drops
Respiratory inhalers

Respiratory nebules
Emollients

NB GTN spray should be locked away as normal. Patients experiencing chest pain should notify nursing/medical staff

**Patients who have administered a PRN medication to themselves must inform the nurse in charge of their care to enable the nurse to annotate the prescription chart in the usual way.**

**B (v) Ongoing assessment**

Patients will be informally assessed daily at each drug administration time for that patient, for their suitability to continue on the scheme. The individual registered nurse responsible for the care of each patient will carry out this assessment. Nurses are responsible for acting upon changes in a patient's condition. Such information will be documented in EPR. Any patient in whom the scheme is subsequently deemed unsuitable should be withdrawn from the scheme and form 4 completed to that effect.

Changes in a patient's condition which affect their suitability to continue on the scheme include:

- A deterioration in a patient's mental state
- The initial period post surgery/procedure
- The professional judgement of the nurse/pharmacist/Doctor regarding the patient's ability to safely continue.
- Medications that are changing frequently in response to a patient's condition.

Untoward incidents related to self-administration should be reported to medical staff and the pharmacist and recorded in EPR and PRISM incident forms completed. Nursing staff, pharmacists and pharmacy technicians have a joint responsibility to ensure any medication that has changed (dose, frequency, discontinuation) is promptly removed from the patient's drug cabinet and re-labelled or discarded as appropriate.

**B (vi) Prescription endorsements**

- Patients self-administering will not be supervised when taking their medicines but the nurse should ask them which INDIVIDUAL medicines they have taken at drug administration times. If the drug has been highlighted on the EPR system as being self-administered then this will appear as a note in the work list manager. By signing their name, nurses acknowledge the drug was self-administered. If the annotation "self -administers" does not appear in work list manager a doctor, pharmacist or technician must be asked to select "self administer" for any drugs administered in this manner.
- PRN medications can be self-administered and endorsed on EPR in the usual way by the nurse.

**A. ACCOUNTABILITY**

The nurse must take responsibility for the initial and subsequent assessment of patients who are self-administering. Once consent has been given, if the initial and ongoing assessments have been carried out appropriately and all relevant documentation is completed, patients share the responsibility for their actions relating to self-administration of their medicines.

Whilst the nurse has a duty of care towards all patients, the nurse is not liable if a patient makes a mistake self-administering as long as the assessments (both initial and ongoing) are completed as the policy describes. Appropriate actions should be taken to prevent re-occurrence of the incident. The UKCC supports the development of self-administration systems and views them as good practice (UKCC – Standards for the administration of medicines 1992). The nurse must always base all decisions (even those not related to self-administration) in accordance with the Code of Professional Conduct 2020.

**Form 1**

**Form for assessment of patients for self-administration of medicines**

**Ward: …… Patient: ……..... Unit No: ……..…**

| Questions | ( Please Circle) | |
|---|---|---|
| **1. Is the patient responsible for administration of their own medicines in the community?** | **Yes** | **No ↓ Exclude** |
| **2. Is the patient confused or disorientated?** | **Yes ↓ Exclude** | **No** |
| **3. Can the patient read the labels and open bottles or foil strips?** | **Yes** | **No ↓ Exclude & Refer to pharmacist** |
| **4. Does the patient, to your knowledge, have a history of drug or alcohol abuse?** | **Yes ↓ Assess carefully** | **No** |
| **5. Has the patient read and understood the information leaflet for self-administration?** | **Yes** | **No ↓ Exclude** |
| **6. Has the patient signed a consent form?** | **Yes** | **No ↓ Exclude** |

***The above named patient has been assessed and is suitable for self-administration***

**Nurses signature …… Date: …….**

**Pharmacist's signature (if required) ……..**

***Or***

***The patient has been found to be unsuitable for self-administration*: ……**

**Nurses Signature …… Date: ……..**

**Form 2**

**Guidelines for Completion of the**
**'Assessment of Patients for Self-Administration of Medicines'**

**This set of guidelines is to be used in conjunction with the assessment form. The main objective of the assessment form is to highlight possible areas of extra education and supervision that may be required by a patient before they are able to self-administer.**

**If the assessing registered nurse, in his or her professional judgement, is at all unhappy to let the patient self-administer then the patient will be excluded and reassessed at another point in the current admission.**

Question 1. **If a patient is resident in a nursing home or anywhere that will not allow them to self-administer then they are to be excluded. Patients whose relatives or friends have responsibility for the administration of medicines whilst at home are also to be excluded.**

Question 2. **Patients who may be confused must not be given custody of their medicines. This may include patients immediately post-procedure and under the influence of anxiolytic drugs, acutely ill patients or acutely confused patients newly admitted to the ward. The assessment should then be carried out at an appropriate time in the course of the patient's admission to determine if they could then be entered into the scheme at a later stage i.e. when the anxiolytic drugs have worn off or the acute stage of their illness is over.**

Question 3. **The patient needs to understand the written directions in English and be able to open the medicine bottles. If they cannot do either of these then assistance may be required from another discipline for some kind of compliance aid.**

Question 4. **Patients with a past history of drug or alcohol abuse do not have to be excluded from the scheme but the need for extra supervision and reinforcement of education will be highlighted and documented.**

Question 5. **The information leaflet is written information about the self-administration system and the perceived benefits for the patient if they wish to be involved (Form 3). This is given to every patient to read *before* they commence on the self-administration scheme so the patient knows what is expected of them. This must be read and understood by the patient before they consent.**

Question 6. **Consent must be obtained before a patient can be entered into a self-administration scheme. If consent is not given the patient is to be excluded but information about their medicines and what to do after discharge must still be given.**

These guidelines are to be used when assessing patients for the self-administration scheme. They are for guidance only and do not replace or restrict the professional judgement of any health care professional.

**Form 3**

## Self-Administration of Medicines

On this ward a system is used that will enable you to be responsible for taking your own medicines as you do at home. This system is known as self-administration.

Your own medicines, if suitable, will be used as this allows you to continue with familiar medicines and containers. If you need further supplies or a new medication is started then this will be supplied by the hospital pharmacy.

Self-administration may help to improve your knowledge of your medicines and the reason for taking them especially if new medication is started.

This system is not compulsory so you do not have to take part. If you do not take part the nurse will administer your medicines in the normal way and give you information about them for when you go home.

If you agree to take part then a nurse or pharmacist will explain any new medicines and what they are for.

Keep all medicines out of the reach of children. Medicines, if not properly used, can be dangerous.

It is *your* responsibility to keep the medicines in a safe place. This is important as it prevents visiting children and confused patients from gaining access to your medicines. Most of your medicines will be locked in your medicines cabinet but you may be allowed to keep some medicines with you for easier access e.g. creams, eye drops etc. **It is essential that you keep these out of sight and in your bedside locker when not using.**

If a visitor or other patient tries to take your medicines, inform a nurse immediately.

Never share your medicines with anyone else.

If you forget to take a dose of medication, tell a member of the nursing staff.

Do not exceed the prescribed dose.

**Please *return* your key, if one has been issued to you, to your nurse before you go home**.

**Form 4**

## Patient Consent Form for Self-Administration

**For patients assessed as potential candidates for self-medication complete section A or B(+/- C)**

A. The patient does not wish to self-administer his/her medication

**Nurses Signature.....Date:……...**

**B**

**Consent to self-administer**

The self-administration scheme has been explained to me and I am willing to take part. I have received the information leaflet and understand that I can withdraw my consent at any time. I understand I have a responsibility at all times to keep my medicines securely locked away in my medicines cabinet when not in use. I understand certain "when required" medicines can be kept out of sight in my bedside locker when not in use.

Patient Signature ……

Witnessed by ……

Designation ……..……

Date **……..……**

**Withdrawal of consent to self-administer**

**C.**

**I do not wish to remain involved in the self-administration system on this ward due to:**

……
**I therefore withdraw my consent to participate in this system.**

Patient Signature ……

Witnessed by ……

Designation ……..……

Date **……..……**

**APPENDIX 7c**

## SELF-ADMINISTRATION OF INSULIN (all wards)

In accordance with the NPSA, NHS organisations should ensure that they have systems in place to enable hospital inpatients to self-administer insulin where feasible and safe. Similar support is also advocated by NICE quality standard for diabetes inpatient care.

Insulin can have significant deleterious consequences when prescribed, dispensed or administered incorrectly. It is imperative; therefore, that patients in whom self-medication is deemed appropriate (and staff responsible for their care) conform to the strict requirements of this policy.

### Diabetic patients requiring insulin

The Trust acknowledges this special cohort of patients. It is essential, where appropriate, to facilitate self-administration of insulin to enhance patient care and patient experience and to promote safe and effective use prior to discharge. Diabetic patients requiring consideration for self-medication can be classified into 2 groups:

- Those patients who have been self-administering insulin prior to admission to hospital. Such patients need to demonstrate they are safe and competent at administering (including dose adjusting) and blood glucose measuring and recording.
- Patients newly started on insulin that will be self-medicating on discharge. Such patients need to be *instructed* in the first instance on administration (injection technique, dose adjustment) and blood glucose measuring and recording. Subsequently they need to demonstrate safe practice in this regard.

### Patient expectations

Clinicians and nursing staff should discuss with the patient at the earliest opportunity how their insulin may be managed during inpatient stay. Patients must be informed that patient safety is the top priority and that they will be given the option to self-manage their insulin provided they are well enough to do so. Staff should explain that there may be a period of time (e.g. peri-surgery) that would be unsuitable for them to self-manage and the reasons for this.

### Safe storage of insulin

Many patients taking insulin who are admitted to hospital are prescribed their doses at rigid times which may not reflect when they actually eat. Delays in access to insulin that is locked away in medicines trolleys can lead to patient frustration, deranged blood glucose levels and undermines a core principal of self-medication.

A pragmatic solution when balancing access with safe storage is to enable patients to keep their insulin device stored in a bespoke insulin locker that has a secure keypad access and which is fixed to a patient's bedside locker. **This locker must not be used to store anything else.**

***It is essential that patients who are self-medicating are fully aware of their responsibilities in this regard and sign the necessary consent form (form A)***

**Use of patients own insulin**

Suitability of patients own insulin should be assessed as per Appendix 7 A(iii)- Patients Own Drugs. Particular attention should be paid to the following, ensuring:

- The expiry date has not passed
- Vials/cartridges/pens have been open for less than 4 weeks
- Insulin pens/devices have a patient identification label

**Patient Assessment and Consent**

| **Patients to be excluded from the scheme** |
|---|
| • Patients on ITU/POCCU/CCU/HDU<br>• Patients on iv insulin |

Patients being considered for insulin self-administration must be assessed by either a diabetes nurse specialist (DNS) or an ANP (Advanced Nurse Practitioner) (CF diabetes) using form A. Suitable patients must also be given "Patient information about self-administration of insulin on wards" (form B). This ensures a systematic process is followed that ensures patient competency and safety. This process also clearly outlines a patient's responsibilities.

**Patient information, teaching and supervision**

Before consenting to self-administration, patients must read and understand Form B "Patient information about self-administration of insulin on wards".

During assessment by a DNS or ANP (CF diabetes), suitable patients will be entered into the scheme at one of two levels:

| | |
|---|---|
| **LEVEL 1** | **Nursing staff supervise self-administration**<br>• This level is suitable for patients requiring support /supervision of insulin administration during hospital admission and includes those people who are learning to self-administer insulin.<br>• Before administering insulin, the patient should demonstrate that they can safely remove an unused insulin needle if using a pen device. If not, consider vial and syringe or BD AutoShield needle (DNS or ANP (CF diabetes))<br>• The nursing staff must supervise/observe subcutaneous insulin administration and document patient ability to self-inject and prepare correct number of units for injection (DNS or ANP (CF diabetes)).<br>• The nursing staff must provide a sharps disposal unit and explain use of insulin locker (see safe storage of insulin). Level 1 patients can store insulin in lockers but must not access without a nurse being present (DNS or ANP (CF diabetes)).<br>• Nursing staff must assist patient to monitor blood glucose (see below) (DNS or ANP (CF diabetes) or ward staff)<br>• Nursing staff must report suboptimal glycaemic control to medical staff for review of current management (ward staff)<br>• Nursing staff should plan and facilitate appropriate support for discharge e.g. follow up with community diabetes team (DNS or ANP (CF diabetes) or ward staff) |

| | |
|---|---|
| **LEVEL 2** | **Self-administration of subcutaneous insulin**<br>• This level is suitable for people who wish to maintain maximum independence during hospital admission, typically this will be stable patients who have been self-administering at home without problems.<br>• Before administering insulin, the patient should demonstrate that they can safely remove an unused insulin needle if using a pen device. If not, consider vial and syringe or BD AutoShield needle (DNS or ANP (CF diabetes)).<br>• For safety reasons **all** insulin administration must be documented on EPR and subcutaneous insulin and blood glucose monitoring chart (ward staff)<br>• Nursing staff must provide sharps disposal unit and explain use of insulin locker (see safe storage of insulin) (DNS or ANP (CF diabetes))<br>• Patients to monitor their own blood glucose using own quality controlled meter (see below) (DNS or ANP (CF diabetes))<br>• Patients will review glycaemic control and facilitate insulin prescription adjustment (by discussing their control with the medical team/ nursing staff) as required to optimise glycaemic control (see self-titration) (DNS or ANP (CF diabetes)) |

**Measuring and documentation of blood glucose levels and insulin dose**

Clear and accurate measurement and recording of blood glucose levels and insulin doses is of paramount importance. All patients must be given an insulin/blood glucose paper monitoring chart (see below)

**Level 1 patients**- nursing staff will continue to use standard hospital practice for recording blood glucose levels either via hospital meter or patient's own calibrated meter (some patients may wish to measure their blood glucose but nursing staff will record on the paper chart (CF patients only) or EPR as normal)
Patients should have their insulin units recorded on the paper chart (CF patients only) or EPR in the usual way by nursing staff*.

**Level 2 patients**- The patient's meter must be calibrated by the DNS or ANP (CF diabetes) prior to use. Patients must enter the dose taken and blood glucose level on the subcutaneous insulin and blood glucose monitoring chart. Patients need to inform the nurse looking after their care of the number of units they have self-administered and blood glucose level so that the paper chart (CF patients) or EPR (non CF patients only) can be updated*. Nursing staff should also record on EPR if the number of units self-administered is different from the dose prescribed and get the prescription amended accordingly.

Self –titration - A patient who has been deemed competent by the DNS or ANP (CF diabetes) to self-titrate their insulin dose may do so within a specified amount that has been prescribed by either the nurse specialist or medical team. This amount will be clearly stated on EPR and communicated to the nursing ward team.

*Nursing staff caring for patients self-medicating insulin do not need to obtain a second nurse signature for administration. The patient will provide this check.

**On-going Assessment**

As with general self-medication, nursing staff must ensure that any such patients are informally assessed at each medication round. Whilst this is informal and does not require any documentation, it is important to ensure patients under their care maintain capability to safely administer their insulin and adhere to the strict storage requirements of this policy.

Any changes to a patient's condition that warrants cessation of self-administration of insulin should be acted upon in a timely manner and the DNS or ANP (CF diabetes) should be informed. Form A should be signed by nursing staff as appropriate and the patient's insulin removed from their insulin locker and locked away in the medicines trolley or medicines locker to restrict subsequent access. The patient should be informed of the reasons for this action if possible.

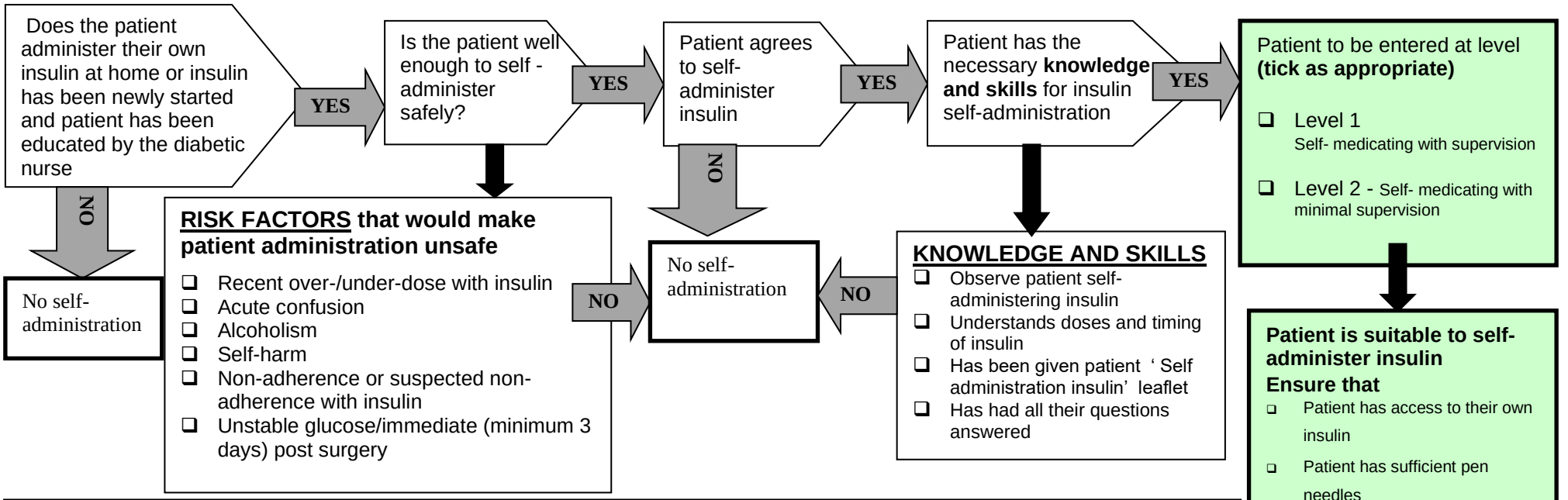
Any changes to a patient's insulin prescription need to be highlighted to both the patient and the nurse looking after their care as soon as possible.

If the patient becomes hypoglycaemic treatment should follow Trust guidelines. The medical team or the DNS or ANP (CF diabetes) must decide whether or not the patient is safe to continue to self-medicate.

If the patient becomes hyperglycaemic ask the patient what they would normally do in this situation. Relay this information to the doctor for agreement/further assessment (as treatment may need to be adjusted)

**Audit**

It is recommended that adherence to this insulin self-administration policy is audited yearly by the pharmacy department in conjunction with the diabetes nurse specialists.




**Signature of patient:**

- **I have read and understood the leaflet "Patient Information about Self Administration of insulin" and have had my questions answered.**
- **I consent to administering my own insulin whilst in hospital and know what doses to give and when**
- **I agree to confirm with the nurse that actual dose and time of each insulin I administer to myself (level 2)**
- **I will ensure that all insulin is safely and securely stored and that used needles are disposed of in the yellow sharps bin**
- **I understand that I may withdraw consent at any time and will alert the nurse if I have any problems or feel unwell**

**Sign:** **Print name:** **Date**

**Signature of DNS or ANP (CF diabetes):**

- ❑ **I am satisfied this patient meets the criteria above and is suitable for self-administration insulin at level..... OR**
- ❑ **This patient is unsuitable or does not consent to self-administering insulin**

**Sign:** **Print name:** **Date:**

**Signature of ward nurse or DNS/ ANP (CF diabetes):**

- ❑ **Change in patients condition. Patient self-administration stopped due to……..**

**Sign:** **Print name:** **Date:**

****Complete a new form if reassessment required later****

**Contact DNS on bleep 2141 or ANP (CF diabetes) on bleep 2144 for any advice**

# Form B

# Patient information about self-administration of insulin on wards

**This leaflet aims to answer your questions about giving your own insulin whilst in hospital. It explains the benefits, risks and alternatives, as well as what you can expect when you come into hospital**

**What is self- administration?**
Self-medication of insulin allows you to take your own insulin whilst in hospital, rather than it being given by a nurse.

**Can everyone who uses insulin self-administer?**
Your diabetes nurse will need to assess that it is safe and in your best interests to administer your own insulin doses. The nurse will need to ask you some questions to make the assessment so they can assess your understanding of insulin, including your doses and injection timings.

If the diabetes nurse feels you are safe to self- administer insulin you will be asked to sign a form that says you agree to do so. You should read this leaflet and ask any questions you have before signing.

If you are very unwell or other changes have been made to your treatment that can affect your glucose, it may not be possible for you to self- administer at this time. In this case a ward nurse will give you the doses.

**What are the benefits to injecting insulin myself?**
We recognise that people with diabetes are often very knowledgeable about their condition and its treatment.

Letting patients with diabetes inject their own insulin whilst in hospitals has been shown to improve timing of doses and therefore give better glucose control

**What are the risks?**
Insulin can be dangerous if a wrong dose is given, this is why we need to ensure that you are well enough to give your own doses during your hospital stay.

For the safety of other patients on the ward **insulin must be stored OUT OF SIGHT** in your special bedside insulin locker. Any used needles must be immediately disposed of in a yellow sharps bin.

You will be approved to self-administer at level 1 or level 2

Level 1- You can store your insulin in your insulin locker but you must only access it when a nurse is present.

Level 2- You may access your insulin locker when you need to.

**What will I need to do?**
If you have any questions after reading this leaflet please ask your diabetes nurse. When you are happy that your questions have been answered and you wish to give your own insulin then the diabetes nurse will ask you sign the consent form.

Make sure you have enough supplies of your insulin and needles for your hospital stay. If not please alert your ward nurse or ward pharmacy team.

Your insulin will be kept in your special bedside insulin locker. Medicines should not be left out unattended. Once you have given a dose you should lock it away in your insulin locker.

Level 1 patients-
The ward nurse will enter your insulin dose and blood glucose level straight onto the electronic system.
If there are any doses changes made whilst you are in hospital you will be made aware of them by the medical or nursing team looking after you.

Level 2 patients-
After dosing write the result on the insulin chart and let your ward nurse know the time and actual dose you injected so the nurse can sign for it on the electronic medication chart.
After checking your blood glucose level write the result on the insulin chart let your nurse know so that they can update the electronic system.
These two things are very important to ensure you are being cared for to the best of our abilities.

**What happens if I change my mind?**
You can change your mind at any time, even if you have signed the consent form. Let staff know immediately if you have changed your mind.

**What if I get confused about my insulin?**
Don’t panic. It is better for us to find out that you have a problem with your insulin while you are in hospital. Together we can seek solutions to these problems.

