Our Ref: LW/lmw/FOI.309.23
Date: 19th October 2023

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Dear

**Freedom of Information Act Request**

I am writing in response to your e-mail of the 26th September 2023**.** Your request has been processed using the Trust's procedures for the disclosure of information under the Freedom of Information Act (2000).

***Requested information:***
I request a copy of 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.

**Please see Appendices 1-9 attached.**

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review of the management of your request. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to: Dr Buki Adeyemo, Chief Executive, North Staffordshire Combined Healthcare Trust, Trust Headquarters, Lawton House, Bellringer Road, Trentham, ST4 8HH. If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely

L. Wrench.

**Laurie Wrench**
**Deputy Director of Governance**

**Document level: Trust Wide**
**Code: 08.23**
**Issue: 2**

# Best Practice Policy: Medicines Administration - Swallowing Difficulties

| | |
|---|---|
| Lead executive | Interim Medical Director |
| Authors details | Rachel Tarbuck, Senior Pharmacist<br>Principal Pharmacist<br>Deputy Director of MACE |

| | |
|---|---|
| Type of document | Policy |
| Target audience | All clinical staff working in inpatient services |
| Document purpose | For information |

| | | | |
|---|---|---|---|
| Approving meeting | CEG | Meeting date | 29th March 2023 |
| Implementation date | | Review date | 31st March 2026 |

| Trust documents to be read in conjunction with | |
|---|---|
| 1.03 | Medicines Management Policy |
| 1.14 | Clinical Risk Assessment Policy |
| 1.24 | Nutrition Hydration Policy |
| 1.62 | Physical Health |
| 1.64 | Effective Care Planning |
| 1.78a | SOP End of Life Care |
| 1.84 | Care Management Policy |
| 1.85 | Staffordshire and Stoke-on-Trent Supporting Patients Choices<br>Add NF/OL/UL policy |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | This document previously was incorporated as an appendix item within the Medicines Policy and is now presented as a standalone Policy to ensure version control and make it easier for staff to source.<br>Medicines listed were updated to remove nitrates due to lack of usage and to include medicines more relevant to mental health.<br>Roles and responsibilities have been defined.<br>The risk to nursing staff and others in the vicinity of opened capsules/ crushed tablets is clarified. | 0.1 | June 2019 |

| | | | |
|---|---|---|---|
| | The policy scope was broadened to include any GI feeding lines and to comply with any thickened fluid requirements to ensure holistic, personalised patient care is delivered.<br>A form was created to allow accurate documentation of pharmacy advice around dose forms and any amendments required to a prescription.<br>The document has been reformatted to make it clearer. | | |
| | Review 18/7/22. Amendment required to reflect use of EPMA.<br><br>Review 23/9/22<br>Amended to increase content to include more background information | V0.2 | |
| Appendices / electronic forms | Total review | | |
| What is the impact of change? | Clarification of guidance and updated to include most recent information/ amended as above | | |

| | |
|---|---|
| Training requirements | Nil |

| Document consultation | |
|---|---|
| Directorates | All members of Clinical Effectiveness Group (CEG) |
| Corporate services | N/A |
| External agencies | N/A |

| | |
|---|---|
| Financial resource implications | Nil |

External references

1. Dr David Wright (University of Bradford 2002)
2. Specialist Pharmacist Service Swallowing difficulties – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (accessed December 2022)
3. NICE Guideline: NG5 published March 2015 Overview | Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes | Guidance | NICE (accessed December 2022)
4. Camden and Islington NHS Foundation Trust, Dysphagia Policy (2016) -Dysphagia Policy_CL11_May 2016.pdf (candi.nhs.uk)

| | |
|---|---|
| Monitoring compliance with the processes outlined within this document | Ward level by ward managers and clinical pharmacists. |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favourable / More favourable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |
| – **Age** (e.g. consider impact on younger people/ older people) | No | |
| – **Disability** (remember to consider physical, mental and sensory impairments) | No | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | No | |
| – **Gender identity and gender reassignment** (i.e. impact on people who identify as trans, non-binary or gender fluid) | No | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | No | |
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | No | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not) | No | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | No | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | | |
| – **Other equality groups?** (may include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | No | |
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | | |
| Enter details here if applicable | | |

| | |
|---|---|
| If you have identified potential negative impact:<br>- Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | |
| Enter details here if applicable | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | No |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | N/A |
| Enter details here if applicable | |
| Where an adverse, negative or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | |
| Was a full impact assessment required? | No |
| What is the level of impact? | Low |

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## 1. Introduction

This Policy provides guidance for the administration of medicines to **adult** patients with swallowing difficulties or those who cannot take oral medication for other reasons. This guidance applies to all Registered Professionals working within UHL who prescribe and / or administer or supply medicines to adult patients.

This Policy is adapted from the Swallowing Difficulties Protocol designed by Dr David Wright (University of Bradford 2002) and is for use for people:

- Who find it difficult to swallow tablets or capsules.
- Who inappropriately chew tablets and capsules before swallowing.
- Who keep tablets or capsules in their mouths for a prolonged period of time.
- Who have a PEG or other gastrointestinal tube in situ.
- Who are nil by mouth.

## 2. Policy Synopsis

Policy regarding medication dose forms for patients with swallowing difficulties. Addressing the needs of these patients is more complex than simply crushing the tablets or opening the capsules and there are a number of issues that must be considered before any medicines are administered including:

- Identifying patients with swallowing difficulties and the reasons for this
- Medicines management of patients with swallowing difficulties.
- Administering medications via an enteral feeding tube.
- Legal implications of crushing tablets / opening capsules.
- Pharmaceutical and pharmacological implications of crushing tablets / opening capsules.

## Definitions

### Swallowing difficulty

Dysphagia or difficulty swallowing is a symptom of many different medical conditions. These can include nervous system and brain disorders, muscle disorders, and physical blockages in the throat. Treatment for swallowing issues varies depending on the cause of the issue, but can include antibiotics, changes to eating habits and sometimes surgery.

**Swallowing** is the process by which fluid or food is transported from the mouth to the stomach for digestion. Successful swallowing is the result of a sequence of complex events involving anatomical oral and pharyngeal structures and multiple neural pathways. Swallowing is also influenced by features of what is being swallowed and factors specific to the individual (cognitive, physical, medical, psychological and social). Humans swallow on average once every minute and, when eating, this increases to between 6-8 times a minute.

**Dysphagia** is defined as difficulty, discomfort, or pain in swallowing. Dysphagia is usually caused by another health condition and may be mild to severe. Dysphagia can result from any disruption at the preparatory, oral, pharyngeal and/or oesophageal stages of swallowing.

**Aspiration** occurs when fluid, food, saliva, medication, or refluxed material enters the airway. People with dysphagia are at a significantly increased risk of aspirating. Aspiration may occur 'silently' with the individual showing no outward signs of difficulty (such as coughing) although more subtle symptoms may be detectable to a trained observer.

**Aspiration pneumonia** refers to lower respiratory tract infection caused by the inhalation of oropharyngeal secretions colonised by pathogenic bacteria.

**Aspiration pneumonitis** (Mendelson's Syndrome) is a chemical injury caused by the inhalation of sterile gastric contents. People who have seizures or taking sedating medication are most at risk.

**Choking / asphyxiation** occurs when the airway becomes occluded. This may result in sudden death. People with dysphagia are at increased risk of choking.

## 3.0 Identifying Patients with Swallowing Difficulties

### 3.1 Who is at risk of Dysphagia?

The prevalence of dysphagia is thought to vary according to aetiology and age of the individual. Dysphagia is reported to occur in 6% of the general population. People with dysphagia often have other health conditions that they are being treated for which affects their eating, drinking and swallowing abilities. Dysphagia in adults is associated with many conditions, including:

- Stroke
- Dementia
- Multiple Sclerosis
- Cerebral Palsy
- Head Injury
- Parkinson's Disease
- Motor Neurone Disease
- Patients with Tracheostomies
- Surgery to head & neck
- COPD
- Learning Disabilities
- Psychogenic causes

Staff must be aware of the following warning signs of swallowing difficulty and be vigilant for these signs especially in high-risk patients starting or changing medication regimes**.**

### 3.2 Associated Risks

Serious health and quality of life risks may result as a consequence of dysphagia if it is undiagnosed and untreated/unmanaged:

- Poor appetite, weight loss and malnutrition
- Dehydration
- Choking
- Aspiration, respiratory infections and aspiration pneumonia
- Inaccurate drug levels/ dosing
- Increased risk of pressure sores and slower wound healing
- Anxiety, distress and depression
- Reduced quality of life.

### 3.3 Additional Risk Factors for people with Mental Health problems

Evidence from the literature suggests that dysphagia is a common problem in adults with mental health problems. Prevalence rates vary from 19% - 32%. There are also additional factors that may increase the risk for and negative consequences of dysphagia, aspiration and choking in this client group:

- Cognitive / behavioural factors - poor organisation, reduced attention and poor self-monitoring at mealtimes leading to eating very quickly / in a disinhibited / impulsive way and cramming or bolting food (particularly in schizophrenia and bipolar disorder); swallowing without chewing, talking whilst eating.
- Mood – pacing and agitation when eating and drinking, talking whilst eating.
- Poor oral care including missing and decayed teeth. Higher levels of poor oral care are recorded in people with mental health problems. Respiratory pathogens may be aspirated and predispose to lung infections.
- Reflux
- Use of alcohol, antipsychotics and other medication and polypharmacy – may affect levels of alertness, muscle tone and coordination, increase / decrease salivation, delayed swallow, tardive dyskinesia.
- Co-morbid medical diseases / other neurological or other causes of dysphagia.
- Heavy smoking
- Reduced insight into level of own difficulties

## 4.0 Choking & Mental Health Problems

Craig (1980) found that 0.7 % deaths could be attributed to asphyxiation consequent on choking after a meal in a psychiatric hospital. Corcoran et al (2003) reported that 6% of psychiatric in-patient deaths in a 10 year period were due to asphyxiation consequent on choking. Fioritti et al (1997) reported that 19% patients experienced choking incidents in an 18 month period. Ruschena et al (2003) report that the risk of death by choking was 30 times greater in people with schizophrenia than in the general population and people with an organic disorder had 43 times increased risk of death by choking than the general population. The death rate from choking in the mental health population was found to be 100 times more than the general population by Mittleman & Welti (1982). A review of choking incidents – at Broadmoor & St Bernard's Hospitals (Bryan et al 2002) found that 3 patients died as a result of choking on food and there were a further 14 incidents of patients choking

where nursing and medical interventions were successful in preventing possible death.

**5.0 People with Dementia**
Prevalence studies of dysphagia in people with dementia show that 68% of patients with dementia / in care home present with dysphagia- which is associated with increased risk of choking and aspiration due to problems with chewing, difficulty swallowing, effects of medication and eating too fast. The majority of people with advanced dementia have significant dysphagia. Oropharyngeal dysphagia is an important factor leading to pneumonia in the elderly, with pneumonia being the leading cause of death among nursing home residents. Those most at risk of aspiration pneumonia are those who are reliant on others for both oral care and assistance with eating & drinking.

**5.1 Learning Disability**
People with a learning disability are at higher risk of choking as a result of dysphagia, behaviour presented (e.g. bolting food) and the effects of medication.

**6.0 Can Dysphagia be treated?**
Treating dysphagia depends on what underlying condition or conditions a person may have and can be for only a short period of time, whereas others might experience for a longer period of time. Dietician advice should be sought if patient experiencing problems beyond a number of days. Pharmacist advice should be sought for medication administration issues.
The overall aim is to ensure that patients at risk of, or presenting with, dysphagia are identified and are enabled to eat, drink and take medication as safely and comfortably as possible.

**6.1 Signs and symptoms**
Staff may notice any or a combination of the following signs of dysphagia:

- Avoidance or refusal of certain foods or drink or medications
- Patient complains of difficulty swallowing or a sensation of something “sticking”
- Difficulty chewing or prolonged chewing with a delayed or absent swallow
- Retention of food residue or medication in the patient’s mouth
- Difficulty keeping food, drink, medication or saliva in the mouth
- Drooling of saliva or excessive salivation
- Food, fluid or medication coming down the nose
- Gagging, retching or vomiting at mealtimes or medication administration
- Choking episode with food or medication
- Coughing or spluttering during or after eating or drinking or taking medicine
- Throat clearing during eating / drinking or taking medication
- Difficulty breathing or changes in breathing pattern when eating, drinking or taking medication
- Eyes watering or face reddening when eating, drinking or taking medication

- Patient needs to swallow more than once per mouthful to clear food or fluids or medicine
- When eating or taking medicine or following eating/ medicine, inability to cough or a weak non-existent cough although the patient is trying to cough
- Gurgling sound (wet voice) after eating or drinking or taking medicine
- History of repeated chest infections
- Increased shortness of breath or respiratory rate when eating and drinking or taking medicine
- Lack of interest or attention to food and drink
- Increased time taken to eat and drink/take medication
- Panic or anxiety when eating or drinking or taking medicine
- History of aspiration pneumonia
- Inability or reluctance to talk during mealtimes or medication administration
- Dry mouth
- Weight loss

**6.2 Nursing / Care Staff**

The following standards of good practice should be in place in services providing care for those at risk of dysphagia:
As part of each patient's assessment staff must consider the following:

a) Has the patient experienced or is the patient experiencing swallowing difficulty (e.g. is the patient coughing on oral intake).

b) If the patient has a known history of dysphagia has he/she been assessed by Speech and Language Therapists, and are there recommendations or a care plan for eating and drinking in place?

c) Has the patient ever had a previous choking episode?

d) What is the status of the patient's teeth/dentures and level of oral care?

e) Are there are any risk factors for dysphagia, including other medical conditions?

f) Does the patient's medication need to be considered (is it easier / safer to swallow liquids / capsules /or not at all/ withheld) and administer via another route?

Dysphagia symptoms and any known / suspected risks of aspiration or choking should be recorded in the appropriate section of the patient Electronic Patient Record (EPR) system.

All staff need to be aware of, trained in and adhere to Basic Life Support procedures for managing choking in line with the Cardiopulmonary Resuscitation (CPR) policy.

## 7.0 Administration of Medications to Patients with Dysphagia

Dysphagia can make taking medication more difficult leading to medications remaining in the mouth, being spat out or getting stuck in the pharynx or oesophagus. If a dysphagia assessment recommends thickened liquids, all fluids consumed should be thickened, including those taken with or as part of medication.

**It must not be assumed that patients with dysphagia cannot swallow solid oral formulations** (whole tablets and capsules) and need to be prescribed liquids. This is a misconception; patients must be assessed according to the degree of dysphagia as thinner liquid medicines can increase the risk of coughing and aspiration in a patient with dysphagia. **Liquid formulations can be used, but only if thickened to the appropriate consistency**. If a medication is thickened, potential effects on absorption and availability should be considered, including whether any additional monitoring is required.

A multi-disciplinary approach is required to ensure appropriate knowledge of fluid consistency, food texture, medications and drug-food interactions are understood in order to advise patients on the safest and most efficacious formulation. This requires highly individualised care planning.

### 7.1 General Principles

Alternative formulations of the medication in question are available, for example:

- Transdermal
- parenteral/injectable
- buccal
- rectal
- intranasal
- sublingual

If a suitable formulation is not available:

- for patients who are not able to take medicines orally: consider prescribing an alternative medicine or discontinuing the treatment
- for patients able to take medicines orally: consider prescribing an alternative medication
- if no alternative exists, altering a solid-dose oral formulation may need to be contemplated (see below)

## 7.2 Switching to Liquid or Dispersible Oral Formulations

### Liquid Medicines

Liquid medicines consist of more than just the drug and its solvent, as manufacturers spend a considerable amount of time ensuring the reliability of dosing and maximising patient acceptability in order to improve compliance. There are several general characteristics of liquid or dispersible medicines:

- potencies are designed to result in 5 ml dosages (maximal for both measurement and swallowing, which is an important consideration for administering the dose)
- ingredients and flavours are included to mask the taste of the drug
- suspending agents ensure even distribution of the drug within each dose
- solvents are chosen to maximise drug stability—a number of liquid formulations available contain no water at all and this is due to the instability of the drug. The existence of a liquid formulation of a drug provides no guarantee of the stability of a crushed tablet in water
- liquid medicine manufacturers also consider the texture of their medicine, acknowledging that thicker more ‘gloopy’ formulations are often better for swallowing as there is a reduced likelihood of aspiration.
- Changing the formulation of a product may alter its bioavailability, efficacy and/or side-effect profile
- do not assume that the dose of a liquid/dispersible formulation will be the same as the solid oral form of a particular product; check dose equivalence
- when switching from a sustained-release to a standard-release form of a medicine, dose/ frequency will need to be adjusted accordingly
- evaluate efficacy and side effects frequently
- Dispersible tablets may not give an even solution so part dosing is potentially inaccurate
- Some medicines are available as non-licensed liquid 'specials' or extemporaneous preparations, which are formulated to meet the requirements of a doctor for specific use by an individual patient
- dose uniformity or reproducibility may not have been tested for extemporaneous preparations, or some 'specials’
- to minimise the variability of supply, the product specification should be documented: the formulation, method of preparation, and strength should be noted.

## 7.3 Appropriateness

The problem of tablet swallowing may be overcome by simple adjustments, which is important given the need to reassure this patient group, e.g. changing the tablet from a circular to a torpedo shape. If a patient is unable to swallow a tablet whole, owing to problems with the oral phase, the appropriateness of chewing prior to swallowing should be considered.

Chewing, crushing, or dispersing a tablet increases the amount of contact between the active drug and the tongue surface; this can cause a previously palatable tablet to become inedible or unpleasant. If patients are chewing a tablet prior to swallowing, then they should be asked whether the taste is acceptable.

Adults with learning disabilities and other patient groups might struggle to communicate information about appropriateness.

If tablets cannot be swallowed, an alternative liquid medicine or route of administration (patches, orodispersible or suppositories) should be considered.

Thickeners should be used with caution as they may alter the effect of some medicine.

Where licensed liquids are unavailable then unlicensed 'specials' might be available. However, licensed preparations should be considered in most clinical cases before unlicensed products.

## 7.4 Safety

Tablets and capsules are frequently designed to optimise how and where the drug is released into the body (e.g. gastro-resistant coatings and modified-release designs) or are coated to mask the flavour (e.g. film and sugar coatings).

In addition to altering the taste, crushing, dispersing, or chewing tablets/capsules before swallowing can affect how and where the drug is released into the body. The consequences of such actions should always be considered. Modified-release preparations should generally never be altered as the resultant dose release can increase the chance of side-effects and alter the release of the drug into the system.

Concerns for the person administering opened capsules or crushed tablets; general advice is that cytotoxic and hormonal products should not be crushed. Consider risks for the administrator in cases of pregnancy and allergy.

## 7.5 Legality

Crushing or dispersing most medicines prior to administration renders the medicine off-label as it no longer resembles the original licensed medication and has been 'assembled' by the administrator. As such, liability transfers from manufacturer to prescriber and administrator if the prescriber has authorised the process, or just to the administrator if authorisation has not been provided. Manipulation of oral medicines and their administration via enteral tubes without informing the patient could be misconstrued as covert administration.

### Legal implications of moving from oral administration of drugs to administration via enteral feeding tubes

The Human Medicines Regulations 2012 allow only independent prescribers to authorise unlicensed administration of medicines to patients; however, crushing,

dispersing and mixing can be undertaken by a person acting under the written instructions of an independent prescriber

If the only option is crushing, dispersing, or compounding medication, then the independent prescriber should assume responsibility by recording their authorisation in the patient's prescription, medical, and care notes. A pharmacist should only dispense this request if satisfied that the form prescribed is suitable to be amended.

Administration of medicines via enteral tubes must be with the informed consent of the patient to avoid any suggestion of covert administration

Administration of medicines via enteral tube to a patient who lacks capacity must be subject to a prescribing best interests decision and management plan (Mental Capacity Act 2015

General Medical Council guidance states that when an unlicensed medicine is prescribed, the prescriber must:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow-up treatment, or ensure that arrangements are made for another suitable doctor to do so
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed or off-label medicine

| **Legal Implications of Altering a Solid-dose Formulation** | |
|---|---|
| To protect patients, the law imposes a duty on healthcare professionals to give the: | |
| | **Right** medicine to the<br>**Right** patient at the<br>**Right** time in the<br>**Right** dose and in the<br>**Right** formulation. |
| Breaching this duty is negligence and causing harm would give the patient a right to compensation. Administration of a medicine by altering a solid-dose formulation, such as by crushing a tablet or opening a capsule, is an unlicensed use. If harm occurs then liability would arise.<br>To protect the patient, before crushing a tablet, a healthcare professional must consider whether:<br>• Alternative products such as liquid preparations are available | |

- The patient knows of any risks and consents to the tablet being crushed
- The decision to alter the formulation is evidence-based and safe.

## 7.6 Continual Patient Review

Medication reviews should be conducted regularly and a structured review process should be created in order to improve care, reduce risk, and address compliance issues.

**Note: Every effort should be made to provide medication in liquid / dispersible/ another form.**

General guidelines for administration of medications to patients with swallowing difficulties.

a. Crushing tablets and opening capsules is almost always outside the product license. Risk should be considered and documented in patient notes. The prescriber will be issuing a licensed product to be used in an unlicensed way. Consequently, the manufacturer assumes no liability for any harm that may occur to the patient or the person administering the medication.