**Can I monitor my own blood sugar?**
Yes provided your own blood glucose monitor has been assessed as being accurate. If not you can always ask your nurse to check your blood glucose using our own ward meters

**PLEASE CONTACT YOUR WARD NURSE OR PHARMACIST IF YOU HAVE ANY QUESTIONS OR CONCERNS**

## Form C - Self-Administration of Insulin Record Sheet NON CF PATIENTS

Patient Name: _____ D.O.B: _____ Unit Number: _____

Ward: _____ Signed Self Administration Form? Yes ☐ No ☐

Current Insulin and doses: _____

| | | | | | Blood Glucose Levels | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Date | Insulin/Dose Time Given | Insulin/Dose Time Given | Insulin/Dose Time Given | Insulin/Dose Time Given | Pre Breakfast | Pre Lunch | Pre Dinner | Pre Bed | Other | DSN Signature |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

## Form D - Self-Administration of Insulin Record Sheet CF PATIENTS ONLY

**Cystic Fibrosis- diabetic chart**
(Insulin Regime / Blood glucose monitoring)

**NAME:** _____

**CT No:** _____

Regime, as per ANP/Nurse Specialists' direction:

| | Date: | Date: | Date: | Date: | Date: | Date: | Date: |
|---|---|---|---|---|---|---|---|
| Pre breakfast check | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| Breakfast Insulin Dose | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| 2hrs post breakfast | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| Lunch Insulin Dose | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| 2 hrs post Lunch | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| Tea Insulin Dose | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| 2 hrs post Tea | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| Supper Insulin Dose | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| 2hrs post Supper / pre feed | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| L-acting Insulin dose | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| Ward Nurse signature | Time: | Time: | Time: | Time: | Time: | Time: | Time: |
| | | | | | | | |
| CFNS signature | | | | | | | |

Short acting insulin: _____

Long acting insulin: _____

**APPENDIX 8**

## MEDICATION ADMINISTRATION AND STUDENT NURSES

See Section 5.7. LHCH follows single nurse administration except for Controlled Drugs, where the dose has to be calculated or where the dose is weight related.

| ROUTE / CLASS / ACTIVITY | YEAR 1 | YEAR 2 | YEAR 3 |
|---|---|---|---|
| **Single nurse medication administration** | No | No | No |
| Oral excluding Controlled Drugs (CDs) | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse |
| Intravenous medication preparation and administration and flushing cannulae | Can observe only | Can observe only | Can observe only |
| Subcutaneous / intramuscular medication preparation and administration | Can prepare and administer under DIRECT supervision of Registered Nurse | Can prepare and administer under DIRECT supervision of Registered Nurse | Can prepare and administer under DIRECT supervision of Registered Nurse |
| Rectal and vaginal administration | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse | Can administer suppositories and enemas under DIRECT supervision of Registered Nurse |
| Inhaled therapy | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse |
| Topical therapy | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse | Can administer under DIRECT supervision of Registered Nurse |
| Controlled Drugs administration | Can observe administration of CDs | Can act in role of 3rd checker | Can act in role of 3rd checker |
| Via nasogastric tube or percutaneous endoscopic gastrostomy | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse | Can administer medications under DIRECT supervision of Registered Nurse |
| Blood products | Can observe only | Can observe only | Can observe only |

## MEDICATION ADMINISTRATION AND TRAINEE NURSING ASSOCIATES

| | |
|---|---|
| Single trainee associate administration | No |
| Oral medication excluding Controlled Drugs (CD's) and cytotoxic medications | Can administer under the direct supervision of a Registered Nurse. |
| Controlled drugs administration (CDs) | Can act in role as 3rd checker. |
| Intravenous (IV) medication preparation | Not part of training |
| Intravenous (IV) medication administration | Not part of training |
| Subcutaneous (SC) Preparation and administration | Can prepare and administer under direct supervision of a Registered Nurse |
| Intramuscular (IM) Preparation and administration | Can prepare and administer under the direct supervision of a Registered Nurse |
| Per Rectum (PR) | Can administer suppositories and enemas under the direct supervision of a Registered Nurse |
| Per vagina (PV) | Not part of training |
| Inhaled therapy / Oxygen | Can administer under the direct supervision of a Registered Nurse |
| Topical | Can apply under the direct supervision of a Registered Nurse |
| Nasogastric (NG) /Percutanous Endoscopic Gastrostomy (PEG) | Can administer under the direct supervision of a Registered Nurse |

**MEDICATION ADMINISTRATION AND QUALIFIED NURSING ASSOCIATES**

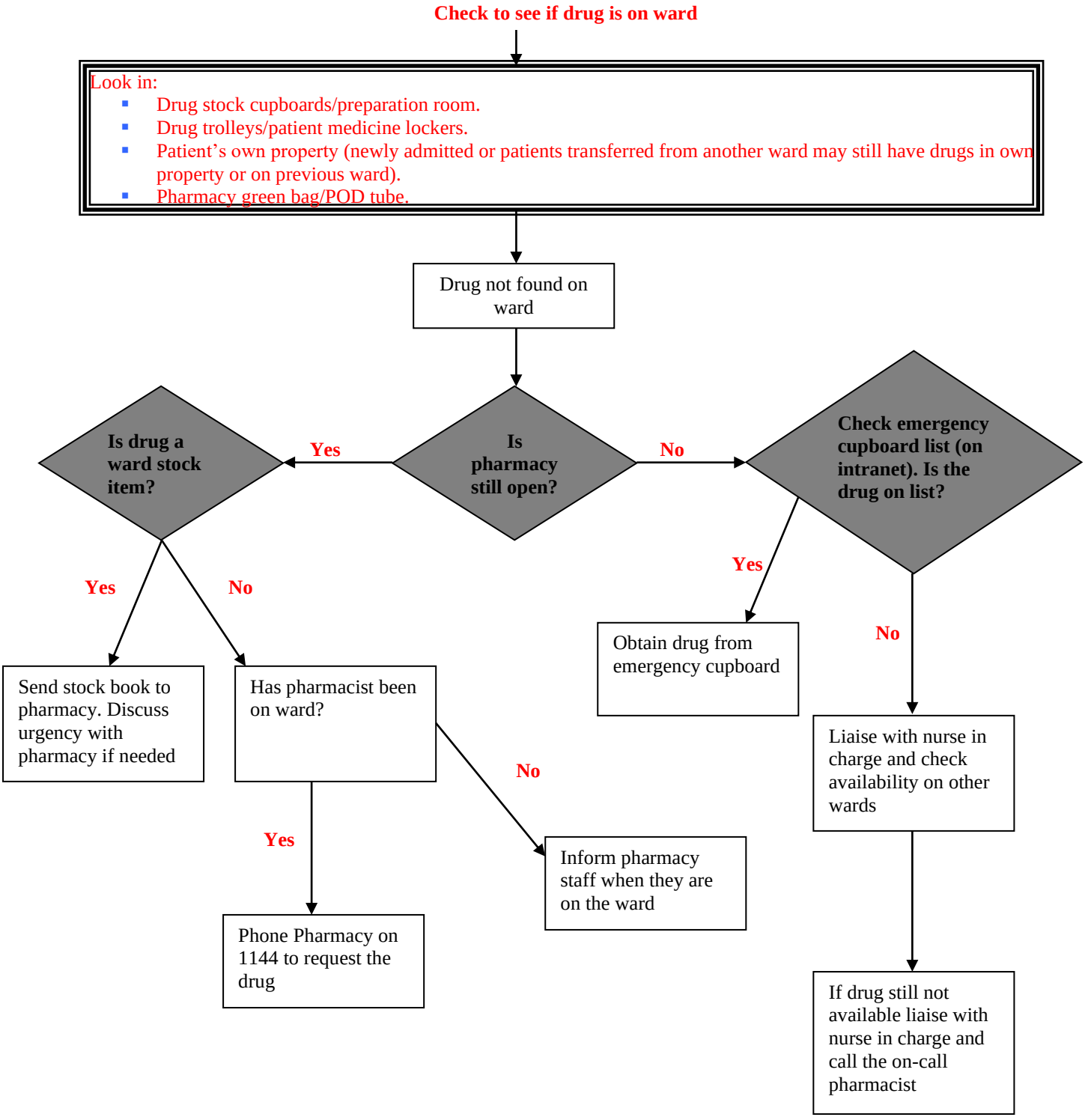
Registered nursing associates are staff registered with the Nursing and Midwifery Council as Nursing Associates. In order to undertake unsupervised administration of medicines the Nursing Associate must have completed LHCH training in medicines management. Registered Nursing Associates can hold the medication keys (BUT not the Controlled Drug keys). Registered Nursing Associates must not supervise Nursing or Nursing Associate students.

| | |
|---|---|
| Oral medication **excluding Controlled Drugs (CD's) and cytotoxic medications** | Can administer oral medications with the exception of Controlled Drugs and cytotoxic agents. |
| Controlled Drugs | Cannot initiate the administration of a Controlled Drug but can be the second checker.<br>Can check and sign the entry in the Controlled Drug Register and the patient's own Controlled Drug Register. Can be the second checker for the Controlled Drug daily reconciliation.<br>Cannot order Controlled Drugs from pharmacy or sign for delivery in the Controlled Drug order book. |
| Intravenous (IV) medication | Cannot be involved in the administration or second check of IVs |
| Subcutaneous (SC) and Intramuscular (IM) injections | Can administer. **Excludes Controlled Drugs, cytotoxic medication and vaccines.**<br><br>Insulin doses must be double checked by registered nurse as per Trust policy.<br>Any manipulations of volumes from a syringe or vial must be double checked by a registered nurse<br><br>To administer Insulin – must have undertaken eLearning, session and associated training |
| Per rectum (PR) | Can administer. |
| Per Vagina (PV) | **Cannot** administer |
| Inhaled therapy / Oxygen | Can administer.<br>**Excluding inhaled antibiotics and inhaled Controlled Drugs** |
| Tropical creams/gels/ lotions & washes | Can administer. |
| Eye drops or ointment, ear drops or sprays, nasal drops, sprays or ointments | Can administer |
| Nasogastric (NG) / Percutaneous Endoscopic Gastrostomy (PEG) | Can administer once attended NG tube training. |
| Blood / Blood products | Cannot administer or act as a 2nd checker for blood or blood products. |
| Cytotoxic medications | **MUST NOT** administer<br>Examples of cytotoxic agents include methotrexate, cyclophosphamide. |
| Unlicensed medications | **MUST NOT** administer |
| Patient Group Directives (PGD) | **MUST NOT** supply and/or administer medicines even under direct supervision if the medicines are supplied / administered under a Patient Group Directive (PGD). |

**APPENDIX 9**

## Action for the Apparent Non-availability of a Medication on the Ward

Before documenting that a drug is not available use the following protocol:



**APPENDIX 10**

| Date: | Ward: | Pharmacist |
|---|---|---|
| Intervention Details | | |
| **Prescriber where appropriate:** | | |
| Outcome | | |

## APPENDIX 11 – MANAGEMENT OF CHEMOTHERPEUTIC MEDICATION (INTRAVENOUS)

In its core business the Liverpool Heart and Chest Hospital does not routinely care for patients that require the administration of cytotoxic and/or cytostatic medication and the Trust is also not licenced as a provider of chemotherapy services. There are, however, rare occasions where this therapy may be required and this appendix aims to set out the processes to be followed by LHCH staff in order to prevent their exposure and the exposure of others (patients and relatives) to the harmful effects of these drugs. This appendix covers the use of one cytotoxic medication only, Cyclophosphamide. This drug has been used in the Trust for treatment of Vasculitis (an up to date version of the vasculitis policy will be available from LUFT). Cyclophosphamide will be referred to as a cytotoxic agent for the remainder of the policy. The administration of cytotoxic agents to patients within LHCH will only occur in the acute phase of illness, as soon as patients are stable for transfer to specialist care.

### A. Roles and Responsibilities

All systemic cytotoxic medicines should be regarded as hazardous and therefore should be handled with caution. This appendix aims to reduce the risk to staff from exposure to substances that are hazardous to health. Cytotoxic agents may be mutagenic, teratogenic and/or carcinogenic. There is now evidence to conclude that health care personnel exposed to these agents, through preparation and administration of cytotoxic agents, the care of patients during chemotherapy and in waste disposal may be at risk if not adequately protected.

The preparation of cytotoxic agents cannot be performed on the LHCH site as this requires specialist facilities; the drug is therefore transferred into pharmacy already prepared in a specifically designed yellow cytotoxic bag. Specialist Nurses and/or medical clinicians with expertise in this area and who are external to the Trust will be responsible for the administration of cytotoxic medication on this hospital site.

<u>Role of Managers</u>

Managers must ensure that a COSHH (Control of Substances Hazardous to Health) assessment is carried out in all areas where cytotoxic drugs are handled in order to assess the level of risk and the adequacy of control measures in place.

The Health and Safety Executive (HSE) has produced general guidance on carrying out a risk assessment (Five steps to risk assessment) as follows:

● identify the hazards – which cytotoxic drugs are handled and what are their potential adverse effects on health?

● decide who might be harmed and how – which employees and others (e.g. other patients, relatives etc.) might be exposed to cytotoxic drugs and how this might happen? For example, through surface contamination of drug

vials or leakage of drugs during preparation and administration, pay attention to groups of workers who may be at particular risk, e.g. young workers, trainees and new and expectant mothers. Pregnant workers are especially relevant, as some drugs may be harmful to the unborn child. Further guidance is contained in New and expectant mothers at work: A guide for employers. Consider others also who could be indirectly exposed, such as cleaners, contractors and maintenance workers too.

● assess how likely it is that cytotoxic drugs could cause ill health and decide if existing precautions are adequate or whether more should be done. Exposure from all routes should be prevented or adequately controlled and you should protect the health of employees from any potential adverse effects. Factors to consider include: -the frequency and scale of contact with cytotoxic drugs; -any relevant information available from accident records; -the effectiveness of control measures.

● record the significant findings of the assessment and keep a written record for future reference.

● review the risk assessment if there are any significant changes and revise it if necessary. It is good practice to review the assessment from time to time anyway, to ensure that precautions are still working effectively.

Precautions must be in place at all times to minimise exposure by using protective garments, appropriate equipment, (Personal Protective Equipment PPE) as well as safe and validated work practices.

All incidents that involve accidental contamination of the skin, eye or blood (needle stick injury) must be reported to the Occupational Health Department and an incident form completed.

Staff Responsibility

Employees have a legal duty to take care of their own health and safety and that of others affected by their actions. Employees must make full and proper use of control measures put in place by the employer. In addition, staff are required to cooperate with their employer, so that the employer can comply with any legal duties placed on them.

Employees should notify their manager as soon as possible if they are pregnant, trying to conceive or are breastfeeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. This is also to comply with HSE guidance, stating that all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.

Any member of staff who suffers an adverse effect as a result of handling a cytotoxic drug, no matter how small, must report this to the Occupational Health Department and complete a critical incident, as soon as possible.

If correct preventative measures are strictly adhered to, personal protective equipment is used and good handling practices followed there should be no significant exposure to cytotoxic agents.

**B. Scope**

The appendix will be used in line with the Vasculitis treatment protocol (see LUFT policy) and applies to all staff working within the Liverpool Heart and Chest Hospital who will be involved in the care of patients who are to receive or have received cytotoxic agents.

- Medical staff
- Nursing staff
- Therapies staff
- Medical Engineering staff
- Pharmacy staff
- Porters and domestic staff

It is the responsibility of each staff member to read, understand and apply this document, thus ensuring that they are aware of what constitutes safe practice in relation to the administration and disposal of consumables used during the administration of cytotoxic agents and the subsequent risks associated with management of the patient.

**C. Standards**

Safe handling of cytotoxic agents

Direct exposure to cytotoxic agents can occur during administration or handling and involves inhalation, ingestion or absorption. The health risk of any procedure involving cytotoxic agents stems from the inherent toxicity of the drug and the extent to which workers and patients are exposed.

At LHCH only external specialist trained nursing or medical staff will administer cytotoxic agents to a patient. The rationale to support this is that LHCH is not licenced to provide this service and that all staff involved in the handling of cytotoxic drugs must attend training sessions which involve: handling of the drugs, the management of cytotoxic spillages and be updated regularly in order to maintain their competence. This training and the required updates are not available at LHCH and the frequency of clinical practice in order to maintain clinical competence is limited.

LHCH staff will have knowledge of the risks associated with cytotoxic agents and the management required as the administration and disposal of the medication and the on-going care for the patient will occur in the clinical area.

Under the Personal Protective Equipment at Work Regulations 1992, personal protective equipment (PPE) should be provided and used wherever there are risks to health and safety that cannot be adequately controlled in other ways. Personal Protective Equipment is necessary when handling cytotoxic agents and their waste products to decrease the risk of occupational exposure.

External expert staff that attend LHCH to prepare and administer cytotoxic agents to patients will follow the standards set out within their parent organisation and this will include:

- The use of PPE for administration of the drug and disposal of waste products

- The availability at each medication administration of a spillage package and be fully conversant with the process required if a spillage were to occur (LHCH pharmacy will store a spillage package in addition, as a precaution)

Staff will not handle cytotoxic agents or waste unless they understand the risks and appropriate techniques for avoiding exposure.

A no touch approach should be adopted when handling cytotoxic agents or their waste products

PPE worn during administration and disposal of cytotoxic agents and when dealing with a cytotoxic spillage should include:

- Disposable gloves
- Gown/apron
- Eye protection

FFP3 masks should be worn during administration and when managing a spillage if there is a risk of spraying, splashing or aerosols.

PPE should be worn by all staff handling patient excreta (urine, vomit, faeces) for 7 days after the administration of medication and includes:

- Plastic apron
- Gloves
- Eye protection
- Eye protection should also be worn for endotracheal suction if not a closed suction system

<u>Disposable gloves</u>
Staff will wear disposable gloves at all times when contact with cytotoxic drugs is possible e.g. handling, administering. They should fit appropriately

and be close fitting to ensure dexterity. Only gloves designed for handling cytotoxic chemotherapy should be used i.e. purple / blue nitrile gloves and it should never be assumed that all gloves are impermeable.

- Change gloves regularly and always between patients
- Damaged gloves should be changed immediately
- Wash hands properly before and after use of gloves
- Powder-free gloves must be used since the powder may absorb cytotoxic contamination
- Use of latex must be risk assessed due to potential for latex allergy in staff and patients. In line with the Department of Health and the National Patient Safety Agency, the department supports the move toward a latex free working environment. PURPLE / BLUE NITRILE GLOVES must be used when handling or administering cytotoxic agents
- For spillages DOUBLE PURPLE / BLUE NITRILE GLOVES must be used

Plastic Aprons/Gowns

Disposable plastic aprons provide immediate protection and prevent absorption into clothing. Where splashing or spraying is possible they provide limited protection and disposable gowns are preferred and should have:

- Closed front
- Long sleeves
- Elastic or knit cuffs

Eye Protection

The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example when clearing up cytotoxic spillages. If splashes or sprays enter the eyes then rinse with copious amounts of water and saline irrigation. Seek medical attention immediately.

Eye protection should:

- Should fully enclose the eyes, meeting British Standard EN 116
- The most suitable form of eye protection for clinical use is safety goggles, giving the eyes protection from dust and splashes

- Goggles should be disposable where possible or capable of undergoing decontamination cleaning

Disposal and Decontamination of Personal Protective Equipment

- All aprons, gowns, gloves and disposable personal protective clothing should be disposed of as cytotoxic waste according to the Hazardous Waste Regulatory Guidelines 2005
- Reusable equipment (eyewear) may be cleaned thoroughly with mild detergent and water before re-use

Patient Waste/Body Fluids

- Personal protective clothing must be worn when dealing with blood, vomit, tracheal aspirate or excreta from affected patients. Patient waste/body fluids may contain high concentrations of cytotoxic drugs or active metabolites both during administration and up to 48 hours after treatment has ceased. It has been shown that these unchanged cytotoxic agents or active metabolites can be an irritant to the skin, eyes and mucous membranes. Invasive lines/devices, ventilator tubing, ET tubes will be handled with caution for up to 7 days, this will also include HF circuits. Although evidence of long-term toxicity is inconclusive and conflicting, all staff and family members handling patient waste should take reasonable precautions to limit exposure and ensure absorption does not occur

- All body fluids (urine, faeces, vomit) will be disposed of as soon as possible

- Disposable items, (e.g. bedpans, urinals, vomit bowls, incontinence pads and nappies) are recommended over re-useable ones

- Soiled bedding and linen should be treated and handled as infected linen and be double bagged

- Invasive devices listed above will be disposed of in purple lidded sharps boxes

**AS A GENERAL RULE BODILY WASTE FROM PATIENTS RECEIVING CYTOTOXIC AGENTS WILL BE ASSUMED TO BE HAZARDOUS FOR 7 DAYS AFTER THE COMPLETION OF TREATMENT. PATIENTS WILL BE CLEARLY IDENTIFIED TO ALL RELEVANT STAFF.**

Patients receiving cytotoxic agents in LHCH will wear hospital night garments for the duration of their period of toxicity to manage the risks associated with home washing.

Environmental

- Pharmacy will hold a spillage kit to cover potential for spillages following their receipt of the cytotoxic agent

- The Specialist Nurse will bring a spillage kit to cover for potential spillages during administration of the cytotoxic agent
- Ward/department facilities must include the necessary medication to deal with anaphylaxis and a defibrillator
- **Protecting Other Patients:** The administration of the cytotoxic agents will be carried out in a quite designated area away from passing traffic (ideally in a side room)
- If a side room is not available, prior to administration of the cytotoxic agents all efforts will be put in place to protect other patients in the clinical area from spillage, contamination with treated patients body fluids

Used Equipment

- While wearing gloves and plastic apron place any needles, syringes, giving sets, empty ampoules/vials or infusion bags into the appropriate rigid sharps disposal box with purple lids

- Giving sets should not be removed from infusion bags prior to disposal

- The sharps disposal box with purple lid should be clearly labelled as cytotoxic waste. Ensure the bag or container is securely closed and is marked with the unit identity

- Sharps disposal boxes containing cytotoxic waste will not be allowed to build up must be regularly collected

- Protective clothing, wipes, aprons and gloves worn during the administration of chemotherapy should be placed in a clinical waste bag and double bagged

**DO NOT STORE OR TRANSPORT CYTOTOXIC WASTE WITH OTHER CLINCIAL OR DOMESTIC WASTES.**

**The administration of cytotoxic agents out of hours will occur only in exceptional circumstances. If there are concerns around the management of body fluids/waste issues outside the scope of this policy then Ward 6A or Ward 9B at the RLBUHT can be contacted for guidance. For clinical concerns the Renal Registrar maybe contacted for advice.**

# APPENDIX 12- Pharmacist Prescription Amendment Protocol “Pharmacist Amendment Prescribing”

## **Pharmacist Amendment of Prescriptions “pharmacist amendment prescribing”**

This Appendix provides clear guidance as to the amendments that can be made to a prescription without being an independent prescriber. This includes inpatient, outpatient and discharge prescriptions. It also aims to clarify permitted practice for pharmacists to other healthcare professionals working in the Trust.

Prior to the advent of electronic prescribing systems, it was common practice for pharmacists to make several different types of amendments on the paper prescription chart, without contacting the prescriber, to ensure prescriptions were clear, correct and appropriate for the patient. This typically included adjustments in:
Timing of administration
Dosage forms
Identification of the drug
Device choice (e.g. inhalers, insulin)
Deletion of duplicate prescriptions

Following the introduction of electronic prescribing, the ability to make such amendments has been lost as it is now necessary to discontinue medicines and re-prescribe the appropriate one. For the clarity of this policy a distinction should be made between conventional prescribing and “pharmacist amendment prescribing”. Although such a process produces a clear audit trail (name of prescriber, date and time stamp), the potential for drug/timing/preparation mis-selection is still possible. For this reason, all pharmacist amendment prescribing should be second checked by another pharmacist. Hence during on call, pharmacists may not make such amendments. Amendments to schedule 2 and 3 Controlled Drugs (beyond those clarifications already permitted by the Misuse of Drugs Act) should be made by the prescriber.

In most instances the pharmacist will discuss with the prescriber before a change to the prescription is made. This policy also details instances when a pharmacist can amend a prescription without first making contact with the prescriber, e.g. when additions are made to clarify a particular aspect of an individual patient’s medication regime.
Where the policy specifies that a discussion with the prescriber is required, pharmacists can make adjustments to drug therapy, provided that the change is discussed with the prescriber and the discussion documented in the patient’s record (as a “pharmacist note”). The record should include the name of the prescriber who agreed the change, the name of the intervening pharmacist and the date.

The independent prescriber is responsible for the accuracy and appropriateness of the medication that they prescribe. Prescribers already receive feedback on prescribing errors and medication safety issues via various routes (pharmacy bulletin, teaching sessions, medication incidents, pharmacist intervention audit).

Although the implementation of this policy may suggest a certain loss of prescribing accuracy feedback to individuals, currently generic prescriber notes are generated and these not necessarily seen/acted upon by the original prescriber. Prior to electronic prescribing, prescribers were often neither consulted with nor received feedback on certain errors.

Within the direction of this policy, if a pharmacist is not comfortable making a specific amendment then they should contact the prescriber to do so.

## 1. Clarification of drug history

Medicines reconciliation and collation of an accurate drug history is critical for ensuring patient safety. Occasionally, the initial prescription may be ambiguous or incorrect.

| Problem | Action by Pharmacist |
|---|---|
| Medication dose on chart differs from medication history or formulation unclear.<br>e.g.<br>Calcium (Brands&Doses)<br>Laxatives (Doses)<br>Inhalers (Dose,Device,Strength)<br>Insulin (Device and Type) | Establish if a deliberate change is documented in the patient records. If not:<br>• Discuss with appropriate prescriber or medical team.<br>• Add note in EPR<br>• Amend the prescription accordingly. |
| **Example:**<br>Seretide accuhaler 500 1puff BD prescribed instead of seretide evohaler 250 2puffs bd<br>Novorapid prescribed instead of novorapid 30<br>Novorapid 10ml vial prescribed instead of 3ml cartridge | |

## 2. Amending the prescribed route of administration

Within the electronic prescribing system, in order to change the route of administration the current prescription needs to be discontinued and re-prescribed with the correct route of administration selected.

| Problem | Action by Pharmacist |
|---|---|
| Prescriber has failed to select an appropriate route of administration. | • Where the prescriber's **intention is clear**, the prescription can be amended without contacting the prescriber.<br>• Where the prescriber's **intention is in any doubt**, the prescriber must be contacted;<br>Discuss with appropriate prescriber or medical team.<br>Add note in EPR<br>Amend the prescription accordingly. |
| **Example:**<br>Hypromellose eye drops are prescribed with no route of administration chosen; the pharmacist can amend the prescription to "affected eye(s)" without contacting the prescriber.<br>Lorazepam injection is prescribed with no route of administration chosen; the pharmacist should contact the prescriber as the intended route is unknown. | |
| Route of administration has changed, but the prescription has not been amended accordingly. | • Where the intended route of administration is clear, the prescription can be amended without contacting the prescriber.<br>• Where there is any doubt, the prescriber must be contacted;<br>Discuss with appropriate prescriber or medical team.<br>Add note in EPR<br>Amend the prescription accordingly. |

| | |
|---|---|
| **Example:**<br>Patient has a naso-gastric (NG) tube inserted as they are unable to swallow safely. The pharmacist has been asked for advice on what medication can be given via the NG tube.<br>In these instances, the pharmacist can amend the relevant prescription(s) to the route “via NG tube” without contacting the prescriber.<br>NB It must be clear that NG administration is appropriate (i.e. patient is absorbing, tube position correct, patient is not aspirating etc) | |

**3. Incorrect dosing schedule - i.e. timing**

| **Problem** | **Action by Pharmacist** |
|---|---|
| Medicines prescribed at inappropriate schedules in terms of patient preference, clinical efficacy, potential for drug interaction or medicines prescribed regularly which may be more appropriate on a PRN schedule. | • The pharmacist can amend schedules to improve efficacy, promote compliance or take account of patient preference without contacting the prescriber or medical team.<br>• No documentation is required in EPR.<br>• Contact with the medical team should occur retrospectively for education purposes where indicated. |
| **Examples:**<br>A Parkinson’s medicine taken at atypical times<br>A quinolone antibiotic prescribed at the same time as ferrous sulphate. These medicines interact resulting in reduced absorption of the antibiotic so the times of administration need amending.<br>Metformin which is not prescribed at meal times (e.g. 500mg 3X which schedules administration at 08:00, 14:00 and 22:00 hours) needs the times of administration changing (i.e. to 500mg 3X MEALS which schedules medicines at breakfast, lunchtime and teatime).<br>A bisphosphonate prescribed at a meal-time when it needs to be on an empty stomach.<br>Changing the day of a weekly drug to correspond with the day the patient usually takes the medicine. | |
| Medicines prescribed "when required" where they are unlikely to be therapeutically effective unless given regularly. | • The pharmacist can amend a prescription to a regular schedule without contacting the prescriber or medical team.<br>• No documentation is required in EPR.<br>• Contact with the medical team should occur retrospectively for education purposes where indicated. |
| **Example:**<br>Nystatin oral solution or chloramphenicol eye drops prescribed PRN can be amended so they are given regularly, for example QDS. | |

## 4. Obsolete medicines

| Problem | Action by Pharmacist |
|---|---|
| Medicines which are obsolete. | • The prescriber should be contacted to confirm obsolete medicines.<br>• The pharmacist can discontinue obsolete medicines, such as regular or when required medicines which are no longer clinically necessary and are not being administered.<br>• Document in EPR |
| **Examples:**<br>Laxatives may be discontinued when they are no longer required and a patient has been refusing therapy.<br>Theatre Drugs still prescribed on ward post procedure.<br>ITU/POCCU drugs still prescribed on ward post transfer | |

## 5. Duplicate therapy

Duplicate orders may result in overdose.

| Problem | Action by Pharmacist |
|---|---|
| Identical duplicate medicines prescribed | • Establish this is not intentional e.g. EPR won't allow a higher frequency to be prescribed<br>• The pharmacist can discontinue a duplicate prescription without contacting the prescriber or medical team.<br>• No documentation is required in EPR.<br>• Contact with the medical team should occur retrospectively for education purposes where indicated. |
| **Examples:**<br>Warfarin prescribed twice<br>Lansoprazole prescribed twice | |

## 6. Incorrect Dosage Forms

| Problem | Action by Pharmacist |
|---|---|
| Patient unable to swallow solid dosage forms or patient now able to swallow solid dosage forms.<br>(This includes patient's with enteral tubes.) | • The pharmacist can change a prescription to/from liquid medicines if appropriate without contacting the prescriber or medical team.<br>• *Pharmacists should be mindful of dose inequivalencies and refer to standard sources for guidance*<br>• Add note in EPR |
| **Examples:**<br>The patient may have an enteral feeding tube or be unable to swallow tablets. The pharmacist can amend the prescription to a suitable liquid formulation to ensure the patient receives the correct medicines.<br>e.g. Phenytoin, Iron, Digoxin<br>If switching from citalopram 20mg tablets to drops, the pharmacist may amend the dose to 16mg as described in the BNF. | |
| Patient is prescribed a drug but using an inappropriate strength product, i.e. when a higher or lower strength preparation is available. | • Check if reason e.g. swallowing difficulties of higher strength preparations<br>• The pharmacist can change a prescription so that the prescribed product is the same strength as the dose required without contacting the prescriber or medical team.<br>• No documentation is required in EPR. |
| **Example:**<br>Clexane 40mg syringe prescribed for a treatment dose e.g. 98mg | |
| Patient is prescribed a dose of a drug that is not measurable | • The pharmacist can change a prescription to the nearest measurable dose (provided there will be no likely therapeutic consequence) without contacting the prescriber or medical team.<br>• No documentation is required in EPR. |
| **Examples:**<br>Patient prescribed 100mg enoxaparin, the pharmacist may amend the dose to 99mg (which is measurable in a 120/150mg syringe) | |

## 7. Prescription therapy that may result in significant patient harm

Very occasionally medicines are prescribed which if administered to a patient could cause fatality or significant harm. The pharmacist has a duty of care to protect the patient from such events.

| Problem | Action by Pharmacist |
|---|---|
| Where a pharmacist considers that the prescribed therapy presents an immediate danger to a patient | • The pharmacist will liaise with nursing staff to ensure the drug is not given.<br>• The pharmacist should suspend the order from the prescription. Immediate attempts must then be made to contact the prescriber or medical team.<br>• The pharmacist should be prepared to offer advice on alternative therapy.<br>• Add note in EPR<br>• The pharmacist must complete an LHCH Clinical Incident Form. |
| **Example:**<br>A patient is prescribed daily methotrexate<br>Penicillin prescribed to a patient who has previously suffered an anaphylactic reaction to penicillin | |

## 8. Antibiotics

The prescribing of antibiotics raises some specific issues that are addressed in this section. For issues regarding amending doses, dose frequencies, and routes of administration see earlier sections in this policy.

| Problem | Action by Pharmacist |
|---|---|
| No stop date is indicated on the antibiotic prescription, or the review date on the prescription has passed. | • If the stop date or new review date is clearly documented on EPR (e.g. a Ward Round note), the pharmacist can modify the prescription to include the stop date or new review date.<br>• If not clearly documented, the prescriber must be contacted to clarify and the pharmacist can then modify the prescription.<br>• Add note in EPR including name of prescriber contacted |
| Incorrect indication is included on the antibiotic note for the prescription. | • If the indication is known (e.g. from the medical notes) the pharmacist can change the indication on EPR to the correct one.<br>• Contact with the medical team should occur retrospectively for education purposes where indicated. |

## 9. Suspending and resuming items

| Problem | Action by Pharmacist |
|---|---|
| Patient requires a medicine to be suspended for a period of time. | • Contact the prescriber or medical team to confirm the need to suspend the medicine, and the period of time required.<br>• Add note in EPR<br>• Amend the prescription accordingly. |
| Patient normally uses tiotropium inhaler. Currently prescribed ipratropium nebs. | |
| A medicine is suspended that now needs to be resumed. | • Contact the prescriber or medical team to confirm the need to resume the medicine.<br>• Add note in EPR<br>• Amend the prescription accordingly |
| Example:<br>Patient had metformin suspended prior to going for an angiogram which they have now had. The pharmacist can resume the medicine after contacting the prescriber. | |

## 10. TTO amendments

Specific amendments that may be required on a discharge prescription.

| Problem | Action by Pharmacist |
|---|---|
| The course length for a drug on the TTO does not match the course length indicated on the inpatient prescription or that detailed within the notes section | • The pharmacist can modify the prescription to amend the stop date, without contacting the prescriber or medical team, where the intended course length is clear.<br>• The prescriber should be contacted to clarify if there is any uncertainty regarding their intended course length.<br>Document in the patient's medical notes or add a note to the patient's electronic prescribing record only if the prescriber has been contacted. |
| The TTO indicates that a prescribed item is not to be continued by the GP, but is in fact a long-term medication (or vice versa). | The pharmacist can amend the "GP to continue" flag, without contacting the prescriber or medical team.<br>No documentation is required in the patient's medical notes.<br>Contact with the medical team should occur retrospectively for education purposes where indicated. |
| A prescribed medicine on a TTO needs further information for the GP regarding ongoing prescriptions in primary care (e.g. recommended dose changes, monitoring requirements, etc) | The pharmacist can add relevant details as a "note to appear in the discharge letter" without contacting the prescriber or medical team, where deemed appropriate.<br>No further documentation is required in the patient's medical notes. |
| Flushes and diluents required for TTO antibiotics not prescribed either as inpatient or on tto<br>*This also applies to outpatient prescriptions* | • The pharmacist can modify the prescription to add flushes/diluents without contacting the prescriber or medical team |

**Summary table: must be read in conjunction with the full section of the document**

| Section Heading | Prescriber must be contacted | Document in EPR notes |
|---|---|---|
| **1. Clarification of drug history** | | |
| Medication dose on chart differs from medication history or formulation unclear (IF NOT DELIBERATE) | Y | Y |
| **2. Amending the prescribed route of administration** | | |
| Prescriber has failed to select an appropriate route of administration.(IF INTENTION IS CLEAR) | Y | Y |
| Route of administration has changed, but the prescription has not been amended accordingly. | N-IF INTENTION IS CLEAR<br>Y-IF INTENTION IS UNCLEAR | N-IF INTENTION IS CLEAR<br>Y-IF INTENTION IS UNCLEAR |
| **3. Incorrect dosing schedule - i.e. timing** | | |
| Medicines prescribed at inappropriate schedules | N | N |
| Medicines prescribed "when required" where they are unlikely to be therapeutically effective unless given regularly. | N | N |

| | | |
|---|---|---|
| **4. Obsolete medicines** | | |
| Medicines which are obsolete. | Y | Y |
| **5. Duplicate therapy** | | |
| Identical duplicate medicines prescribed | N | N |
| **6. Incorrect Dosage Forms** | | |
| Patient unable to swallow solid dosage forms or patient now able to swallow solid dosage forms. (This includes patient's with enteral tubes.) | N | Y |
| Patient is prescribed a drug but using an inappropriate strength product, i.e. when a higher or lower strength preparation is available. | N | N |
| Patient is prescribed a dose of a drug that is not measurable | N | N |
| **7. Prescription therapy that may result in significant patient harm** | | |
| Where a pharmacist considers that the prescribed therapy presents an immediate danger to a patient | SEE FULL DETAILS SECTION 7 | |
| **8. Antibiotics** | | |
| No stop date or review date is indicated on the antibiotic prescription – but documented in notes. | N | Y |
| No stop date or review date is indicated on the antibiotic prescription and NOT documented in notes. | Y | Y |
| Incorrect indication is included on the antibiotic note for the prescription. | N | Y |
| **9. Suspending and resuming items** | | |
| Patient requires a medicine to be suspended for a period of time. | Y | Y |
| A medicine is suspended that now needs to be resumed. | Y | Y |
| **10. TTO amendments** | | |
| The course length for a drug on the TTO does not match the course length indicated on the inpatient prescription or that detailed within the notes section | N-IF CLEAR<br>Y-IF UNCLEAR | N-IF CLEAR<br>Y-IF UNCLEAR |
| The TTO indicates that a prescribed item is not to be continued by the GP, but is in fact a long-term medication (or vice versa). | N | N |
| A prescribed medicine on a TTO needs further information for the GP regarding ongoing prescriptions in primary care (e.g. recommended dose changes, monitoring requirements, etc) | N | N |
| Flushes and diluents required for TTO antibiotics not prescribed either as inpatient or on tto<br>*This also applies to outpatient prescriptions* | N | N |

## Medicines Supplies to suspected/positive COVID Patients and COVID Cohort Areas

The following changes are designed to minimise cross contamination and risk to staff

**Medicines**

- **No medicines should be returned to pharmacy from a COVID cohort area or POSITIVE/SUSPECTED COVID patient under any circumstances**. Any unwanted medicines must be double bagged and destroyed on ward (put in a yellow bin with blue lid- *Pharmaceutical waste only*). This is similar to the process followed for patients with seasonal flu
- **Medicines (stocks, patients own etc) MUST NOT be moved from a COVID cohort area or POSITIVE/SUSPECTED COVID patient under any circumstances to a NON COVID area**
- If a COVID +ve patient becomes negative during their inpatient stay and moves wards, a full medicines resupply should be made. Existing medicines should be destroyed as above and NOT transferred with the patient.
- Patient own Drugs (PODs) should be kept locked away as normal in the patient's locker/drawer. These should be wiped down adequately when the patient leaves.
- **Controlled Drug** (CD) PODs - wards to contact pharmacy to check if stocked/able to obtain in timely fashion. If yes- patient's relatives should take POD CD home if possible.
- If not possible/delay in pharmacy stock- Contents should be recorded in patients own CD register as normal by 2 ward staff. 2 Ward staff should place CD POD into red plastic tamper evident plastic bag (available from pharmacy) labelled with contents and stored as below.
- **CD PODs should be kept in the patient's room/bedside and adequately secured with other medicines and NOT in the standard ward CD cupboard. Unwanted CD PODs should be denatured using DOOP kits (available from stores) and incinerated as above. 2 ward staff should enter destruction record in patient's own CD register.**
- Staff should avoid using patients own CDs if possible. Where it is necessary (i.e. dose due and no stock) the red bag should be

opened, dose given & recorded in register, new red bag resealed with 2 ward staff and relabelled with contents.

Appendix 13

| **WARDSOP016**<br>Page 1 of 4 | |
|---|---|
| Liverpool Heart and Chest Hospital NHS Foundation Trust | Compiled by: B. Davies / M. Vincent |
| | Approved by: G. Holland |
| | Date: 06.05.2021 |
| Revision Date: see below | Supersedes Document: None |
| **SUPPLY OF PRE-LABELLED MEDICINES FROM A WARD** | |

## Purpose

This SOP covers the process for the supply and documentation of pre-labelled medicines supplied on discharge. This process must only occur after the discharge prescription for the medicine has been completed by an authorised prescriber and verified by a pharmacist.

## Scope

Wherever possible, prescriptions for medicines should be dispensed in the pharmacy department. This SOP covers pre-labelled medicines supplied by pharmacy for issuing to patients when the Pharmacy is closed.

Pre-labelled medicines for discharge are available in the following authorised locations:

1. The emergency drug cupboard (EDC) located in Pharmacy (see Emergency Cupboard Procedure in Appendix 2 of the Medicines Policy).
2. Authorised ward areas:
    a. Acute Cardiac Unit (ACU)
    b. Birch Ward
    c. Holly Suite

Pre-labelled medicines are those that already have a dispensing label with directions to complete along with the patient's name and date of supply with the specific purpose of discharge prescription supply.

This SOP will provide instruction and outline staff responsibilities when providing pre-labelled medicines to patients. All nursing staff issuing medicines in this way must have read and understood this SOP and signed the signature sheet in Appendix 3. Any medicines that are not pre-labelled are excluded from this SOP. This SOP does not replace the 'TTO teach-back' process.

## Procedure

Only authorised ward areas are permitted to use pre-labelled medicines from their area and only when the pharmacy is closed. Areas without this facility should follow the EDC procedure.

| | |
|---|---|
| Liverpool Heart and Chest Hospital NHS Foundation Trust | Compiled by: B. Davies / M. Vincent |
| | Approved by: G. Holland |
| | Date: 06.05.2021 |
| Revision Date: see below | Supersedes Document: None |

**SUPPLY OF PRE-LABELLED MEDICINES FROM A WARD**

**Procedure for issuing pre-labelled medicines from authorised ward area:**

1. The verified TTO should be printed by a registered nurse on the ward. Items to be dispensed at ward level will be identified in the quantity box on the discharge summary by 'Ward TTO'.
2. A registered nurse will check the TTO against the label ensuring the following details match and any blank dose instructions are completed where required:
    a. drug
    b. strength
    c. dose
    d. directions
    e. formulation
3. The registered nurse MUST check the expiry date of the medicine.
4. The patients name, date of supply and, where applicable, the dose and frequency must be completed on the label by the registered nurse.
5. A second registered nurse or doctor must second check the labelled medicine corresponds with the prescribed dose, strength, frequency, quantity and is in date. They must also check the patients name and date of issue are correctly endorsed.
6. The issue log (Appendix 1) must be endorsed, signed and dated indicating the quantities given by the nurse. The record must be then separately endorsed by the nurse and second checker.

**Procedure for issuing pre-labelled medicines from the EDC out of hours:**

1. The verified TTO should be printed by a registered nurse on the ward. Items to be dispensed from the EDC will be identified in the quantity box on the discharge summary by 'EDC'.
2. A member of the ward team will obtain the required pre-labelled discharge medicines from the EDC
3. The 'items taken log' must be endorsed, signed and dated indicating the quantities taken. This ensures stock can be replenished in a timely fashion.
4. A registered nurse will check the TTO against the label ensuring the following details match and any blank dose instructions are completed where required:
    a. drug
    b. strength

c. dose
d. directions
e. formulation



5. The registered nurse MUST check the expiry date of the medicine.
6. The patients name, date of supply and, where applicable, the dose and frequency must be completed on the label by the registered nurse.
7. A second registered nurse or doctor must second check the labelled medicine corresponds with the prescribed dose, strength, frequency, quantity and is in date. They must also check the patients name and date of issue are correctly endorsed.
8. The issue log (Appendix 2) must be endorsed, signed and dated indicating the quantities given by the nurse. The record must be then separately endorsed by the nurse and second checker.

**Procedure for replenishing ward discharge medicines stock by pharmacy:**

1. Discharge medicines packs are on the stock lists for the authorised wards and stock will be replenished as part of the weekly top-up service.
2. The pharmacy assistant technical officer will check the issue log on a weekly basis and check the log correlates with the number of pre-labelled medicines stock left in the cupboard and replenish as needed.
3. Any discrepancies will be brought to the attention of the Ward Manager and Deputy Chief Pharmacist for investigation.
4. Issue logs in Appendices 1 and 2 will be brought back to Pharmacy on a monthly basis to be archived.

| Annual review | 2022 | 2024 | 2026 |
|---|---|---|---|
| Date | | | |
| Signature | | | |

## Appendix 1: Ward Issue Log for Pre-labelled Discharge Medicines (Ward TTO Cupboard)

| **ISSUE LOG: WARD**<br>**PRELABELLED DISCHARGE PACKS** | **Date:** | | **Date:** | | **Date:** | | **Date:** | | **Date:** | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Ward: _____** | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | |
| | **Unit No:** | | **Unit No:** | | **Unit No:** | | **Unit No:** | | **Unit No:** | |
| | **Nurse / Checker signature below:** | | **Nurse / Checker signature below:** | | **Nurse / Checker signature below:** | | **Nurse / Checker signature below:** | | **Nurse / Checker signature below:** | |
| **Aspirin 75mg tabs** One tab each morning | | | | | | | | | | |
| **Atorvastatin 80mg tabs** One tab at night | | | | | | | | | | |
| **Bisoprolol 1.25mg tabs** One tab once a day | | | | | | | | | | |
| **Bisoprolol 2.5mg tabs** One tab once a day | | | | | | | | | | |
| **Bisoprolol 5mg tabs** one tab once a day | | | | | | | | | | |
| **Clopidogrel 75mg tabs** One tab once a day | | | | | | | | | | |
| **Eplerenone 25mg tabs** One tab once a day | | | | | | | | | | |
| **GTN 400mcg spray**<br>One or two puffs when required for chest pain | | | | | | | | | | |
| **Lansoprazole 30mg caps** one cap once a day | | | | | | | | | | |
| **Nicotinell TTS 20 14mg Patches**<br>One patch every 24 hours | | | | | | | | | | |
| **Nicotinell TTS 30 21mg Patches**<br>One patch every 24 hours | | | | | | | | | | |
| **Nicorette 1mg Oral Spray (Quickmist)**<br>One to two sprays prn | | | | | | | | | | |
| **Ramipril 1.25mg caps** Take….caps…..times a day | | | | | | | | | | |
| **Ramipril 2.5mg caps** Take….caps…..times a day | | | | | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Spironolactone 25mg tabs** One tab once a day | | | | | | | | | | |
| **Ticagrelor 90mg tabs** One tab twice a day | | | | | | | | | | |

## Appendix 2: Ward Issue Log for Pre-labelled Discharge Medicines (EDC Cupboard)

| **ISSUE LOG: WARD**<br>**PRELABELLED DISCHARGE PACKS** | **Date:** | | **Date:** | | **Date:** | | **Date:** | | **Date:** | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Ward: _____** | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | | **Patient Name:** | |
| | **Unit No:** | | **Unit No:** | | **Unit No:** | | **Unit No:** | | **Unit No:** | |
| | **Nurse / Checker signature below** | | **Nurse / Checker signature below** | | **Nurse / Checker signature below** | | **Nurse / Checker signature below** | | **Nurse / Checker signature below** | |
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## Appendix 3: SOP Signature Sheet

Please add your name to the list and sign and date against your name when you have read and understood procedure:

| Ward:_____ | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Surname** | **Forename** | **Signature** | **Date** | **Surname** | **Forename** | **Signature** | **Date** |
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## 8. Endorsed By:

| Name of Lead Clinician / Manager or Committee Chair | Position of Endorser or Name of Endorsing Committee | Date |
|---|---|---|
| Dr Watt | Drug & Therapeutics | 16/11/2022 |

| Record of Changes to Document version | | | | |
|---|---|---|---|---|
| Changes approved in this document: | | | Date: | |
| **Section Number** | Amendment (***shown in bold italics)*** | Deletion | Addition | Reason |
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# Patient Group Directions

## Protocol

| For completion by Author | | | |
|---|---|---|---|
| Author(s) Name and Title: | Rebecca Renfrew (Clinical Pharmacist), Danny Forrest (Chief Pharmacist) | | |
| Scope: | This document applies to all registered nurses, pharmacists and allied health professional who are able to supply pharmaceuticals under a patient group directions (see Appendix 1) | Classification: | Clinical |
| Version Number: | 9.0 | Review Date: | 31/05/2024 |
| Replaces: | 8.0 | | |
| To be read in conjunction with the following documents: | Medicines Policy, Non-Medical Prescribing Policy, Administration of Discretionary Medicines Policy | | |
| Document for public display: | Yes | | |
| Executive Lead | Dr Raph Perry | | |

| For completion by Approving Committee | | | |
|---|---|---|---|
| Equality Impact Analysis Completed: | | No | |
| Endorsement Completed: | Yes | Record of Changes | Yes |
| Authorised by: | Drug & Therapeutics | Authorisation date: | 18/05/2022 |

| For completion by Document Control | | | | | |
|---|---|---|---|---|---|
| Unique ID No: | TD03(09) | Issue Status: | Approved | Issue Date: | 30/05/2022 |
| After this document is withdrawn from use it must be kept in archive for the lifetime of the Trust, plus 6 years. | | | | | |
| Archive: | Document Control | | Date Added to Archive: | | |
| Officer responsible for Archive: | IG and Document Control Facilitator | | | | |

# Contents

# Document Statement

This protocol is designed to provide clarification regarding the use of Patient Group Directions (PGDs) at Liverpool Heart and Chest Hospital (LHCH) and is referred to within the Trust's Medicines Policy. This protocol defines when a Patient Group Direction may be used at LHCH and which LHCH staff can

- Supply/Administer under a PGD
- Write PGDs
- Provide training on the use of PGDs
- Approve PGDs for use at LHCH

# 1. Roles and Responsibilities

The Drug and Therapeutics committee is responsible for approving this protocol.

The Director of Nursing is responsible for identifying suitable personnel for training in the use and application of this protocol, via the ward managers/line managers.

The ward managers/line managers are responsible for recommending which staff members from their ward/ area should be trained in the use and application of PGDs. On completion of training, ward managers/ line managers are responsible for assessing competency of staff using appendix four for this purpose. Ward managers/ line managers will authorise the staff member (once competent) by witnessing the signing of the record sheet on the ward/ department (appendix 3) and indicating this by adding their signature. The individual member of staff is responsible for ensuring all forms are completed before authorisation to supply under a PGD. The ward manager/line manager is responsible for ensuring that only staff deemed competent (following completion of appendix 3, 4 and 5) administer/supply under a PGD.

The Training Pharmacist is responsible for providing training for nursing staff on the PGDs. Nurse facilitators, designated Physiotherapists, clinical practice facilitators, clinical educators, hospital co-ordinators and designated nurse specialists may be responsible for providing training for members of staff in certain specialist PGDs, as stated in the individual PGD.

# 2. Procedure

### 3.1 Definitions

**Patient Group Direction (PGD**)
A Patient Group Direction (PGD) is a written instruction for the supply or administration of a specified medicine (or medicines) to patients, where these patients may not be individually identified before presenting for treatment. This should not be interpreted as indicating that the patient must not be identified; patients may or may not be identified, depending on the circumstances. PGDs may only be used by individually named Healthcare Professionals (see appendix 1) working in a specified clinical area. The named healthcare professional is responsible for supplying/administering the specific medicine and **cannot** direct another member of staff to do so.

A PGD is NOT the same as a 'Patient Specific Direction' which is the traditional written instruction, from a doctor, dentist, nurse or pharmacist independent prescriber, for medicines to be supplied or

administered to a named patient. The Health Service Circular (HSC 2000/026) states that 'the majority of clinical care should still be provided on an individual, patient-specific basis'. Prescribing or a Patient Specific Direction remains the preferred option for the majority of care. Nurses, Pharmacists and other Allied Healthcare Professionals considering the supply/administration of medicines outside the legal framework of a PGD (or the legal exemptions from the Medicines Act for the sale, supply and/or administration of certain medicines) should refer to the Trust's Non-Medical Prescribing Policy.

PGDs should only be used in circumstances where there is no opportunity in the care pathway for a prescriber (medical or non-medical) to write a patient specific direction.

**Prescription Only Medicines (POM)**
A Prescription Only Medicine can only be sold/supplied in accordance with a prescription written by a doctor, dentist or other approved prescriber.

**General Sales List Medicine (GSL)**
General Sales List medicines are those which are able to be sold or supplied otherwise than by or under the supervision of a pharmacist i.e. can be sold in general shops as well as through pharmacies, albeit often in small quantities. All of the products are sold in manufacturer's original packs.

**Pharmacy Medicine (P)**
A Pharmacy medicine can only be sold through a registered pharmacy under the personal supervision of a pharmacist.

### 3.2 Contents of a Patient Group Direction

For a Patient Group Direction to be legal it must contain the following information:

- Date from which the PGD shall have effect and after which it should be reviewed (at least every 2 years)
- Clinical situations which the specified medicine(s) may be used to treat
- Clinical criteria under which a person shall be eligible for treatment
- Details of patients excluded from treatment under the PGD
- Legal status of the drug i.e. POM, P, GSL
- Applicable dosage or maximum dosage
- Frequency of administration
- Strength, or maximum strength, at which the specified medicine(s) is to be administered
- The route of administration
- Details of relevant warnings/contraindications to note
- Whether there are circumstances when further advice should be sought from a doctor/dentist, and, if so, what circumstances
- The pharmaceutical form or forms i.e. capsule, liquid which the specified medicine(s) is to be administered/supplied
- Where the PGD relates to supply, any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what those restrictions are.
- Any minimum or maximum period of administration applicable to the specified medicine(s)
- Details of any follow up action to be taken and the circumstances in which this applies
- Arrangements for referral for medical advice

- Details of the records to be kept of the supply and/or the administration of medicines under the PGD
- Signature of a doctor/dentist and a senior pharmacist

All relevant evidence used to develop the PGD should be referenced in the PGD e.g. SPC or NICE guidance.