   Under the 'Medicines Act 1968' only medical and dental practitioners can authorise the use of 'unlicensed' medicines in humans. This is now extended to all independent prescribers. Opening a capsule or crushing a tablet prior to administration makes the product use 'off-label' unless it specifically states in the SPC this is a method of administration.

b. When a medicine is authorised for administration as 'off label' by the prescriber, a percentage of liability for any harm that may occur will lay with the nurse giving the medication. A Judge in legal proceedings would assess the balance of this liability on an individual case basis. Authorisation for off label medication administration (i.e. crushing of tablets opening of capsules) should therefore always be obtained in writing and not accepted verbally.

c. Sometimes medication can be added to food (outside product license). When this is done it should be added to the first mouthful of a suitable consistency of food so the whole dose is given once drug-food interactions have been excluded.

d. Crushing modified-release preparations in patients with swallowing difficulties is not appropriate. If a modified-release tablet is crushed, an increase in the expected peak plasma level may occur ("dose-dumping"). The patient will be initially exposed to significantly higher-than-normal levels which will increase the chance of side effects. Later, the drug will not last the full dosage interval, resulting in a period with little or no drug present, possibly resulting in loss of

control of the patient's condition. If kept whole, modified release preparations can be administered with a suitable consistency of food (outside product license) once any drug-food interactions have been excluded.

e. To ensure a robust record is kept of MDT decisions, the agreement form should be completed and kept with the patient drug chart (if they are not prescribed their medications via EPMA), as well as scanned into Lorenzo/ filed in the patient record. The EPMA prescription should be updated to reflect the result of the review- e.g. “open capsules, off label”

Nurses must be aware that they may be liable for any harm ensuing if medication is administered by an unlicensed route unless:

- the prescriber has given written authorisation, stating that they are aware of the situation and accept full liability
- the patient has given informed consent if relevant
- the pharmacist has advised on dose, formulation and administration (Adapted from the ‘Swallowing Difficulties Protocol’ designed by Dr David Wright, Senior Lecturer in Pharmacy Practice, University of Bradford).

The person administering the medication should take care when crushing any tablet or opening any capsule, as they may be sensitive to the substance and could suffer a serious reaction. This risk potentially also applies to others in the vicinity.

When it is necessary to crush medication/ provide alternative forms for administration to a patient with swallowing difficulties, the medication MUST be given in line with the risk assessed swallowing requirements of that patient e.g. thickened fluids, soft diet etc. to ensure that the patient is not put at unnecessary risk of aspiration or other complications.

Table 1. Examples of oral medication and advice on crushing / opening, including those that should **NEVER** be crushed or opened. This list is not exhaustive. Pharmacy input must always be sought.

| Formulation Type | Comments | Notes |
|---|---|---|
| **Liquids** | **Liquid formulations can only be used if thickened to the appropriate consistency[5].** | • If a liquid medication is thickened, potential effects on absorption and availability should be considered, including whether any additional monitoring is required.<br>• Sorbitol-containing preparations can cause diarrhoea when large volumes are given.<br>• Hyperosmolar liquids can cause nausea, bloating, and diarrhoea.<br>• Dilution of liquids with water can reduce their osmolality and so reduce the rate of adverse effects. |
| **Standard tablets** | If tablets need to be halved for the right dose use a tablet splitting device. Such devices split tablets more accurately. Scored tablets are designed to be split. | • Crushed tablets are often unpalatable and may sometimes have an anaesthetic effect on the oral mucosa, which can put the patient at risk of burns.<br>• Rinsing the mouth with an appropriately thickened fluid after administration of tablets may help to reduce this. |
| **Sugar-coated (s/c) and film-coated (f/c) tablets** | Usually coated to improve appearance or to mask unpleasant taste, usually suitable for crushing, although the presence of the coating may make crushing difficult. | • Crushed tablets are often unpalatable and may sometimes have an anaesthetic effect on the oral mucosa, which can put the patient at risk of burns.<br>• Rinsing the mouth with an appropriately thickened fluid after administration of tablets may help to reduce this. |
| **Dispersible and effervescent tablets** | Dispersible and effervescent tablets can usually be administered to patients with swallowing difficulties in the normal manner | • Should not be mixed with fluids other than water unless specifically indicated in the product information as this is outside the product licence. Please check the resulting suspension is of an appropriately thickened consistency.<br>• Most dispersible and effervescent formulations contain sodium, which may be a problem in sodium restricted patients. |
| **Capsules** | Ensure that the capsule is not modified release or controlled | • Capsule contents are often unpalatable, and they may have an anaesthetic effect on the oral |

| | | |
|---|---|---|
| | release ( see below) | mucosa, which can put the patient at risk of burns.<br>• The capsule shell may provide stability to the medication or protect it from gastric acid. |
| **Buccal and sublingual tablets –** Do not crush | Can usually be used as normal. | • Even if nil by mouth, provided that the patient is safe to have tablets held in their mouth, and is still producing normal quantities of saliva. |
| **Chewable tablets** Do not crush | These can be used as normal in patients with swallowing difficulties. | |
| **Hormone, steroid, antibiotics** | Crushing or opening may cause some of the medicine to go into the air as dust particles. | • The particles may cause side effects to the person crushing the tablets (measures must be taken to prevent skin contact and inhalation by wearing gloves and/or masks ) and advice taken from a pharmacist on how to safely prepare the product for administration |
| **THESE FORMS ARE NOT SUITABLE:** | | |
| **Enteric-coated (e/c) tablets** Do not crush | The coating is designed to prevent drug dissolution in the stomach and promote absorption in the small intestine. | Crushing may result in undesirable side effect such as stomach irritation and also a decrease in drug effectiveness. |
| **Modified-release (MR) and controlled-release (CR) preparations (also ER, SR, LA, XL, XR, Retard, Once Weekly)** Do not crush | **A conversion to a non-modified-release preparation is necessary, usually requiring a dose decrease and a dosing frequency increase** | **BUT:** Some modified-release capsules contain beads or granules which can be given in water or food at a suitable consistency for the patient. However there is a risk of excessive dose if the beads / granules are crushed prior to swallowing. This method should only be used where it is the best possible option for a specific patient, and only if the patient has the ability and understanding to be able to swallow the water / food without chewing. |
| **Cytotoxic medication** Do not crush | Avoid contact with cytotoxic drugs: Risk of cytotoxic powder being aerosolized if tablets are crushed, exposing staff to hazardous materials. Cytotoxics should be handled in accordance with local procedures. | |

## 8. Duties and Responsibilities

As outlined above. All prescribers and administering professions, e.g. Nurses, Nursing Associates, Pharmacy Technicians and Pharmacists should be aware of their role and responsibilities.

**Appendix 1**

**Patient Name …….**
**Ward / Unit ……...**
**Date of review……..**

| Drug | Dose | Frequency | Method/ dose form - NB include any amendments to dose/ frequency and any other pertinent information |
|---|---|---|---|
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Date of next review: ……

NB- The opening of capsules or crushing of tablets prior to administration will (in the majority of cases) make its use ‘off label’.

Medication plan agreed with the following:

| | Doctor/ prescriber | Nurse | Pharmacist |
|---|---|---|---|
| Name | | | |
| Designation | | | |
| Signature | | | |
| Date | | | |

**Training Needs Analysis for the policy for the development and management of Trust wide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| Staff Group | ✓ if appropriate | Frequency | Suggested Delivery Method (traditional/ face to face / e-learning/handout) | Is this included in Trust wide learning programme for this staff group (✓ if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |

| | | | | |
|---|---|---|---|---|
| Non-clinical non patient contact | | | | |

| |
|---|
| Please give any additional information impacting on identified staff group training needs (if applicable) |

| |
|---|
| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |

| |
|---|
| Any other additional information |

| | | | |
|---|---|---|---|
| Completed by | | Date | |

**Document level:** Trust
**Code:** 1.03
**Issue number:** _____

# Medicines Policy

| | |
|---|---|
| Lead executive | Medical Director |
| Authors details | Deputy Director of MACE and Medicines |

| | |
|---|---|
| Type of document | Policy |
| Target audience | This Policy is **mandatory** for all Trust staff. It also applies to any staff who are contracted to work on a sessional or secondment basis. The Policy should be regarded as a working document and should be referred to when necessary for guidance. |
| Document purpose | For information |

| | | | |
|---|---|---|---|
| Approving meeting | Quality Committee<br>Trust Board | Meeting date | 5th September 2019<br>26th September 2019 |
| Implementation date | 26th September 2019 | Review date | 31st October 2023 |

| Trust documents to be read in conjunction with | |
|---|---|
| | Controlled Drug Policy |
| MHA16 | Mental Capacity Act |
| 4.25 | Consent Policy |
| 1.55 | Policy and Procedure for Advance Statement and Advance Decisions to Refuse Treatment |
| | High Dose Antipsychotic Treatment Policy |
| 1.27 | Rapid Tranquilisation Policy |
| MHA28 | Convert Medication Policy |
| 1.35 | Observation Policy |
| 1.62 | Physical Health Policy |
| 1.62a | Physical Health SOP |
| | Prescribing, Preparing and Administering Injectable Medicines SOP |
| 5.44 | Medical Gases Policy |
| 5.44a | Oxygen SOP |
| 1.67a | NRT Clinical Guideline and Protocol |
| 1.35 | NICE Guidance |
| 5.01 | Incident Reporting Policy |
| 4.40 | Being Open Duty of Candour |
| | Medicines Monitoring Guidance |
| | Clozapine Prescribing and Monitoring Policy |
| | Patient Group Direction Policy |
| 5.06 | Waste Policy |
| 5.35 | Management of Medical Devices Policy |

| Trust documents to be read in conjunction with | |
|---|---|
| 5.36 | Central Alert System Policy |
| 5.11 | Security Policy |
| 1.52a | Research Governance and Management Policy |
| 028 | Pharmacy Support of Clinical Trials SOP |
| | Best Practice Policy Medicines Administration Swallowing Difficulties |
| | SOP 066 Supply of Medicines via Polarspeed to Community Teams |
| | Non-formulary, Off-label and Unlicensed Medicines Policy |
| 4.02 | Standards of Business Conduct Policy |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | The policy has been reviewed and reformatted therefore is presented as a new policy removing appendix documents which are considered to be more appropriate as standalone documents. | | |
| Appendices / electronic forms | | | |
| What is the impact of change? | Developing this new format of the Medicines Policy has be brought about to make the Medicines Policy a more succinct policy, ensure greater version control of the policies and guidance documents that underpin the Trusts medicines management structures and allow for staff to navigate relevant documents more efficiently and effectively. | | |

| Training requirements | N/A |
|---|---|

| Document consultation | |
|---|---|
| Directorates | All Directorates and CEG membership |
| Corporate services | Estates<br>Medicines and Clinical Effectiveness<br>Mental Health Law Team<br>Patient and Organisational Safety Team |
| External agencies | N/A |

| Financial resource implications | N/A |
|---|---|

| External references |
|---|
| 1. The Safe and Secure Handling of Medicines: A Team Approach (RPSGB, 2005)<br>2. Safe and Secure Handling of Medicines (RPS, 2018)<br>3. Safer management of controlled drugs: Guidance on strengthened governance arrangements (DH, 2007) |

4. Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs (DH, 2007)
5. Professional Guidance on the administration of Medicines in Healthcare Settings (RPS & RCN, 2019) 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
6. Administration Guidance on Administration of Medicines in Healthcare Settings (HEE, 2019) https://www.hee.nhs.uk/sites/default/files/documents/Advisory%20guidance%20-%20administration%20of%20medicines%20by%20nursing%20associates.pdf
7. The Medicines Act 1968
8. The Misuse of Drugs Act 1971
9. Misuse of Drugs (amendment 2) regulations 2006
10. Shipman Inquiry 2005/6
11. The Medicines labelling Regulations 1976
12. Audit Commission. (2001). A Spoonful of Sugar - Medicines Management in NHS Hospitals. London: Audit Commission.
13. Health Act 2006 (c1). London: The Stationery Office.
14. Health and Social Care Act 2001. London: The Stationery Office
15. The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates. Nursing and Midwifery Council (October, 2018). https://www.nmc.org.uk/standards/code/
16. Patient Group Directions (Health Service Circular 2000/026. England only). Yellow card Scheme. Website https://www.gov.uk/search?q=patient+group+directions

**Monitoring compliance with the processes outlined within this document**

The performance of clinical areas with respect to all aspects of medicines and this document must be monitored by the relevant directorate senior management team.

This document will form the basis of local and Trust-wide audits or checks to monitor implementation. As a minimum, audits or checks will be undertaken by relevant parties at the following minimum frequency:

| Subject | Monitored by | Minimum Frequency |
|---|---|---|
| Controlled Drugs (Full Audit) | Pharmacy | Annually |
| Controlled Drugs | Pharmacy | Quarterly |
| Medicines Storage | Pharmacy | Annually |
| Prescription Standards | Divisions | Quarterly |

Additional audits and checks are set out clearly in associated medicines policies and procedures e.g. rapid tranquilisation, use of antimicrobials.

In addition to this, directorate senior management teams are responsible for regularly monitoring and seeking to improve:

| | |
|---|---|
| | • performance of their staff with respect to relevant aspects of medicines training<br>• medication safety indicators e.g. omission of medicines, medication incidents |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favourable / More favourable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |
| – **Age** (e.g. consider impact on younger people/ older people) | N | |
| – **Disability** (remember to consider physical, mental and sensory impairments) | N | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | N | |
| – **Gender identity and gender reassignment** (i.e. impact on people who identify as trans, non-binary or gender fluid) | N | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | N | |
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | N | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not) | N | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | N | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | | |
| – **Other equality groups?** (may include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | N | |
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | | |
| Enter details here if applicable | | |
| If you have identified potential negative impact: | | |

| | |
|---|---|
| - Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | |
| Enter details here if applicable | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | N/A |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | N/A |
| Enter details here if applicable | |
| Where an adverse, negative or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | |
| Was a full impact assessment required? | No |
| What is the level of impact? | Low / medium / high |

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## 1.0 INTRODUCTION

This policy has been developed to provide guidance to assist and support Trust staff working in Mental Health services in the delivery of all aspects of medicines management relevant to their role. This Guidance should be read in conjunction with the other related policies and procedures referenced above.

The ultimate aim of this policy is to ensure that effective systems are in place to safeguard the welfare of patients / service users, visitors and staff with regard to the use of medicines.

The aims of the policy are to:

- Set out the principles by which medicines are managed within the Trust in line with Department of Health guidance, legal professional requirements and any future guidance that relates to medicines management.
- Ensure that all staff employed by the Trust are aware of their roles, responsibilities and limitations with regard to medication.
- Provide an audit trail for the handling of medication, including the use of controlled drugs. Manage the risks to ensure that service users receive their medication safely and effectively.

Presently this Policy does not cover all aspects of medicines management processes within the Primary Care Directorate, these services have approved local policies in place which must be adhered to.

## 2.0 PHARMACY SERVICES

2.1 Trust Pharmacy services are responsible for the supply of pharmaceuticals, some medical supplies and devices; and providing information and advice to Trust personnel in all aspects of medicines use, assisting clinical areas where necessary and ensuring compliance with the relevant legislation.

### 2.2 Trust Pharmacy Services

2.2.1 All Pharmacy services operate in line with:

- The General Pharmaceutical Council (GPhC) Code of Ethics and Practice
- Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy Services
- All relevant national standards pertaining to pharmacy and medicines practice

2.2.2 Pharmacy services and their staff are expected to follow agreed Standard Operating Procedures in order to ensure the safe use and management of medicines.

### 2.3 The Medicines Supply Chain

All medicines for use in clinical areas of the Trust must be ordered from the Harplands pharmacy service or an authorised pharmacy provider under the terms of an acceptable contract/SLA e.g. approved list of food supplements from UHNM stores.

The due diligence process must ensure that medicines are procured according to the principles of the laws on value added tax (VAT) and that assurances can be gained that the pharmacy provider is satisfactory in all respects.

When the Trust pharmacy department is closed an FP10 written by a Trust prescriber may be used by ward staff to order any urgent medication.

2.4 Types of Medicines Supply

Medicines are supplied by pharmacy in several ways, as follows:

- As stock medicines
- Against an individual patient's prescription for inpatient use only
- As a leave or discharge prescription
- As an outpatient, or community prescription

## 3.0 PRESCRIBING

3.1 Introduction to Prescribing

> The prescribing of Controlled Drugs (CD) is explored in more detail in the Controlled Drug Policy which is accessible on the intranet under clinical policies

3.1.1 Medication must only be administered to a patient on the authorisation of a suitable prescriber, using an appropriate means, such as:

- A valid prescription from a prescriber on official stationary or prescribed electronically
- A verbal order from a prescriber to a registered nurse or pharmacist (see Section 3.13)
- By use of an approved Patient Group Directive (PGD)
- According to a protocol that allows administration of a locally approved list of medicines that are not prescription-only e.g. patient specific direction in place for provision of nicotine replacement therapy (NRT) to newly admitted patients who have not yet seen a prescriber.

3.1.2 Eligible prescribers include:

- Doctors
- Independent Prescribers
- Other groups authorised to do so in specific contexts, described as Exemptions in the up-to-date version of Medicines, Ethics and Practice: the professional guide for pharmacists.

Independent Prescribers (IP) must be approved through application to Clinical Effectiveness Group (CEG) supported by their clinical director, supervisor and pharmacist.

3.1.3 Medical Students
By law medical students are not permitted to prescribe medicines. However, to gain experience whilst on a clinical attachment within the Trust they are permitted to write up drug charts under direct supervision, but these must be checked and signed by a registered doctor of Foundation Level 2 (F2) or above. The consultant is responsible for the actions of all

medical students on their clinical attachment.

3.2 Policy for Doctors and Independent Prescribers Prescribing for Themselves, Family Members or Work Colleagues

3.2.1 General Medical Council (GMC) professional guidance advises doctors to avoid treating themselves or those close to them; independent medical care should be sought whenever the doctor or someone with whom they have a close personal relationship requires prescription medicines.

3.2.2 IP's must not prescribe any medicine for themselves or for anyone with whom they have a close personal or emotional relationship, other than in exceptional circumstances. (See NMC's Code of Conduct, Standards for Conduct Performance and Ethics and the RPSGB's Code of Ethics and Standards).

3.2.3 Exceptional circumstances happen if:

- There is no other prescriber available with the legal right to prescribe
- Treatment is necessary to save life, avoid a significant deterioration in the patient's condition or alleviate otherwise intolerable pain.

3.2.4 Staff requiring General Sales List (GSL), Pharmacy Medicines (P) or Prescription Only Medicines (POM) should be advised to visit their General Practitioner (GP) or a Community Pharmacy.

3.2.5 It is better practice if a doctor asks another medical colleague to prescribe for them. As a general rule, a consultation which is not recorded in the patients NHS clinical record must be considered to be a private consultation and that any resulting prescription will, by definition, also be considered private.

3.2.6 Under no circumstances will Pharmacy dispense private prescriptions for staff. Trust prescription stationary must only be used to prescribe for patients under the Trust's care.

3.2.7 Any concerns will be raised with the Medical Director.

3.3 Restriction to Practice

Where a prescriber has any restriction to their practice specified by the relevant regulatory or registered body these must be clearly communicated to the pharmacy service in order to ensure awareness and that these restrictions are suitably considered and enforced.

3.4 Local formularies and Guidelines

The first-line prescribing reference source is the current British National Formulary (BNF and BNF for Children).

All Trust clinical areas and prescribers must be aware, and ensure compliance with the following:

- North Staffordshire Joint Formulary. http://www.northstaffordshirejointformulary.nhs.uk/ (Complete Non- Formulary request

where appropriate (see Non-formulary, Off-label and Unlicensed Medicines Policy)
- North Staffordshire Clinical Guidelines including local Antimicrobial Guidelines for primary care 2012 see http://www.stokeccg.nhs.uk/joint-formulary
- NICE guidance. http://www.nice.org.uk/

## 3.5 Prescribing Principles

### 3.5.1 Clinical Appropriateness

Prescribing must be undertaken in an evidence based manner, taking into consideration the limited evidence base that may exist in some areas of clinical practice. Prescribers must consider the patient's overall wellbeing, including any other medication that they are taking and any other co-morbidities that they have in addition to the condition under consideration.

To ensure safe and effective prescribing the prescriber should refer to material noted in section 3.4.

The patient's Mental Health Act status must be taken into consideration when prescribing to ensure compliance with standards for consent to treatment. Relevant Trust policies exist to support clinicians with respect to:

- Mental Health Act status
- Consent to treatment
- Issues of capacity

Where in place, any consent to treatment paperwork must be securely attached to the patient's prescription form(s).

For good clinical reasons, the use of medicines without a UK Marketing Authorisation (unlicensed) or outside of its terms of license (off-label) may be accepted practice in certain clinical conditions or for certain patient groups e.g. children. Prescribers MUST document rationale for choice and confirmation of discussion with patient regarding side effects and risks such as 'off-label' or unlicensed medication. For more information refer to the Non-Formulary, Off-label and Unlicensed Medicines Policy.

### 3.5.2 Involving the Patient

Prescribing must be undertaken, wherever possible, with the input of the patient. Prescribers must aim to work with patients to:

- Involve them in decision making
- Explore their beliefs about, and experience of taking medicines
- Identify any barriers to adherence, and address these
- Document any changes to their treatment as a result.

Patients must always be offered information about any new medicine that they are prescribed, this information must be provided in a format that they can understand. Information is available in a range of formats on the Trust intranet, including from the Choice and Medication website: https://www.choiceandmedication.org/combined/

3.5.3 Monitoring

The prescriber is responsible for monitoring the patient's baseline condition and subsequent physical and mental health status, including any side effects that the patient experiences. The results of any tests must be documented along with any actions taken as a result.