### 3.3 Patient Group Directions at LHCH

#### 3.3.1. Medicines Suitable for Supply / Administration under a PGD

All **licensed** medicines (POM, P and GSL) may be considered for inclusion in a Patient Group Direction **except** in the following circumstances:

**a) Licensed medicines used outside the Summary of Product Characteristics (SPC) - 'off license' use**

Only in exceptional circumstances where the use is justified by best clinical practice should these medicines be considered for use under a PGD. The PGD must clearly state that the product is being used outside the terms of the SPC and state the reasons why its use is necessary.

**b) Newly licensed drugs (Black Triangle drugs)**

These should only be considered if supported by best clinical practice. The PGD must clearly state the status of the product.

**c) Antimicrobials**

These should only be considered where it is clinically essential and justifiable and where measures to combat resistance will not be compromised. A local microbiologist should be involved in the development of the PGD and this should be clearly documented within the PGD.

**d) Controlled Drugs**

Certain controlled drugs may be supplied under a PGD but this is not routinely recommended by the Trust. Where a circumstance arises in which there may be a need for a controlled drug PGD, this should be discussed with pharmacy to check current legislation.

Dosage ranges are allowed under a PGD as long as the dose and clinical criteria for selecting the dose within the range are specified. The person supplying or administering under the PGD must be assessed as competent to make the dosage decision. A PGD should not be used in the management of chronic disease or for medication requiring frequent dose adjustment.

It is recognised by the Trust that General Sales List and Pharmacy medicines (including Oxygen) do not legally require a PGD but, to ensure safe administration, the Trust has agreed that these medicines should only be supplied/administered by non-prescribers either under a PGD or under the 'Administration of Discretionary Medicines Policy'. Furthermore, since there is no enshrined legislation for non-prescribers to make dose adjustments without making a supply or administering a medicine, the Trust recognises that in certain circumstances the format of a PGD will protect healthcare professionals to make these necessary adjustments (see ticagrelor PGD as an example).

#### 3.3.2 How to Write a PGD

Healthcare professionals listed in Appendix 1 working at band 6 or higher with at least 6 months experience at the LHCH may write a PGD for use in their clinical area of expertise.
All PGD proposals must initially be submitted by email to the PGD pharmacist. These proposals will then be reviewed by the PGD working group. The PGD working group which includes:

- PGD pharmacist
- Training pharmacist
- Nursing manager
- Respiratory Consultant
- Any other co-opted member

All members of this team should ensure that they understand the legal implications and requirements for a PGD that must be in place before a PGD can be in operation.

Once the PGD has been reviewed and considered appropriate by the team above, the PGD must be submitted to the Drug and Therapeutics Committee for approval. The approved paper copy must have the written approval of the:

- Head of all staff that may be using the PGD (e.g. Director of Nursing, Chief Pharmacist or Head of Physiotherapy or Radiology)
- Senior pharmacist
- Clinical Lead (Department specific PGDs only)
- Chair of Drug and Therapeutics

The template listed in Appendix 2 must be used to write a PGD. Any Healthcare professional considering writing a PGD for use at LHCH should refer to the algorithm in Appendix 5 as a quick reference guide.

### 3.3.3 Approval of PGDs

All PGDs to be used at LHCH are subject to approval by the Drug and Therapeutics Committee and hence require the signature of the Chair of this committee. All PGDs must be reviewed and resubmitted to the
Committee every 2 years. The committee reserves the right to withdraw any PGD it considers no longer appropriate.

### 3.3.4 Using PGDs

Before practising under a PGD, a health professional should ensure that they:

- Meet the staff requirements
- Receive training and be assessed competent and authorised
- Have signed the appropriate documentation
- Are using the most recent version of the PGD (available on the Trust intranet)
- Have read and understood the context and content of the PGD

When practising under a PGD, the health professional should:

- Not delegate responsibility
- Ensure the patient meets the inclusion criteria and there are no exclusions
- Assess each individual patient’s preferences
- Recognise when referral to another health professional is required

- Understand how to administer the medicine (including dosage calculations) and how it acts on the body
- Understand potential adverse events, drug interactions, precautions, contraindications and storage of the drug(s)
- Understand follow up arrangements

When supplying (rather than administering the medication) the healthcare professional must use an appropriately labelled pack and collect the appropriate NHS prescription charge unless the patient is exempt.

The healthcare professional must record the following information (unless the supply/administration was via EPR in which case this information will be provided automatically) when supplying/administering under a PGD

- Date and time of supply/administration
- Patient name, DOB, allergies, previous adverse events and how the patient met the criteria
- Details of medicine (Name, strength, dose, frequency, quantity and route of administration) and that is was supplied/administered under a PGD

Name and signature (may be electronic) of healthcare professional supplying/administering the medicine relevant information that was provided to the patient/carer

### 3.3.5 Experience and grade of staff who can supply under a PGD at LHCH

Any named healthcare professional listed in Appendix 1 working at Band 5 level or higher with at least 6 months experience at LHCH may supply or administer under a PGD. The following staff (where administration/supply is an essential component of their post) may be excluded from the requirement for 6 months experience at LHCH at the discretion of their line manager:

- Hospital Co-ordinators
- Specialist Nurses
- Nurse Practitioners

The healthcare professional must have been trained in the supply/administration of medicines listed in the individual PGD within the last 2 years (unless the individual PGD states otherwise) and have signed themselves as competent to supply under a PGD. It is the individual healthcare professional's responsibility to ensure that they receive training every 2 years and this will form part of the annual PDR and evidence will be required. Any staff member without an up-to-date training record must NOT supply/administer under a PGD.

**3.3.6**. **Training** (Appendix 4 contains the competence assessment)

The following staff may provide training in the use of individual PGDs:

- Senior Pharmacists (Band 7 and above)
- Practice Educator Facilitators
- Designated Physiotherapists
- Clinical Educators
- Hospital Co-ordinators
- Designated Nurse Specialists
- Doctors

The format of training for individual PGDs must be of a standard format regardless of who is providing the training and include guidance on the legal implications of a PGD.

Once the member of staff has received training, competency should be assessed by the ward manager/line manager using mock scenarios or, if possible, witnessing the member of staff administering/supplying under a PGD within one month of attending training. The ward manager/line manager should complete the Competency Assessment form (appendix 4) and this should be kept in the staff member's portfolio. Where the ward manager is the trainee it is permissible for them to be signed competent by another senior member of staff on the ward.

Following completion of the Competency Assessment form, the member of staff and ward manger/line manager should jointly sign the Training/Competency record form (appendix 3) and this should be kept in the clinical area in which the PGDs may be used. A copy of this form should be sent to the Learning and Development team and to the PGD Pharmacist.

Following receipt of this form in pharmacy the member of staff will be authorised to administer/supply under the stated PGD. After 2 years, all staff using a PGD are required to attend a PGD refresher training session and both staff and line manager should re-sign the Training and Competency record (appendix 3) and send a copy to the PGD Pharmacist and Learning and Development Team.

Failure to attend training and send a new form to the pharmacist will result in the staff member being removed from the list of staff able to supply under that individual PGD. Staff who are not signed competent within 1 month of training will need to have approval from their Line Manager before attendance at another training session is agreed.

### 3.3.7. Record Keeping

A paper record of training (see Appendix 3) should be kept in the clinical area in which the PGD is to be used as described above. In addition, a copy should be sent to the Learning and Development team so that a central electronic record can be kept on the Trust's Electronic staff record (ESR). It is the responsibility of both the ward manager/line manager and member of staff to ensure that the electronic record has been updated before
the staff member operates under a PGD. A copy should also be sent to the PGD Pharmacist to allow authorisation under EPR. The individual member of staff is responsible for ensuring all the above forms are completed before authorisation to supply under a PGD. The ward manager/line manager is responsible for ensuring that only staff deemed competent (following completion of appendix 3 and 4) administer/supply under a PGD.
All patient safety incidents, medication errors, near misses and suspected adverse events relating to Patient Group Direction use should be clearly documented on Datix.

### 3.3.8 PGDs at LHCH

A copy of all the PGDs in use at LHCH is available on the Trust intranet, found under 'Patient Group Directions for LHCH'.

# 3. Policy Implementation Plan

All staff described above will receive training in the use of PGDs in the trust. All staff administering / supplying under PGDs will be required to sign that they have received training and are competent to administer / supply under a PGD.

Individual staff members and their line managers will be responsible for ensuring that their training records remain current. Each ward / clinical area will maintain lists of PGDs in use in their area (appendix 3) which will contain names and signatures of staff members able to supply medication under that protocol. A record of staff attending the training will be held centrally as part of the Trust's Learning Management System.

# 4. Monitoring of Compliance

The extent of the use of PGDs will be audited every 2 years by the PGD pharmacist and the report sent to the Drug and Therapeutics committee.

# 5. References


- NICE Medicines Practice Guidance – Patient Group Directions August 2013 updated March 2017 https://www.nice.org.uk/guidance/mpg accessed 11/05/2022
- Medicines & Healthcare Products Regulatory Agency Guidance – Patient Group Directions and who can use them. Updated 4 December 2017. Patient group directions: who can use them - GOV.UK (www.gov.uk) Accessed 11/05/2022

- Quality PGDs – 7 steps for success https://www.sps.nhs.uk/wp-content/uploads/2020/09/Quality-PGDs-Steps-To-Success-V3-March-2021-update.pdfaccessed 12/05/2022

- Home Office Circular 009/2012 https://www.gov.uk/government/publications/nurse-and-pharmacist-independent-prescribing-mixing-of-medicines-possession-authorities-under-patient-group-directions-and-personal-exemption-provisions-for-schedule-4-part-ii-drugs/circular-0092012-nurse-and-provisions-pharmacist-independent-prescribing-for-schedule-4-part-ii-drugs accessed 12/05/2022

- Legislation (SI 2012 No 973. The Misuse of Drugs (Amendment 2)(England, Wales and Scotland) regulations 2012 http://www.legislation.gov.uk/uksi/2012/973/pdfs/uksi_20120973_en.pdf accessed 12/05/2022

- Legislation (SI 2012 no 1916). The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf accessed 12/05/2022

# 6. Appendices

## APPENDIX 1

**Classes of Persons Permitted to Supply or Administer Medicines under PGD.**

- State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval;
- Pharmacists;
- Registered dietitians;
- Registered health visitors;
- Registered midwives;
- Registered nurses;
- Registered occupational therapists;
- Registered ophthalmic opticians;
- Registered orthotists and prosthetists;
- Registered speech and language therapists;
- State registered podiatrists;
- State registered orthoptists;
- State registered physiotherapists;
- State registered radiographers.

## APPENDIX 2

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST PHARMACEUTICAL SERVICE**

| **PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF ENTER DETAILS HERE** | |
|---|---|
| Version Number | Enter Date |

**Statement:**
The staff indicated in 'Staff Group' may administer, without medical prescriptions, **enter name of drug** in the manner detailed below.

**Staff Group:**
**Individual/professional group and grade (where appropriate),** working in **is/are (delete as appropriate)** entitled to **administer/supply (delete as appropriate)** medicines without medical prescription under this Patient Group Direction if they have:

- The professional qualifications **enter details**
- Attended ENTER DETAILS OF THE TRAINING
- Completed a training record form relating to this PGD within the last 2 years
- Had their names added to the Electronic PGD training record

**Clinical condition to be treated and Criteria under which a Patient shall be Eligible:**
**Enter details of clinical condition, patients to be treated and where necessary evidence based protocols. If use is 'off license' justification for use must be detailed here**

**Exclusion criteria:**
**Enter any individual patient exclusion criteria for this PGD. All core PGDs must include this statement 'Patients who are pregnant/breast-feeding are excluded from this PGD and must be referred to the appropriate medical officer**

Unless otherwise indicated, patients under the age of 16 years of age are excluded from treatment within this PGD

If the patient is receiving any concomitant medication or treatment it is the responsibility of the healthcare professional identified in **'Staff group'** to ensure that treatment with the drug detailed in this PGD is appropriate. In case of any doubt further advice must be sought from the appropriate healthcare professional and recorded as having been sought before the drug is given.

**Legal Status of Drug:**
**Enter details … POM, P, GSL, etc**

**Dose to be given:**
**Enter details. If a variable dose then indicate criteria for choosing dose**

**Frequency of Administration:**
**Enter details. If a variable dose then indicate criteria for choosing frequency**

**Number of Doses to be given:**
**Enter details**

**Route or Method of Administration:**
**Enter details …**

**Contraindications to use of Drug**
**Enter details as stated in the manufacturer's Summary of Product Characteristics**

**Training requirements;**
**Enter details …**

**Advice to be given to patient**
**Enter details …**

**Follow up arrangements (if applicable)**
**Enter details**

**Documentation**
**Enter details e.g. The nurse administering this drug must record the drug name, the dose, the form, the route and the time of administration in the "once only" section of the prescription chart. "RGN" must be added to the nurse's signature.**

**Protocol prepared by**
**Name of person preparing protocol, job title and signature below**
……
**Protocol approved by**
**Name of Lead Clinician, job title and signature below**

……..
**Enter name of Senior Pharmacist, job title and signature below**

……..
**Name of Chair of D & T Committee, title 'Chair of Drug and Therapeutics Committee' and signature below**

……..
**Review**
It is the responsibility of the head of nursing services or the head of any other professional body to whom this PGD applies to action the review process. This protocol must be reviewed by
**Enter date**

If continued use is appropriate this PGD must be submitted to the Chair of the Drug and Therapeutics (D & T) Committee for approval. This PGD will remain valid until the next available meeting of the D & T Committee following the review date at which time a decision will be made regarding its future use.
All PGDs should be subject to regular review in line with changes in clinical practice.

Reference

## APPENDIX 3

**PGD Training/Competency Generic Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the
Patient Group Direction for

……..

The following staff have received training and sign themselves competent to administer/supply (delete as appropriate) ……..in accordance with the above Patient Group Direction.

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | **SIGNATURE OF STAFF MEMBER** | **SIGNATURE OF LINE MANAGER (WITNESS)** | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
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**PGD Training/Competency Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the PCI and PPCI
Patient Group Directions

The following staff have received training and sign themselves competent to supply or administer ticagrelor, clopidogrel and aspirin in accordance with the above Patient Group Directions.

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | SIGNATURE OF STAFF MEMBER | SIGNATURE OF LINE MANAGER (WITNESS) | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
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**PGD Training/Competency Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the Knowsley Community Respiratory Service
Patient Group Directions for COPD

The following staff have received training and sign themselves competent to supply or administer amoxicillin, prednisolone, salbutamol MDI, doxycycline, salbutamol 2.5mg nebules, ipratropium 500microgram nebules, erdosteine, sodium chloride 0.9% nebules in accordance with the above Patient Group Directions.

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | SIGNATURE OF STAFF MEMBER | SIGNATURE OF LINE MANAGER (WITNESS) | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
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**PGD Training/Competency Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the Knowsley Community Respiratory Service
Patient Group Directions for Bronchiectasis

The following staff have received training and sign themselves competent to supply or administer ciprofloxacin, amoxicillin, prednisolone, salbutamol MDI, salbutamol 2.5mg nebules, ipratropium 500microgram nebules, erdosteine, sodium chloride 0.9% nebules in accordance with the above Patient Group Directions.

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | SIGNATURE OF STAFF MEMBER | SIGNATURE OF LINE MANAGER (WITNESS) | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
| | | | | | |
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**PGD Training/Competency Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the Knowsley CVD service
Patient Group Directions

The following staff have received training and sign themselves competent to supply or administer GTN tablets, GTN spray and aspirin tablets in accordance with the above Patient Group Directions

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | SIGNATURE OF STAFF MEMBER | SIGNATURE OF LINE MANAGER (WITNESS) | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
| | | | | | |
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**PGD Training/Competency Record (staff and line managers must sign every 2 years following training)**

**LIVERPOOL HEART AND CHEST HOSPITAL NHS TRUST**

Staff Record of Authorisation for the use of the Lidocaine
Patient Group Direction

The following staff have received training and sign themselves competent to administer lidocaine in accordance with the above Patient Group Direction.

| WARD / CLINICAL AREA | DATE OF TRAINING | NAME | SIGNATURE OF STAFF MEMBER | SIGNATURE OF LINE MANAGER (WITNESS) | VALID UNTIL (2 years) |
|---|---|---|---|---|---|
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## APPENDIX 4

**Observational Assessment of Competency for Patient Group Directions (Staff who have previously been assessed as competent do not need to complete this form following attendance at a refresher PGD training session)**

| **Previous learning and development** | **Date achieved** |
|---|---|
| Has attended session on administration of patient group directions | |
| Has read and understands the parameters of each PGD signed up for | |

**Ward Manager/Sister to assess the following criteria**

**PGD being assessed against**

| **Element** | **Competent Yes/No** | **Further Practice Required** |
|---|---|---|
| **1.ask member of staff to verbalise differences between a PGD (administration under an agreed protocol) and prescribing** | | |
| **2. Is the PGD suitable for use within the patient's current treatment plan?** | | |
| **3. can member of staff correctly identify dose<br>frequency indications contra-indications effects<br>side effects for the medication** | | |
| **4. Is the PGD documented on the prescription sheet in the correct manner?** | | |
| **5. Is the patient informed of the administration in the correct manner?** | | |
| **6. Does staff member administer this medicine themselves (not asking another member to staff to administer) according to Trust policy** | | |

**All the above must be achieved to pass the assessment.**

If this is successfully passed the staff member must sign the PGD authorisation list held locally within the Department

**Please keep this record in the staff member's portfolio**

## APPENDIX 5 – FLOW CHART

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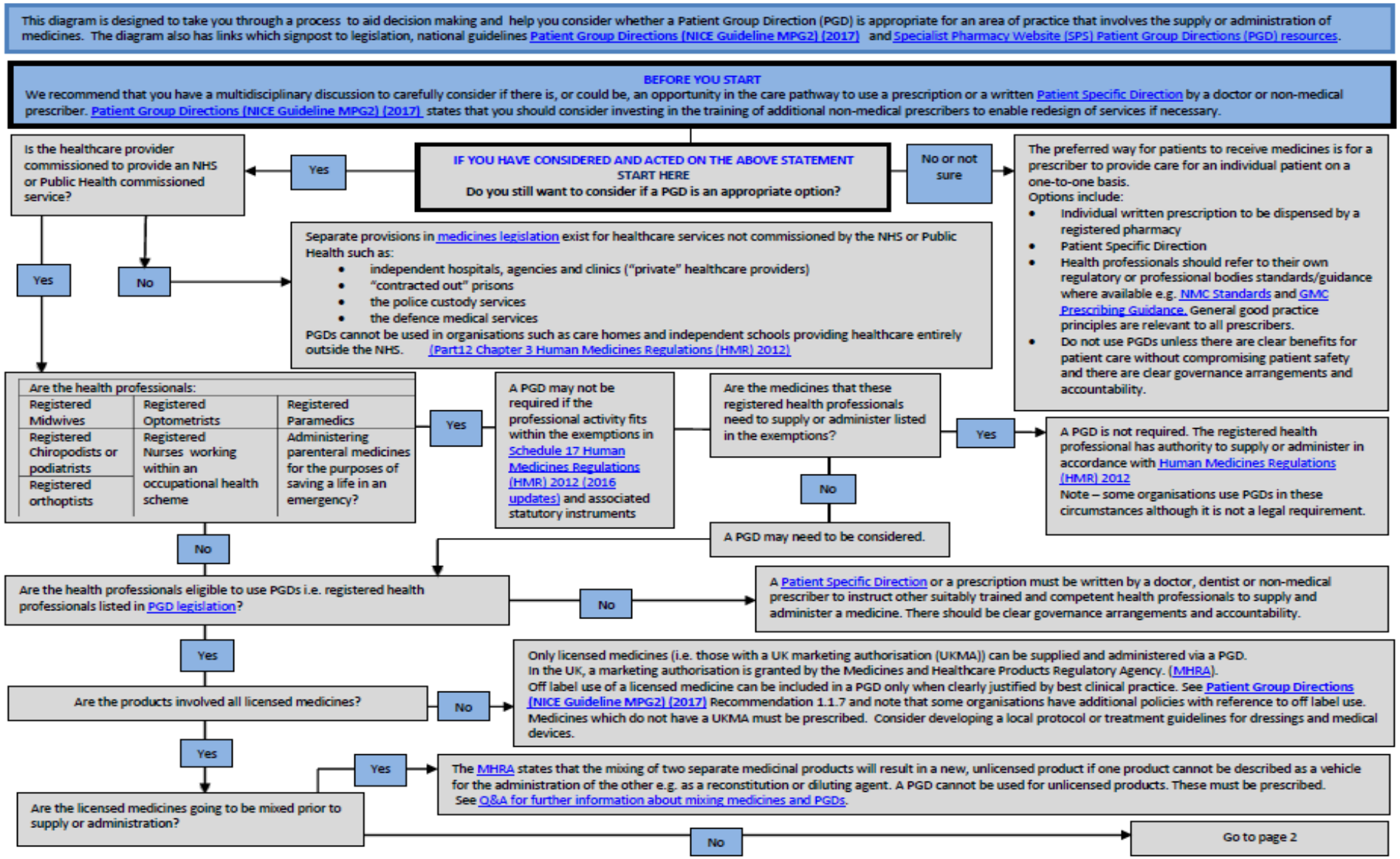
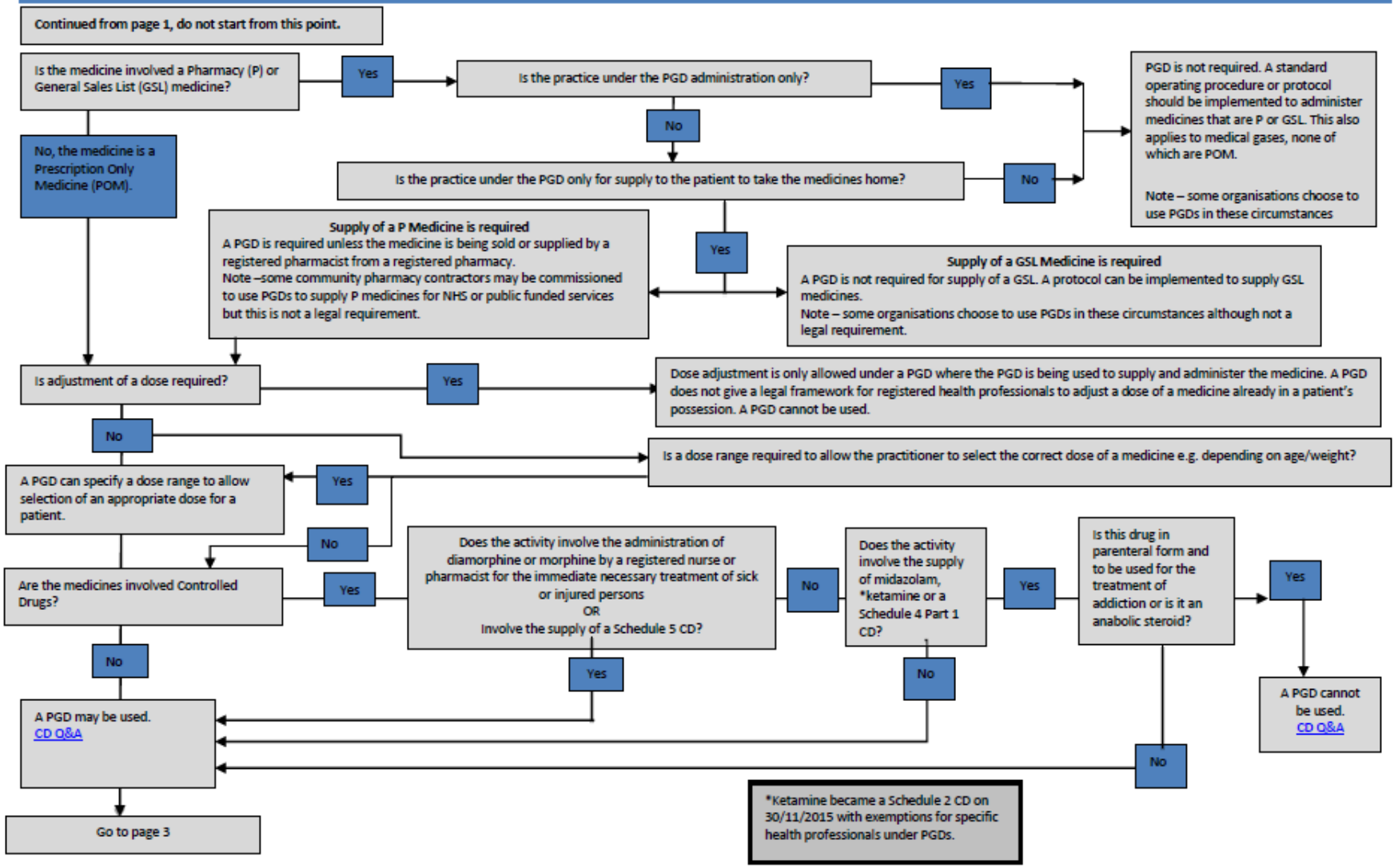
## TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations




To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.

## TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which signpost to legislation, national guidelines Patient Group Directions (NICE Guideline MPG2) (2017) and Specialist Pharmacy Website (SPS) Patient Group Directions (PGD) resources.




To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.