Consideration must be given to the use of structured and approved tools for the examination of side effects, and other patient experience aspects of the use of prescribed medicines.

Systems must be put in place to target those patients at high risk of harm from their medicines, and ensure that medication review takes place at a suitable frequency to reduce the risk of harm. The use of tools to support decision making around medication review and de-prescribing must be considered for relevant clinical areas.

**All clinical staff should monitor for side effects during any review.**

Refer to the Trust Physical Health Monitoring Policy and the Medication Monitoring Guidance available on the intranet under clinical policies for further information.

3.5.4 Children

For the purpose of this document children are under 18 years of age, although many medicines are used in the same doses as for adults in children above 12 years of age.

The BNF for children is the primary reference source for prescribing for children. The prescriber must gain and record the child's, and parental consent before initiating treatment (the latter is essential if the child is not 'Fraser competent').

The prescriber should inform the child about their treatment in a developmentally appropriate way, supported by written information where appropriate.

3.6 Prescription Paper Work

3.6.1 All prescription paperwork and forms used in the Trust must be approved by the Clinical Effectiveness Group (CEG) to ensure that it meets the latest regulations, to ensure legality and safety. In hospital settings, prescription charts used for inpatients constitute patient specific directions and authorise administration of the medicines by an appropriate healthcare professional.

3.6.2 Prescribing should where possible be restricted to the use of a single prescription chart.

3.6.3 Where more than one prescription form is needed, each form must be marked to indicate others are in use (e.g. 1 of 2, 2 of 2), and all forms must be held securely together.

3.7 Patient Group Directions (PGD's)

In some circumstances and settings, care may be delivered by health professionals who do not have prescribing authority. In such circumstances, where an advantage to patient care can be demonstrated, it may be possible to supply and/or administer medicines via a patient group directive (PGD). Trainee Nursing Associates (TNA's) and registered Nursing Associates (NA) are not permitted to supply or administer medicines under PGD's (see Appendix 1) further information please refer to the Trust's Patient Group Directive Policy.

3.8 In-patient Prescribing

3.8.1 When a patient is admitted into one of the Trust wards or units a review of current medication should be carried out (see Medicines Reconciliation section 3.30). Medicines should be prescribed within the appropriate section of the chart for example single dose or regular dose and reviewed as appropriate. A separate line should be used for each medication and including different forms e.g. intramuscular and oral.

3.8.2 The initiating prescriber must communicate with the multidisciplinary team to ensure that any baseline or regular monitoring is carried out. This should include a time for review of efficacy or adverse effects.

3.8.3 For medications given in variable doses i.e. clozapine or warfarin use relevant section on the chart to record monitoring and dosage. Further supporting information should be written on the medicines chart Prescribers must inform the senior nurse of any new medicines prescribed to ensure prompt ordering from pharmacy. This will minimise delays in patients starting their medication.

3.9 Discharge / Leave Prescriptions

3.9.1 Leave prescriptions should be used to prescribe medication to cover a period of leave from the in-patient ward / unit.

3.9.2 Discharge prescriptions should be completed when a patient is to be discharged from an in-patient area of the Trust. As well as securing medication, the discharge prescription aims to provide quality information for the patient's GP on their discharge, and to ensure continuity of care across the interface

3.9.3 The discharge and leave prescription forms allow prescribers to indicate how many days' supply are required, and if the medicines are then to stop. Usually 14 days' supply is dispensed on discharge. The prescriber must specify the number of days' supply required. Patients with a history of self-harm in the last 3 months should be assessed and should it be necessary be provided with shorter periods of supply on installment e.g. one week on discharge followed by a second week being collected from the ward. If the total supplied is less than 14 days the patient's GP must be promptly informed to ensure on-going treatment.

3.9.4 Discharge prescriptions must state all regular and 'as required' medicines that the patient usually takes. The prescriber, wards nurse or authorised pharmacy staff may annotate the prescription if any items do not need to be supplied (e.g. if patient already has own supply).

3.9.5 Discharge and leave medication must be prescribed by an authorised prescriber and dispensed by the pharmacy department for the individual.

3.9.6 If medication is to be dispensed in a monitored dose device this should be written on the leave / discharge prescription. Patients should only be provided medication in a medicines organiser following a thorough review of individual need using the medication organizer request form (see Appendix 2) taking into consideration the care setting the patient will be discharged to and their on-going means of medication supply.

3.10 Outpatient Prescribing

3.10.1 In most cases out-patient prescribing will be for a single issue of a new medication or following dose alteration. Where an urgent prescription is required a maximum of 14 days' supply should be issued. Longer term supplies if needed should usually be obtained via the patient's GP or issued in accordance with Effective Shared Care Agreements (ESCA's). A green FP10 should be used for all patients who are not in-patients. This includes regular prescriptions including Clozapine and depots issued from community settings.

3.10.2 Where possible non-urgent changes can be requested in writing to be made by the patient's GP. Keep a copy or note of any prescriptions issued in the patients electronic record (EPR) for future reference.

3.10.3 Prescriptions are valid for up to 26 weeks (specify the time period when prescribing). Prescriptions for clozapine and depots requested through the Harpland's dispensary may be repeated within that time period. The original prescription should include details for length of repeat and monitored dosage if necessary. A copy of this prescription should be kept in the EPR for review. The prescription should be reviewed prior to rewriting towards the end of the 26 weeks. Prescriptions issued in resource centres should be dispensed via community pharmacy (FP10) or as per the Polarspeed Guidance.

3.10.4 Prescriptions for controlled drugs including benzodiazepines are valid for a maximum of 28 days' supply.

3.10.5 Prescribers should ensure that they familiarise themselves with local Effective Shared Care Agreements (ESCA) arrangements. Prescribers have duty to ensure all the terms of the ESCA are adhered to, including completion of appropriate documentation. The current list of ESCA's is accessible via the following link:
http://www.northstaffordshirejointformulary.nhs.uk/docs/esca/

3.11 Electronic Prescribing

In those areas of the Trust where electronic prescribing is used separate SOPs for certain aspects of the prescribing processes are in place to make the procedural steps clear, however the general principles are the same.

3.12 Prescription Standards

3.12.1 All prescriptions must state the patient's full name (including aliases), date of birth, NHS number and hospital/prison number. The patient's biological sex is only occasionally required on prescription from a medicines perspective, and is more often included as part of a demographics information; and to support identification. Where the prescription calls for 'gender', the patient's biological sex should be stated along with the gender as reported by the patient, where this differs.

3.12.2 The patient's age (or date of birth) and weight (or a derivative of this e.g. body mass index) should be included on all prescriptions for patients under the age of 18 years. Weight (in Kg) should be included on adult prescription where this is relevant to drug dosage e.g. low molecular weight heparins.

3.12.3 It is imperative to complete the allergy section on the drug chart/electronic prescription listing any known drug allergies/hypersensitivities and sign and date this section. Where a

patient states that they have an allergy or hypersensitivity to an antimicrobial, this should be confirmed through questioning; and the patient informed and the patient's medical records updated accordingly.

3.12.4 Where there are no known allergies/sensitivities this must also be stated, signed and dated. Any registered healthcare professional can document this information and transfer it to subsequent prescription charts.

3.12.5 Trust pharmacy services may refuse to supply medicines against a prescription without complete allergy information, at the discretion of the pharmacist on-duty, in order to prevent the administration of medicines to patients that they may be allergic or hypersensitive to.

3.12.6 The ward/department/clinical area name must be written on the chart, in addition to the name of the patient's consultant/doctor or lead IP where applicable.

3.12.7 Photographic patient identification may be included on certain inpatient drug charts/electronic prescriptions to support identification of patients. In the absence of photographic patient identification a brief description of distinguishing patient characteristics must be provided to reduce the risk of administration of medicines to the wrong patient.

3.12.8 There is no current stipulation in the law or regulations as to the colour of ink to be used however as the ink must be legible when photocopied, the Trust states that:

- All prescriptions should be legible and if handwritten, be written in blue or black indelible ink
- Annotations by pharmacy staff or other professionals must also be in dark indelible ink.

## 3.13 Remote Prescriptions (Verbal Prescription/Orders)

3.13.1 The Nursing and Midwifery Council (NMC) Standards for Medicines Management covering remote prescribing or direction to administer were replaced from January 2019 by the Royal Pharmaceutical Society professional guidance on The Safe and Secure Handling of Medicines. All registered nurses must ensure they are familiar with this guidance.

3.13.2 Remote prescribing of medication over the telephone is only acceptable practice in an emergency, or where the prescriber is not immediately available to write the prescription before the drug is administered; where delay would be detrimental to patient care. Verbal orders can be given to a registered nurse by a prescriber when they are in the same room, but are unable to write up a prescription (e.g. in an ECT suite).

3.13.3 The use of secure GOLD FAX must be used as the preferred method of communication regarding messages between prescribers, registered nurses and pharmacy. Text messaging is **not** an acceptable form of communication regarding remote orders relating to medicines.

3.13.4 Patients requiring medication should be seen and examined by the prescriber. Verbal instructions to administer a previously un-prescribed medicine are not acceptable.

3.13.5 The proforma (see Appendix 3) should be completed by the prescriber and e-mailed or faxed to the home/unit where the patient/client is residing. Upon receiving an e-mail or secure fax, the receiving registered nurse should make telephone contact with the prescribing medical officer and repeat the e-mailed/faxed message back, to check accuracy and understanding via verbal conversation and to avoid translation errors.

When confirmed, the registered nurse will record the treatment details on the prescription chart in the appropriate section (if a single dose then in the 'once only' section), which should include the date and time of the instruction, name and form of medication, the dose to be given, the route and time(s) of administration and the name of the prescriber together with 'VERBAL MESSAGE'.

3.13.6 If unable to access e-mail or fax then a verbal conversation must occur directly between the nurse in charge and the prescriber (this method should only be used as a last resort). The registered nurse will repeat the message back to the prescriber and record treatment details as outlined above. If for any reason the nurse is unsure off the identity of the caller or has any reservations, the verbal order should be refused.

3.13.7 Trainee nurses, trainee nursing associates and registered nursing associates may not undertake the responsibility of receiving, accepting, documenting or administration of remote prescribing.

3.13.8 The prescriber should sign the prescription chart within 24 hours of the verbal or faxed/e-mail order. At weekends / bank holidays this may be extended to 72 hours.

3.13.9 Medicines should be re-ordered or relabelled by pharmacy to ensure patient has correct instructions. The patient should have the changes explained to them.

3.13.10 Verbal orders are not permitted in Offender Health settings.

**Verbal messages involving controlled drugs, including benzodiazepines are not acceptable in any circumstance.**

3.14 Prescribing a Medicine

3.14.1 Naming

The name of the medicine should be written in block capitals. Chemical formulae (e.g. FeSO4, Li+, Na valproate) are not acceptable. Generic drug names must be used instead of brand names. Exceptions include:

- A branded compound preparation e.g. the topical cream Daktacort
- A preparation with specific pharmacokinetic properties such as a modified release (MR) formulation (e.g. Adalat LA, Tildiem LA, Adizem SR, Epilim Chrono)
- All preparations of Lithium must be endorsed with brand e.g. Priadel
- A preparation that could be confused with another preparation (e.g. Depakote).

3.14.2 Form

The form of the medicine must be stated e.g. oral solution, suspension, cream etc. For liquids the strength (e.g. 25mg/5ml) must be stated, wherever possible.

For topical preparations, the strength (e.g. 1%) and form (e.g. cream. gel/ointment) must be

stated. Orodispersible tablets, as opposed to soluble tablets, should be clearly marked as such.

3.14.3 Dose

The dose must be clearly prescribed in the relevant section, using only approved abbreviations and forms for dosing units. The abbreviations that are approved for use are:

| | |
|---|---|
| g | Gram |
| kg | Kilogram |
| L | Litre |
| microgram | microgram (no abbreviation) |
| mg | Milligrams |
| ml | Millilitres |
| mmol | Millimole |
| nanogram | nanograms (no abbreviation) |
| min | Minute |
| hr | Hour |
| units | units (no abbreviation) |

Decimal points that are unnecessary must not be used e.g. 3mg not 3.0mg, 125 micrograms rather than 0.125mg. Where use of a decimal point is unavoidable, a zero must be written in front of the decimal point where there is no other figure e.g. 0.5ml not .5ml.

Doses of medicines in a liquid form must be prescribed by weight (e.g. amoxicillin syrup 500mg) or international units or millimoles (e.g. ergocalciferol 30,000 units, potassium chloride 3 mmol), not by volume alone.

Only standard liquid preparations that cannot be expressed by concentration may be prescribed by volume alone (e.g. Lactulose, Peptac liquid).

Mega units must be expressed using the term “mega units”, this must not be abbreviated.

Roman numerals or other symbols, for example “ii”, are also the cause of medication errors and must **not** be used. If there is no obvious or practical tablet/capsule strength e.g. senna tablets, the number of tablets to be administered must be expressed in numbers e.g. “2 tablets” not “ii”.

A fixed dose, rather than a dose range, must be written for regular medicines e.g. furosemide 40mg and not 40–80mg. Dose ranges are permitted only for medicines that are used when required e.g. lorazepam 0.5-1mg.

MEDICINES ADMINISTERED PERIODICALLY (NOT DAILY): - Medicines prescribed for administration every 48 hours, 72 hours, 96 hours or once a week (e.g. alendronic acid 70mg tablets, oral methotrexate, buprenorphine patches, fentanyl patches) should state the actual day(s) of the week the dose should be given.

The prescriber should cross out the days of the week the drug should not be given to avoid accidental administration on intervening days.

3.14.4 Route

The route should be specified using the following permitted abbreviations:

| | |
|---|---|
| Buccal | Buccal |
| IM | Intramuscular (state if *deltoid*) |
| IV | Intravenous |
| INH | Inhaled |
| NEB | Nebulised |
| NG | Via Nasogastric tube |
| Oral/PO | Oral, by mouth |
| PEG | Via Percutaneous endoscopic gastrostomy tube |
| PR | Rectal |
| PV | Vaginal |
| SC | Subcutaneous injection |
| SL | Sublingual |
| TOP | Topical |
| TD | Transdermal |
| 'Covert' | Covert administration |

3.14.5 Frequency

The following is a list of the commonly used Latin abbreviations used when prescribing:

| | |
|---|---|
| a.c. | Before food |
| b.d. | Bis die (twice daily) |
| o.d. | Omni die (once daily) |
| o.m. | Omni mane (in the morning) |
| o.n. | Omni nocte (at night) |
| p.c. | After food |
| p.r.n. | Pro re nata (when required) |
| q.d.s. | Quarter die sumendus (four times daily) |
| t.d.s. | Ter die sumendus (three times daily) |

Pharmacists may, at their discretion, specify the time of day that a medicine should be taken against a prescription for once daily (o.d.) medication in order to guide the patient to take the medicine optimally e.g. at night for a hypnotic or in the morning for a loop diuretic.

The prescriber should indicate the time(s) at which the drug is to be administered. If the medicine is to be administered at non-standard times the prescriber must legibly amend the time in the relevant section of the prescription chart. If more than two non standard times are intended, all the standard times should be crossed out and new times clearly written.

If a patient is reluctant to take medications at a set time, prescribers may prescribe certain once or twice daily medicines to be taken at variable times. The staff member undertaking administration must clearly sign at the time the medicine was given or refused.

The correct time of administration is often crucial for certain *critical medicines* (see Appendix 5). The prescriber should ensure nursing staff are made aware of any medicines where timeliness of administration is crucial; this must be incorporated into the patient's care plan and routine of the clinical area.

It is the responsibility of the prescriber to verbally inform nursing staff if they have prescribed a medicine to be given 'once only' or 'stat' (immediately), to enable the medicine to be administered in a timely manner. Any instructions or information particular to the medicine must be specified on the prescription in the relevant section e.g. where omission is necessary according to certain criteria.

13.15 Start Date and Validity

3.15.1 The start date is the date the prescription is actually written on the drug chart, unless administration is to be deferred, in which case the start date is the first date that it should be administered from e.g. a scheduled dose increase, or planned depot injection. As a general rule, prescriptions should not be post-dated by more than one week in order to ensure that scheduled changes always reflect the patient's up-to-date presentation and requirements.

3.15.2 Inpatient charts are valid for up to 8 weeks for any single admission.

3.15.3 If a medication is prescribed for a stated duration this is only valid from the date annotated for the period stipulated (oral antibiotic prescriptions are only valid for periods stipulated within formulary unless stated otherwise).

3.15.4 Prescription charts must be cancelled when the end of the administration line is reached. Each administration column must only be for one date.

3.15.5 Depot antipsychotics or regular out-patient prescriptions in community settings are valid for 26 weeks from the date written. Medicines may not be supplied to, or administered to a patient against a prescription for a period of more than six months. Multiple prescriptions, each lasting 6 months, can be written on the same community prescription card where there is space to do so, in order to reduce the need for rewriting of all other aspects of the card.

13.16 Signature

3.16.1 The prescriber should sign each prescription and print their name and profession, where called for by the prescription form. It should be legible and recognisable to pharmacy and nursing staff.

3.16.2 All new prescribers are required to leave a copy of their sample signature with Pharmacy as soon as possible, and before they start prescribing in the Trust.

13.17 When Required or *Pro Re Nata* (PRN) Prescriptions

3.17.1 When required or *Pro Re Nata* (PRN) prescriptions must be prescribed on the appropriate section of the prescription form. This allows for medicines (e.g. hypnotics, anxiolytics, anticholinergics, analgesics and laxatives) to be administered to patients at the discretion of the clinical team, according to the needs of the patient. The prescription must clearly state:

- The indication (reason for use)
- The dose (or dose range)
- The route – ONLY one route may be specified
- The frequency or minimum time interval between doses
- The maximum dose to be given in any rolling 24 hour period, taking into account the maximum cumulative dose where a medicine is prescribed regularly and when required, or by more than one route of administration

A clear trigger point for seeking medical advice/medical review should be stated where this is considered appropriate.

Care must be taken not to duplicate with medicines being taken regularly and thus inadvertently overdose the patient e.g. combination analgesics frequently contain paracetamol, which may already be prescribed on the regular section of the drug chart.

Rapid dose escalation using combinations of PRN and regularly prescribed antipsychotics may be a causal factor of sudden death and Neuroleptic Malignant Syndrome (NMS); and confer the need for additional monitoring if the total combined dose exceeds recommended BNF limits. Refer to the High Dose Antipsychotic Therapy Policy for further guidance.

A PRN prescription must be reviewed regularly by the clinical team to determine its clinical need. To prevent the accumulation of unnecessary PRN prescriptions, and the risk of unintended administrations, the following guidelines should be observed:

- Any PRN medicine that has not been required for 3 months should be cancelled
- No more than one medicine from any BNF therapeutic category should be prescribed at any one time (unless a clear rationale and instructions for use is documented)

If a patient requires a medicine that is in current use as a PRN medicine, more regularly, it should be re-prescribed as a regular prescription and the PRN prescription cancelled.

3.17.2 Pharmacist Discretion

Pharmacists may review and cancel PRN prescriptions that are not in use and no longer appear to be clinically appropriate (e.g. PRN IM medicines for rapid tranquilisation for a patient who is now well enough to have leave from hospital), as part of their work in clinical areas.

Pharmacists who are considering the suitability of a PRN prescription for supply may use their discretion in reducing the amount of a medicine dispensed against the prescription, to half of the total amount that is called for.

For example, a prescription calling for paracetamol 1g q.d.s in theory calls for 56 x 500mg tablets per week but it may be prudent to supply a smaller amount according to available pack sizes e.g. 32 x 500mg tablets.

3.18 Immediate Variable and ‘Stat’ Dose Prescriptions

3.18.1 There is a defined section on prescription charts used in inpatient clinical areas for writing up variable dose prescriptions. This section is particularly suitable for dose

titrations or detoxification prescriptions where the dose is changing every one or two days e.g. clozapine initiation, diazepam withdrawal regimens for alcohol detoxification.

To avoid these doses being missed the prescriber should also write the drug on the regular section of the drug chart but state “See variable dose section”.

3.18.2 Any doses of medicines that are prescribed for immediate ‘STAT’ administration must be prescribed in the defined area of the chart and the prescriber should ensure a member of nursing staff is informed to ensure availability of the prescribed drug and avoid delay in administration.

3.19 Changing or Discontinuing a Prescription

3.19.1 If some of the ordered doses are not to be given, they must be cancelled individually by blocking in the individual administration box; it is best practice to document any planned dose omissions in the patient’s notes. There is a code on the prescription chart which can be used for prescribed omissions.

3.19.2 To cancel a prescription:

- A bold X (2 transverse lines) should be drawn across the area where the name of the medicine concerned is written. Two parallel lines through the prescription is also acceptable as long as the intention is clear
- The cancellation must be signed, dated and a reason code stated
- A vertical line should be drawn at the end of the last day that a drug is required to be administered and a bold X across the remainder of the administration section.

3.19.3 Following any change in dose or route of administration, or alteration in times of administration, a new prescription must be written. Amended prescriptions demonstrably cause confusion and can lead to medication incidents.

3.19.4 Discontinuation of a prescription must be clearly marked by drawing a bold X or double score through the name of the medicine concerned, with signature, date and reason code, and at the end of the administration period, a vertical line and cross, to ensure no further doses are given.

3.19.5 Prescriptions with a pre-ordinated stop date e.g. short courses – the stop date must be clearly stated and the remainder of the administration record must be crossed through in order to prevent unintended continuation of the item.

3.20 Mental Health Act

Where applicable, only medicines that are covered by the relevant Consent to Treatment Form, consistent with the requirements of Section 58 of the Mental Health Act can be prescribed for the treatment of mental disorder.

Short delays in the development or ratification; and availability of Consent to Treatment forms may be deemed acceptable to cover treatment in some instances but must not exceed 72 hours.

3.21 Prescribing for Covert Administration

For information about the covert administration of medicines, refer to Covert Medication Policy.

3.22 Oxygen

Oxygen therapy must be prescribed in the appropriate section of the patient's prescription form where ongoing treatment with oxygen is needed. Where oxygen is needed in an emergency situation, according to oxygen saturations and trigger systems, it does not need to be prescribed. Please refer to the oxygen SOP for further guidance.

3.23 Wound Care

Wound care products should be written on the appropriate section of the prescription chart by prescribers or Tissue Viability Nurses.

3.24 Dietetic Products

Dietetic products should only be used on the advice of dieticians, and must only be supplied for 14 days on discharge from ward supplies where appropriate; at which point the GP must seek further review of the use of the products.

3.25 Transdermal Patches

Transdermal patches present a high risk of duplicate or inappropriate application. Patients should be examined on admission and existing application site recorded on the EPR and medication chart. Ensure that the application site is rotated appropriately as per the product information; patches remain affixed and are removed when a new patch is applied. The patient's medication chart and EPR must clearly document site of application.

3.26 Prescribing Infusions

Infusions should only be prescribed and administered with in clinic areas where staff are appropriated trained (refer to Vascular Devices Policy). All infusions should be prescribed in the relevant section of the prescription chart, including infusion-drug additives.

All prescriptions must be clearly written in BLOCK CAPITALS and must state:

- The infusion fluid including strength, where appropriate
- The dose /volume
- The precise method of administration
- The rate of administration
- The dose of any drug to be added
- Signature of the prescriber
- Date of prescribing
- Date of administration, if different from the date of prescribing.

When medicines are added to infusion fluids the doctor or designated nurse must ensure that the medicine is appropriate for this method of administration and that it is compatible with the infusion fluid and any other drugs that may also be present. Advice can be obtained from the BNF or from the pharmacy department.

Medicines must **NOT** be added to:

- Blood.
- Plasma or other blood products.
- Intravenous feeding solutions.
- Amino acid solutions.
- Fat emulsion preparations.
- Mannitol infusions.
- Sodium bicarbonate infusions.

3.27 Prescribing Injectable Medication.

When prescribing injectable medication prescribers, in addition to general requirements the additional relevant information, should include, additional information as specified in the Prescribing, Preparing and Administering Injectable Medicines Standard Operating Procedure. Where a 'high risk' medicine is prescribed the prescriber should ensure that the practitioner(s) who will be administering the medication have the required competency and equipment to administer safely and this is documented in the patients care plan

High risk medication

- Injectable potassium via any route MUST NOT be prescribed or administered within the Trust settings / by Trust staff
- Injectable chemotherapy via any route MUST NOT be prescribed or administered within the Trust settings / by Trust staff (excluding appropriately trained staff within primary care surgeries)
- Epidural route MUST NOT be used for prescribing or administering any medication within the Trust settings / by Trust staff
- Insulin should only be used where the dose and device has been checked against patient condition and Insulin passport (NPSA requirement)
- Injectable midazolam MUST NOT be used for conscious sedation
- Injectable opioids should be prescribed with CAUTION especially in opioid naive patients

Nurse and pharmacist Independent Prescribers can mix injectable medicines themselves and direct others to mix.

3.28 Unlicensed / Off-label Prescribing

3.28.1 Prescribers should only prescribe those medicines which have been issued a product license for use within the United Kingdom in the particular dosage range via the specified route, for a specified purpose.

3.28.2 If a prescription is written for a product which does not have a product license, then the pharmacist should bring the matter to the attention of the prescriber concerned prior to dispensing the medicine and ensure the appropriate documentation is completed.

3.28.3 The practitioner required to administer the medicine should refuse to do so until a check has been made that the prescriber has formally accepted responsibility for any adverse effects by signing the appropriate documentation available from the pharmacy department.

3.28.4 'Off-label' is the term used when using a licensed medicine' for an 'unlicensed indication' or at a dose outside the product license or administration/supply in a different way to the product

license e.g. crushing tablets or supply in monitored dosage system. When prescribing a medicine in this category then the appropriate documentation must be completed. It is not always possible for pharmacy to know if a medication is being used outside of it's license. An example of off-label medication would be the prescribing of an antipsychotic medication at doses higher than BNF and data sheet limits.

3.28.5 Many medicines prescribed for children are 'off label'**.** A form does not need to be completed when the medicine is being used as detailed in the Children's British National Formulary).

3.28.6 For any unlicensed or off-labelled prescribing for children and adult prescribers must complete the Non-formulary, off-label and unlicensed medicines form (See Non-formulary, Off-label and Unlicensed Medicines Policy).

3.29 New Medicines

Newly licensed medicines or medicines with a newly licensed indication should **not** be prescribed before completing the local formulary request form for new medicinal products.

Requests for new medicines or interventions not currently used or on current Joint Formulary will be reviewed by the New Medicines Committee (NMC) to ensure safe and effective use. Applications will also be submitted to Area Prescribing Committee by the NMC when the medicine is suitable for primary care use.

3.30 Medicines Reconciliation (NICE/NPSA Patient Safety Guidance 2007)

3.30.1 Medication errors pose a threat of harm to patients, leading to increased morbidity, mortality and economic burden to health services. Errors occur most commonly on transfer between care settings and particularly at time of admission. Typical problems that can occur at transition points when medicines have not been reconciled include:

- The patient might receive the wrong dose of their medicine
- The patient may not receive their medicine at all
- Pharmacy could order in the wrong medication for a patient
- There could be delays to a patients treatment while these issues are resolved
- The patient's stay in hospital might be extended or their discharge may be delayed
- Confusion and lack of confidence in the system, for patients, their carers and families, as well as for health care professionals.

When a patient is admitted to hospital from home, then the medications written up for the patient at the time of admission should match the medication history provided by the patient's GP and if it does not, then changes should be documented.

3.30.2 Medicines Reconciliation Process **("Three C's of Medicines Reconciliation")** for managing patient medicines on handover between care settings.

**A. Collecting:**

'Collecting' involves the collection of the medication history. This may be from a variety of sources (some potentially more reliable than others) including:

- A computer print-out from a GP records system or Summary Care Record
- The tear-off side of a patient's repeat prescription request

- Verbal information from the patient, their family, or a carer
- Patient's own medicines with labelled directions
- Medical notes from a patients previous admission to hospital
- Medical notes transferred from another ward or unit.

The medication history should be collected from the most recent and reliable source and the person recording that information should always record the date that the information was obtained and the source of the information.

**B. Checking:**
'Checking' is the process of ensuring that the medications and doses that are now prescribed for the patient are correct. Obviously, this does not mean that they will be identical to those contained in the medication history – the doctor now caring for the patient may make some intentional changes … and that leads into the final step of the process …

**C. Communicating:**
'Communicating' is the final step in the process where any changes that have been made to the patient's prescription are documented and dated, ready to be communicated to the next person that sees them. It includes documenting such things as:

- Source of information
- Name of medicine Dosage
- Frequency
- Route of administration
- When a medicine has been stopped, and for what reason (including topical preparations)
- When a medicine has been initiated, and for what reason
- The intended duration of treatment (e.g. for antibiotics and hypnotics)
- When a dose has been changed
- When the route of the medicine has been changed (especially important when a patient is being transferred from a high dependency unit to a medical ward and the medication route has changed from IV to oral)
- When the frequency of the dose has changed

3.30.3 Responsibilities
Ward teams must ensure that medicines reconciliation (MR) is carried out within 24 hours of admission and that any changes to medication are clearly communicated on transfer. Pharmacy staff support MR during scheduled ward visits. However, this does not cover all patients admitted to our wards. Once completed the person completing the reconciliation should sign and date the section on the front of medication chart.

All members of the multidisciplinary team are involved in the process and should recognise that the accurate communication of changes to a patient's medication, especially when their care is transferred to another setting, is essential if adverse drug events are to be avoided. It therefore becomes everyone's responsibility to make sure that, where they have been involved, they have "**C**ollected, **C**hecked, and **C**ommunicated" the changes they have made.

A pharmacist should be involved in MR as soon as possible. The ward pharmacist may review this information when reviewing admissions during scheduled ward visits and should be contacted for advice at other times.

The ward pharmacy technician may identify issues relating to medicines e.g. dosage during

weekly top up visits but would not be expected to review notes to check all admissions. The role of the technician will include supporting the multidisciplinary team in gathering medicines information and supporting the ward pharmacist in reviewing new admissions.

Prescribers should ensure that this information is used to support medicines prescribed on admission and ensure follow up of additional sources of information if not immediately available e.g. GP information out of hours.

3.31 Procedure for The Provision Of Leave and Discharge Medication

3.31.1 Leave or discharge medication must be prescribed relevant prescription. Medication should be written up with sufficient time allowed for dispensing in normal pharmacy hours. The aim is to discharge the patient home with at least 14 days' supply of medicines, unless there is a clinical reason for shorter or longer supply e.g. risk of harm or shared care medication. If a longer supply is required please request on the discharge form.

3.31.2 On receipt of the completed prescription to the ward/unit a registered nurse must check the medication against the prescription, prior to handing them to the patient or relative with any supporting information. The pharmacy should be notified of any discrepancy immediately. If there is a delay before the patient is to be discharged home, their take home medicine should be stored in the appropriate medicines/drug cupboard or refrigerator. Prior to discharge, if community workers are to take charge of prompting patients to administer their medication then the patient may need to be assessed for a compliance aid / medicines organiser (see Appendix 2).

3.31.3 Patients who have been self-administering medicines (see Appendix 6) during their in-patient stay should have a good knowledge about their medication. However, there should be a final discussion between patient/carer and ward staff covering the following points:

- Medicine name, form and its purpose
- Dose, frequency and times of the day for administration
- Any additional information on the label e.g. before/after food
- When to commence treatment at home
- How to obtain further supplies if necessary
- Advice regarding any medicine that has been discontinued or which is for a time-limited period.

3.32 Transcribing

Transcribing is the act by which the details of medicines and related items are written from one form of direction to another in order to allow administration. It does not apply to other information such as demographic information.

The NMC states that transcribing 'should only be undertaken in exceptional circumstances and should not be routine practice'. Transcribing must not take place where an appropriately qualified and competent prescriber is available, as writing and re-writing prescriptions is the responsibility of prescribers.

Therefore transcribing is only acceptable where:

- The circumstance can be deemed as exceptional e.g. in a business continuity situation
- There is no prescriber available now, or in a suitable timeframe
- Failure to act will put the patient at risk of harm, for example, by omission of treatment

The following staff groups can transcribe:

- Registered nurses who have completed appropriated transcribing training
- Pharmacists, although in practice this is rarely necessary
- Independent Prescribers (although see below)

Independent Prescribers are not required to transcribe items that sit within their area of competence, as they may prescribe these. Independent Prescribers may transcribe any item that is not within their area of competence.

When a prescription or authority to administer is transcribed by any of the above professionals, the transcriber must state 'transcribed' or 'transcription' clearly on the prescription or authority form, against all relevant items. Where this is not stated, the transcriber will be viewed as having prescribed the items, and will be regarded as entirely responsible for this from a medicolegal perspective.

Transcribed prescription or authority forms must be reviewed and countersigned by a prescriber at the first opportunity.

## 4.0. DISPENSING A MEDICINE

4.1 General Principles

Dispensing is the preparing, packaging, labelling and record keeping, where appropriate of a medicines or medicines for a patient.

4.1.1 Dispensing of Medicines in the Pharmacy

The Trust pharmacy service has SOPs to cover all aspects of the dispensing process, including ensuring that medicines are:

- Clinically appropriate, including consideration of relevant guidance
- Issued against appropriate orders or prescriptions
- Supplied in the most cost effective manner e.g. issue of a generic instead of a brand where this is judged as safe by the pharmacy team
- Processed in an order of priority to minimise the risk of omission or delayed treatment
- Labelled for safety in line with legal requirements
- Dispensed or prepared accurately
- Stored in accordance with manufacturer advice and distributed in a satisfactory manner
- Accompanied with patient information leaflets at an appropriate frequency

4.1.2 Should any practice not follow that written in the pharmacy standard operating procedures the Responsible Pharmacist must make a note of the change. Any major changes to procedure in should be reviewed by the Deputy Director of Medicines & MACE for further review.

4.2 Errors Made in the Dispensing Process

4.2.1. Errors made in the dispensing process may be discovered by pharmacy staff, staff working in clinical areas or other parties e.g. patients or carers.

4.2.2 Dispensing errors made in pharmacy services are categorised as:

- Internal errors that have been identified and rectified before leaving the pharmacy
- External errors that have left the pharmacy and conveyed to a clinical area or recipient.

4.2.3 Such errors must be reported to the pharmacy service as soon as they are identified; and advice sought where necessary to ensure the safety of the patient.

4.2.4 All internal errors must be recorded using the agreed form, according to the SOP 027 - Recording of near misses in pharmacy department, in order to ensure that investigation can take place for root causes and to share learning.

4.2.5 As soon as an external dispensing error is identified involving supply of the wrong medicine, wrong strength, labelled with the wrong directions or that could lead to patient harm:

- Urgent action must be taken to recover the item(s) and to ensure the safety of the patient and replace as appropriate
- Reported to the dispensing pharmacy (or on-call pharmacist, if out-of-hours)
- It must be reported as a medication incident
- If the patient has taken the wrong medication as a result of the error, this must be reported to the prescriber, or the person responsible for the patient's care.

4.2.6 In such instances, the incident must be investigated according to the Trust Incident Reporting Policy; and procedures/guidance used to support investigations, where necessary.

4.3 Monitored Dosage Systems / Compliance Aids

Prior to dispensing pharmacy need to receive a 'Medicines Organiser Assessment Form' (see Appendix 2) which includes a completed risk assessment including declaration from medical staff accepting that stability data is not available for all medicines and that compliance aid is best option for individual patient.

4.4 Patient Information on Medicines

To support adherence patients should be provided with or signposted to Choice and Medication for validated patient information via www.choiceandmedication.org/combined/ Pharmacy team will supply relevant leaflet for mental health medicines with discharge medication and for out-patients as part of dispensing process.

4.5 Insulin Passport (NPSA)

Supporting information about insulin will be issued to patients where insulin is changed or initiated during admission.

4.6 Obtaining Medicines

4.6.1 The system for **ordering** medicines is outlined in ward procedure. Staff should familiarise themselves with the system in use in their area. The supply of medication may follow ward top-up / pharmacist ward visit or ad-hoc request from the ward.

4.6.2 Secure GOLDFAX may be used to send urgent requests on inpatient prescription charts for sites not based at Harplands. The nurse in charge should contact pharmacy to alert the team to the request and organise collection. Outpatient, discharge and leave prescriptions can be prepared against a fax but cannot be released until the original prescription is received in pharmacy.

4.6.3 Some areas have 'stock items', supplied by the pharmacy team on a top-up basis. The, stock list should be reviewed at least annually to ensure it meets local requirements. Medicines routinely stocked may be requisitioned from pharmacy.

4.6.4 Patient specific medication is supplied via the pharmacy against the patient's prescription. Any stock received from pharmacy should be checked against details in accompanying documentation e.g. delivery note. If there is any discrepancy the pharmacy should be contacted and the discrepancy reported. Pharmacy will advise on appropriate action.

4.6.5 Patients own drugs can be used if they have been checked for appropriate use. The patients consent to use their own drugs should be gained for their use and destruction.

4.6.6 In some community facilities medicines are obtained from a designated community pharmacy in accordance with FP10 or FP10 (HP) prescription from a registered prescriber.

4.6.7 Medicines should only be transferred between wards or departments in exceptional circumstances. If a patient is transferred to another ward, ALL items bearing their name should be transferred with them.

4.7 Medicines Availability Including Out of Hours to Minimise Omissions

4.7.1 Omissions of critical medicines (see appendix 5) must be avoided whenever possible. It is not acceptable to omit a critical medicine due to not having the item on the ward when stock is available from pharmacy (in hours), or the out of hours cupboard or via the FP10s.

4.7.2 The out of hour's cupboard is based at Harplands hospital and access is limited to designated staff members only. Staff should familiarise themselves with the system in place in their area of employment and inform the pharmacy, using the relevant documentation, if any of the medicines are taken. This will ensure the medication is replenished.

4.7.3 If a nurse is in doubt as to whether a medicine is critical or not, he or she should consult the doctor on duty or a pharmacist.

4.7.4 All doses of all medications, whether given or omitted, should be annotated appropriately on the prescription chart. In the event of a medicine being omitted because it is not in stock, an order should be placed with pharmacy as soon as possible during pharmacy opening hours.

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| A pharmacist is available for advice in emergencies. Access is limited to calls from medical staff and designated senior nurses via the switchboard at Harplands hospital. |

## 5.0 TRANSPORT OF MEDICINES

It is important that medicines are transported appropriately and that high standards are maintained in the transport and delivery of medicines, in light of previous reviews into this area by the media and patient safety Groups e.g. https://www.pharmaceutical-

journal.com/news-and- analysis/news/poor-medicines-delivery-practices-prompt-safety-review/20203050.article?firstPass=false

5.1 Transport Standards
Medicines should be transported between the pharmacy and the ward/unit in a sealed, tamper evident container. The container should be opened and checked against documentation by nursing staff authorised to hold the medicine keys, then locked in the appropriate storage area immediately after checking. Pharmacy must be informed of any discrepancies.

5.1.1 Any refrigerated items must be transported in such a way that the cold chain is maintained. Delivery vehicles that transport medication must not be left unoccupied nor carry unauthorised passengers. Medicines MUST NOT be transported unaccompanied via taxi service.

5.1.2 In the community, the collection of medicines is the responsibility of the patient or carer. In exceptional circumstances a registered nurse may collect medication; this should be transported in the locked boot of a car. The period of transport should be kept to a minimum. Details of staff collection and handover to patient should be documented in the patients' notes.

**Note:** medication MUST NOT be held overnight in a car.

5.1.3 If medicines are required to be returned to the pharmacy department they must be returned in a sealed, tamper-evident container or may be collected from the ward by pharmacy staff. In community settings, staff should return medicines to the community pharmacy where the medicines were dispensed.

5.1.4 If the medicines that are required to be return to the pharmacy are Controlled Drugs refer to the Trust's Controlled Drug Policy.

## 6.0 FRAMEWORK FOR ADMINISTRATION OF MEDICINES

6.1 Approved Medicines Administrators

6.1.1 The Medicines Act (1968) states that any person may legally administer a prescription-only medicine provided that this is done in accordance with the written directions of a qualified prescriber (independent or supplementary). This task is, therefore, not legally restricted to medical and nursing staff.

Staff groups who the Trust considers may therefore administer medicines include:

- All registered medical practitioners in the course of their work, in accordance with the requirements of the Medicines Act/Human Medicines Regulations, associated regulations and local protocols

- All qualified, registered nurses and registered nursing associates (see restrictions relating to the nursing associating role in Appendix 1)

- A student nurse as part of their training, but only under direct supervision of a qualified registered nurse. The supervising registered nurse must accept full responsibility for the correct administration and recording of the medicines prescribed. The registered nurse must countersign the signature of any student who is being supervised in the administration of medicines

- A trainee nursing associate as part of their training, but only under direct supervision of a registered nurse or registered nursing associate working within their competencies (see restrictions relating to nursing associates undertaking supervision in Appendix 1). The supervising registered nurse/registered nursing associate must accept full responsibility for the correct administration and recording of the medicines prescribed. The qualified nurse/registered nursing associate must countersign the signature of any trainee who is being supervised in the administration of medicines

- A pharmacist or pharmacy technician, but only after completion of approved training and assessment to demonstrate competency to do so.

Medication can be administered by a wide range of health care professionals provided they are professionally competent and confident to do so. This role may also be undertaken by patients/carers (See Appendix 6 – Self-medication Guidelines).

| For more information about administration of Controlled Drugs, refer to the<br><br>'Controlled Drug Policy' |
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6.1.2 For reference purposes, all areas should hold a list of signatures of those staff that administer medication, to be readily available using the standard form.

6.1.3 Health Care Support Workers must not be involved in the administration of medicines, but they may assist with compliance under the direct supervision of a registered nurse.

## 6.2 Principles for the Administration of Medicines

When administering medicines, healthcare professionals are expected to adhere to best practice and any guidance issued by their relevant professional body. Whether administering a medicine, assisting in its administration or overseeing self- administration, the authorised person must be satisfied that they:

- Have a sound knowledge of the therapeutic uses of the medicine being administered, its normal dosage, main side effects, precautions and contra-indications.
- Are able to justify any actions taken and be accountable for them.
- Are using the correct method of administration e.g. injectable medication and accurate measurement of oral liquids using oral syringe or measured spoon (see NPSA Patient Safety Alert 19; March 2007). Insulin must be measured and administered using an insulin syringe or insulin pen device. (NPSA Safer Administration of Insulin Alert 2010).'
- Be certain of the identity of the patient to whom the medicine is being administered.

## 6.3 Duties

6.3.1 Managers must be clear what their responsibilities are in ensuring that they are confident in the competence of the individual to carry out the procedure for the administration of medicines.

6.3.2 Newly qualified staff or those moving to a new area of practice will undertake an assessment as part of their preceptor ship / induction programme.