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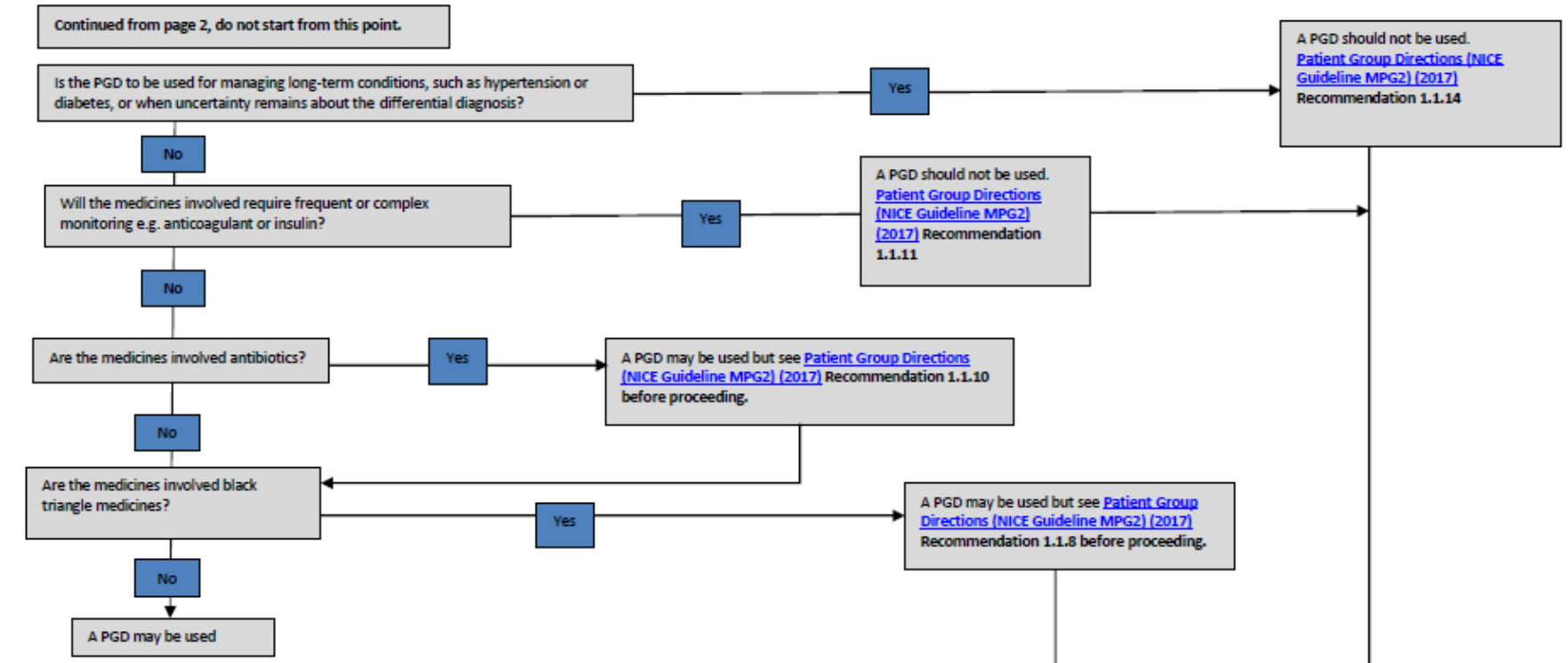


This chart may not cover all situations proposed for using PGDs. The proposed activity should meet the principles stated in Patient Group Directions (NICE Guideline MPG2) (2017)
*Supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.*

If having considered all of the above, you decide that a PGD may be an appropriate route to provide this clinical activity, also ensure that you consider other medicines legislation and clinical governance issues at each stage of the process. We recommend that you also refer to the following:

PGD Q&A – abortifacients
PGD Q&A - labelling of POMs supplied under PGD
PGD Q&A - delegation
PGD Q&A – trainee supervision
Quality PGDs -7 Steps to success and other resources such as PGD Q&As on the SPS website
Patient Group Directions (NICE Guideline MPG2) (2013) Pathway and Tools and Resources
PGD multi-disciplinary e learning package
Your local Medicines and PGD Policies

To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.

## 7. Endorsed By:

| Name of Lead Clinician / Manager or Committee Chair | Position of Endorser or Name of Endorsing Committee | Date |
|---|---|---|
| Dr Scawn | Drug & Therapeutics | 18/05/2022 |

## 8. Record of Changes

| Section No | Version No | Date of Change | Description of Amendment | Description of Deletion | Description of Addition | Reason |
|---|---|---|---|---|---|---|
| 1 | 9.0 | May 2022 | | CORE PGDs no longer used, replaced with the Administration of Discretionary Medicines policy. | | |
| 3.3.8 | 9.0 | May 2022 | | CORE PGDs no longer used, replaced with the Administration of Discretionary Medicines policy. | | |
| 5 | 9.0 | May 2022 | References updated | | | |
| Appendix 3 | 9.0 | May 2022 | PGD training record removed for ASD/ PFO and influenza vaccine as PGD no longer in use. | | | |

# Safe Management of Controlled Drugs

## Policy

| For completion by Author | | | |
|---|---|---|---|
| Author(s) Name and Title: | Mr D Forrest, Chief Pharmacist | | |
| Scope: | This policy applies to all staff (inc temporary staff) working within LHCH who are involved in the purchase, prescribing, dispensing or administration of controlled drugs. | Classification: | Clinical |
| Version Number: | 8.0 | Review Date: | 30/06/2024 |
| Replaces: | 7.0 | | |
| To be read in conjunction with the following documents: | The Medicines Policy, Medicines Administration Procedure, | | |
| Document for public display: | Yes | | |
| Executive Lead | Dr Raph Perry | | |

| For completion by Approving Committee | | | | |
|---|---|---|---|---|
| Equality Impact Analysis Completed: | | | No | |
| Endorsement Completed: | | Yes | Record of Changes | No |
| Authorised by: | Drug & Therapeutics | | Authorisation date: | 15/06/2022 |

| For completion by Document Control | | | | | |
|---|---|---|---|---|---|
| Unique ID No: | TC36(08) | Issue Status: | Approved | Issue Date: | 24/06/2022 |
| After this document is withdrawn from use it must be kept in archive for the lifetime of the Trust, plus 6 years. | | | | | |
| Archive: | Document Control | | Date Added to Archive: | | |
| Officer responsible for Archive: | | IG and Document Control Facilitator | | | |

# Contents

# Document Statement

In accordance with the Government's response to the Shipman enquiry, NHS bodies and the private sector must have arrangements in place for the management of controlled drugs (CDs) by all healthcare professionals who they employ or with whom they contract. NHS bodies are required to appoint an accountable officer to monitor the use of controlled drugs within their organisation and take appropriate action where necessary.

The documents in place in this Trust in order to meet the legal and good practice guidance specified by the Department of Health and the General Pharmaceutical Council are as follows:-

- Trust Policy for the Safe Management of Controlled Drugs (includes ward SOPs)
- Medicines Policy
- Pharmacy Department Standard Operating Procedures (SOPs) for
    - Issue of CD Record and Order Books
    - Handling of Controlled Drugs
    - Ward / Department CD checks
    - Handling of CD discrepancies
    - Role of Accountable Officer
- Trust Medicines Administration Procedure

This document aims to provide guidance to all Trust staff on the procedures relating to the safe and secure handling and storage of controlled drugs to ensure that: -

- staff are clear on the standards that are expected of them in relation to the handling and storage of controlled drugs
- patients, staff and visitors are not put at risk as a result of the incorrect handling of controlled drug medicines
- all legislation and guidance is adhered to with respect to controlled drugs
- risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum.

**The Gosport Report**

The report of the independent panel highlighted a number of failings at Gosport War Memorial Hospital where CDs were prescribed inappropriately for patients in the 1990s. A large number of people had their lives shortened. There were other factors apart from prescribing. Importantly this included lack of clinical challenge and a failure to speak up.

It is imperative that all Trusts learn from Gosport. One key point is the absolute need to challenge any practice that is felt to be unsafe. The Trust has a number of ways in which staff can raise concerns around prescribing, dispensing, administering, supplying and disposing of CDs that might negatively impact patient/relatives/staff safety (HALT, SOS, Freedom to Speak Up, Datix reporting, Safety Huddle, contacting safeguarding leads). It is a CQC recommendation that all healthcare professionals should speak up on areas of concern.

*Enhanced monitoring and control of CDs*

In 2019/20 the Trust has improved its capability to record and monitor CD incidents and usage;

- Formation of a mini MDT to review medication incidents - this feeds into the Safe Medicines Practice Committee for discussion including review of any CD trends and any appropriate action.
- Regular medication incidents summaries discussed at Divisional Governance meetings.
- Cascade of relevant issues to staff through safe medicines bulletin, safety huddles and doctor's teaching.
- Introduction of a medicines incident dashboard gives wide visibility to managers of any CD incidents and trends.
- Introduction of an electronic CD tracker system to identify any areas where usage increases unexpectedly
- Formation of EPR administration reports enables rapid triangulation against stock usage. This is particularly useful to monitor lower schedule CDs that have less stringent controls.
- Tighter monitoring of supply and delivery of CDs, especially lower schedule CDs (4 and 5) with introduction of sealed red bags, double checks and signatures on supply and receipt.
- Pharmacy staff instructed to notify senior pharmacy managers of any increase in ward use of "vulnerable lines" (CDs schedules 4 and 5)

# 1. Roles and Responsibilities

All Trust staff should report any concerns of diversion/misuse of CDs by patients or colleagues to the CDAO and most senior person within their area e.g. head of nursing

### a. The Accountable Officer

The Accountable Officer for Liverpool Heart and Chest Hospital is the Chief Pharmacist.

The Accountable Officer's responsibilities are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006 and requires he or she to be a fit and proper suitable person who does not routinely supply /administer or dispose of controlled drugs as part of his or her duties. There is an SOP within the pharmacy department which specifies the duties more thoroughly.

Suitable arrangements should be in place to support the Accountable Officer in their role of managing the safe use, handling and relevant statutory requirements concerning controlled drugs within the Trust. At LHCH reports for the accountable officer are produced by the pharmacy departmental software managers (Senior Pharmacy technicians) and nursing support is provided by the Divisional Heads of Nursing. The Accountable Officer will report to the Local Intelligence Network (LIN) on a quarterly basis any incidents or concerns regarding Controlled Drugs.

The CDAO will share any concerns and information, as appropriate, with relevant bodies (Police, CQC, CDLin, Home Office, Safeguarding etc)

### b. Directorate Management

It is the responsibility of Divisional managers (Divisional Head of Operations, Associate Medical Director and Matron / Head of Nursing) to ensure that all staff are trained to carry out the tasks

required of them in the prescribing, administration and management of controlled drugs (see training section).

The responsibility for ensuring that the policy for the handling and storage of controlled drugs is being adhered to rests with the Chief Pharmacist and they must ensure action is taken in response to deficiencies reported following audit reviews/incidents/areas of concern expressed by their own staff or other staff.

**c. Ward/Departmental Managers**

Ward/Departmental Managers are responsible for ensuring that:

- The Trust standard operating procedures (SOPs) are available for staff (and that these are followed) for the storage, handling and security of controlled drugs in their designated area. Ward CD SOPs are appended to this Policy which is available via the Intranet. Access should always be through the Intranet to ensure that the current Policy is followed.
- The senior pharmacist is informed of any potential amendments required to these local procedures.
- Expiry date checking of drugs is undertaken.
- The written procedure for the holding and handover of controlled drug keys between staff at shift changes is adhered to.
- All staff have been trained on the handling and storage of controlled drugs.
- An adequate system is in place for ordering controlled drugs and that appropriate stock levels are maintained.

**d. Nurse or operating department practitioner in charge**

The nurse/ODP in charge is ultimately responsible for controlled drugs whilst in charge of that ward/department (see Section 3.4). They are responsible for ensuring the pharmacy department is informed, and an incident report form completed, in the event of discrepancies or apparent loss. The nurse/ODP in charge cannot be responsible for illicit drugs present on the ward/department of which they are unaware.

**e. Ward/Departmental staff**

Ward/Departmental staff have a responsibility to:

- Read and adhere to all policies and procedures for the storage and handling of controlled drugs. Ward CD SOPs are appended to this Policy which is available via the Intranet. Access should always be through the Intranet to ensure that the current Policy is followed.
- Support the ward manager in ensuring that the security of controlled drugs and their own local procedures concerning controlled drugs are being followed.
- Ensure controlled drug cupboard keys are held by and/or passed to suitably qualified staff.
- Report all incidents involving controlled drugs to the nurse in charge and complete an incident report form.
- Undertaking ward to ward transfer of any patient's own CDs as required.
- Undertaking ward destruction of patient's own CDs brought in from the community that are no longer required (RNs only). Destruction must be witnessed by the ward pharmacist.

Operating Department Practitioners as registered with the Health Professional Council are legally entitled to order, possess and supply CDs for administration to patients in accordance with the

directions of a doctor, dentist, supplementary / independent prescriber in the department within which they work.

### f. Pharmacy

Pharmacy staff are responsible for:

- Providing information and advice to Trust personnel on the handling and storage of controlled drugs used within the Trust.
- Assisting where appropriate in formulating local procedures at ward/departmental /divisional level.
- Undertaking checks on wards/departments and audits on the safe handling and storage of controlled drugs every 3 months.
- Ensuring that the laws relating to the safe and secure handling and storage of controlled drugs are complied with.
- Removing any controlled drugs no longer required or expired ward stock (as advised by the nurse in charge) from that ward/department within 72 hours (up to 96 hours in case of weekends and bank holidays) of the request for removal as a minimum requirement.
- Assisting with the training on the storage and handling of controlled drugs to Trust personnel.
- Undertaking ward destruction of patient's own CDs brought in from community that are no longer required. Destruction must be witnessed by an RN or pharmacy technician.
- Compile audits and reports to support the Accountable Officer in their role.
- Receive and action calls from wards areas involving discrepancies. This may involve e.g. balance adjustments following appropriate investigation, escalation to the Chief Pharmacist (if unresolved), recording of discrepancies within the pharmacy discrepancy log.

### g. Prescribers

All prescribers must adhere to any prescribing requirements for CDs as specified in this policy and the Medicines Policy.

### h. Human Resources Department/L&D Department

All new prescribers will be asked to supply a reference signature by the HR/L&D department and this must be passed to the pharmacy department before that member of staff is able to prescribe Controlled Drugs. Nursing staff, who will be responsible for ordering and recording the administration of Controlled Drugs, must supply a sample signature to their ward manager who must authorize prior to that staff member carrying out duties related to Controlled Drugs. Electronic copies of nursing signatures will be kept in pharmacy.

### i. Individual Members of Staff

All members of staff involved in delivery of the service relating to controlled drugs must keep up to date with this Policy and the relevant associated procedures.
Changes/updates to this policy will be communicated to staff via the intranet.

# 2. Controlled Document Standards

The Misuse of Drugs Act 1971, as amended, prohibits certain activities in relation to CDs, in particular their manufacture, supply, and possession (except where permitted by the 2001 Regulations or under license from the Secretary of State).

The Misuse of Drugs (Safe Custody) Regulations 1973 as amended details the storage and safe custody requirements for Controlled Drugs.

The Health Act 2006 introduced the concept of an accountable officer (see above).

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced as part of the Government's response to the Shipman Inquiry's Fourth report in 2004. The aim of these regulations was to strengthen the governance arrangements for the use and management of controlled drugs.

As a consequence of passing the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the new architecture in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England on 1st April 2013.

The Misuse of Drugs Regulations 2001 (and subsequent amendments) defines the classes of person who are authorised to supply and possess CDs while acting in their professional capacities and specifies the conditions under which these activities may be carried out. In the 2001 regulations, drugs are divided into 5 schedules, each specifying the requirements governing such activities (import, export, production, supply, possession, prescribing and record keeping which apply to them)

**Schedule 1** - includes drugs not used medicinally such e.g. LSD, ecstasy, raw opium. A Home Office order is generally required for their production, possession or supply. The Trust is unlikely to see any of these drugs (unless brought in by a patient/relative- see SOP for appropriate action).

**Schedule 2* –** includes opiates (e.g. diamorphine, morphine, methadone, oxycodone), major stimulants (e.g. cocaine, ketamine) and cannabis-based products for medicinal use in humans (see section on cannabis). They are subject to the full CD requirements relating to prescriptions, safe custody and the need to keep a CD register.

**Schedule 3* -** includes barbiturates, buprenorphine, gabapentin, pregabalin, temazepam, midazolam and tramadol. They are subject to special prescription requirements as per schedule 2.

**Schedule 4 -** includes CDs subject to minimal control (e.g. benzodiazepines (except those in schedule 3 above), hypnotics (e..g. zolpidem, zopiclone) and androgenic/anabolic steroids.

**Schedule 5** – includes preparations of certain CDs (e.g. codeine, pholcodeine, low strength oral morphine liquid*), which due to their low strength are exempt from virtually all CD requirements.

***N.B. There are certain CDs in schedules 2, 3 and 5 (oral morphine low strength liquid) that are exempt from certain requirements (safe storage, registers, prescription requirements). However, to ensure compliance in safe management and use and for simplicity, the Trust requires that all schedule 2 and 3 CDs (and low strength oral morphine liquid) are treated as full CDs.**

# 3. Procedure

## 3.1 Prescribing of Controlled Drugs

Controlled Drugs must be prescribed in accordance with the Trust policy for the prescribing of such medicines (see Medicines Policy).
http://nww.staffintranet.lhch.nhs.uk/media/2408/medicines-v181.pdf

All prescriptions must have a unique patient identification number (NHS Number / Hospital Number).

Prescriptions for Controlled Drugs (Schedules 2,3 or 4) are valid for 28 days (6 months for schedule 5) from either the date of prescribing or a "valid from" date specified by the prescriber on the prescription.

Prescriptions for Outpatients or discharge (take home prescriptions, TTOs) should be limited to a maximum of 30 days' supply. If a longer period is required the reasons for this must be recorded on the prescription.

Prescriptions for Outpatients or discharge (take home prescriptions, TTOs) must contain all the required information in accordance with the Misuse of Drugs Regulations (as specified in the current BNF). Prescriptions with minor technical errors may be amended by the dispensing pharmacist and an appropriate record made of each alteration (e.g. if one of the requirements for words and figures has not been included). The patient's details must either be handwritten, or if a pre-printed label is used then the prescriber must also sign across the label.

Controlled drugs for inpatients can be prescribed and administered using the electronic prescribing system without the need for full prescription requirements expected for an outpatient/discharge prescription. Foundation 1 doctors cannot prescribe controlled drugs.

Prescriptions must be on official Trust prescription stationery – carbon copies/faxes or electronic prescriptions for out-patient or discharge medication are not acceptable for dispensing.

Prescribers must not prescribe / administer controlled drugs for themselves, close family or friends except in exceptional circumstances. Refer to Medicines Policy for further details.

Specimen signatures must be obtained by human resources or L&D on appointment of medical staff and be available for cross checking. Independent prescriber signatures will be retained in the Independent Prescribers Register and held in the pharmacy department.

***NB.*** *Should a patient who receives an out-patient/discharge prescription containing controlled drugs need to travel abroad, they may require a Home Office export license depending on the amount. Applications should be supported by a letter from the prescribing doctor and sent to the Home Office.*

Prescribing of controlled drugs to opioid dependent patients and supply of such medication on discharge must be made only following consultation with the patient's usual community drugs team or community pharmacy.

### 3.1.1 Potassium chloride strong injection

Potassium chloride injection (ampoules of 15%, 20mmol/10mL) must be requisitioned by wards / departments in the CD requisition book. The ampoules must be stored in a controlled drug cabinet. A record of their receipt and issue must be made in a CD record book and a running balance kept. However, it is not a legal requirement to know who has administered the drug, therefore a single signature to issue the drug to the patient will suffice. Wherever possible pre-made bags containing potassium must be used, which are available from pharmacy in various strengths.

### 3.1.2 **Cannabis-based products for medicinal use in humans**

On 1st November 2018 legislation was introduced moving cannabis products for medicinal use (CBPM) from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations 2001. This allows defined cannabis based products for medicinal use and restricts routes of access and limits the prescribing of these products to doctors on the GMC's Specialist Register. Doctors can only prescribe CBMPs for conditions within their area of speciality.

**Types of Cannabis-based product**

There are a wide range of cannabis-based products, with varying constituents including THC and covered by different aspects of legislation. These can be broadly categorised as:

*Unlicensed cannabidiol (CBD) products*

There are a range of products marketed as herbal or nutritional supplements. Provided no medicinal claims are made, these products fall outside medicines law. Products must not contain THC, which remains a controlled substance.

Patients may have bought products which are illegal in the UK over the internet or from non-reputable sources. Any preparations where CBD is not listed or is listed with other cannabis based preparations (e.g. THC) are illegal to possess in the UK.

Ward/department CD procedures (SOPs below) should be followed for any patient being found to be in possession of an illegal, or suspected to be illegal, CBD or cannabis product.

CBD oil preparations/herbal preparations are not usually prescribed within the Trust nor are they procured by pharmacy. However, they are widely available and purchased as over the counter preparations by patients.

It is recognised that patients in pursuit of improving their health and well-being may turn to alternative products. Due to the difficulty in ascertaining the quality of such products and the potential impact they may have on prescribed medication the usual recommendation will be for such products to be omitted during a hospital admission. They will not normally be prescribed or administered by trust staff.

Where this is deemed to have a significant impact on the patient's well-being and continuity of care such products may be self-medicated where specific agreement is reached with the consultant overseeing the patient's episode of care. This agreement must be documented in the medical notes. Prescribers need to use the "drug see note" facility on EPR. The "self-administers" box needs to be ticked such that nurses will sign work list manager as a self-administration.

Patients bringing products in with them should make staff aware so that any potential interactions can be considered.

*Licensed products/synthetics*

There are a range of cannabis-based products and synthetic products that are already available or being assessed for a marketing authorisation and **not affected by the new laws on CBPMs**:

Sativex® - (cannabis extracts containing THC and CBD) is a licensed cannabis based medicinal product that is available in the UK. It has been authorised by the MHRA as a treatment for spasticity in multiple sclerosis since 2010. Sativex is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 at present.

Nabilone - a synthetic, non-natural cannabinoid, is licenced in the UK for use in treatment resistant nausea and vomiting caused by chemotherapy.

Dronabinol, a synthetic nature-identical, version of THC is listed under Schedule 2 of the Misuse of Drugs Regulations 2001, but it does not have a Market Authorisation from the MHRA in the UK, although it is available internationally. It has been approved by the US Food and Drug Administration (FDA) to treat loss of appetite in people with AIDS, and to treat severe nausea and vomiting caused by cancer chemotherapy in patients with inadequate response to conventional antiemetic treatments.

Epidiolex® - (pure cannabidiol (CBD)) is licensed for Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2 years of age and older.

*Cannabis-based products for medicinal use (CBPMs)*

There are three broad requirements that a product should satisfy:

- The product is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative; and
- It is produced for medicinal use in humans; and
- It is a product that is regulated as a medicinal product, or an ingredient of a medicinal product.

The definition is necessarily broad to take account of the range of preparations which are cannabis-based that have been used for therapeutic purposes. This area is still evolving following the changes in the legislation. Product choice, suitability for prescribing and supply arrangements are being put in place nationally.

Currently the only CBPMs are unlicensed medicines. As with prescribing any other unlicensed medicine, it is a clinical decision to determine the most appropriate medication or course of treatment to prescribe for a patient, having taken into account the patient, the clinical condition, the clinical evidence of efficacy and safety and the suitability of licensed medicines.

CBPMs are schedule 2 CDs and staff must follow all the legal and Trust CD requirements.
Prescribing is restricted to clinicians listed on the Specialist Register of the General Medical Council (hospital specialist doctors). The decision to prescribe must be in line with guidance from the NHS England and the Trust's unlicensed medicines and CD processes. Patients and or carers must be involved in the treatment decision.

Patients should be made aware that the product being prescribed is an unlicensed medicine and a note of this should be included in the patient's medical records.

The Trust CD Accountable Officer should be made aware of all prescribing for CBPMs.
There is currently very little domestic availability of these products but pharmacy will be able to advise on available products and routes of supply.

Patients should be informed that there may be a delay in obtaining the product as there is a limited number of THC-containing products that are available in this country and so may have to be imported and the process for the supply of unlicensed medicines followed.

### 3.1.3 Independent Non-Medical Prescribers

From 23rd April 2012 both Independent nurse prescribers and pharmacist prescribers can prescribe schedule 2,3,4 and 5 controlled drugs. This does not include prescribing of diamorphine, dipipanone or cocaine for treating addiction but does include these drugs for treating organic disease or injury. Physiotherapists are allowed to prescribe the following Controlled Drugs: oral or injectable morphine, transdermal fentanyl and oral diazepam, dihydrocodeine tartrate, lorazepam, oxycodone hydrochloride or temazepam.

Non- Medical Prescribers may not prescribe CBPMs- see above.

### 3.1.4 Patient Group Directions (see Trust policy for PGDs)

Certain CDs can be administered or supplied under a PGD. Contact pharmacy for further advice.

### 3.1.5 Supplementary Non-Medical Prescribers

Supplementary nurse and pharmacist prescribers can prescribe and administer any CD as long as it is within the Clinical Management Plan specific to that patient and agreed between the independent prescriber, the supplementary prescriber and the patient.

Chiropodists, podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers are also able to prescribe CDs, in partnership with a doctor and according to a patient's Clinical Management Plan.

### 3.1.6 Private Prescriptions

Private Prescriptions for controlled drugs to be dispensed by community pharmacists must be written on designated standard form FP10 PCD Prescriptions available from the CCG. The NHS Business Authority will issue unique 6 digit Private Prescriber codes to enable this. Prescribing will be monitored by the CCG. Where a private prescription is both issued and dispensed within the Trust, a standardized form is not required although it must be written on Trust headed notepaper.

### 3.2 Ordering of Controlled Drug Stocks (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam)*

Controlled drugs ordered for ward/departmental stock can only be used to administer to patients on that ward against the inpatient prescription signed (electronic signature) by an authorised prescriber.

Ward stocks must not be issued to patients by ward staff for purpose of taking home on discharge.

Controlled drugs must be ordered for ward stock using the official controlled drug order book for that ward/department (and specific to a particular cabinet if the area has more than one cabinet).