6.3.3 Staff operating under a Patient Group Direction (PGD) should adhere to the criteria

specified in the PGD and not delegate the administration of a medicine to any other person (including students).

6.4 Preparing for Medicines Administration

Before commencing the administration of medicines, staff must take steps to prepare themselves and their environment:

- Ensure, as far as possible, that the environment is safe, secure and appropriate for the activity to be undertaken. This is of particular importance for lone workers
- Ensure that all medicines and related items are out of reach from patients to reduce the risk of attempts to reach or grab medicines or associated items.
- Ensure the area to be used for medicines administration is fit for purpose and adequately lit and ventilated.
- Ensure that the area is clean and tidy and all necessary equipment is readily available and fit for use. The area should be kept tidy throughout the administration session, and cleaned when session completed.
- Take action to minimise distraction before commencing administration (e.g. noisy environment, people wandering in and out or engaging in conversation). All unnecessary distractions during administering medication should be ignored (i.e. telephone ringing, non- urgent requests etc.) or deferred until after the medication procedure has been completed.
- All areas used for the administration of medicines should have in place internal/external systems for calling assistance when necessary (safety alarms/radio/mobile phone).
- In the event of an emergency situation occurring during the administration of medication (e.g. a fire alarm, crisis situation) the medication should be put in a secure place, for example the nearest lockable cupboard, or handed to another competent person if appropriate. After the emergency situation has passed either recommence administration of medication procedure, taking into account the time span, or follow local waste procedures for disposing of any spoiled medication; and then restart the administration process.
- Ensure all necessary cards/medication administration sheets are present/accounted for, including all cards for any patient that has more than one card in use.
- Check all prescriptions are legible, legal (including checking consent to treatment status and paperwork, where appropriate), complete (including prescriber's signature) and are otherwise valid. Any discrepancies noted should be addressed before commencing administration.
- All staff have a responsibility to make themselves aware of any changes to an individual's medication prior to any administration of medication. Check the card/prescription and any communication book/care/support plan/handover notes for any medicines intended to be withheld for any reason/or special instructions.

- All staff administering medication should have knowledge of the individual and of their medication. This should include understanding the prescription and having knowledge of the common indications, side-effects and dosages of the medicine prescribed. Any particular monitoring requirements must be observed e.g. checking the medicine is swallowed if risk of secreting, diversion or misuse.

- Wash hands before and after commencing medicines administration

6.5 Process for the Administration of Medicines

The healthcare professional administering the medicine is responsible for ensuring that:

- The agreed criteria for prescribing have been followed.

- The label on the medicine is clearly written and unambiguous and, where possible/practicable, the contents are checked and correspond with the label.

- All relevant details including known drug sensitivities have been recorded on the patients prescription chart and checked against the patient's identification (e.g. wristband or photograph).

- The dosage, method of administration, route and timing of administration is appropriate to the patient's condition and co-existing therapies.

- Check the expiry date of the medication to be given, if available. If not present (i.e. medicines that have been dispensed into a pharmacy container and labelled with the date of dispensing) then use the dispensing date as a guide. The expiry date for tablets can be several months from the date of dispensing. Health professionals must use their professional judgement in determining the appropriateness of administering the medication. If the date is more than six months previous/or the appearance of the medicine is unusual then seek advice from the pharmacist.

- Make a clear, accurate and immediate record of all medicines administered, ensuring that the signature is clear and legible.

- Where, intentionally withheld or not administered e.g. patient on leave, refused or medicine on order, code appropriately using codes indicated on the chart. It is essential that the medication chart is completed fully to ensure a robust audit trail of medicines prescribed.

- To minimise delay in patients receiving medication if not available on the ward, the senior nurse should ensure that the medication is ordered as soon as possible or when 'out of hours', use stock from Trust emergency cupboards.

- Record the effect of 'once-only' / 'as required' medication.

- In relation to immunisation / vaccination/ intravenous infusion, batch numbers must be recorded in the patient's records and prescription chart.

6.5.1 Contact the prescriber without delay where:

- Contra-indications to the prescribed medicine are discovered.
- The patient develops an **untoward reaction** to the medicine or where assessment of the patient indicates that the medicine is no longer suitable.

6.5.2 In the case of an **untoward reaction** to the medicine:

- Stop the medication
- Report the reaction to the medical officer/GP
- Record the reaction in the patient's records
- Check whether a **yellow card** should be completed for the Committee on the Safety of Medicines (CSM). (See current British National Formulary: Adverse reactions to drugs). Detailed information on reporting can be accessed via the MHRA Website: www.mhra.gov.uk
- Ensure an incident form is completed if an allergic reaction has occurred; write the name of the medicine on the drug sensitivities section of the patients prescription chart and in their records and sign / date the entry.

## 6.6 Day Service Settings

Trust staff administering medication that has been dispensed by non-trust providers e.g. patients own medicines must ensure that it is suitable to use and raise any concerns before administering.

Clients/patients will self-medicate, though some may require assistance to take their medication (local protocols apply). Staff should record administration of medication in the individuals care plan.

## 6.7 Administration of Controlled Drugs (CD's)

6.7.1 The use of Controlled Drugs (designated as such by the Misuse of Drugs Act 1971) in medicine is permitted by the Misuse of Drugs Regulations 2001 and other regulations dealing with the safe custody of controlled drugs and the notification and supply of drugs to treat and manage addiction (See Controlled Drugs Policy).

6.7.2 The healthcare professional administering a schedule 2 or 3 CD **must** have the administration checked by another responsible person (i.e. registered nurse, registered nursing associates, doctor, second or third year student nurse). Registered nursing associates are not permitted to be the senior administrator of CDs (see Appendix 1).

6.7.3 A record should be made of the date and time of administration and the, form and strength of the preparation.

6.7.4 Particular care should be taken with the administration of CD's by injection – with regard to aseptic technique, compatibility, expiry dates, programming of syringe drivers and selecting the correct dose strengths of ampoules.

6.7.5 Independent non-medical prescribers are able to prescribe and administer/or authorise the administration of some CD's for some indications either as listed with regulations or approved by clinical director in specified situations.

6.8 Single Person Administration of Medicines

Authorised health professionals may administer medicines unsupervised except for those who have not yet attained the level of competence to do so. This includes newly qualified staff may require a period of supervision as part of their preceptor ship.

In accordance with the NMC Code of Professional Conduct (2004) registered bank/agency nurses are accountable for their practice and must not administer medicines unsupervised unless they feel competent to do so.

Nurses must ensure that the risks of distraction from medicines administration are minimised.

6.9 Two Person Administration of Medicines

6.9.1 Two-person administration of medicines is not always possible / practical. However, two people **must** be involved in the administration and checking of:

- Medicines controlled by the Misuse of Drugs Act 1971 Schedule 2 & 3
- Medication for children under the age of 16 years
- Blood and blood components
- Injectable medicines used for rapid tranquilisation
- Medicines given under Section 62
- Administration involving a complex calculation (e.g. a dose based on the weight of a patient). For the majority of medicines administered across the Trust, the calculations involved are considered not to be complex. However, in any situation requiring additional support or guidance to ensure patient safety the calculation should be checked by a second nurse. **If you are in any doubt about administering a medicine you MUST seek advice first.**

6.9.2 Registered nurses at Darwin and Dragon Square Respite may administer medicines (except controlled drugs schedule 2 and 3) single handed but the nurse in charge may make a decision to undertake two-person administration of all medicines if they feel it is appropriate.

6.9.3 The first practitioner must be a registered nurse or medical officer, who must directly administer the medication and is therefore responsible. The second person can be a registered nurse, medical practitioner or pharmacist. A second or third year pre- registration student nurse can also act as the second person if, through their knowledge base, they feel competent to do so.

6.10 Self-administration of Medicines

In certain circumstances it may be appropriate for the patient to be responsible for their own medication. Where this is taking place, the patient must be deemed competent to carry out the task and staff / patients must follow the appropriate guidelines **(**see appendix 6).

6.11 As Required Medicines

When administering medicines that are prescribed on the ‘as required’ section of the medication chart the nurse/nursing associate administering medication should be assured that:

- The patient requires medicines for the prescribed indication at that time
- The dose is being administered within required time interval and does not exceed the maximum dose in 24 hours.

## 6.12 Administration of Medicines by Injection and Infusion (Including Intravenous)

The use of injectable medication has many healthcare benefits for patients. The complexities associated with the prescription, preparation and administration of injectable medicines means that there are greater potential risks for patients than for other routes of administration. Safe systems of work minimise these risks. For further information see the Trust's Prescribing, Preparing and Administering Injectable Medicines SOP.

For the procedure for the administration of medicines via injection/infusion please refer to the current edition of The Royal Marsden Manual of Clinical Nursing Procedures, which is available in all clinical areas.

### 6.12.1 Prescribing and Documentation

All infusions (only permitted in some localities, see Vascular Devices Policy) should be prescribed in the relevant section of the prescription chart, including infusion-drug additives. All prescriptions must be clearly written in BLOCK CAPITALS and must state:

- The infusion fluid including strength, where appropriate
- The dose / volume
- The precise method of administration
- The rate of administration
- The dose of any drug to be added
- Signature of the prescriber
- Date of prescribing
- Date of administration, if different from the date of prescribing.

When medicines are added to infusion fluids the doctor or designated nurse must ensure that the medicine is appropriate for this method of administration and that it is compatible with the infusion fluid and any other drugs that may also be present. Advice can be obtained from the BNF or from the pharmacy department.

Medicines must **NOT** be added to:

- Blood
- Plasma or other blood products
- Intravenous feeding solutions
- Amino acid solutions
- Fat emulsion preparations
- Mannitol infusions
- Sodium bicarbonate infusions

Wherever possible, commercially available drug-infusion mixtures should be prescribed in preference to those requiring preparation. Mixtures involving multiple drug additions to infusion fluids should be avoided unless positive information on compatibility is available.

### 6.12.2 Storage and prevention of contamination

Before an infusion fluid is connected to a giving set always check:

- The name and strength of the infusion fluid

- The expiry date
- For evidence of damage to the container and/or evidence of leakage
- For particle formation
- For cloudiness/opalescence
- For change in colour

If there are any concerns about the quality of the infusion fluid then do not use but retain for further investigation, together with its outer wrapper, any drug additive vial or ampoule and any packaging. Inform the senior nurse, who should notify the pharmacy. Arrangements must be made to inspect the remainder of the containers in that batch. Should any abnormalities only be noticed after administration of the infusion, then stop it immediately. In these circumstances the doctor must be notified urgently.

Good aseptic technique is essential when adding medicines to infusions and when inserting giving sets into the intravenous container. Under no circumstances should an infusion container be used on more than one occasion. Any unused solution **MUST** be discarded on disconnection from a giving set.

6.12.3 Personnel who can Administer Infusion Fluids and Medication

Designated nurses may check and administer infusion fluids and drugs alone including first doses **EXCEPT**:

- When infusion fluids or medication are being administered to children under the age of 16 years
- Controlled drugs – the procedure for the preparation, checking and administration of Controlled Drugs must be carried out by two people as described in section 6.9.
- Where calculations are involved i.e. weight-related doses.
- In any circumstance where the nurse feels it necessary to have a second person present.

6.12.4 Intravenous/subcutaneous Fluid Administration

Intravenous/subcutaneous fluids may be administered by a doctor or a designated nurse who has the necessary knowledge and competence i.e. nursing staff employed within the Trust who have been trained and understand the principles of the NMC document “The Code of Professional Conduct”. (2004). Where necessary, practitioners will be given the opportunity to observe and practice the siting of subcutaneous infusion under the direct supervision of nursing staff competent in this procedure. The prescription details on the relevant chart must be followed.

6.12.5 Administration of Infusion Fluids Containing Drugs

Certain drugs may be available ready-mixed in intravenous infusion fluids. Administration of such pre-mixed drug and infusion fluid combinations, whether commercially manufactured or prepared in pharmacy, may be undertaken by a designated nurse or a doctor. The prescription details on the relevant chart must be followed.

6.12.6 Addition of Drugs to Infusion Fluids

This procedure may be carried out by a designated nurse or a doctor. Drugs should not be added to fluids where pre-mixed solutions are available. An approved additive label must be fully completed and attached to the infusion container. It must be placed so that it is easily read and must not obscure the details of the infusion fluid.

6.12.7 Use of Mechanical Pumps /Syringe Driver

Designated nurses competent in the use of mechanical pumps/syringe drivers may administer medicines in this way.

Designated nurses must not prepare solutions for injection in advance of their immediate use, nor administer a medicine that has not been drawn up into the syringe by themselves or in their presence, unless prepared in the pharmacy.

Designated nurses will be required to assume responsibility for established intravenous infusion in progress via a mechanical pump, where there is a valid prescription and a responsible practitioner has signed to identify that the infusion is correct.

All infusions must be checked on a regular basis to ensure administration is timely and that there are no mechanical failures. This should be recorded on the appropriate chart at the specified intervals.

6.12.8 Bolus Intravenous Injection

Bolus injections may be given by a doctor. A designated nurse may administer drugs in this way providing there is a cannula *in situ.* The injection of a drug into a cannula or the tubing of a giving set should be done slowly and in accordance with the instructions in the package insert or BNF. **NOTE** some medicines are unsuitable for peripheral cannula administration.

*In situ* intravenous cannulae that are not being used should be flushed through with 5ml of 0.9% sodium chloride for injection every 6 hours to maintain their patency, except for paediatrics where separate advice should be sought. The flushing solution must be prescribed on the prescription chart. The times for administration should correspond with other intravenous therapy or if the patient is not receiving intravenous medicine therapy, the times should indicate 6 hourly.

When a bolus injection is to be given through an intravenous cannula, the cannula should be flushed both before and after the injection with 5ml 0.9% sodium chloride as above (unless the drug is incompatible with sodium chloride 0.9%). If two or more bolus injections are to be given consecutively the intravenous cannula must always be flushed with 0.9% sodium chloride injection between the bolus injections, to avoid the possibility of interaction between the two drugs (unless the medicine is incompatible with sodium chloride 0.9%).

6.12.9 Monitoring of Prescribing and Medicine Compatibilities

The pharmacist should routinely monitor prescription charts and intravenous fluid charts and where appropriate, advise medical and nursing staff on any specific problems regarding appropriateness, safety, stability and compatibility. As a minimum, Acute and Older Persons wards should be checked once a week and other wards / settings once a month.

The pharmacist can be consulted for any advice that is required relating to infusion therapy, including compatibility of drug additions to infusion fluids. A clinical pharmacist check includes:

- Patient's age
- Allergy Status
- Choice of medicine
- Dose
- Frequency (regular and "as required" medications)
- Route of administration
- Stop/review dates if applicable e.g. for antibiotics, oral potassium
- Compliance with form T2/T3 (where relevant)
- Drug interactions

- Compliance with formulary and guidelines (endorse this on chart)
- Use of product within licensing or locally agreed unlicensed use
- Appropriate monitoring e.g. INR monitoring, Lithium levels
- Correct use of variable dose section
- Legal requirements for controlled drugs, including signature of a Doctor or IP as per current guidance)
- Charts should be checked for administration issues such as omitted medications and reasons for omissions e.g. out-of-stock medications
- Refused doses
- Use of 'when required' and 'once-only doses'

Standard up to date references will be used including latest version of British National Formulary and NICE clinical guidelines.

6.12.10 Administration of Intramuscular Injection

The manufacturer's package information must always be consulted to ascertain the correct site for administration of intramuscular injections, and the site of choice documented in the patient's notes.

## 6.13 Parenteral or Nasogastric Feeding

The administration of medication for patients with swallowing difficulties, who are receiving nutrition via Parenteral / nasogastric feeds, should be accordance with Trust Medication Administration for Patients with Swallowing Difficulties Policy. Designated nurses or doctors administering nutrition via these routes must be trained and competent in the use of the apparatus involved.

## 6.14 Patients Own Medicines (including respite patients)

6.14.1 Patients and/or carers are positively encouraged to bring in their own medicines with them on admission to hospital so that the confirmation of the patient's medication history can be facilitated following admission. This includes those medications purchased from pharmacies or health food outlets.

6.14.2 Whenever safe and practical these medicines should be retained on the clinical area for administration to the patient, particularly where there is a plentiful supply and especially if no stock of the medicine is held on the ward.

6.14.3 Medicines brought in remain the patient's property and patients have the right not to agree to their use, in which case they must be stored securely and either:

- Returned to the patient on discharge, subject to a satisfactory risk assessment, or
- Treated as a medicines waste (for more information about handling of medicines waste the Trusts Waste Policy)

6.14.4 Pharmacy staff will normally check Patient's Own Medicines (PODs) during their next scheduled ward visit. If necessary, pharmacy staff will re-label medicines as soon as practical. In instances where pharmacy are not available to checks PODs two qualified nurses when must undertake this responsibility.

6.14.5 Patients may refuse to voluntarily surrender medication in which case the Medical Officer and Senior Nurse Manager must be informed.

6.14.6 Medication surrendered by patients should be placed in lockable secure storage. Any medication bought in by the patient, but not prescribed or deemed unfit for use, should be returned to the pharmacy for destruction together with a completed copy of the Patients Own Medicines Form (See Appendix 7).

6.14.7 If the patient refuses permission for the medication to be destroyed, the medication should be placed in a sealed envelope labelled with the patients' name. The envelope should then be stored in a locked medicine cupboard suitable for the storage of medication until the medication can be returned to the patients' home by a responsible adult, or on the patient's discharge. This action should be discussed with the patient and relative/carer/friend and documented in the patients' notes.

6.14.8 Should they bring in any Controlled drugs these must be entered on a designated page for the patient's own drugs in the ward Controlled Drugs Record Book in the approved manner and stored appropriately until they can be returned to the patient or carer or to pharmacy for destruction (Refer to the Controlled Drugs Policy).

6.14.9 Patients admitted for respite care (e.g. dragon square) once their own medication has been checked by registered staff, may continue to use it during their admission. If the patient's medication is changed in any way during their stay in hospital, they must be given a clear explanation and information regarding its use and side effects. The change in medication must be clearly identified on the patients medication record and discharge form.

## 6.15 Administration of a Patient's Own Medicines

6.15. 1 Medicines brought into a clinical area by an individual patient may, if appropriated be used for the treatment of that patient provided that the staff member administering the medicines examines concerned, and can confirm:

- The identity and strength of the medicines(s)
- That the medicine(s) were dispensed in the last six months
- That the medicine(s) have not exceeded any marked expiry date
- That the medicine(s) are prescribed on the patient's prescription or authorisation to administer is in place
- That the patients has given consent for these medicine(s) to be used
- That the labelling and directions on the medicines(s) are clear and are in accordance with the patient's prescription

6.15.2 If there is any doubt as to the identity, quality or labelling of the patient's own medicines or if the medication is out of date, the medicines must not be administered. It must be handled according to the procedures for medicines waste.

## 6.16 Administration of General Sales List Medicines Without Prescription Adults

The previously approved list of medicines for administration without prescription has been removed from the policy as rarely used.

6.17 Procedure for the Governance, Prescription, Administration and Recording of Oxygen and Other Medical Gases

6.17.1 Use of medical gases will follow principles for medicines as set out in this policy. Governance arrangements and incidents relating to medical gases will be overseen by the Clinical Effectiveness Group (CEG).

6.17.2 Currently oxygen is the only medical gas used within the Trust usually for use in emergency or as prescribed for patients with respiratory problems.

6.17.3 Under normal circumstances, oxygen must be prescribed by the medical staff on the patient's prescription sheet. The prescription must state the mode of administration and flow rate/ percentage of oxygen to be given.

6.17.4 A registered nurse must check oxygen administration at intervals appropriate to the patient's condition, situation and the equipment being used. Each check must be recorded against the prescription chart or in the nursing records.

6.17.5 In the situation of a **CARDIO – RESPIRATORY ARREST ONLY**, oxygen should be administered as specified in the Resuscitation policy.

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| On inpatient wards small oxygen cylinders must be stored and available on the bottom shelf of the resus trolley whilst large cylinders must be securely chained or clamped in clinic rooms to avoid the risk of them falling and causing potential injury to patients or staff as per HSE guidance. |

6.18 Emergency Treatment of Opiate Overdose

6.18.1 Opiate overdose is characterised by heavy sedation or collapse with very poor respiratory output; the breathing is either very shallow, laboured or non-existent. The patient's history or recent behaviour may suggest opiate use.

6.18.2 Naloxone hydrochloride is an opiate reversal agent, administered in cases of suspected opiate overdose. Naloxone is available in 2ml prefilled syringes containing 5 metered doses of 0.4 ml (400 micrograms) available under the brand name Prenoxad 1mg/1ml . It is stored in the medicines cupboards within Adult Acute Psychiatric Wards and the Psychiatric Intensive Care Unit at the Harplands hospital.

6.18.3 Anyone can administer naloxone without prescription for the purpose of saving a life, within the inpatient setting, the most appropriate person to administer will be professionally registered nursing and medical staff.

6.18.4 In the event of a suspected opiate overdose:

- Follow medical emergency procedures first, in accordance with the Harplands Emergency Policy.
- Commence the first cycle of CPR if necessary or place in recovery position if not.
- Administer the first metered dose of naloxone from the prefilled syringe either into the thigh or upper arm. There is no need to undress the patient as the gauge of the needle will pass through the clothing.
- If the patient does not respond to the first dose, give the next metered dose every 2-3 minutes (3 cycles of CPR).

6.18.5 The injection should be safely stored in between doses. It is not necessary to change the needle in between doses. Once spent (partly or fully) it should be disposed of in its entirety within the sharps box. Do not re-sheath or remove needles from the syringe once attached.

6.18.6 The patient will need to be continually monitored throughout the emergency period and post any response to naloxone. Naloxone remains active in the body for less time (20 mins) than opiates do, therefore a further deterioration could result after an initial positive response to Naloxone. For this purpose it is essential that the details of naloxone use are comprehensively communicated to attendant paramedics at the point of the transfer of care.

6.19 Stoke Heath Exceptions

The service at Stoke Heath prison is provided in partnership with RAPT, Shropshire Community Team and Prison team. Exceptions to our current Medicines Management policy are:-

- Site is set up as ‘Medical store’ i.e. medicines are obtained via wholesaler on direct order by authorisation of Dr Watts and Dr Adeyemo. Supplies are obtained within current legislation i.e. supplier to have relevant Home Office and Wholesaler Dealers licence.
- The prison medication chart in use to document administration of methadone or buprenorphine.
- Prescribing is recorded on an electronic prescribing / record ‘System 1’. This gives access to previous and current medicines prescribed by healthcare team.
- Non nursing staff from Rapt or nurses from Shropshire community team are authorised to occasionally provide second signature for controlled drugs.
- Methasoft device in use to measure methadone and procedure

## 7.0 MEDICINES STORAGE AND SAFE CUSTODY

7.1 Responsibility

7.1.1 The manager of a clinical area or their nominated deputy is responsible for all aspects of medicines handling and ensuring that the security of medicines is maintained. On a day-to-day basis it may be necessary to delegate some of the duties to an appropriately trained and authorised registered healthcare professional; usually a registered nurse or pharmacy technician.

7.1.2 The manager of the clinical area must ensure that medicines remain securely stored at all times, including in areas that may have automatic or fob access, and where doors may open automatically in the case of an emergency e.g. a fire. Additional digilocks may be needed on clinic room doors in some cases, refer to trust pharmacy services for advice.

7.2 Controlled Stationary

7.2.1 Controlled Stationary includes:

- Medicines Prescription/Administration Charts
- Ward Controlled Drug Registers
- Controlled Requisition/Order Book
- Discharge and Out-Patient prescription forms
- FP10 Prescription pads

7.2.2 All controlled stationary must be securely stored with controlled access (i.e. stored in a locked secure stationary cupboard or drawer when not in use). Only minimum stocks of prescription stationary should be held at any one time to reduce the number of forms vulnerable to theft.

7.2.3 The security of FP10 prescription pads is the responsibility of the prescriber, or team to whom they have been issued. The prescriber must ensure administrative and clerical staff are made aware of the potential value of and inherent dangers in the loss of prescription forms.

7.2.4 An appropriate procedure must be in place for the secure receipt, storage and use of prescription forms and for the immediate reporting of any loss or theft of prescription stationary to the issuer (see 7.2.7 for more information).

7.2.5 All FP10 prescription pads must be signed for on receipt by the prescriber or if it has been agreed by the issuer, their designated representative.

7.2.6 If prescription pads are to be collected from Pharmacy, staff must bring their Trust ID badge with them. The delivery form accompanying each prescription pad request must be signed by the prescriber or the designated person receiving the order and returned to the issuer. Any discrepancies at the delivery stage must be reported immediately to the issuer.

7.2.7 For more information about the management and control of prescription forms, see the NHS Counter Fraud Authority guidelines entitled ‘Management and control of prescription forms: a guide for prescribers and health organisations. March 2018’.

7.2.8 In the case of the loss or theft of prescriptions, or any suspicion of misuse or misappropriation of prescriptions refer to Trust Controlled Drug Policy and inform the Chief Pharmacist/Deputy Director of Medicines and MACE as soon as possible.

7.3 Security of Medicines

7.3.1 The healthcare professional in charge of a clinical area for that span of duty must

ensure the safe custody of all keys to medicines storage areas and medicines cupboards, know their whereabouts at all times, and ensure they are handed personally from one authorised member of staff to another where necessary.

7.3.2 Arrangements should be in place, by means of staff induction/orientation schemes, training courses and the carrying out of regular checks to ensure a high degree of security awareness in respect of medicines exists within the Trust.

7.3.3 For Controlled Drugs, please refer to the Controlled Drugs Policy. Cupboards must meet required standards and stock checks should be carried out at least once each working day.

7.3.4 The keys to access medicines should be held by the registered nurse in charge and should only be passed to staff authorised to hold them. At least once a month a member of staff should regularly inspect all areas where medicines are stored with regard to:

- Cleanliness/tidiness of the storage area
- Expiry dates:-

  **NOTE** Before administering a medicine check the expiry date *if available*. If not present, for example patient's own medicines or labelled for discharge, then the dispensing date must be used as a guide. The expiry date for tablets can be several months from the date of dispensing

  Nurses must use their professional judgement in determining the appropriateness of administering the medication and if in any doubt are advised to contact the dispenser and/or the prescriber
- Identifying stock that is no longer required that must be returned to the pharmacy
- Medicines must be kept in the containers they were dispensed in and never be transferred from one container to another
- Ensuring that the medicines refrigerator is functioning with parameters, between 2 ºC and 8 ºC and all alerts from Tutela have been checked and actioned appropriately (refer to the Tutela Operation procedure for further advise)
- Ensure room temperatures where medicines are stored are within safe parameters, must not exceed 25 ºC and all alerts from Tutela have been checked and actioned appropriately (refer to the Tutela Operation procedure for further advise)
- If the clinic area does not have the Tutela digital monitoring system, calibrated manual thermometers in the refrigerator and clinic room where medicines are stored must be monitored on a daily basis using a manual thermometer and the readings must be recorded.

7.3.5 Local systems must be in place for accessing keys and the steps to be taken should keys be lost or inadvertently taken home by a member of staff.

7.3.6 Summary Storage of Medicines

| **Principles** | **Rationale** |
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|---|---|
| **Security**: medicine cupboards and trolleys must be to current British standard, made of metal, lockable and fixed to the wall. An open drug trolley or cupboard should never be left unattended. | To prevent unauthorised access and deter abuse and/ or misuse |
| **Separate storage**: medicines including injections and inhalers, must be in a separate cupboard or shelf within a cupboard. **Separate storage**: for Controlled Drugs (Schedule 2 and 3).<br>**Separate storage**: for preparations for oral use those for topical use. | To prevent unauthorised access and deter abuse and/or misuse<br>To comply with legislation and provide security,<br>To prevent confusion and risk to patients/clients |
| **Stability**: no medical preparations should be stored where it may be subject to substantial variations in temperature, i.e. next to a radiator<br>Some preparations require storage under defined conditions e.g. refrigerator.<br>Medicines requiring refrigeration should be kept in a locked medicines refrigerator.<br>Temperature records must be kept for both medicines refrigerators and room temperature where medicines are stored. | To ensure medicine is suitable quality for administration to patient.<br>To prevent deterioration of the medicines<br>To prevent deterioration in medicines<br>Maximum and minimum temperatures in the refrigerator and room where medicines are stored must be monitored and recorded daily |
| **Medicinal preparations** should never be transferred from one container to another except in the pharmacy. Inadequate labeling of repackaged medicines is dangerous. | The type of container may significantly influence the stability of the contents and risk of error. |
| **Stock control**: A system of stock rotation must be operated to ensure that there is no accumulation. | All medicinal preparations kept are suitable for administration. Reduce waste through 'out of date' medicines. |

**If there is any doubt about the storage requirements of any preparation then seek the advice of the pharmacy team.**

7.3.7 Products with Specific Storage Requirements

- Aerosol containers should not be stored in direct sunlight or near radiators
- Creams may deteriorate rapidly if subject to extremes of temperature
- Eye drops and eye ointments may become contaminated with micro-organisms during use and should be discarded 14 days after opening. On opening the date should be recorded on the label
- Mixtures may have a short shelf life once opened

- Some antibiotic mixtures require refrigerated storage
- Always check the label for details
- Tablets and capsules are susceptible to moisture unless correctly packed therefore only store in the containers in which they are supplied from pharmacy
- Vaccines and similar preparations usually require refrigerated storage and may deteriorate if exposed to heat.

7.3.8 Patient bedside medicine lockers may only be used for the storage of medicines specifically labelled for that individual patient, and which are suitable for this type of storage.

## 7.4 Custody of Medicines Keys

7.4.1 The registered healthcare professional that has the keys in their custody at any given time is responsible for ensuring their safe-keeping.

7.4.2 Keys must be returned to a locked cupboard, or the custody of a senior staff member (e.g. duty manager) when not in use e.g. if the clinical area is closed over a weekend. Spare keys must also be kept securely in a central location, which is known by the designated person.

7.4.3 Medicine storage area or cupboard keys must not be labelled as such to improve security.

7.4.4 The loss of any medicines cupboard keys must be reported immediately to the manager of the clinical area and the Trusts Pharmacy service. If keys have been taken home in error by a staff member, every effort must be made to retrieve the keys as soon as possible.

7.4.5 Where medicines cupboard keys cannot be located after a simple investigation, this must be reported as a medication incident. Where keys remain unaccounted for, all locks must be changed as a matter of urgency.

## 7.5 Misappropriate or Misuse of Medicines

7.5.1 Any losses of medicines, or discrepancies in the stock holdings of medicines must be investigated as a matter of urgency.

7.5.2 Where there is any suggestion that misappropriation or misuse of medicines may have occurred, this must be reported to the manager of the clinical area and the relevant pharmacist immediately; advice regarding the ongoing safe and secure handling of medicines will be provided by the Trusts Pharmacy service.

## 7.6 Patient Custody of Medicines

7.6.1 Patients may keep custody of medicines subject to a satisfactory risk assessment, where it is clear that:

- this permits timely administration of the item e.g. nicotine replacement lozenges or inhalators

- the patient is required to self-administer on demand, or intimately e.g. clotrimazole cream
- this is in keeping with the approved in-possession protocol for the clinical area

7.6.2 Where the patient maintains custody of medicines item(s), processes must be in place to appropriately handle medicines waste, monitor use of the item(s), limit diversion or misuse and document medicines use appropriately on the relevant care or prescription records.

## 8.0 CONSENT

| Refer to Mental Capacity Act regulations for further details |
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8.1 Every adult must be presumed to have the capacity to consent or refuse treatment, including medication, even where this may be detrimental to their health/condition. The Mental Capacity Act 2005 Code of Practice sets out a two stage test of capacity:

**Stage 1:** Does the person have an impairment of, or a disturbance in the functioning of, their mind or brain?

**Stage 2**: Does the impairment or disturbance mean that the person is unable to make a specific decision when they need to?

The Act states that a person is unable to make a decision if they cannot either

Understand information about the decision to be made (relevant information)

Or

Retain that information in their mind

Or

Use or weight that information as part of the decision-making process

Or

Communicate their decision (by talking, using sign language or any other means).

(i.e. If any one of the above for conditions applies, the person effectively lacks capacity)

8.1.1 In general patients have the right to refuse medication. However, areas where further consideration would apply are:

- An unconscious patient.
- A client on a Section of the Mental Health Act, when a second opinion has been sought and agreed (A patient on a Section 2 or the first three months of a Section 3 does not necessarily have the right to refuse medication for their mental disorder).
- A patient who is incapable of consent by virtue of their condition.
- In life threatening situations, would require immediate action

In these instances the doctor or senior nurse must be contacted.

The multidisciplinary team caring for the patient should decide whether or not the patient has

the capacity to consent. Patient's relatives (even a spouse) cannot consent on the patient's behalf unless a valid lasting power of attorney (LPA) is in place. However the views of family and friends may be helpful in clarifying the patient's wishes.

8.1.2 In some cases the patient may have indicated consent or refusal at an earlier stage, while still competent, in the form of an Advance Decision to refuse treatment. If this decision is applicable to the present circumstances and there is no reason to believe that the patient may have changed their mind, then the patient's wishes as expressed should be respected. (See the Covert Administration of Medicines Policy). Good practice suggests that discussions and decisions involving consent should take place during periods when capacity is present.

## 8.2 Mental Health / Learning Disability

Patients who are unable to consent due to their mental health condition/learning disability may have medicines administered to them where the appropriate safeguards have been met:

- Their capacity to consent must have been formally assessed and the decision recorded in their notes
- The treatment proposed must be essential for their well-being, and the benefit outweighs any risks
- Decision to treat is made after discussion with their representative - relative/ carer /attorney/advocate/Independent Mental Capacity Advocate
- Covert administration of medicines must only be used in exceptional circumstances
- Capacity to consent must be reassessed at regular intervals.
- No-one is able to consent on behalf of another adult apart from a donee of a lasting power of attorney or a Court of Protection Appointed Deputy.

## 8.3 Children

Children under the age of 16 are legally assumed to lack the capacity to consent, unlike those 16 years and over that are assumed to have capacity to consent. It is the clinicians responsibility to ascertain whether the child has the capacity and competence to consent. It should be noted that children under the age of 16 are unable to refuse treatment. Therefore offering a range of treatment options will be beneficial to the child. Where a child is deemed incapable of consenting to treatment; the right to do so remains with the person who has parental responsibility for the child. However, the child should always be involved in the decision making processes to their fullest capacity. Where a child is considered to have significant understanding and intelligence (sometimes referred to as Gillick competency) to make up his/her own mind and understand the associated costs and benefits, the child should be the person that gives informed consent.

Children aged 16 or 17 are presumed to be able to consent for themselves, but the refusal of a child of any age may be overridden by those with parental responsibility for the child in exceptional circumstances. In very exceptional circumstances this may involve seeking an order from the court or making the child a ward of court.

## 8.4 Covert Administration of Medicines

| Refer to the Covert Medication Policy for further guidance. |
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Covert administration of medication is a complex issue that involves the fundamental principles of patient autonomy and consent to treatment. The covert administration of medicines is only likely to be necessary or appropriate in the case of patients who actively refuse medication but who are judged not to have the capacity to understand the consequences of their refusal.

## 9.0 MEDICINES FOR DISPOSAL/WASTE

| Refer to the Waste Policy and Controlled Drugs Policy for further guidance. |
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9.1.1 All unwanted medicines must be disposed of safely and in accordance with special waste regulations.

9.1.2 Most medicines that are intact i.e. not contaminated and in complete packaging should be returned to pharmacy in secure packaging for pharmacy to dispose of. Pharmacy will store all waste medicines separately to stock medicines and will consign the waste as hazardous prior to collection by Tradebe on a monthly basis.

9.1.3 Controlled drugs require complete records to identify return to pharmacy in the ward register.

9.1.4 Contaminated medicines waste for example syringe and needles containing medicines residue or giving sets should be disposed of at ward level in suitable yellow ‘sharps’ bins. Wards should ensure these go into site waste stream with appropriate European waste code.

9.1.5 Medicines may be ‘unwanted’ for the following reasons:

- Out of date
- Damaged
- Stock no longer used
- Excess stock.

### 9.2 Unwanted Patients Own Medicines

Medicines brought in by a patient are their own property and should not be removed without their consent. It will be assumed that unless confirmed otherwise patients own medications received in pharmacy have been sent for safe disposal with the patients consent.

## 10.0 MEDICATION SAFETY

An open, fair-blame culture exists in the Trust in order that health professionals feel able to immediately admit to errors without fear of unjustified retribution (ref. Nursing and Midwifery Council: Guidelines for The Administration of Medicines – October 2007).

10.1.1 Medicines incidents are defined as any unintended, unexpected or unwanted incident involving the medicine; that could have, or did, lead to harm of one or more

patients under the care of the Trust. A near miss incident is an incident that has occurred that had the potential to harm, but harm was avoided by actions or interventions by others.

10.1.2 Medicines incidents can occur at any stage of the medicines management process, such as ordering, prescribing, dispensing and administration of medicine, as well as the transfer of information regarding medicines.

10.1.3 Any medicine error should be reported immediately to the relevant line manager and the appropriate medical officer contacted for advice. The area where the error has occurred is then responsible for completing an incident form, investigating the error and taking any necessary action to prevent any recurrence and to identify relevant learning points.

10.1.4 Untoward incidents have to be distinguished from adverse drug reactions, which constitute an inherent risk in any treatment and do not arise as a result of error or accident, (See section 6.5.2). However, sometimes an untoward incident may lead to an adverse drug reaction, in which case full details should be reported.

10.1.5 All medication incidents and errors that require reporting or investigation are handled according to the relevant Trust policies, procedures and guidance for reporting incidents and conducting investigations (complaints, incidents and claims). Duty of Candour applies to medication incidents in the same way as it does to any other incident.

10.1.6 Directorate leads will share learning from errors identified following local review of medicines incidents with Clinical Effectiveness Group (CEG) at each meeting. CEG members should highlight issues raised through other networks which may be applicable to our care settings. Learning will include review of trends, proposed changes to policy or clinical guidelines to minimise future errors related to medicines use. CEG will review the learning and agree how to share to relevant areas of Trust of more widely across the Health Economy.

## 10.2 Dispensing Errors

If a medicine leaves the pharmacy and has been dispensed incorrectly, even if it has not been given to the patient, an incident report must be completed and the pharmacy team must be informed.

## 10.3 Prescribing Errors

10.3.1 All prescribing errors must be reported by either the prescriber or the person who identified the error as a medication incident, in line with Trusts Incident Reporting Policy. Prescribing errors must also be directly reported by the prescriber to their line manager as appropriate for the area of work, and type of prescriber, as outlined below.

10.3.2 Where an error in prescribing results, or may result, in a patient receiving a treatment not as intended then this must be reported to the person in charge of the patient's care, either by, or with the knowledge of the prescriber. Where there is no single person in charge of the patient's care, alternative arrangements must be in place with clear lines of accountability. Prescribing errors must also be directly reported by the prescriber to their line manager as appropriate for the area of work, and type of prescriber, as outlined below.

10.3.3 Where the prescription is correct but the drug is wrongly administered then see below 'Administration Errors'.

10.4 Error in Administration of Medicines

10.4.1 As soon as an administration error is identified the following action must be taken:

- Remedial action taken to ensure the safety of the patient, seeking advice where necessary
- Where appropriate, the doctor/prescriber overseeing the patient's care must be contacted and informed
- The person who has made the error must report this to their line manager as soon as possible
- The Pharmacy team should be informed if the packaging or labeling of the medication has contributed to the cause of the error so any appropriate action can be taken to mitigate against reoccurrence elsewhere.

10.4.2 All administration errors including omissions must be reported as a medication safety incident.

10.4.3 The nurse in charge of the ward /unit must:

- Inform the patient and/or next of kin
- Observe the patient based on the advice given by the medical officer
- Report and record any effects of the drug that has been administered
- Complete an incident form and forward it to the senior nurse who will initiate a thorough investigation
- Record all details in the patient's notes.

10.4.4 Following completion of the investigation it may be identified that the competence of the member of staff is in question. In this case it may be necessary to suspend the member of staff from administering medicines whilst training and re-assessment of competence takes place.

10.4.5 Senior managers should seek advice from the Director of Nursing and Quality if, on investigation, there appears to be an issue of professional misconduct or if there are recurring trends in maladministration of medicines.

10.5 Adverse Drug Reaction

10.5.1 All healthcare professionals and members of the public can now freely report Adverse Drug Reactions (ADR) to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme. Reports can be made on prescribed medicines and medical devices, over the counter medicines and complimentary medicines including herbal remedies.

10.5.2 Online reporting can be completed through https://yellowcard.mhra.gov.uk/ or reports made by telephone (by patients only) via the Yellow card hotline on free phone 0808 100

3352.

Paper copies of the Yellow card are also available from community pharmacies, GP surgeries and other NHS outlets as well as at the back of the BNF, NPF and MiMS publication.

10.5.3 Trust staff must report any suspected ADR to the prescriber or person responsible for the person's care, and ensure that details of the suspected reaction are clearly documented in the patient's medical records; and where an Electronic Patient Record (EPR) is in use, in the relevant alerts section.

10.5.4 If the ADR is reported to the MHRA via the Yellow Card Reporting Scheme, a copy of the ADR reporting form and responding letters from the MHRA must be included into the EPR. Where the ADR is judged to have caused harm to the patient, this must be reported as a medication incident.

10.5.5 Where a patient experiences an ADR following suspected use of a Novel Psychoactive Substance (NPS) this must be reported. The MHRA and Public Health England have launched a pilot scheme for reporting the effects of new psychoactive substances (NPS) and other illicit drugs through the Report Illicit Drug Reactions (RIDR) scheme:

Healthcare professionals can report the effects of New Psychoactive Substances (NPS) via the Report Illicit Drug Reactions (RIDR) web form https://report-illicit-drug-reaction.phe.gov.uk/.

10.6 Drug Alerts

10.6.1 When an error occurs in the manufacture of a medicinal product, the Medicines and Healthcare Products Regulatory Agency (MHRA) will issue a Drug Alert. This alert is emailed to pharmacy services and circulated via the Trust 'CHCT Medicine Alert Cascade' email group. Alerts will usually detail the following:

- the affected product(s)
- the relevant strength
- the relevant dose form
- the relevant pack size(s)
- the batch number(s) of affected product(s)
- the manufacturer
- the nature of the product defect
- what action is required by clinical areas

10.6.2 All clinical areas must respond to drug alerts and other similar safety notices according to the request of the nominated lead for that alert.