The order book must be kept in a secure place, and, if missing, the most senior nurse in charge must inform the senior nurse manager, the pharmacy department and complete an incident form. All sections of the order book must be completed. Controlled drug stationery should be issued against a written requisition approved by only those ward or department staff authorised to order CDs.

Only authorised nursing staff or operating department practitioners can order controlled drugs for ward stock – authorisation is given by the senior nurse manager and an authorisation sheet for controlled drugs completed and signed and sent to the pharmacy department. The signature list held by the pharmacy department will be reviewed on an annual basis. Authorised signatures are now kept electronically.

During the COVID pandemic clinical areas that are designated red zones can place a telephone order for CDs. This is in order to reduce staff movement and the transfer of paperwork Pharmacy will hold CD order books for affected areas for this purpose. The nurse/OPD will have their name transcribed into the book as the requester.

Each ward/department should have a list of controlled drugs usually held as stock. This list should be agreed by the pharmacist/technician controlling stocks of medicines in that area and the registered nurse in charge, however, items additional to the stock list may be held as stock when required.

In an emergency, out of hours, Schedule 2 and 3 CDs may be issued to a patient on another ward. It is the responsibility of the nurse who is requesting the CD to notify pharmacy by leaving a message on the pharmacy EPR order line so that a pharmacist can check the process below has been correctly followed the next working day. The CD registers of both the supplying ward and receiving ward must be signed by the nurses in charge of both the wards. Only single doses can be administered in this manner. The “supplying” ward must enter the following in their CD register:

- Name of patient
- Location of patient
- Dose
- Signature of nurse on supplying ward
- Signature of nurse on receiving ward
- Running balance

The “receiving” ward must enter the following into their register:

- Where the item has been received from
- Signature of nurse from supplying ward
- Signature of nurse on receiving ward
- Running balance

The next line in the register must be completed in the usual manner identifying the patient according to normal practice.

During the COVID pandemic amendments to the usual processes have been made to reduce the risk of cross contamination.

Where possible, the need for borrowing controlled drugs between areas will be minimised as much as possible.

Clean wards must not borrow CDs from infected ward areas.

**Ordering of Stock CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)***

Only qualified staff or operating department practitioners are able to order these CDs using the standard pharmacy stock requisition book. Stocks may need to be ordered in between weekly pharmacy top ups on an ad hoc basis depending on patients admitted. There is now enhanced monitoring by pharmacy of ad hoc requisitions. Stock levels may need to be adjusted (this must be discussed between the ward manager and a senior pharmacist).

Out of hours wards may borrow **single doses only** of Schedule 4 and 5 CDs. Alternatively, wards can access the emergency cupboard in pharmacy if larger quantities are required until pharmacy is open.

*As outlined elsewhere in this document LHCH treat some Schedule 4 and 5 CDs (for example, morphine sulphate 10mg/5ml oral liquid) as Schedule 2 and should be managed as such.

### 3.3 Dispensing and Collection/Delivery of Controlled Drugs

There is a departmental procedure for the dispensing of CDs within the pharmacy department.

**3.3.1 Stock CDs** (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam)*

Controlled drugs for ward stock may be delivered by pharmacy staff or collected by ward staff. Both qualified and non-qualified ward staff can collect CDs for ward stock provided they are official Trust employees with a full permanent contract (i.e. not temporary/students) and with a Trust identity badge on display when collecting the drugs. A member of pharmacy staff will assist the person acting as the messenger (ward staff) to check the items against the requisition. This check includes: correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength and quantity. The staff member should sign the CD requisition book to accept delivery. Pharmacy staff delivering CDs will also follow the above process. The CDs will then be sealed in a red plastic bag for transportation.

During the COVID pandemic if CDs have been ordered via telephone for a red area the CD order book will remain in pharmacy. The ward staff will therefore sign a photocopy of the order so that once delivered supplied drugs can be reconciled.

**Stock CDs** (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)*

The process for ward staff is the same as above, except they will sign the general stock requisition book. Pharmacy staff issuing these CDs as part of weekly stock tops up will be second checked and sign on the stock issue list for the particular ward. CDs will be sealed in a red plastic bag for transportation. Any pharmacy staff delivery of ad hoc stock requisitions will follow this same process.

Ward stock CDs (all Schedules) may not be transported in pneumatic tubes.

*As outlined elsewhere in this document LHCH treat some Schedule 4 and 5 CDs (for example, morphine sulphate 10mg/5ml oral liquid) as Schedule 2 and should be managed as such.

### 3.3.2 TTOs or Outpatient CDs (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam)*

Controlled drugs for TTOs or Outpatients may be delivered by pharmacy staff or collected by ward staff. Outpatient CDs may be collected by patients or relatives. Both qualified and non-qualified ward staff can collect these controlled drugs provided they are official Trust employees with a full permanent contract (i.e. not temporary/students) and with a Trust identity badge on display when collecting the drugs.

The identity of the person collecting schedule 2 & 3 CDs must be confirmed. The following details must be recorded on the TTO/Outpatient prescription and in the CD register in pharmacy for schedule 2 & 3 CDs supplied:

- Whether collection was by the patient, relative, carer or healthcare professional
- If by a healthcare professional, their name and place of work within LHCH
- If by the patient or representative their name and whether evidence of identity was given, and if evidence was not given, the reason for this must be documented.

A member of pharmacy staff will assist the person (ward staff/patient/relative) to check the items against the prescription. This check includes: correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength and quantity. The staff member/patient/relative should sign the CD TTO/Outpatient prescription to accept delivery. Pharmacy staff delivering CDs will also follow the above process. The CDs will then be sealed in a red plastic bag for transportation. Outpatient CDs given to patients/relatives will be in standard pharmacy bags.

**TTOs or Outpatient CDs (Schedules 4 and 5** e.g. diazepam, zopiclone, dihydrocodeine, codeine)*

These CDs are exempt from the above controls

*As outlined elsewhere in this document LHCH treat some Schedule 4 and 5 CDs (for example, morphine sulphate 10mg/5ml oral liquid) as Schedule 2 and should be managed as such.

### 3.4 Receipt / storage / discharge of controlled drugs on ward and entries required in controlled drug register

The red bags for transportation of CDs are highly visible and should prompt nursing staff to realise they contain CDs. Staff are reminded to keep vigilant. Any red bags should be opened on wards and CDs secured in a timely fashion.

On delivery a qualified nurse must open the red bags and sign the delivery paperwork (CD requisition book (pink page), stock requisition book (blue page), outpatient or TTO copy) to accept delivery of the correct CDs. It is the responsibility of the receiving qualified nurse to ensure CDs are secured in a timely fashion.

**CDs (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam)***

On arrival on the ward / department, each item must be signed for in the CD order book/photocopy of the CD order book/TTO/Outpatient by an authorised receiver (until this happens the drugs are in the possession of the messenger and they must be handed over to an authorized member of staff so that they become the ultimate responsibility of the nurse/operating department practitioner in charge of the ward at that time). The items should be checked against the

requisition/TTO/Outpatient for correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength, expiry date and quantity.

Stock CDs must then immediately be entered into the controlled drug register and the entry and balance checked and countersigned by a second member of staff, which could be the ward staff member who has collected the item(s) from the pharmacy department, i.e. the messenger. Entries must be in ink (or otherwise indelible) and in chronological order.

Controlled drugs for patients supplied on a discharge prescription (TTO) or Outpatient prescription should be entered into the Patient's Own CD register. **On discharge the patient, or their representative, should sign this book, along with a nurse, to indicate they have received the medication.**

**Any discrepancies, loss, or suspected theft or diversion should be reported immediately to the nurse in charge. Pharmacy should be notified as soon as possible during working hours. If out of hours, and the nurse in charge believes the issue to be serious, they should contact the on call pharmacist.**

**CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)***

Stock CDs- On arrival to the ward/department, either the stock list from the ward top up or the stock requisition book (blue page) must be signed by an authorised receiver (until this happens the drugs are in the possession of the messenger and they must be handed over to an authorized member of staff so that they become the ultimate responsibility of the nurse/operating department practitioner in charge of the ward at that time)

The items should be checked against the stock list/requisition for correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength, expiry date and quantity

The items should then be secured in the standard medicines cupboard.

TTOs or Outpatient CDs - These CDs are exempt from the above controls and should either be given to patients immediately or secured in the standard medicines cupboard until such time.

**Any discrepancies, loss, or suspected theft or diversion should be reported immediately to the nurse in charge. Pharmacy should be notified as soon as possible during working hours. If out of hours, and the nurse in charge believes the issue to be serious, they should contact the on call pharmacist.**

*As outlined elsewhere in this document LHCH treat some Schedule 4 and 5 CDs (for example, morphine sulphate 10mg/5ml oral liquid) as Schedule 2 and should be managed as such.

### 3.4.1 Balance checks

Balance checks for Schedule 2 and 3 CDs must be carried out at least once every 24 hours by authorized staff and the check documented and signed by both staff. A single separate page (usually at the back of the register) in the CD register can be used for documenting that this has been carried out on ALL CDs (staff will perform a visual estimate balance check on liquids). A standard operating procedure for this process is appended to this Policy (see Appendix 1). The process consists of two parts: firstly, the contents of the CD cupboard should be emptied and the balances checked against the relevant pages in the register; secondly, every page in the CD register not already checked should be reviewed to ensure all have zero balances. In this way,

items which should still have been in the cupboard will be spotted. The balance check should be undertaken with all ward CD registers including the patients' own CD register. Once a week, documentation that the check has taken place must be written on each page of the CD register instead of using the back of the register (the record at the back of the CD register can be used on every other occasion). Every 3 months pharmacy staff will carry out a reconciliation audit on every ward / department in the Trust. During this audit, the register balance will be checked against the cupboard contents and CD requisitions for the previous three months will have their entry in the register confirmed. For CD liquids, pharmacy staff will perform a visual estimate balance check.

**Any discrepancies, loss, or suspected theft or diversion should be reported immediately to the nurse in charge. Pharmacy should be notified as soon as possible during working hours. If out of hours, and the nurse in charge believes the issue to be serious, they should contact the on call pharmacist.**

Liquid discrepancies - These can be minimised by ensuring bungs and syringes are always used, however they cannot be entirely avoided. Following investigation and correction for e.g. calculation errors, doses given but not entered etc, low level discrepancies as a result of over/under fill of unopened bottles and multiple small dose measurements are acceptable. A pragmatic approach is required that accommodates such discrepancies but identifies any potential misappropriation (see appendix SOP)

### 3.4.2 Storage cupboards, fridges and keys

The controlled drug cupboard and / or controlled drug fridge must be kept locked when not in use and the key must not be common to any other key in the hospital. The controlled drug cupboard/ fridge must be used for the storage of controlled drugs only and not for any other medication or items (including any stationery or patient's property). Drugs for epidural administration must be stored separately from other drugs. Keys for storage areas (cupboards and / or fridges) must be kept separately from other keys used for other drug storage. If keys are misplaced the line manager for the ward must be informed immediately and a decision taken as to the appropriate action required. Pharmacy must be informed in a timely fashion.

### 3.4.3 Transfer of patients

When transferring a patient from one area of the hospital to another, e.g. from theatre to POCCU or from POCCU to a ward, there must be clear documentary evidence regarding the transfer of any controlled drug being administered to the patient at the time of transfer. This will include the transfer of approximate balances in epidural infusions, patient controlled analgesia bags and other infusions still running. The in-patient prescription should be checked during this process to ensure all currently running infusions are prescribed and signed for. It may be appropriate for the back page of the ward register to be used for the purpose of entering approximate balances on receipt of a patient stating that the item is being administered to the patient. Subsequently if the container needs to be destroyed and still contains some medication then the destruction can be recorded using the same page. This will complete the audit trail for the transferred item. Document:

- name of patient,
- ward being transferred from,
- name of drug, form, strength and presentation,
- approximate quantity remaining and then approximate quantity destroyed, if subsequently destroyed,
- signature of ward staff.

### 3.4.4 Transfer of patient's own controlled drugs

When transferring a patient from one LHCH area to another, patients' own controlled drugs (including CD TTOs recently dispensed to the patient) must be signed out of the patient's own CD register (specifying the receiving ward and countersigned by another staff witness). The CD must then be signed into the receiving ward's patient own CD register (specifying the transferring ward and countersigned by another staff witness).

COVID
Medicines must not be moved from a COVID cohort area or positive/suspected patient to a clean area. Unwanted CDs should be denatured using DOOP kits and signed for (see below). This must be double bagged and destroyed on ward (put in a yellow bin with blue lid- labelled pharmaceutical waste only)

### 3.4.5 Temporary Closure of a Ward

Whenever a ward is to close for a significant period of time (longer than 72 hours), the ward must return their CDs to pharmacy for storage. The drugs should be placed into a pharmacy green delivery bag (fridge lines in a second bag) along with the Ward's CD register, sealed, and taken to pharmacy where they will be stored and returned in this same manner. The drugs do not need to be individually returned from the CD register, nor do they need to be counted at this point.

COVID
Where a ward is to close for deep cleaning following step down from red and yellow area to a green area, the CDs must remain on the ward for the duration of the quarantine.

## 3.5 Administration of Controlled Drugs

There must be two members of staff involved in the administration of a controlled drug, one of whom must be a registered healthcare professional

COVID
The exception to this rule is when the CD cupboard is not sited within the yellow or red area and the nurse administering is working alone (see appendix 3).

The second person i.e. the checker can be an RGN, doctor, pharmacist or registered Operating Department Practitioners (ODP). In addition other healthcare personnel who have received training and have been assessed as competent to check controlled drugs can perform the second check (see Medicines Policy).

Administration must be in accordance with the Trust Medicines Administration Procedure (section 3.6 of the medicines administration procedure is repeated here for completeness:

- An appropriately registered practitioner should take the prescription to the CD cupboard (using an EPR trolley, the PC in the treatment room near the CD cupboard or a handheld device).
- Obtain keys and ensure another appropriate practitioner is available to provide a second check / witness signature.
- Read the prescription independently and one person should remove the required quantity of the required drug from the cupboard.
- This drug should be shown to the witness who confirms that this is consistent with the prescription.

- Both practitioners should confirm the remaining balance of the drug left in the CD cupboard.
- Both practitioners should confirm that the medication to be administered is in date, and if labelled individually, bears the patient's name.
- The administering practitioner should open the CD register at the correct page and complete the entry, witnessed by their colleague. Both should confirm the remaining balance.
- Lock the CD cupboard / fridge.
- Both practitioners should return to the patient and confirm the identity of the patient.
- Administer the medication and both practitioners must sign the prescription and the entry in the CD register.

**Controlled Drugs must not be administered if the prescription is unclear, illegible or ambiguous or there is any other reason for doubt (e.g. patient condition / response to previous doses).**

It is important that controlled drugs are administered at the specified time and if not, the reason must be documented.

**Any discrepancies, loss, or suspected theft or diversion should be reported immediately to the nurse in charge. Pharmacy should be notified as soon as possible during working hours. If out of hours, and the nurse in charge believes the issue to be serious, they should contact the on call pharmacist.**. A similar line management approach should be used should the CD cupboard keys go missing.

The second person must sign the CD book to confirm that the administration and appropriate disposal of excess / waste has been correctly carried out and recorded. The reason for any doses drawn up but not then given should be documented in the CD register. Injectables should be for single use only unless the label specifically indicates it is licensed and intended for use on more than one occasion or to provide more than one dose on any one occasion.

Each drug in the CD record book must have a separate page and all entries must be made in ink. Therefore, if a dose requires the use of 2 strengths of a preparation both pages of the controlled drug register must be completed.

### 3.5.1 Administration of medicines without a prescription

During certain procedures e.g. PCI, EPS, or device implantation / explanation, controlled drugs may be given on the verbal instruction from the doctor provided that the name, route and dose are recorded either on the drug treatment section of the integrated care pathway, or on the prescription and, in both cases, signed by the doctor at the end of the procedure. In these procedures, the second person i.e. the checker may complete the entry into the CD register

## 3.6 Record Keeping Requirements

Record keeping requirements will be in accordance with current Department of Health guidance.

### 3.6.1 Controlled Drug Registers

Registers that meet current recording requirements will be maintained in the pharmacy and in all wards and departments where controlled drugs are stored.

Registers must be bound (not loose leaf) with sequentially numbered pages.

Registers, requisitions, orders and private prescriptions for controlled drugs must be kept for two years from the date of the last entry whether in the original paper form or on a computer.

The CD Register may be used to record additional information / clarification in addition to the mandatory columns relevant to the CDs.

The CD Register must contain a running balance and the stock regularly checked to the agreed procedure.

### 3.7 Disposal & Destruction

#### 3.7.1 Return and Destruction of Stock Controlled Drugs (for COVID also see below)

Schedule 1 and 2 Controlled Drugs stock can only be destroyed in the presence of a person legally authorised to witness destruction (see below). The Trust also mandates that schedule 3 CDs are treated in a similar manner. When a controlled drug is destroyed, details of the drug must be entered in the Controlled Drugs Register. This should include the name of the drug, form, strength and quantity, the date it was destroyed and the signature of the authorised person who witnessed the destruction and the professional destroying it (i.e. two signatures).

Ward stocks of controlled drugs for destruction (e.g. date expired/partly used liquids which would not be possible to return into pharmacy stock for re-issuing to another ward) or unused/unwanted TTOs may be written out of the ward controlled drugs register, countersigned by a pharmacist and the nurse in charge of the ward at the time, and entered into another register in the pharmacy department specifically for that purpose (there is an SOP in pharmacy for this purpose which includes the use of an auditable destruction form which is used by the pharmacist returning the CDs).

NB. Individual doses that are prepared and not administered/fully administered should be destroyed on the ward/department in the presence of a second person (who could be a pharmacist, authorised nurse or doctor). This includes the remains of partly used vials. An entry of the destruction is to be made in the register with both parties witnessing the destruction.

Small volumes e.g. part ampoules or vials drawn up but not given (less than 50mL) can be destroyed on the ward by emptying into a sharps bin with the then empty container and labelling the bin as mixed pharmaceutical waste and sharps – for incineration.

This can be done by, and witnessed by, authorised ward staff (registered nurse/ operating department practitioner or doctor). For volumes greater than 50mL (e.g. for epidural or PCA destruction) DOOP kits should be used (see Appendix 1).

<u>COVID</u>
Generally, medicines must not be moved from a COVID cohort area or positive/suspected patient to a clean area (e.g. pharmacy). However, due to legal constraints, any unsuitable ward stock CDs requiring destruction (e.g. expired) need to be destroyed in the presence of a suitable witness. Such CDs should be double bagged, kept in the CD cupboard for 5 days clearly marked as expired and then returned to pharmacy for normal destruction as above.

#### 3.7.2 Persons currently Authorised to Witness the Destruction of Controlled Drugs

These are specified in the “Misuse of Drugs Regulations 2007”. The persons relevant to Liverpool Heart and Chest Hospital NHS Foundation Trust are as follows:

1. Chief Executive
2. Senior Officers who report directly to the Trust Chief Executive and who have responsibility for Health and Safety Security or Risk Management matters in the Trust, appointed by the accountable officer and notified to the Trust Board.
3. Police Officers

It should be noted that these individuals must be independent of the routine supply and administration of controlled drugs. Accountable Officers should not be authorised people to witness destruction as one of the criteria for Accountable Officers is their independence from day to day management of controlled drugs.

### 3.7.3 Method of Destruction

Recommended methods of destruction are provided by the Royal Pharmaceutical Society of Great Britain and include systems for denaturing. This is covered by the Pharmacy Department Controlled Drugs' procedure.

### 3.7.4 Destruction of Patients' Own Drugs

It should be noted that witnessed destruction as described above does not apply to controlled drugs that have been brought into hospital by a patient. However, there is a general duty of care to ensure appropriate disposal of waste medicines. Patients' own Schedule 2 and 3 controlled drugs will be destroyed on the ward using DOOP kits. The destruction will be carried out by a pharmacist and witnessed by a registered nurse. An entry of the destruction will be made in the patient's own CD register. Ideally the DOOP kit will be used to destroy as many patients own CDs no longer required at that time. Destruction of patients own CDs will take place during the CD quarterly stock. However, pharmacy can carry out destruction in between stock checks if needed. A stock of DOOP kits is to be obtained by the ward. To avoid delay of destruction, a stock of DOOP kits will be available in pharmacy that the pharmacist can book out to the ward if no stock available on the ward.

## 3.8 Training

### 3.8.1 Doctors

All doctors will receive training regarding writing a controlled drugs prescription as part of their Medicines Management training session**.**

### 3.8.2 Nurses

<u>Student Nurses</u>
All Student Nurses will be given controlled drugs supply, administration, storage and destruction training as part of their practice based learning seminars.

<u>Registered Nurses</u>
Training on controlled drugs supply, administration, storage and destruction is available on induction/via updates through the Training Department.

### 3.8.3 Operating Department Practitioners (ODPs)

Training on controlled drug supply, administration, storage and destruction is available on induction and via updates from the Training Department.

### 3.8.4 Pharmacists

Pre-registration graduates will receive formal training on controlled drugs supply, administration, storage and destruction as part of their pre-registration competency training programme. A competency based training package must be successfully completed before pharmacists can dispense controlled drugs.

### 3.8.5 Pharmacy Technicians

A competency-based training package must be successfully completed before pharmacy technicians can dispense controlled drugs.

## 3.9 Standard operating Procedures (SOPs)

Trust procedures will include details of the ordering, collection/transport, receipt, storage, administration, handover of keys, returns, checking/audit trail, destruction and disposal, use of patient's own CDs, borrowing of CDs out of hours in an emergency, and dealing with patients/staff suspected of illicit drug usage. These SOPs should be approved by the Accountable Officer as they are accountable for all systems for the safe management of CDs within the Trust. They should also ensure that all staff are aware of these SOPs as part of a training programme. See appendix 1.

For the purposes of business continuity should this policy be unavailable via the Intranet, printed copies of SOPs are kept in the emergency drugs cupboard for wards to take reference from.

Pharmacy Procedures are in place covering responsibilities within the pharmacy and the interface with wards/departments/patients and external agencies. The Pharmacy Procedures also include details of stock control/security, issue and supply to patients, control of CD stationery and signature verification.

Clinical matters relating to the prescribing of controlled drugs will also be covered by Medicines Management procedures including Acute Pain guidelines, Sedation guidelines and Palliative Care Guidelines which may be found on the trust Intranet.

## 3.10 Governance and Monitoring

The Care Quality Commission will be using their existing self-assessment methods to assess whether Healthcare Organisations are meeting National Standards. The Care Quality Commission will report specifically on any points of concern about controlled drugs in secondary care including hospital pharmacy. They will do this as part of their routine assessment of whether a Trust is meeting core standards and through the clinical audit programme.

The General Pharmaceutical Council may also carry out occasional inspections.

The regulations also require Accountable Officers to complete a periodic declaration covering whether or not their organisation keeps stocks of controlled drugs and whether there are special circumstances that might explain any seemingly unusual patterns of prescribing or supply. A self-assessment of CD management will be completed including the availability of appropriate Standard Operating Procedures.

### 3.11 Incident Reporting

The Trust Incident Reporting system should be used to record any incidents or near misses relating to any aspect of controlled drug management. Additionally, the Accountable Officer may be contacted directly if there are any concerns regarding the clinical use or management control of controlled drugs. Incidents will be reviewed at the Trust Safe Medication Practice Committee in order to ascertain if there are any trends or other wider issues arising. If necessary, incidents and reports will be notified to the Risk Management Committee at the discretion of the Accountable Officer and/or the Risk Manager.

### 3.12 Audit Framework

Audit proformas will be used to audit the safe handling and storage of controlled drugs on ward/department areas and within the pharmacy department. These can be found as appendix 2.

### 3.13 Duty of Collaboration and Information Sharing

Healthcare organisations, police services, inspector bodies and others have a statutory duty to work together to share intelligence on controlled drugs issues.

## 4. Policy Implementation Plan

This policy has been adapted from a draft policy produced by Quality Control North West which was written by a working party of Chief Pharmacists established following the fourth report produced by the Shipman enquiry.

Senior pharmacists, Senior Nurse Managers, Medical Director, Associate medical Directors, Nurse Trainers, and members of the Drug & Therapeutics Committee have been consulted during the approval of this policy and all will be involved in its dissemination. This document requires dissemination throughout all wards and departments in which controlled drugs are used. Managers have a responsibility to ensure staff have read and understood the policy and a record of this should be kept.

## 5. Monitoring of Compliance

The audit department will be instructed to conduct an annual audit as set out in appendix 2 (part 2). The CDAO will audit the pharmacy dept and ward areas as per appendix 2 on a quarterly basis. Pharmacy will conduct quarterly ward audits (requisition check, balance checks, unsuitable stock). The policy will be reviewed every 2 years as a minimum, alterations in legislation or practice may necessitate a more frequent review.

# 6. References


1. Misuse of Drugs Act 1971.

2. The Misuse of Drugs (Safe Custody) Regulations 1973 as amended

3. The Controlled Drugs (Supervision of Management and Use) Regulations updated 2013

4. The Misuse of Drugs Regulations 2001 (and subsequent amendments)

5. The Health Act 2006

6. Medicines Act 1968.

7. Medicines, Ethics and Practice July 2019.

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# 7. Appendices

## Appendix 1

**Procedures for the Handling and Storage of Controlled Drugs (Proformas for Wards)**

### Procedures for the Handling and Storage of Controlled Drugs

### Ordering of Controlled Drugs for Ward Stocks (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam) and morphine sulphate 10mg/5ml oral solution)

***The controlled order book specified for the ward must be used for the ordering of controlled drugs using a separate page for each item. An authorised registered nurse or ODP can generate an order for the required controlled drugs.***

1. Place the carbon paper in between the top and lower page with the carbon placed down.
2. Orders must contain the following details :-

- Trust name
- Ward name - specify the cabinet if more than one.
- Name, form strength, volume, quantity of the controlled drug to be ordered. (Only agreed abbreviations should be used.)
- Signature of person ordering
- Person ordering should print name also
- Date of the order.

3. Send the order book down to pharmacy.

During the COVID pandemic clinical areas that are designated red zones can place a telephone order for CDs. This is in order to reduce staff movement and the transfer of paperwork Pharmacy will hold CD order books for affected areas for this purpose. The nurse/OPD will have their name transcribed into the book as the requester.

**NOTES**

- Ward stocks must not be issued to patients by ward staff for the purpose of taking home on discharge.
- Controlled drugs must be ordered in the controlled drug order book specific to that ward or department.
- Should an area have more than one controlled drugs cabinet then each cabinet must have an order book and register, specific to that cabinet.
- Controlled drugs order book, like all controlled stationery, must be kept in a secure place. Should an order book go missing, the most senior nurse in charge must inform the Directorate Manager and pharmacy. An incident report form must be completed.
- In the event of an emergency, where the CD order book cannot be accessed, emergency orders can be placed in an “ad hoc order book” which is held by pharmacy.
- Order books from other areas cannot be used.

- Controlled Drugs must be ordered directly from pharmacy and cannot be obtained from other controlled drug cabinets on the ward or anywhere else in the Trust, except in an emergency when the following procedure should be followed:

In an emergency, out of hours, CDs may be issued to a patient on another ward. It is the responsibility of the nurse who is borrowing the CD to notify pharmacy by leaving a message on the pharmacy EPR order line so that a pharmacist can check the process below has been correctly followed the next working day. The CD registers of both the supplying ward and receiving ward must be signed by the nurses in charge of both wards. Only single doses can be administered in this manner. The “supplying” ward must enter the following in their CD register:

- Name of patient
- Location of patient
- Dose
- Signature of nurse on supplying ward
- Signature of nurse on receiving ward

The “receiving” ward must enter the following into their register:

- Where the item has come from
-
- Signature of nurse from supplying ward
- Signature of nurse on the receiving ward

The next line in the register must be completed in the usual manner identifying the patient according to normal practice.

**Ordering of Stock CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)**

Only qualified staff or operating department practitioners are able to order these CDs using the standard pharmacy stock requisition book. Stocks may need to be ordered in between weekly pharmacy top ups on an ad hoc basis depending on patients admitted. There is now enhanced monitoring by pharmacy of ad hoc requisitions. Stock levels may need to be adjusted (this must be discussed between the ward manager and a senior pharmacist)

Out of hours wards may borrow single doses only of Schedule 4 and 5 CDs. Alternatively, wards can access the emergency cupboard in pharmacy if larger quantities are required until pharmacy is open.

## Procedure for the Collection of Controlled Drug Stocks (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam) from Pharmacy

1 When the controlled drugs are ready in pharmacy and are to be collected by the ward, pharmacy will ring the ward to collect.
2 The ward sends down an approved member of staff, known as the messenger, to collect the controlled drugs.
3 The messenger, with a member of the pharmacy staff, checks the controlled drugs; i.e. an actual check of the drugs dispensed against the order in the requisition book. This check includes:-

The correct drug
The correct form
The correct presentation size, (eg 1mL or 10mL amps)
The correct strength
The correct quantity (this would include opening packages which are unsealed and counting the contents)

4 If all items are correct, the messenger signs and dates each page ordered.
5 The top copy (white copy) is torn out and left with the pharmacy.
6 The CDs will then be sealed in a red plastic bag for transportation. The ordered stock is transferred up to the ward by the messenger. The messenger must go directly to the ward with the supply and hand directly and in person to the staff in charge of the ward for receipt.

During the COVID pandemic if CDs have been ordered via telephone for a red area the CD order book will remain in pharmacy. The ward staff will therefore sign a photocopy of the order so that once delivered supplied drugs can be reconciled.

## Stock CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)

The process for ward staff is the same as above, except they will sign the general stock requisition book.

## NOTES

- Both registered and non-registered staff who the ward manager considers competent, (this can include porters), can undertake collection of controlled drugs for ward stock. The member of staff however must be an official Trust employee and possess the full permanent Trust identity badge. This badge must be on full display when receiving the controlled drugs from pharmacy.
- Staff making a collection are acting in the capacity as a “messenger”.

## Procedure for the Collection of Controlled Drug TTOs or Outpatient CDs (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam) from Pharmacy

Controlled drugs for TTOs or Outpatients may be collected by ward staff. Outpatient CDs may be collected by patients or relatives

The process is largely the same as for CD stocks above with the exception of the CD paperwork.

The identity of the person collecting schedule 2&3 CDs must be confirmed. The following details must be recorded on the TTO/Outpatient prescription and in the CD register in pharmacy for schedule 2&3 CDs supplied:

- Whether collection was by the patient, relative, carer or healthcare professional
- If by a healthcare professional, their name and place of work within LHCH
- If by the patient or representative, their name and whether evidence of identity was given. If evidence was not given/requested, the reason for this must be documented.

The CDs will then be sealed in a red plastic bag for transportation. Outpatient CDs given to patients/relatives will be in standard pharmacy bags.

**Procedure for the Collection of Controlled Drug TTOs or Outpatient CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine with the exception of morphine sulphate 10mg/5ml oral solution**)

These CDs are exempt from the above controls

## Procedure for the Receipt of Controlled Drugs on Wards

The red bags for transportation of CDs are highly visible and should prompt nursing staff to realise they contain CDs. Staff are reminded to keep vigilant. Any red bags should be opened on wards and CDs secured in a timely fashion.

On delivery a qualified nurse must open the red bags and sign the delivery paperwork (CD requisition book (pink page), stock requisition book (blue page), Outpatient or TTO copy) to accept delivery of the correct CDs. It is the responsibility of the receiving qualified nurse to ensure CDs are secured in a timely fashion.

### CDs (Schedules 2 and 3 e.g. oxycodone, gabapentin, temazepam)

On arrival on the ward / department, each item must be signed for in the CD order book/TTO/Outpatient by an authorised receiver (until this happens the drugs are in the possession of the messenger and they must be handed over to an authorized member of staff so that they become the ultimate responsibility of the nurse/operating department practitioner in charge of the ward at that time). The items should be checked against the requisition/TTO/Outpatient for correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength, expiry date and quantity.

### Stock CDs

The drugs must then immediately be entered into the controlled drug register and the entry and balance checked and countersigned by a second member of staff, which could be the ward staff member who has collected the item(s) from the pharmacy department, i.e. the messenger. Entries must be in ink (or otherwise indelible) and in chronological order.

### TTOs/Outpatients

Controlled drugs for patients supplied on a discharge prescription (TTO) or Outpatient prescription should be entered into the Patient's Own CD register.

On discharge the patient, or their representative, should sign this book, along with a nurse, to indicate they have received the medication.

### CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)

Stock CDs- On arrival to the ward/department, either the stock list from the ward top up or the stock requisition book (blue page) must be signed by an authorised receiver (until this happens the drugs are in the possession of the messenger and they must be handed over to an authorized member of staff so that they become the ultimate responsibility of the nurse/operating department practitioner in charge of the ward at that time).

The items should be checked against the stock list/requisition for correct drug, form, presentation (e.g. 1mL or 10mL ampoules), correct strength, expiry date and quantity
The items should then be secured in the standard medicines cupboard.

### TTOs or Outpatient CDs (Schedules 4 and 5 e.g. diazepam, zopiclone, dihydrocodeine, codeine)

These CDs are exempt from the above controls and should either be given to patients immediately or secured in the standard medicines cupboard until such time.

**NOTE**

- Once the controlled drugs have reached the ward or department they become the ultimate responsibility of the sister/ acting sister/ operating department practitioner who at that time is in charge of the ward or department.
- Each controlled drugs cabinet or fridge must have a controlled drugs register specific to that cabinet or fridge, unless the cabinets or fridges are in close proximity.
- Any discrepancies must be reported to pharmacy immediately.

- A separate part of the register must be used for different preparations and presentations of controlled drug with the drug identification being written at the top of each page including the strength.

- No cancellation, obliteration or alteration of any entry may be made.
- Corrections must made be by way of marginal notes or footnotes which must be dated.
- Errors in the register are to be bracketed and endorsed “error”, signed and as good practice countersigned by a witness.

- Every entry and correction must be in ink or be otherwise indelible.
- All records must be stored for two years from the date of the last entry in the register.
- It is good practice for the ordering and receiving of controlled drugs not to be done by the same person where possible.

## Procedure for the Administration of Controlled drugs to Patients

See also Medicines Administration Procedure.

For COVID areas/patients- see appendix 3

When authorised prescribers prescribe controlled drugs for patients, an entry must be made in the controlled drugs register against the item each time the dose is administered. This books out the dose.

The entry must include :-

the date
the time
patient name
amount given
signature of staff member administering
signature of witness to the administration
balance (should be countersigned as correct)

**NOTES**

- Controlled drugs ordered for ward stock can only be administered to patients on that ward and cannot be transferred to patients on another ward.
- Controlled drugs ordered for ward stock can only be administered to patients on that ward against an inpatient prescription written by an authorised prescriber employed by the Trust or acting as a locum for the Trust.
- The Administration of Medicines Policy must be adhered to.
- Administration to patients requires that a second authorised member of staff checks all aspects of the administration and countersigns the register and administration record as per Trust policy.
- Should a dose be wasted (e.g. a liquid dose measured and then refused by the patient) then the dose should be destroyed by emptying into a sharps bin which is then labelled as mixed pharmaceutical waste/sharps. An authorised member of the ward staff must witness the destruction. The destruction of the wasted dose must be documented in the controlled drugs register and the entry countersigned by the witness.
- If the dose prescribed is made up of two presentations then two entries are required in the CD Register, each entry giving the patient's total dose as well as the quantity /dose booked out for that item.
- Liquid doses must be measured out using an appropriate oral syringe and bung. This ensures accurate measurement and minimises losses.

## Procedure for the Checking of Controlled Drugs

1. Each controlled drug must be checked against the balance in the register by the nurse/ ODP (operating department practitioners) in charge and another authorised nurse/ODP acting as a witness.
2. An entry in the controlled drugs register (using the back of the CD register) must be made stating that the balance has been checked, using one page at the back of the register to indicate that ALL have been checked.
   The following should be written in the register record:
   - Date and time of check
   - The words “balance check completed and all correct” or “balance check completed” and details of any discrepancy noted
   - Signatures of the two members of staff conducting the check.

This is acceptable for six days each week, however, once a week the back of the register must not be used, rather every page should be reviewed and the following entry made where a page is in current use:

- Date and time of check
- The words “balance checked and found to be correct” or “balance check completed” and details of any discrepancy noted
- Signatures of the two members of staff conducting the check.

3. The daily and weekly check MUST include checking patient’s own CDs and include those dispensed by the pharmacy for discharge (for process – see note below).
4. Only Controlled Drugs should be stored in the CD cupboards / fridges.

## NOTES

- The reconciliation of the stock balance is to be carried out by two qualified nurses or ODPs, one of whom should be the assigned nurse/ODP in charge and the check countersigned by both nurses or ODPs.
- The balance of controlled drugs are to be checked at least every 24 hours by nursing or ODP staff. For liquid medicines the check can be by sight unless a significant balance discrepancy is suspected in which case either a syringe (for small quantities) or a conical flask (pharmacy will supply wards with 250mL, 100mL, 50mL and 10mL cylinders for this purpose) should be used.
- **Any discrepancies, loss, or suspected theft or diversion should be reported immediately to the nurse in charge. Pharmacy should be notified as soon as possible during working hours. If out of hours, and the nurse in charge believes the issue to be serious, they should contact the on call pharmacist.** Because the designated nurse/ODP in charge will change from shift to shift it would seem appropriate to reconcile the stock at shift change, the check being undertaken by the nurse/ODP in charge of both shifts.
- A balance check must be made each time there is stock movement of a controlled drug.
- Any *discrepancies must be fully investigated and reported as above
- On discovering a discrepancy, action should include
  - Recounting balance again and by a different individual authorised to do so.
  - Rechecking all entries have been made
  - Rechecking the balance has been calculated correctly
  - Stock has not been separated and stored in another area of the controlled drugs cabinet
  - CD Liquids - a 10% or less differential is considered acceptable in the case of liquids. The 10% calculation can only apply when 10 or more doses have been taken from the same bottle (although this may be challenged by an investigating pharmacist depending on the size of the bottle)

    - Nursing staff must inform pharmacy when a bottle is finished and a discrepancy noted. This will ensure the discrepancy is not carried forward to the new bottle.
    - **N.B nursing staff must not amend balances**.
- Pharmacy will advise on the requirement to complete an incident form, endorsements to be made in the register, and adjustments to the running balance.
- Major incidents are to be reported to the Senior Nursing Manager for that area and the Chief Pharmacist as CDAO.
- The Chief Pharmacist (as CDAO) receives all datix CD incidents as a matter of course

Process for conducting the daily and weekly stock check:

- Remove all CD stock (including Patient's Own) from the CD cupboard (a trolley may be needed if there is insufficient space on the work surface)
- Systematically review each page in the CD register and, upon finding a positive balance, locate the product to which the page refers and count the stock.
- If you are conducting the WEEKLY stock check and the counted stock matches that recorded in the register, complete the next line in the register as follows (if conducting the daily check, move to the next page):
    - Date and time of check
    - Balance checked and found to be correct (unless there is a discrepancy – see above)
    - Sign and witness sign – two members of staff to sign
- Turn to the next page and repeat the process.
- When ALL pages have been completed, **including the patient's own records**, there should be no stock left on the bench or trolley, there should also have been stock for every page where a stock was indicated. If neither of these scenarios exist (i.e. you have unaccounted for stock or you have a page in the register indicating that you should have stock and you have none) contact your ward manager or HON and discuss with you ward pharmacist / senior pharmacist on duty.

## Procedure for the Handover of Controlled Drug Keys at Handover

1. The controlled drug keys must be in the possession of an authorised staff member at all times.

2. At Handover, the keys must be returned to the shift leader of that shift who in turn will pass them over to the shift leader taking over.

3. It is good practice to do a balance check of all controlled drugs at Handover. This should be done by the two shift leaders since they hold the responsibility for the controlled drugs during their respective shifts. This may be a good point for the official handover of the keys.

4. If a check is not possible at each handover the CD balance check must be undertaken at least every 24 hrs.

## Procedure for the Handling of Patients Own Controlled Drugs

**Transfer of patients own controlled drugs**

**When transferring a patient from one LHCH area to another, patients' own controlled drugs (including CD TTOs recently dispensed to the patient) must be signed out of the patients own CD register (specifying the receiving ward and countersigned by another staff witness). The CD must then be signed into the receiving ward's patient own CD register (specifying the transferring ward and countersigned by another staff witness).**

**If a patient requires a dose of their own controlled drug (because stock is not available and there would be a delay in obtaining ward stock), the normal process outlined in this policy for administration must be followed.**

COVID
Medicines must not be moved from a COVID cohort area or positive/suspected patient to a clean area. Unwanted CDs should be denatured using DOOP kits and signed for (see below). This must be double bagged and destroyed on ward (put in a yellow bin with blue lid- labelled pharmaceutical waste only)

If the medicines are not needed on the ward

One of the following options should be taken and all actions recorded:-

1. If the patient or the patient's representative agrees, medicines may be destroyed. The pharmacist should take responsibility for destruction, and the record of destruction countersigned by a witness.
2. If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. If the medicines are not safe and/or not appropriate for use, then the patient and/or patient's agent should be advised and they should be encouraged to send them to pharmacy for safe destruction.

**NOTES**

- Controlled drugs belonging to patients should, as with other patient's own medication, be treated as patient's own property.

There may be instances, as with other patient's own medication, when patient's own controlled drugs may require to be administered. In these circumstances the criteria overleaf on using patient's own controlled drugs needs to be followed.

If the medicines are needed on the ward

3. The drugs should be checked for suitability according to the local procedure for patient's own drugs (POD's).
4. The drugs should be entered into the ward's patient's own CD register and stored within the Controlled Drug cupboard.

**NOTES**

- Controlled Drugs belonging to patients may only be used when the presentation is identifiable and in a tamper proof packaging or presentation.

- Ward stock should be ordered at the next available opportunity unless the patient is only in for a short stay and it would not be feasible to obtain hospital stock.
- Patients who may be required to use their own medication which could come under the term Controlled Drugs include palliative care patients who may require an admission to hospital for medication assessment and patients with a chronic / long term pain problem who are self medicating.
- If a patient dies, controlled drugs belonging to that patient cannot be legitimately handed back to a relative and should be disposed of via pharmacy according to Trust policy.
- If a patient's therapy is changed and / or they no longer require a controlled drug preparation, then it is justifiable to ask for the drugs to be destroyed in the presence of a pharmacist. The patient or their next of kin should be informed of this action.
-

**Patients transferred from one clinical area to another with a controlled drug in situ**

- If a patient is transferred to a ward with an epidural or PCA, containing an opiate in situ, then the receiving ward must write, in the transfer section of the CD register, the approximate amount of controlled drug transferred attached to the patient. This then allows a record to be made on the ward of its destruction if necessary.

- It is recommended that each ward have a separate transfer / destruction CD register for this purpose.

## Procedure for Returning Controlled Drugs Back to Pharmacy

1. When a controlled drug is no longer required by a ward, the ward must give notice to pharmacy for its removal.
2. The item is booked out of the controlled drug register and the new balance written against the entry.
3. Removal of all controlled drugs - whether they are ward stock or patient's own must be counted and / or measured by the pharmacist returning/destroying the drugs in the presence of the nurse/ ODP.
4. The balance entry must be countersigned both by the nurse/OPD and the pharmacist removing the drug.

**NB Exceptions to the return of CDs to pharmacy are those which have been attached or applied to a patient in any way. This applies to part used epidurals and PCA bags and also to fentanyl and buprenorphine patches which may have some drug remaining after removal from the patient. These must be destroyed at ward level (see procedure for the destruction of controlled drugs at ward level).**

## NOTES

- All ward stock of controlled drugs no longer required on the ward / department must be returned to pharmacy for destruction or for reissue if appropriate, there is an SOP within pharmacy supporting this process.
- Before a patient's own medicine is destroyed, including controlled drugs, the permission of the patient or their guardian must be sought. The procedure for sending patient's own medicines to pharmacy/destruction on the ward must be followed.
- If controlled drugs belonging to the patients are to be destroyed an entry should be made against the record of the storage, and the destruction countersigned/dated by the pharmacist and authorised nurse/ODP witness.
- During ward closures the controlled drugs together with the ward register should be sent to pharmacy in a sealed pharmacy bag for safe storage unless the closure is for decontamination, in which case the drugs should remain on the ward for a period of quarantine.

COVID

Generally, medicines must not be moved from a COVID cohort area or positive/suspected patient to a clean area (e.g. pharmacy). However, due to legal constraints, any unsuitable ward stock CDs requiring destruction (e.g. expired) need to be destroyed in the presence of a suitable witness. Such CDs should be double bagged, kept in the CD cupboard for 5 days clearly marked as expired and then returned to pharmacy for normal destruction as above.

## Procedure for the Destruction of Controlled Drugs at Ward Level

**All out of date ward stocks of controlled drugs are to be returned to pharmacy for destruction by the Trust Authorised Persons.***

1. Controlled drugs for destruction at ward level are to be destroyed in the presence of a witness who could include another authorised nurse, pharmacist or doctor.
2. An entry of the destruction is to be made in the register and countersigned by both parties witnessing the destruction.
3. Destruction should be by emptying into a sharps bin (unless more than 50mL of liquid is involved, then see notes below) which is then labelled as mixed pharmaceutical waste/sharps.
4. Patients own medication that is no longer required or appropriate for the patients must be destroyed by a pharmacist and an appropriate witness using a DOOP kit.

**NOTES**

- *Controlled Drugs which should be destroyed at ward level include:

    1. Individual doses that are prepared and not administered (State the reason why not administered.) This applies to quantities less than 50mLs. For quantities more than 50mLs follow procedure in point 4 below.
    2. The remains of part doses (eg 25mg from a 50mg ampoule) should be disposed of into a sharps bin. This applies to quantities less than 50mLs. For quantities more than 50mLs follow procedure in point 4 below.
    3. Fentanyl / Buprenorphine patches which have been applied to the patient should be disposed of by folding the patches with the adhesive side together and then place them into a sharps bin.
    4. The remains of partly used vials, epidurals or PCA bags, greater than 50mLs, should be disposed of by using the DOOP kit (see DOOP kit procedure on side of DOOP container) before disposing into a sharps bin.

- A ‘destruction’ page in the ward CD register may be necessary for this purpose, or a separate destruction / transfer register.
- DOOP kits are obtainable from NHS Supplies via the oracle system.

## Procedure for Dealing with Patients or Staff who are Suspected of Controlled Drug Abuse

## Procedure for Dealing with Suspected Abuse of Controlled Drugs Amongst Staff Members

1. If staff suspect another member of staff, including prescribing staff, of abusing controlled drugs, then they should confide their suspicions with a more senior staff member. If the suspecting staff member would rather, then they can make contact with the senior pharmacy manager to discuss their suspicions with them.
2. All actions concerning this will be dealt with in a confidential way and will follow the agreed Corporate Trust procedure relating to this issue.

## Procedure for Dealing with Illicit Drugs Found on Patients

### Schedule 1 Products (CD Lic) and other illicit drugs

Schedule 1 products include such substances as LSD and ecstasy. Production, possession and supply of such substances are limited for the purpose of research and authorised personnel must be granted a licence from the Home Office for them to handle such substances. Under normal circumstances pharmacists, doctors, nurses do not hold such a licence. Other illicit drugs may include other schedules such as Schedule 2, e.g. diamorphine. See above for information regarding cannabis products.

Such medicines are considered illicit if a patient or staff member is in possession of the medicine without a bone-fide authorised supply i.e. if the patient has had no prescription from an authorised practitioner. If a palliative patient has in their possession diamorphine prescribed for their pain by a doctor – such a patient would be in legal possession of the product.

There may be circumstances when illicit/unknown substances are found on the hospital premises or on patients on admission.

1. In these circumstances a pharmacist can take possession of the substance for the purpose of destruction or for handing it over to the police.

2. Where such a substance is found on a patient the pharmacist must be informed. The patient's confidentiality should be maintained and the police be called in on the understanding that there will be no identification of the source.

3. In circumstances where extreme quantities are found, the pharmacy manager and senior hospital managers, legal team and clinicians must be informed. In these circumstances it may be acceptable practice to identify the source. Advice from the DOH may be sought in such cases.

4. When illicit/unknown substances are found on a patient it is not acceptable practice to hand them back on discharge since this may result in the person doing so to be guilty of an offence of the unlawful supply of a Controlled Drug.

5. If a patient does not give authority for the removal and destruction of the drug, the hospital may be required to call in the police.

## Appendix 2

**Audit Aide Memoire Form**

**NOTES FOR GUIDANCE WHEN USING THE AUDIT AIDE**

## MEMOIRE FORM

The audit record should show the area reviewed e.g. members of staff interviewed, and reference should also be made to reference numbers of documents checked. Observations may be noted on the audit record which may lead to systems improvements.

## ACCEPTANCE CRITERIA

Each section is divided into up to five parts:-

1. New legal requirement.
2. Existing legal requirement.
3. New good practice (as per regulatory authorities – DOH: ref 4 and RPSGB ref 5).
4. Existing good practice (as per Regulatory Authorities – RPSGB ref 3 and ref 5, DOH ref 4, and Duthie Report ref 7).
5. Good practice (as recommended by Quality Control North West).

## RESULT RATINGS

**Green ( G) = Compliance with Acceptance Criteria**.

**Amber (A) = Minor (where it is evaluated that the non-conformance has no effect on the legality of the operations or systems or procedures require minor alterations that can easily be accomplished).**

**Red (R) = No such system / procedure currently in place.**

Glossary of terms used in connection with the checks required for each criterion:

Assess: Requires the auditor(s) to use their professional judgment in assessing whether the audit standard is complied with and, if not, attributing a non- conforming grade.

Examine: Generally relates to procedures and/or materials that need to be examined.