10.6.3 Drug Alerts are classified according to the urgency and timescale for action:

- **Class 1** - Action now (including out of hours)
- **Class 2** - Action within 48 hours
- **Class 3** - Action within 5 days
- **Class 4** - Caution in use

10.6.4 Pharmacy staff will, in all cases, check stock holdings and stock records to determine whether a faulty batch has been handled by the pharmacy service. If faulty stock has been received and the fault is serious in nature then it may be necessary to contact all clinical areas in turn in order to identify, isolate and plan to replace any affected stock.

10.6.5 It is the responsibility of the Pharmacy team via Directors and Managers, to ensure that all service areas in their locality are notified of the drug alert and the level of action to be taken.

10.6.6 Quality Improvement Leads Nurses, ward or unit managers and clinical leads should ensure relevant actions are completed at each level for their areas.

## 10.7 Defects in Medicines and Appliance/Devices

10.7.1 Managers of every clinical area must ensure that any devices or appliances that are used as part of the handling of medicines (such as syringe pumps, infusion devices) are on the asset register for that area, to ensure that they are serviced regularly and in good working order.

10.7.2 This section refers to locally identified defects rather than national defect alerts. The aim, in all cases is to isolate the product and report the defect to the manufacturer.

10.7.3 The following are examples of possible medicine defects:

- Hairline cracks in ampoules
- Labelling on containers that do not correspond to the outer wrap
- Different odour or colour than normal
- Unexpected clinical reaction (e.g. pyrexia)
- Quality of dressing lower than normal

10.7.4 All suspected medicine/dressing/appliance defects should be reported as soon as possible to the relevant pharmacist who will inform the Medicines Safety Officer/Medical Devices Safety Officer and Principal Pharmacist as appropriate. The pharmacist should be informed of:

- The nature of the defect
- The manufacturer's name
- The name of the product
- The batch number
- The expiry date

10.7.5 Outside of usual pharmacy opening hours, the on-call pharmacist can be notified. If in doubt, any issues must be reported. All defects must be reported as a medication safety

incident.

10.7.6 Remedial action should be taken to minimise the immediate risk to patients, staff and the environment. The defective material should be isolated, labelled clearly and retained for safe keeping. This includes any associated products such as administration sets/ syringes. If further medication is required, this should be taken from a different batch.

10.7.7 If a patient is involved, use of the suspect material must be immediately discontinued and the professional in charge of the patient notified immediately, and an entry made in the patient's notes.

10.7.8 For further advice on how to manage defective devices refer to the Medical Devices Policy.

## 11 CLINICAL TRIAL MEDICINES

11.1 Refer to the Trust's Standard Operating Procedure for Pharmacy Support of Clinical Trials (SOP No. 028) and Research Governance and Management Policy (No.1.52a)

11.1.1The Trust supports the safe use of Investigational Medicinal Products (IMPs) where appropriate. All staff involved with the research process have an understanding and be aware of their responsibilities with respect to the relevant legislation and guidance, Trust policies and procedures, and act in accordance with these.

11.1.2 Medicines are subject to human testing prior to licensing and established products may be investigated for new indications. All such testing and investigations are regulated in the UK by the Human Medicines Regulations (2012) and the Medicines for Human Use (Clinical Trials) Regulations (2004) (SI 2004/1031 and subsequent amendments). The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the implementation and monitoring of these regulations.

11.1.3 All clinical trials that fall within this remit will require regulatory approvals in the form of a favourable opinion from a Research Ethics Committee (REC), Health Research Authority (HRA) approval, NHS Confirmation of Capacity and Capability (NHS C&C) from the Trust and a Clinical Trials Authorisation (CTA) from the MHRA. All IMP need to be manufactured to Good Manufacturing Practice (GMP) Standards and trial sites (organisations) are subject to MHRA Good Clinical Practice (GCP) inspection.

11.1.4 While some clinical trials will involve the use of existing marketed products used within their licensed indications, others will use new medicines, formulations or methods of administration unfamiliar to staff handling them. IMPs may also be coded to prevent ready identification by Investigator or Patient. Extra precautions need to be taken to ensure safety and security in their use.

11.1.5 Each clinical trial must have a Sponsor, responsible for the initiation, management and financial arrangements of the trial. The Sponsor may be a pharmaceutical company, a clinical research organisation, an NHS organisation, an academic institution, or a combination of these. The Sponsor may delegate responsibility for defined and agreed trial duties.

11.1.6 The National Institute for Health Research (NIHR) Clinical Trials Toolkit can be found at (www.ct-toolkit.ac.uk). This provides information and best practice, and outlines the current legal and practical requirements required for conducting clinical trials.

11.1.7 Any staff involved in the adoption of a clinical trial involving medicines within the Trust must notify the Trust Chief Pharmacist, Medical Director and Trust R&D Governance Officer to seek the relevant guidance and permissions.

11.2 Clinical Trial Support from Trust Pharmacy Services

11.2.1 Trust pharmacy services must provide support for all clinical trials involving medicines within the Trust.

11.2.2 A designated pharmacist must have overall responsibility for the pharmacy clinical trial service, and for organising and overseeing pharmacy support.

11.2.3 The designated pharmacist must be involved in all stages, including feasibility, site selection, site set-up, site initiation, site monitoring, site close-down, working closely with the Trust R&D Department, Investigator(s) and Sponsor(s), ensuring the appropriate arrangements are in place for the safe and secure storage, dispensing, labelling, reconciliation and destruction of all trial medicines.

11.2.4 The designated pharmacist must ensure that NHS confirmation of capacity and capability (NHS C&C) has been received for a trial from the R&D Office at the Trust before commencing any trial activity.

11.2.5 The designated pharmacist must ensure that the pharmacy department has copies of all essential regulatory and technical documents, a copy of the study protocol, an investigator brochure or summary of product characteristics, if applicable and randomization codes, if relevant before the commencement of a clinical trial.

11.2.6 The designated pharmacist must carry out risk assessments for each clinical trial, and put procedures in place to minimize the predictable risks from trial medication to patients and staff.

11.2.7 The designated pharmacist must ensure that all medicines provided or procured for use in a clinical trial are of suitable quality and fit for purpose i.e. are manufactured in accordance with Good Manufacturing Practice, by a holder of a relevant manufacturing authorisation.

11.2.8 The designated pharmacist must ensure that packaging and labelling of clinical trial medication is acceptable and appropriate for use within the Trust and complies with applicable legislation.

11.2.9 The designated pharmacist must ensure that all aspects of ordering, receipt, storage, dispensing, labelling, distribution and destruction of trial medicines are in adherence with Good Clinical Practice (GCP) standards and the trial protocol.

11.2.10 The designated pharmacist must keep records of receipt, storage temperatures, dispensing, issue, return and disposal of trial medicines in adherence with the trial protocol.

11.2.11 The designated pharmacist must be responsible for management of IMP stock, including IMP accountability and any other duties as delegated by the Investigator. A written agreement or contract, detailing these delegated duties and pharmacy fees, should be in place for each clinical trial.

11.2.12 The designated pharmacist must ensure that all stocks of trial medicines are held with trust pharmacy services, not kept in clinical or office areas. Trial medicines must also be stored separately from all other pharmacy stock, in an area with restricted access and appropriate means of temperature control and monitoring.

11.2.13 The designated pharmacist must ensure that appropriate standard operating procedures (SOPs) for pharmacy are in place.

11.2.14 The designated pharmacist must ensure that pharmacy trial files are inspection ready at all times for internal and external monitoring purposes.

### 11.3 Prescribing and Administration of Clinical Trial Medicines

11.3.1 IMP prescribing must be by study specific authorised prescribers only. A record of prescribers will be kept in the trial specific pharmacy file.

11.3.2 IMP prescribing must be on an authorised, study specific prescription form or a clearly annotated trust prescription form. Authorised study specific stickers may be used to facilitate this. In general, a trial prescription should include:

- official trial name and protocol number
- visit number
- patient identifying details: name, address, date of birth, hospital number, and trial subject number if relevant
- quantity of trial medicine required for the prescribed treatment period as outlined in the trial protocol
- dose, frequency, duration and route of administration

11.3.3 Administration of trial medicines to trial participants must be undertaken in line with the trial protocol, and agreed Trust Medicines Policy procedures.

11.3.4 Clinical staff working in areas where there are patients being prescribed with trial medicine(s) must ensure they are aware of all relevant information related to the trial. This should include the procedures for safe storage of trial medicines, and required documentation of medicines administrations. Clinical staff should contact the designated pharmacist or R&D Office for information.

## 12.0 MEDICAL REPRESENTATIVES FROM THE PHARMACEUTICAL INDUSTRY

The medicines and healthcare products regulatory agency (MHRA) is responsible for enforcing legislation on advertising and promotion of medicines. Advertising and promotion is strictly regulated under the Medicines (advertising) Regulations 1994.

All medical representatives promoting medications must comply with this legislation and are asked to identify themselves, their company and the products that they are promoting.

It is recommended that representatives are only seen by pre-arranged appointments, or as part

of formal Trust 'meetings' such as education sessions. Medical representatives must not enter patient/clinical areas.

Any exceptions to this rule should be authorised by the senior manager in charge; patient confidentiality and privacy must be considered and maintained at all times. **No patient information should be given to representatives.** All hospitality accepted from representatives must be clearly identified and should comply with Trust policy Standards of Business Conduct Policy.

## 13.0 DEFINITIONS/GLOSSARY OF TERMS

- **Adverse drug reaction (ADR)** – a broad term referring to an outcome caused by a medicine that is unintended or unexpected, such as harm or injury
- **Allergy** – a reaction the body has to a particular food or substance, like a medicine, that is the result of the reaction of the immune system to that substance
- **Administration (of medicines)** – the giving or application of a medicine to a person for immediate use, under the direction of a prescription or a prescriber, or through another authorised means
- **Clinical area** – a hospital ward, healthcare team or other kind of healthcare department e.g. a healthcare service within an Offender Health setting or a clinic. A clinical area may compromise, or be responsible for a range of areas where medicines are stored e.g. a 'pharmacy' and multiple clinic rooms in house-blocks of an Offender Health setting.
- **Community teams** – will usually refer to community mental health teams that, depending on their configuration or arrangements, may utilise multiple areas for medicines use and storage
- **Critical medicine** – specified medicines that must be administered in a timely manner in order to prevent likely harm to the recipient
- **Delegated pharmacist** – the pharmacist identified as responsible for day-to-day support to that clinical area by the Chief Pharmacist
- **Dispensing (of medicines)** - the preparation, packaging, labelling and record keeping, where appropriate, of a medicine or medicines for a patient
- **External pharmacy provider** – a pharmacy service that supplies medicines to a clinical area under the terms of a contract, or similar arrangement, but that is not part of the Trust
- **Independent Prescriber (IP)** – a healthcare professional other than a doctor or a dentist who is authorised to prescribe medicines, with or without some level of restriction
- **Offender Health settings** – healthcare services within prisons or immigration removal centres
- **Prescribing** – the process of advising or authorising the use of a specified medicine (or treatment) for an individual patient, especially in writing

- **Secondary dispensing** – the re-dispensing of medicines that have already been dispensed by a pharmacy for an individual patient by a healthcare professional, usually into smaller aliquots

## 14.0 DUTIES

- The Executive Medical Director and Deputy Director of Medicines and MACE are responsible for setting the standards by which all staff are expected to act with respect to medicines. Further to this, the Executive Medical Director is accountable for the performance of all Medical Staff and the Deputy Director of Medicines and MASE is accountable for the performance of all Pharmacy Staff.

- The Controlled Drugs Accountable Officer has a statutory responsibility for advising the Trust on, and putting in place systems to ensure the safe use of Controlled Drugs. The Medication Safety Officer has a statutory responsibility for advising the Trust on, and putting in place systems to ensure the safe use of medicines and continuous learning to improve medication safety.

- Directorate senior management teams are responsible for the performance of their services with respect to all aspects of this Code.

- Quality Improvement Leads Nurses and managers of clinical areas in conjunction with directorate and Trust level managers have additional responsibilities for ensuring that staff, working in areas that they are responsible for, are adhering to the standards laid down in this document.

- All managers of clinical areas are responsible for ensuring that their staff, especially new starters and temporary staff members (as practices may differ between organisations), are aware of the content of this document, and practice accordingly.

- All members of staff working in the Trust who are involved in the handling of medicines in any way are responsible for ensuring that they are aware of the contents of this document, and practice accordingly.

## 15.0 IMPLEMENTATION

Implementation of the Medicines Policy is the responsibility of all staff members who are involved in any aspect of the handling of medicines.

## 16.0 TRAINING

16.1 All registered nurses, medical staff and other relevant staff MUST complete eLearning Medicines modules including medicines policy, adverse effects of medicines and drug calculations. This training must be completed on induction and should be repeated if appropriate to change in role.

16.2 Additional training will be made available to support clinical areas on an ad-hoc basis, including on subjects such as Controlled Drugs and High risk medicines (e.g. clozapine) & groups of medicines (e.g. antimicrobials)

16.3 All Trust staff must work according to any professional codes of conduct, performance or ethics that exist governing their professional group. Professional leads must ensure that the Trust Clinical Effectiveness Group are made aware of any update to such Codes, and can

undertake an impact analysis.

NHS North Staffordshire Combined Healthcare NHS Trust

**APPENDIX 1**

# NURSING ASSOCIATES SCOPE OF PRACTICE

Nursing Associates (NA) are a new cohort of healthcare staff who are intended to provide high quality support to the care and nursing workforce. Trainee Nursing Associates (TNA) complete a University level programme of study and proceed to register with, and be regulated by the Nursing and Midwifery Council (NMC).

On completion of the medicines aspects of their University training, a trainee nursing associate (under supervision) and registered nursing associate can independently:

- Order stock medicines from the pharmacy except controlled drugs (CDs)
- Receive and safely store stock medicines except controlled drugs
- Order medicines for an individual patient from the pharmacy
- Transport medicines
- Dispose of medicines except controlled drugs
- Witness the receipt, administration balance/stock check and return of controlled drugs

When on the relevant professional register, nursing associates can proceed to complete a competency assessment and be signed off by their line manager before they may independently:

- Administer regular medicines by the following routes: PO, TOP, SC, PR and INH
- Administer 'STAT' and variable dose prescriptions by the same routes
- Administer medicines covered by Mental Health Act Consent to Treatment paperwork

Subject to completion of further training and competency assessment a registered nursing associate can proceed to independently:

- Administer medicines covertly
- Administer 'when required' (PRN) medicines
- Administer medicines by any other route (subject to an agreed training package and competency demonstration)

Trainee nursing associates and registered nursing associates may not:

- Dispense medicines
- Administer clinical trial medicines unless this is specifically stated in the study protocol
- Supply or administer medicines using a Patient Group Direction (PGD)
- Accept/document/administer remote orders from prescribers e.g. GOLDFAX requests
- Be the designated holder of controlled drug keys on a shift
- Manage illicit substance process on the ward
- Prescribe medicines
- Process verbal orders and instructions
- Transcribe
- Supply or administer medicines using a PGD

- Order CDs from Pharmacy
- Receive CDs from pharmacy
- Administer CDs
- Administer Rapid Tranquilisation
- Act as an authorised witness for the purpose of disposal or destruction of CDs

**Supervision by Registered Nursing Associates**
Once nursing associates have completed their preceptorship and gained 6 months experience following registration they may undertake the supervision of administration by trainee nursing associates. This supervision is only permitted for administration of medicines within the scope of competencies outlined above.

**APPENDIX 2**

## Part 1

## MEDICINES ORGANISER INFORMATION FORM FOR PATIENTS ADMITTED WITH A MEDICINES ORGANISER

| | |
|---|---|
| Surname | Date |
| Forename | Unit No |
| Ward | DOB |
| Discharge Address | |

| |
|---|
| Community Pharmacy Name |
| Address<br><br>Telephone number |
| **Important** if patient was admitted with a compliance aid filled by a community pharmacy contact them to cancel further supplies of the compliance aid.<br>Name of contact:<br>Date: |

**Reason Compliance Aid Required on Discharge**

| | |
|---|---|
| Patient used a compliance aid prior to admission and self-medicated<br>(No ward use required before discharge) | |
| Patient used a compliance aid prior to admission and carer prompted / administered medication<br>(No ward use required before discharge) | |

**Disclaimer**

Stability data for medication packaged into a Compliance Aid is NOT always available from the pharmaceutical manufacturers. The Pharmacy department will endeavour to offer stability advice for individual medicines.
The Doctor needs to sign the form accepting that not all stability information is currently available but this compliance aid is the best option for the patient.

| | |
|---|---|
| Doctors Signature | Date |
| Nurse Signature | Date |
| Pharmacy Signature | Date |

1

**Part 2**

**ASSESSMENT FORM FOR NEWLY IDENTIFIED PATIENTS REQUIRING A MEDICINES ORGANISER**

| | |
|---|---|
| Surname | Date |
| Forename | Unit No |
| Ward | DOB |
| Discharge Address | |

| |
|---|
| Community Pharmacy Name |
| Address<br><br>Telephone number |
| **Important** Contact the community pharmacy to arrange further supplies of the compliance aid.<br>Name of contact:<br>Date: |

**NATURE OF COMPLIANCE PROBLEM**

| | |
|---|---|
| The patient does NOT have a relative who can administer their medication for them | |
| The patient forgets to take their medication | |
| The patient does not understand how much, how often and when to taken their medication. | |
| The patient sometimes decides not to take their medication. | |
| The patient has visual impairment and is unable to read labels on medication | |
| The patient has impaired cognitive function | |
| The patient has lack of dexterity. | |
| The patient has lack of understanding. | |

| | |
|---|---|
| Patient will self-medicate from a compliance aid once discharged<br>(Use on ward for two weeks maximum prior to discharge) | |
| Carer will prompt/ administer medication once discharged<br>(No ward use required before discharge) | |

**Disclaimer**

Stability data for medication packaged into a Compliance Aid is NOT always available from the pharmaceutical manufacturers. The Pharmacy department will endeavour to offer stability advice for individual medicines.

The Doctor needs to sign the form accepting that not all stability information is currently available but this compliance aid is the best option for the patient.

| | |
|---|---|
| Doctors Signature | Date |
| Nurse Signature | Date |
| Pharmacy Signature | Date |

**APPENDIX 3**

**PROFORMA**
**EMERGENCY PRESCRIPTION BY GOLD FAX**

**Doctor …….** **Contact Number ……**

**Name of Patient/client ……**

**Date of Birth ……**

**Name of Ward/unit ……** **Pharmacy Base ……**

**Date ……** **Time ……**

| |
|---|
| **MEDICINE:**<br><br>**DOSE:** **ROUTE:**<br>**SPECIAL INSTRUCTIONS** |
| **REASON FOR EMERGENCY PRESCRIPTION** |

**DOCTORS SIGNATURE ……..**

**PRINT NAME ……...**

**To be completed by nursing staff**

**Date and Time given to patient/client:**

**Effect/Untoward side effects?**

**Appendix 4**

## PRESCRIPTION WRITING

### General Requirements

Basic principles of prescription writing applicable to all, including FP10, inpatient charts, leave and discharge prescriptions.

- All prescribers must recognise and work within the limitations of their competences. Prescribers should be aware of the North Staffordshire Joint Formulary (www.northstaffordshirejointformulary.nhs.uk), prescribing initiatives or preferred prescribing lists that may influence drug choice.
- Prescriptions must be written clearly, in indelible black ink (including type written and computer generated prescriptions).
- Prescribers must sign and date each prescription. It is good practice for the prescriber to also print their name, as identification from a signature can often be difficult.
- Each prescription must contain the address of the prescriber issuing the prescription. For FP10's the authority of the prescriber must be shown - this is often pre-printed.
- The patient should be identified by their full name, date of birth, unit number/NHS number and address. Where anonymity is required an alternative recording criteria should be

identified.

- Prescriptions must not be altered, with the exception of correction or errors, which should be signed and dated by the prescriber. On inpatient drug charts, amendments once administered, must be crossed through, and re-prescribed.

**Drug name**
Most drugs should be prescribed by the generic drug name (International Non-proprietary name). The approved drug name must be printed clearly so that each letter can be read. Do not used abbreviations (e.g. CBZ is not an appropriate way to write carbamazepine) or chemical descriptions (FeSO4 is not appropriate for ferrous sulfate) as they can be misread.

There are exceptions where it is appropriate to use the brand name:

- Differences in bioavailability or release profile between brands, as advised in the British National Formulary (BNF). Examples include lithium, nifedipine, diltiazem long acting formulations, anti-epileptics and theophylline.
- It is appropriate to use both brand name and generic name for insulin, including the device. It may be appropriate to prescribe using the brand name, in addition to or instead of the approved name to avoid confusion, for example some combination products. Combination inhalers should be prescribed by brand and device.
- Patient specific reason such as an allergy to an ingredient has been identified.
- Where through branded prescribing a cost saving has been identified and approved through the Clinical Effectiveness Group (CEG).

Note that for FP10 prescriptions, if a proprietary name is specified, then that brand must be dispensed, and cannot be substituted.

**Formulation/strength**
Where different formulations and/or strengths exist, it is important that details are correctly stated on the prescription.

**Dose**

- The dose must be stated on all prescriptions.
- The dose should be expressed in metric units avoiding unnecessary use of decimal points e.g. 3mg, NOT 3.0mg, as this could read as 30mg.
- Numbers less than 1 should be preceded by a ‘0’, e.g. 0.5mg, NOT .5mg
- Strengths and doses less than 1g, the term ‘milligrams’ or ‘mg’ should be used e.g. 0.5g should be written as 500mg.
- Strengths and doses less than 1mg, the term ‘micrograms’ (unabbreviated) should be used e.g. 0.1mg should be written as 100micrograms.
- The use of a decimal point is acceptable to express a dose range where appropriate, e.g. 0.5 to 1g or 0.5 to 1mg.
- Volume should be expressed in ‘millilitres’ or ‘ml’. Although terms such as c.c. are equivalent to ml, they should not be used.
- Where liquid preparations have a strength, they should be prescribed as milligrams (or other units of weight) NOT millilitres. The strength must be included if there is more than one strength available. Methadone prescriptions can be written in mls as per locally agreed best practice.