Procedure: Relates to written procedures which should be assessed for appropriateness and compliance with official guideline

***CDAO - SAFE HANDLING OF CONTROLLED DRUGS (CDs) AUDIT – PART ONE PHARMACY DEPARTMENT***

**1. LEGAL STATUS**

| No | Acceptance Criteria | Check Required | Evidence | Audit Result<br><br>G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 1.1 | Requisition / prescription checked for completeness (legally acceptable for changes for minor technical errors to be made accordingly by a pharmacist and signed as such). | Procedure | Pharmacy SOP<br>5 yellow CD TTOs<br>5 OPDs | | |
| 1.2 | All prescriptions /requisitions for schedule 2, 3 and 4 CDs dispensed within 28 days of date specified (i.e. date of prescribing/start date specified/ date on requisition). | Examine | Pharmacy SOP<br>5 yellow CD TTOs<br>5 OPDs | | |
| 1.3 | New standard private prescription forms (FP10PCD) used if appropriate (only needed if written in hospital and dispensed in community and contain prescriber identification number). | Assess | N/A | N/A | |
| 1.4 | Prescriptions contain a unique patient identification number (NHS number/hospital number). | Examine | Cannot be dispensed without this therefore always present | **G** | |

| No | Acceptance Criteria | Check Required | Evidence | Audit Result<br><br>G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 1.5 | All CDs supplied by pharmacy in accordance with a requisition or prescription signed by an authorised signatory. | Procedure | Trust Policy. Check:<br>5TTOs<br>5 OPDs<br>5 requisitions | | |
| 1.6 | System in place to enable verification of signatures. | Assess | Ward staff and prescriber signatures scanned into tracker for verification prior to dispensing | G | |

## 2. PROCESS CONTROL INCLUDING DOCUMENTATION/RECORDS

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 2.1 | Standard Operating Procedures (SOPs) cover all activities and are available to all staff at locations where CDs are handled.<br>As a minimum, SOPs should cover:-<br><br>Who has access to CDs<br>Where CDs are stored<br>Security arrangements in relation to the storage<br>and transport of CDs<br>Disposal and destruction of CDs<br>Who to alert if complications / discrepancies arise<br>Record keeping – including maintaining the CD register<br>- maintaining record of schedule 2 CDs returned by patients<br>Dispensing and issue to patients/ wards | Examine | Pharmacy CD SOPs and Trust Policy | G | |

| | | | | | |
|---|---|---|---|---|---|
| 2.2 | Completed prescriptions, requisitions and record books are stored in the appropriate location for the correct minimum period of retention. | Assess | Pharmacy receptionist boxes up and puts destruction date of 2 years on | G | |
| 2.3 | The CD register is completed appropriately.<br>Receipt registers for CDs must contain at least:-<br>· date CD received<br>· name and address of supplier<br>· amount obtained<br>· name, form and strength of the CD<br>Registers of the supply of CDs must contain at least:-<br>· date supply made<br>· name and address of person/firm supplied to<br>· particulars as to the licence/authority of the recipient to be in possession of CDs.<br>· amount supplied<br>·name, form and strength of the CD<br>In addition, registers must:-<br>· be completed in chronological order<br>· have a separate section for each drug, form and strength<br>· have the class of drug specified at the head of each page<br>· be used for no other purpose<br>· kept at the premises to which register relates<br>· have entries made on the day of/next day after the transaction. | Examine | Registers are fit for purpose.<br>Pharmacy SOPs in place<br><br>Check 5 receipts<br>Check 5 supplies | | |
| 2.4 | A running balance of stock is kept in the CD register. | Examine | Pharmacy SOP in place | G | |
| 2.5 | Pharmacy stock levels of CDs are checked at regular intervals in all locations where CDs are kept within the pharmacy department. | Assess | Pharmacy SOP in date<br>Check last 3months completed by different person to that dispensing | | |
| 2.6 | Stock levels of CDs in ward/departments areas are checked by ward/ department staff according | Assess | Check compliance of Pharmacist ward checks % | | |

| | | | | | |
|---|---|---|---|---|---|
| | to Trust policy, and at least every 3 months by pharmacy staff. | | | | |
| 2.7 | All controlled stationery is stored in a locked cupboard. | Examine | All stored in CD room<br>Check none outside | | |
| 2.8 | Controlled stationery is numbered and issue to wards/departments recorded | Examine | Pharmacy SOP in date<br>Check issue records | | |
| 2.9 | SOPs are signed, dated, reviewed and approved by senior staff. | Examine | Check Pharmacy CD SOPs | | |
| 2.10 | Training of staff to dispense/check CD prescriptions and ward stock requisitions are in place, documented and reviewed. | Examine | Check in place | | |
| 2.11 | Dispensing errors/documentation errors involving CDs are recorded and reviewed, followed by staff training as appropriate. | Examine | Datix incidents reviewed and discussed at pharm and tech monthly meetings | | |
| 2.12 | An internal audit is completed annully to ensure all processes including the three monthly checks are carried out | Examine | CDAO annual report includes compliance with 3 monthly pharmacy checks. CDAO conducts 1/4ly audits at ward/pharmacy level. Audit dept conducts annual audit. | | |

## 3. TRANSPORTATION

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 3.1 | Procedures are in place which specify the type of staff who are authorised to transport/sign for receipt of CDs. | Examine | Pharmacy SOP<br>Trust Policy | | |
| 3.2 | SOPs define the responsibilities of pharmacy staff transporting CDs. | Examine | Pharmacy SOP<br>Trust Policy | | |
| 3.3 | A system recording each stage of the transfer of CDs is in place (i.e. receipt, dispensing, collection). | Assess | Trust Policy<br>TTO&OPD collection signature<br>CD stock req nurse signature (order and receipt (pink copy))<br>Stock book req signature<br>Sch4&5 CD top up req- pharmacy ATO and ward sigs<br>Pharmacy sigs on dispensing all above Recorded on ascribe<br>Check 5 TTOs, 5OPD, 5 Req, stock book | | |
| 3.4 | Tamper-evident transport containers are in use. | Examine | Full use of red plastic bags for all CD (2,3,4,5) deliveries/issues | | |

## 4. SECURITY

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 4.1 | A system is in place to ascertain whether the person collecting schedule 2 CDs is the patient their representative or a healthcare professional acting in their professional capacity. | Assess | Trust policy.<br>Stamp on TTOs/OPD filled in correctly and entered in register<br>Check: 5 TTOs 5 OPDs | | |
| 4.2 | CDs are stored in cupboards complying with legal regulations. | Examine | All sch 2/3 CDs in locked CD room in pharmacy | | |
| 4.3 | Only Authorised staff hold cupboard keys and access to the CD cupboard/sign for receiving/administering CDs. | Examine | All pharmacy staff (except clerical) have authorised access | | |
| 4.4 | CDs are kept in locations appropriate to the legal status of the drug and Trust/pharmacy policy.<br>Schedule 2 CD's – stored in a locked CD cupboard/fridge.<br>– all transaction details recorded in CD register (prescription requirements apply).<br>e.g alfentanil/fentanyl/remifentanil<br>amphetamines/methylphenidate<br>codeine/dihydrocodeine injections<br>diconal<br>dihydromorphine/hydromorphine<br>cocaine >0.1% and where cocaine not easily recoverable<br>diamorphine<br>morphine (not if < 2mg/ml and morphine not easily recoverable or constitutes a risk to health).<br>methadone<br>pethidine | Examine | All sch2&3 CDs are treated as full CDs. All stored in CD room. | | |

| | | | | | |
|---|---|---|---|---|---|
| | oxycodone<br>quinalbarbitone (no safe custody requirement)<br>Schedule 3 CDs – stored in a locked CD cupboard (no CD register entry required, prescription requirements apply except for temazepam). Applies only to temazepam, buprenorphine, diethylpropion and flunitrazepam (barbiturates -except quinalbarbitone- currently exempted from safe custody requirements).<br>Schedule 4 part 1 and 2 (no safe custody, prescription or register requirements)<br>Schedule 5 (no safe custody, prescription or register requirements). | | | | |
| 4.5 | A system for signing for the receipt of schedule 2 CDs by hospital staff is in place. | Assess | Above 3.3 | | |
| 4.6 | A system for signing for the receipt of schedule 2 CDs by patients/carers/HCP's is in place. | Assess | Above 4.1 | | |
| 4.7 | Dispensing of more than 30 days supply of schedule 2, 3 or 4 CDs is documented on the prescription and in the register giving reasons for the supply. | Assess | Ascribe max. issue quantity set to 30days on oral MR preps. Report run 1/4ly to check any breaches | | |
| 4.8 | A Trust policy is available for the emergency transfer of CD's between wards/departments as appropriate. | Examine | Trust Policy in situ | | |

## 5. QUALITY AND INTEGRITY

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 5.1 | Fridges are lockable and conform to the standards required for the storage of medicines. | Assess | Cd Fridge in CD room<br>Temp monitored as per all meds fridges | | |
| 5.2 | Fridges are monitored, temperatures recorded and action taken as appropriate. | Assess | As 5.1<br>Regular fridge monitoring audits conducted | | |
| 5.3 | Staff are able to identify the correct product required and have sufficient information available to enable them to use the product appropriately (e.g HCP package insert, patient information leaflet). | Assess | CD room tidy<br>CDs stored in sections<br>All OPD/TTOs supplied with PiLs | | |

## 6. SAFETY ISSUES, STAFF AND PATIENTS

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 6.1 | Trust policy/SOPs are in place covering the risks of handling CDs (including the legality of signing for and storage of CDs.) | Examine | Trust Policy | | |
| 6.2 | SOPs are available for dealing with unplanned events<br>( e.g. documenting spillages). | Examine | Trust Policy | | |
| 6.3 | The Trust has a policy for product recall. | Examine | CAS MHRA Alerts Cascaded by risk dept and actions recorded on M Drive in pharmcy | | |

## 7. RESPONSIBILITIES / ACCOUNTABILITY

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 7.1 | Trust documentation details who is accountable for each activity involving CDs and who is the overall "Accountable Officer". | Examine | Trust CD policy | | |
| 7.2 | Persons in possession/ordering/supplying CDs are legally entitled to and are registered as appropriate. Such tasks are not delegated to staff who are not legally entitled or trained/authorised. | ***Assess*** | Authorised and trained staff<br>Pharmacists- all activity<br>Techs- all activity apart from clinical screen<br>ATOs- delivery to wards. Receipt of CDs at back door. | | |
| 7.3 | A Trust policy is in place that details the course of action to be taken should any discrepancies/incidents involving CDs occur. | ***Examine*** | Trust Policy | | |
| 7.4 | A record of discrepancies/adjustments to CD records is kept and signed by authorised personnel. | Examine | Discrepancy log kept in pharmacy CD room | | |
| 7.5 | A policy is in place that prescribers should not prescribe or administer CDs for themselves or for close family/friends except in an emergency. | Examine | Medicines Policy | | |
| 7.6 | Polices are available in pharmacy and wards/departments that clearly define which staff are responsible for which activities relating to CDs. | Examine | Trust Policy available on intranet | | |

## 8. DESTRUCTION OF CD's

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 8.1 | The destruction of schedule 2 CDs (hospital stock) must be witnessed by a Trust specified Authorised Person who is independent of the Accountable Officer. There is a list of Authorised Persons and their designation. | Examine | CDAO SOP in situ<br>Sch 3 treated same as sch 2<br><br>Interrogate CD destruction register. Look for any chronological gaps and missing signatures of APs<br><br>Check 5 random ward CD returns have been entered in pharmacy destruction/stock register | | |
| 8.2 | SOPs are in place that cover the handling of schedule 2 CDs for destruction from ward stock and pharmacy stock and patients own medication. | Examine | Trust Policy<br>Pharmacy SOPs | | |
| 8.3 | Records of the destruction of schedule 2 CDs include the name of the drug form, strength, quantity, date destroyed, signatures of the professional destroying the CD and the authorised witness. | Examine | Interrogate CD destruction register. Look for any chronological gaps and missing signatures of APs | | |
| 8.4 | All patient returned schedule 2 CDs are recorded before destruction either by the Trust Authorised Person or a pharmacist. | Assess | As 8.3<br>Check ward registers for patients own CD destructions | | |
| 8.5 | Schedule 2 CDs are denatured before destruction. | Assess | DOOP kits in pharmacy | | |
| 8.6 | The frequency/stocks of CDs for destruction is monitored to prevent build up of excessive quantities. | Assess | Assessed 1/4ly. Destruction must occur at least 1/4ly CDs Must fit in filing cabinet in CD room | | |

## 9. MONITORING OF SCH 4&5 CDs

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 9.1 | Pharmacy stocks of sch 4&5 CDs are monitored weekly. Any discrepancy of 14 or more tablets is reported to Chief/Deputy for review. | Examine | | | |
| 9.2 | Ward stock levels/usage mapped against EPR administration records to flag any major discrepancy | Examine | | | |
| 9.3 | Review of ADIOS software. Investigate any spikes in use (3 Standard Deviations) | Examine | | | |

## Safe Handling of Controlled Drugs (CDs) Audit Part Two – WARD/CLINICAL AREAS

### 1. Process control including documentation / records

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 1.1 | Standard Operating Procedures (SOPs) cover all activities and are available to all staff at locations where CDs are handled). As a minimum, SOPs should cover:-<br>Ordering of CDs, collection /delivery from pharmacy Receipt on the ward/ storage<br>Register entries<br>Administration to patients<br>Balance checks*/handover of keys<br>Handling patients own CDs<br>Returns to pharmacy / ward closures<br>Destruction of CDs at ward level<br>Dealing with patients/staff suspected of illicit drug abuse<br>Responsibilities / access to CDs / authorised signatures<br>SOPs must be approved by senior staff, signed, dated and reviewed.<br><br>*A running balance is kept in the register and reconciled against stock levels at least once every 24 hours by ward staff. | Examine | Trust Policy available on intranet<br><br>Review records for 24hourly balance check | | |
| 1.2 | Documentation is kept locked away, and retained for<br>at least 2 years from the date of the last entry. | Assess | Ask ward manager to evidence | | |
| 1.3 | A Trust procedure is available for the emergency transfer of CDs between wards/departments as appropriate. | Examine | Trust Policy available on intranet | | |

## 2. Transportation

| No | Acceptance Criteria | Check required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 2.1 | Procedures are in place which specify the type of staff who are authorised to transport/sign for receipt of CDs. | Examine | Trust Policy | | |
| 2.2 | The cold chain is maintained (where applicable) For the transport/storage of CDs on ward/ clinical areas. | Assess | Medicines policy See fridge monitoring audits | | |

**3. Security**

| No | Acceptance Criteria | Check Required | Evidence | Audit Result G,A,R | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 3.1 | CDs are stored in cupboards/fridges complying with legal regulations | Examine | | | |
| 3.2 | Only authorised staff hold cupboard keys and have access to the CD cupboards/fridges | Examine | | | |
| 3.3 | Only authorised staff sign for receiving /administering CDs | Examine | Check 5 CD stock requisitions (pink copy)<br>Check 5 TTOs entered into patients own CD register | | |
| 3.4 | CDs are kept in locations appropriate to the legal status of the drug and Trust policy.<br>Schedule 2 CDs stored in a locked CD cupboard/fridge<br>and entered in register. Schedule 3 CDs stored in a locked CD cupboard (applies only to temazapam, buprenorphine, diethylpropion and flunitrazepam) – CD register entry not a legal requirement but considered good practice / according to local policy | Examine | All sch 2&3 treated as full CDs as per Trust Policy | | |

## 4. Quality and Integrity

| No | Acceptance Criteria | Check Required | Evidence | Audit Result | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 4.1 | CDs are assessed as fit for use and documentation completed by the administering practitioner | Assess | Asked nurse to describe process when removing CD | | |
| 4.2 | Trust policies are in place governing the storage of CDs in ward/clinical areas | Examine | Trust Policy | | |
| 4.3 | CDs are administered in accordance with an appropriate prescription or patient group direction (PGD) | Assess | Asked nurse to describe process | | |
| 4.4 | Fridges are monitored, temperatures recorded and action taken as appropriate | Assess | Fridge monitoring audit | | |
| 4.5 | Staff are able to identify the correct product required and have sufficient information available to enable them to use the product appropriately (eg. HCP package insert, patient information leaflet) | Assess | Asked nurse to identify an injectable (as chosen by auditor) and can describe access to medusa | | |

## 5. Safety Issues, staff and patients

| No | Acceptance Criteria | Check Required | Evidence | Audit Result | Observations and Non-Conformances |
|---|---|---|---|---|---|
| 5.1 | Trust documentation details who is accountable for each activity involving CDs | Examine | As above | | |
| 5.2 | Persons in possession/ordering/supplying CDs are legally entitled to and are registered as appropriate. Such tasks are not delegated to staff who are not legally entitled or trained/authorised | Assess | As above | | |
| 5.3 | A Trust policy is in place that details the course of action to be taken should any discrepancies/incidents involving CDs occur | Examine | As above | | |
| 5.4 | A record of discrepancies/adjustments to CD records is kept and signed by authorised personnel | Examine | As above | | |

## Appendix 3

### Process to administer CDs to suspected or positive COVID patients

In order to minimise impact on nursing time and reduce excessive use of certain types of PPE, the following process should be followed when administering CDs to a patient in a yellow or red area **AND** where FFP3 masks and full length arm gowns are required.

If the CD cupboard is sited **within** the yellow or red area, follow normal Trust policy for CD administration.

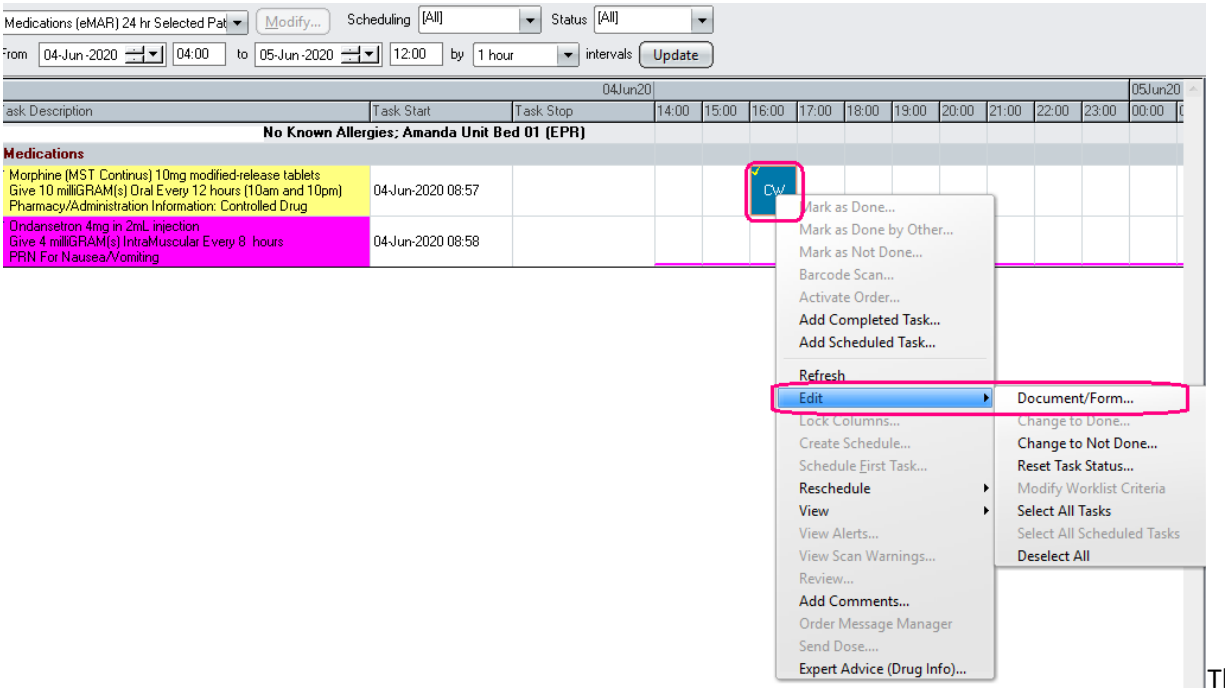
If the CD cupboard is **not** sited within the yellow or red area the following procedure should be followed.

1. Nurse in infected area needs to administer a CD (Nurse No1)
2. Nurse No1 phones colleague outside the area (Nurse No2) to request.
3. Nurse No2 reviews EPR work list manager alongside another colleague (nurse No3).
4. Nurses No2 and No3 follow standard process for removal of required CD from cupboard and register entry and balance checks.
5. Nurses No2 and No3 take register, CD and residual stock box to boundary of yellow or red area. Nurse No2 enables Nurse No1 to clearly identify CD to be administered and shows Nurse No1 register entry and residual stock remaining. Nurse No1 does not touch register or stock box.
6. Nurse No1 takes CD and administers to patient as per normal process.
   If Nurse No1 **has another colleague** present in the yellow or red area, this person will provide the second signature on work list manager for administration.
   If Nurse No1 is **working alone***- they may sign work list manager for administration without the need for a second signature. In the second signature box they should enter the ward specific COVID username and password given by the EPR team.
   ****Extra care should be taken if the medicine requires a pump to be programmed as there will be no independent check performed**.**
7. Nurse No2 (who has prepared the medicine) must add a comment on worklist manager where nurse No1 has signed for the medicine (see screen shot below).
8. Nurses No2&3 take register and remaining CD stock back and secure as normal.
9. Nurse No1 **must** sign CD register as normal for any CDs administered during their shift when they exit the area at the next available opportunity (e.g. for a break)

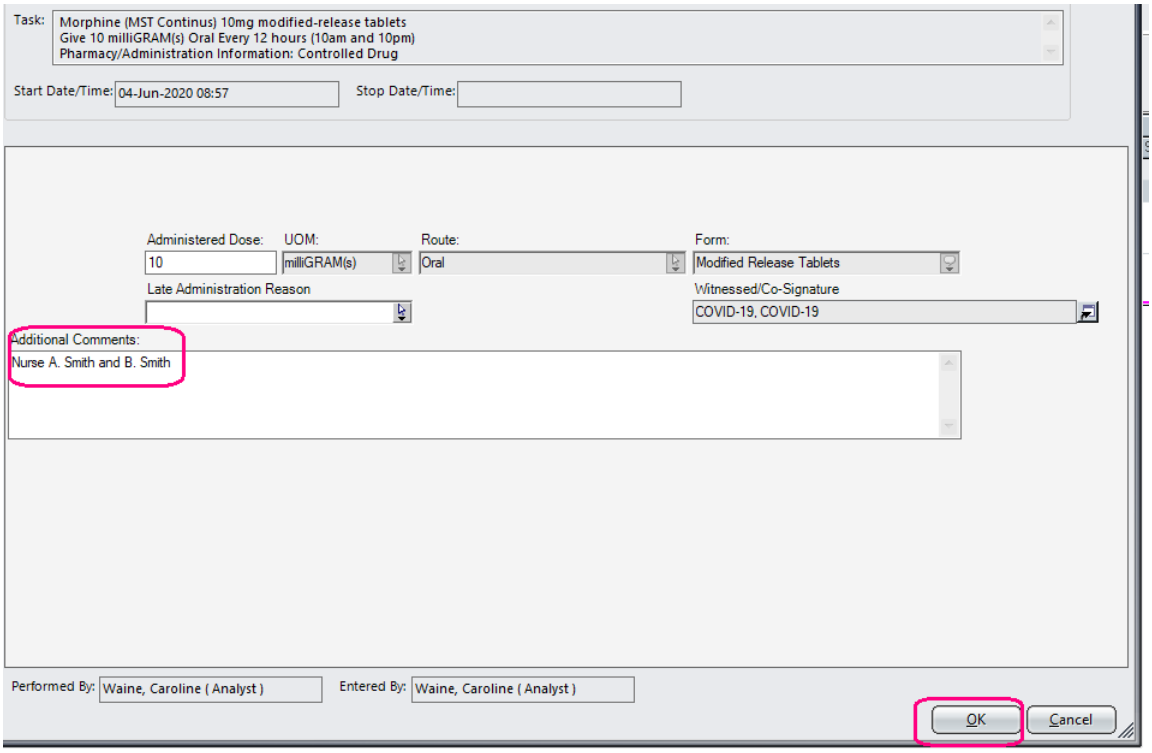
*Only applicable for areas requiring FFP3 mask/full gown.

How to add a comment on worklist manager for the above situation

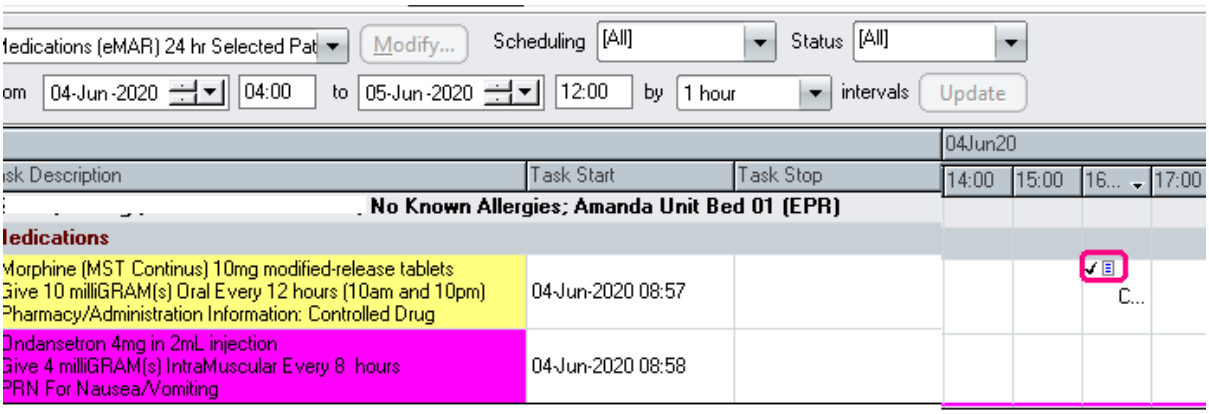
Right click on administered medication signature on Worklist Manager>Edit>Document/Form



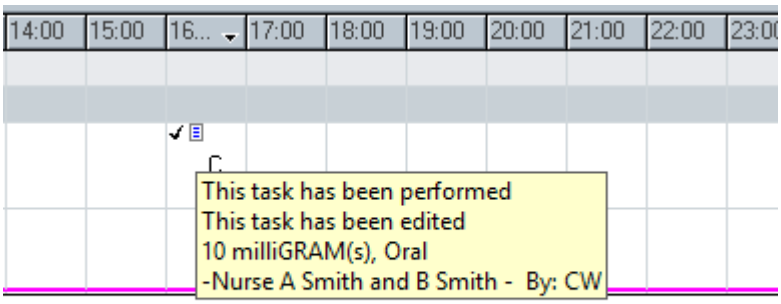

This will open the task form. In the additional comments field, enter the 2 nurses names that have checked and independently checked the medication>Click ok




A comments icon will now appear on the Worklist




By hovering over the icon, you will be able to see the information entered into the comments field:



## 8. Endorsed By:

| Name of Lead Clinician / Manager or Committee Chair | Position of Endorser or Name of Endorsing Committee | Date |
|---|---|---|
| Dr Scawn | Drug & Therapeutics Committee | 16/9/2020 |

# 9. Record of Changes

| Section No | Version No | Date of Change | Description of Amendment | Description of Deletion | Description of Addition | Reason |
|---|---|---|---|---|---|---|
| | | | | | | |