- Liquids for oral use without a specific strength (e.g. simple linctus) must be prescribed in millilitres (mls) using a decimal point as required.

Acceptable abbreviations:

| | | | |
|---|---|---|---|
| ***mg*** | ***milligram*** | ***L*** | ***Litre*** |
| ***g*** | ***gram*** | ***ml*** | ***millilitre*** |
| ***kg*** | ***kilogram*** | ***Mmol*** | ***millimole*** |

- Micrograms, nanograms and units must be written in full

## Route

- Only one route should be indicated for each prescription. It is NOT acceptable to prescribe PRN medication as PO/IM. This is important as the bioavailability of a medicine can be altered by route, therefore, a dose adjustment may be required.

Acceptable abbreviations:

| | | | |
|---|---|---|---|
| ***IV*** | ***intravenous*** | ***IM*** | ***intramuscular*** |
| ***SC*** | ***subcutaneous*** | ***PO*** | ***oral*** |
| ***PR*** | ***rectal*** | ***PEG*** | ***via peg tube*** |
| ***Top*** | ***topical*** | ***S/L*** | ***sublingual*** |
| ***NEB*** | ***nebulised*** | ***PV*** | ***vaginal*** |
| ***LE*** | ***left eye*** | ***BE*** | ***both eyes*** |
| ***RE*** | ***right eye*** | ***INH*** | ***inhaled*** |
| ***TD*** | ***transdermal*** | | |

- Other routes must be written in full.
- Specify the precise location or area to be covered for topical drugs.

## Directions

- The dose frequency must me stated on all prescriptions.
- For ‘as required’ medicines a minimum dose interval, and maximum dose where appropriate should be stated.

Acceptable abbreviations:

| | | | |
|---|---|---|---|
| ***OD*** | ***daily*** | ***OM*** | ***in the morning*** |
| ***BD*** | ***twice daily*** | ***ON*** | ***at night*** |
| ***TDS*** | ***three times a day*** | | |
| ***QDS*** | ***four times a day*** | | |
| ***PRN*** | ***when required*** | | |

- Other dose frequencies must be written out in full.
- When a limited course of treatment is required (e.g. steroids, antibiotics) this must be stated on the prescription.

**APPENDIX 5**

## CRITICAL MEDICINES LIST

Medicine doses are often omitted for a variety of reasons. It is generally considered

acceptable to administer most medicines within two hours of the time the dose is due (before or after). However, for some critical medicines or conditions, delays or omissions can cause serious harm or death.

The following is a list of medications (and conditions where appropriate) where timeliness of administration is critical. This list is not exhaustive. Always check the BNF if unfamiliar with a medicine and contact a doctor or pharmacist if you have concerns about its delay or omission.

| **Drug** (oral and injectable unless otherwise stated) | **Example(s) and Comments** |
|---|---|
| Medicines for alcohol withdrawal | Chlordiazepoxide |
| Opioid Analgesics | |
| Anticoagulants | Low molecular weight heparins, warfarin, rivaroxaban, dabigatran |
| Antidepressants (MAOIs) | Isocarboxazid, moclobemide, phenelzine, tranylcypromine |
| Antidepressants (short half life) | Duloxetine, paroxetine, venlafaxine |
| Antiepileptics | When used for epilepsy |
| Antimicrobial agents (all) | Antibacterial, antifungal, antiviral, MRSA decolonisation |
| Benzodiazepines | In the context of known dependence |
| Short-acting bronchodilators | Salbutamol, terbutaline, ipratropium |
| Chemotherapy, including cytotoxics and adjunctive | |
| Clozapine | |
| Contraception, including emergency | For use as contraceptives, not other off-label uses |
| Corticosteroids | Prednisolone, hydrocortisone |
| Desmopressin | Used for cranial diabetes insipidus |
| Medicines for Extrapyramidal side effects | Procyclidine IM |
| Immunosuppressant medicines | Used post organ transplant or in the management of the acute flare of a chronic condition |
| Injectable medicines for diabetes | Insulin, exenatide, liraglutide, glucagon |
| Medicines for treatment of HIV | |
| Lithium | |
| Nitrates (sublingual) | Glyceryl trinitrate for acute angina |
| Parkinson's disease treatments | Levodopa containing medications, ropinirole |
| Rapid tranquilisation medicines | |
| Resus/emergency medicines | Adrenaline |
| Symptom control medicines at the end of | |
| Vitamin K (phytomenadione) | |

During normal working hours, if the medicine is not available contact the prescriber/supplying pharmacy to obtain a supply. Out of hours the duty doctor or on-call pharmacist (where available) should be contacted without delay and they will use their clinical judgement to advise to defer a dose or make arrangements to supply, as appropriate.

Omission or delay of critical medicines are patient safety incidents and should be reported as such on Ulysses. It is not acceptable to leave a blank space on the administration record grid; a reason code must always be documented if a dose has not been given.



**APPENDIX 6**

# Self-Administration Guidelines

## Definition

The patient in hospital is allowed to retain all prescribed drugs and is responsible for taking them at the appropriate time, with the nurse acting as educator and supervisor.

(Davis 1991)

## Statement

Some areas of the Trust committed to the self-administration programme being developed and supported.

## Principle

To ensure that all patients who meet the criteria for inclusion on the self-administration programme are offered the opportunity to participate, in those areas where the programme is running.

## Purpose

The main aims of the self-administration programme are:

- To improve patient knowledge about their medications
- To improve patient compliance on discharge
- To maintain and/or increase independence.

## Guidelines for Practice

Assess the patient for inclusion on the self-administration programme using pre-set criteria – (section a).

Patients who meet the criteria will:

- Have a full structured assessment completed by both nursing and pharmacy staff. - (section b).
- Receive written information. – (section c).
- Sign a consent form and accept responsibility for their own key on stages 2 and 3 of the programme. – (section d).
- The consultant/GP with clinical responsibility for the patients (or a delegated member of the medical team) will document their agreement to the patient's participation on the programme in the medical notes.
- Patient's individually dispensed medication will be kept in a locked Medication box, securely attached to their locker (or other suitable place).
- In situations where the patients' own medication is used (i.e. from Home) identified guidelines will be followed (section e).

## Controlled Drugs

Use of Controlled Drugs in the self-administration programme is dependent, at present, on the classification of the drug being used. Only controlled drugs classed as schedule 4 and 5 (excluding morphine sulfate liquid 10mg/5ml) maybe permitted on the self-administration programme.

## a. CRITERIA FOR ADMISSION TO THE SELF-ADMINSTRATION PROGRAMME

- Patients who are normally responsible for their own medication at home.

- Patients who are likely to be discharged home with little or no help.
- Patients who wish to take part in the programme.
- Carers of patients who wish to take part in the programme

Patients who have capacity to agree to the programme

**CRITERIA FOR EXCLUSION TO THE SELF-ADMINISTRATION PROGRAMME**

- Patients who lack capacity as defined within the mental capacity act assessment/best interests documentation
- Patients who refuse.
- Patients who are considered incapable following discussion between nursing, medical and pharmacy staff.

**b. PHARMACY ASSESSMENT FOR SELF-ADMINISTRATION**

Questions to ask the Patient:

- Can you tell me the medication that you are taking at present?
- Have you brought your medication into hospital with you?
- Have you left any medication at home?
- Do you buy any over-the-counter medication?
- Do you know the reasons for taking your medication?
- Do you find it easy to remember when to take your medicines?
- Can you tell me when you normally take your medication at home?
- Do you always take the dose written on the labels?
- Do you have any problems that you think may have been caused by your medication?
- Would you ever consider taking medicines prescribed for someone else?
- Would you ever consider sharing your medicines with someone else?

**c. INFORMATION SHEET FOR SELF-ADMINISTRATION**

The self-administration programme allows you to continue to be responsible for your medication whilst you are in hospital. The benefits of self-administration are well researched, the main ones being that you remain in control of your medication whilst in hospital and your knowledge about your present medication and any new medication will improve. This will help you to understand more fully, the purpose and side effects of your drugs, so that you take them at the correct time and in the correct way. Self-administration will also help to address any problems that you may have in taking your medication such as reading the labels and also help you to understand your medical condition more fully.

If you do decide to take part in the self-administration programme, your named nurse and the Pharmacist will explain the programme to you.

You will be given a drug information card, which you should refer to each time that you take your medication. Any problems that you might experience will be addressed on an on-going basis.

**The programme consists of 3 stages:**

**Stage 1**

The nurse will be responsible for the key to your medication box. The nurse will give you your medication and the nurse will supervise you whilst you take your medication.

Teaching about the purpose and side effects of your medication will also take place at this time.

Any problems will be identified and documented in your care plan. Both nursing and pharmacy staff will address these problems.

The nurse signs the drug chart once the medication has been taken.

**Stage 2**

You will now be responsible for the key to your medication box. You will inform the nurse when you are going to take your medication and she will supervise you at this time.

Your progress will be documented in your care plan. Please ask your nurse or pharmacy staff any questions about your medication that you would like answered.

The nurse will continue to sign your drug chart when medication is taken.

**Stage 3**

You will now have full responsibility for your medication. You will inform the nurse when you have taken your medication. The nurse no longer signs your drug chart, but will enter a code to demonstrate that the medication has been taken, and your progress will still be documented in your care plan.

**NOTE**

The stages are designed to be flexible.

Nursing and pharmacy staff will be available if you or your family have any queries relating to self-medication.

Your progress will always be documented in your care plan.

**Finally** here are a couple of reminders if you do choose to participate in the self-administration programme:

Do not exceed the stated dose.

If you forget to take your medication at any time, please inform the nurse.

If you misplace the key to your medication box, please inform a member of staff **IMMEDIATELY.**

Your medication has been prescribed and issued for your use only. It should not be used by anyone else, even though they may appear to have the same symptoms as you.

Remember that if not properly used, medication can be dangerous.

## d. CONSENT FORM: SELF-ADMINSTRATION PROGRAMME

I have read the information about self-administration and request to take part in the self-medication programme.

**I understand that by participating in the self-administration programme, I am responsible for the safekeeping of the key to my medication box when I reach stages 2 and 3.**

**Signed ……**

**Dated ……..**

**Patients name ……..**

**Ward ……..**

## e. GUIDELINES FOR NURSING STAFF WHEN USING PATIENT'S OWN MEDICATION

Directions printed on the label must match with the current prescription chart.

Patients own drugs (POD's) will normally be checked by the Pharmacist / Pharmacy Technician, who will ensure that the medication container is be clearly labelled with:

- Name of the patient
- Name and strength of the drug
- Date dispensed
- Name and address of the supplier
- Prescribed dose and frequency.

The medication in the container should be identifiable as being the same as that written on the label. Any medication which is not clearly identifiable (white unmarked tablets or clear liquids) should not be used.

- The appearance of the container, label and medication should be acceptable, that is: - the container should be intact and reasonably clean.
- The label should be legible.
- Tablets/capsules should be clean, whole and without visible signs of deterioration.
- Liquids, creams, ointments, eye-drops and eye ointments that are in sealed or unused containers can be kept.
- Eye drops or eye ointments that are opened can be kept if within 2 weeks of opening / dispensing.

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**Appendix 7**

## PATIENTS' OWN MEDICINES FORM

**To be signed by the patient or carer on admission, or by a parent, relative or guardian where applicable.**

I, (patient / carer / relative) have been informed that for my benefit I should hand over any medicines* that I bring to the hospital to the nurse in charge.
I understand these may be administered to me whilst I am in hospital and that they may not be returned to me on discharge. I give permission for these to be destroyed if they are no longer needed or unsuitable for use.

| | |
|---|---|
| **Ward** | |
| **Patient name** | |
| **Name of carer or relative if signing on patients' behalf** | |
| **Signature of patient / carer / relative** | |
| **Name of Nurse in Charge** | |
| **Signature of Nurse in Charge** | |
| **Date** | |

*The term 'Medicines' is used to describe any medication, e.g. tablets, capsules, liquid medicines, suppositories, ointments, inhalers and injections etc. used to treat or prevent a medical condition.

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**PATIENTS' OWN MEDICINES FORM (For Use in Community Teams)**

**To be signed by the patient or carer whilst under the care of the team, or by a parent, relative or guardian where applicable.**

I, (patient / carer / relative) have been informed that for my benefit I should hand over any medicines* that are no longer required or for safe keeping.
I understand these may be administered to me and that they may not be returned to me on discharge from the team. I give permission for these to be destroyed if they are no longer needed or unsuitable for use.

| | |
|---|---|
| **Patient Name** | |
| **Community Team** | |
| **Name of carer or relative if signing on patients' behalf** | |
| **Signature of patient / carer / relative** | |
| **Name of Person removing medicines** | |
| **Signature of person removing medicines** | |
| **Date** | |

*The term 'Medicines' is used to describe any medication e.g. tablets, capsules, liquid medicines,

suppositories, ointments, inhalers and injections etc. used to treat or prevent a medical condition.

| **Details of medicines returned (drug name, quantity, formulation etc.) - specify if any are controlled drugs** |
|---|
| |

**Training Needs Analysis for the policy for the development and management of Trustwide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br><br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br><br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| **Staff Group** | **✓ if appropriate** | **Frequency** | **Suggested Delivery Method**<br><br>**(traditional/ face to** | **Is this included in Trustwide learning programme for this staff group (✓** |
|---|---|---|---|---|

| | | | face / e-learning/handout) | if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |

| | | | | |
|---|---|---|---|---|
| Non-clinical non patient contact | | | | |

| |
|---|
| Please give any additional information impacting on identified staff group training needs (if applicable) |

| |
|---|
| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |

| Any other additional information |
|---|
| |

| Completed by | | Date | |
|---|---|---|---|

North Staffordshire Combined Healthcare NHS Trust

**Document level: Trust Wide**
**Code:** 1.27
**Issue number:** _____

# Rapid Tranquilisation Policy

| | |
|---|---|
| Lead executive | Chief Medical Officer |
| Authors details | Deputy Director of Medicines and MACE<br>Head of Nursing and Quality<br>Principle Clinical Pharmacist<br>Head of IPC and Physical Health |

| | |
|---|---|
| Type of document | Policy |
| Target audience | All inpatient clinical staff |
| Document purpose | Information |

| | | | |
|---|---|---|---|
| Approving meeting | Quality Committee | Meeting date | 5th September 2019 |
| Approving meeting | Trust Board | Meeting date | 26th September 2019 |
| Implementation date | 26th September 2019 | Review date | 31st October 2023 |

| Trust documents to be read in conjunction with | |
|---|---|
| 1.03 | Medicines Policy |
| | High Dose Antipsychotic Therapy Policy |
| | Non-formulary/Off-label/Unlicensed Policy |
| | Medication Monitoring Policy |
| 1.62 | Physical Health Policy |
| | Restraint Policy |
| 1.80 | Resuscitation Policy |
| 1.24 | Nutrition and Hydration Policy |
| 5.01 | Incident Reporting Policy |
| 5.32 | Serious Incident Policy |
| R01 | Policy on the use and Reduction of Restrictive Interventions |
| 1.62b | Neurological Observations SOP |
| 1.35 | Observation Policy |
| 1.12a | Safeguarding Policy Statement |
| R11 | Seclusion and Longer Term Segregation Policy |
| 5.19 | Violence and Aggression Policy |
| 1.64 | Effective Care Planning |
| MHA13 | Mental Capacity Act Policy |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | Review of the definition of rapid tranquilisation; updated the requirements for physical health | | 2019 |

| | | | |
|---|---|---|---|
| | monitoring; clarification of roles and responsibilities. | | |
| Appendices / electronic forms | Total review | 1 | July 2019 |
| What is the impact of change? | The changes will give staff greater clarity around the principles of RT including definition, assessment, monitoring, escalation and documentation. Therefore ensuring the consistent delivery of best of practice. | | |

| | |
|---|---|
| Training requirements | As per Trust TNA |

| Document consultation | |
|---|---|
| Directorates | Acute and Urgent care Directorate representatives and members of CEG |
| Corporate services | POST, MACE and CEG |
| External agencies | |

| | |
|---|---|
| Financial resource implications | None |

External references


1. British Association for Psychopharmacology & The National Association of Psychiatric Intensive Care Units. (2018). Joint BAP NAPICU Evidence-Based Consensus Guidelines for the Clinical Management of Acute Disturbance: De-Escalation and Rapid Tranquilisation. Journal of Psychopharmacology. Available From: https://www.bap.org.uk/docdetails.php?docID=105. Last Accessed 25/03/2019.
2. Innes, J & Sethi, F. (2013). Current Rapid Tranquilisation Documentation in the UK: A Review of Drug Recommended, Their Routes of Administration and Clinical Parameters Influencing Their Use. *Journal of Psychiatric Intensive Care Unit.* 9: 110-118.
3. Lambert, L, Evans, D, &Wood, J. (2003), Patient Injury and Physical Restraint Devices: A Systematic Review. *Journal of Advanced Nursing.* Available From: https://www.academia.edu/29575297/Patient_injury_and_physical_restraint_devices_a_systematic_review. Last Accessed: 1/5/19.
4. Loynes, B, Innes, J & Dye, S. (2013). Assessment of Physical Monitoring Following Raid Tranquilisation: A National Survey. *Journal of Psychiatric Intensive Care.* Vol, 9. 2. 85-90.
5. National Institute for Healthcare and Clinical Excellence. (2015). Violence and Aggression: Short-Term Management in Mental Health, Health and Community Settings {NG10}. Available From: https://www.nice.org.uk/guidance/ng10. Last Accessed 1/4/19.
6. Taylor, D, Thomas, B and Young, A. (2018). The Maudsley Prescribing Guidelines in Psychiatry. (2018). 13th Ed. West Sussex: Willey Blackwell.

7. The Resuscitation Council UK. (2006). ABCDE approach. Available from: https://www.resus.org.uk/resuscitation-guidelines/abcde-approach/. Last Accessed;1/5/19.

| | |
|---|---|
| Monitoring compliance with the processes outlined within this document | Rapid tranquilisation auditing carried out through the inpatient safe matrix, Rapid Tranquilisation audit presented to CEG, competency documentation, supervision notes and PDRs, surveillance etc. |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favourable / More favourable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |
| – **Age** (e.g. consider impact on younger people/ older people) | No | |
| – **Disability** (remember to consider physical, mental and sensory impairments) | No | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | No | |
| – **Gender identity and gender reassignment** (i.e. impact on people who identify as trans, non-binary or gender fluid) | No | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | No | |
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | No | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not) | No | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | No | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | | |
| – **Other equality groups?** (may include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | No | |

| | |
|---|---|
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | |
| Enter details here if applicable | |
| If you have identified potential negative impact:<br>- Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | |
| Enter details here if applicable | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | No |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | N/A |
| Enter details here if applicable | |
| Where an adverse, negative or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | |
| Was a full impact assessment required? | No |
| What is the level of impact? | Low |

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## 1. Introduction

Within North Staffordshire Combined Healthcare NHS Trust (NSCHT) all patients, where possible, will be at the centre of the clinical decision making process ensuring safety is the priority throughout each intervention. The purpose of this policy is to outline the use of rapid tranquilisation (RT) within the context of the prevention and management of acute agitation or aggression in order to:

- Reduce psychological suffering and self-harm for patients
- Maintain a safe environment
- Prevent harm

## 2. Background

The Trust recognises the importance of good practice in preventing and managing acute agitation, aggression and potentially violent incidents. Risk of acute agitation or aggression should be identified through the assessment process and where this risk is identified this should be reflected in the person's risk assessment and accompanied by an up to date intervention plan. This intervention plan should identify pro-active primary and secondary strategies and de-escalation techniques that should be utilised to support the person and minimise the risk of escalation.

It is recognised that on occasions acute agitation or aggression may occur despite all attempts to prevent this using de-escalation techniques. It is at these times it may become necessary to use pharmacological interventions to maintain the safety and physical health of an individual. In the management of acute agitation or aggression the administration of medicines using the parental route (usually intramuscular) is termed Rapid Tranquilisation (RT) however it should be noted that RT has a limited evidence base as clinical trials are difficult to conduct.

Moreover, there are a variety of approaches for managing acute agitation or aggression, which should be considered prior to the use of RT. These include de-escalation, distraction techniques, consideration of environment, physical restraint and seclusion. All of these strategies should be considered in each case. Even when RT is used, these alternate treatment strategies should continue to be used alongside RT, as each is likely to augment the effect of the others. The aim of the policy is to:

- Ensure a standard approach to care, based on the best available evidence;
- Minimise risk related to the use of RT
- Advise on best practice in prescribing of medication for RT;
- Provide clarity in relation to staff roles and responsibilities;
- Comply with CQC and NHSLA standards, and national (NICE) recommendations.

## 3. Policy Synopsis

This policy applies to all healthcare staff working within in-patient settings where RT may be utilised. The policy is applicable to both Mental Health and Learning Disabilities Services and applies to in-patients over the age of 12.

RT will not be regularly used within Resource Centres, Rehabilitation Units or within Children's Services. However staff may be faced with extreme emergency situations where the use of RT may be unavoidable. In any event staff must ensure that wherever possible the guidance is fully adhered to.

## 4. Definitions

### De-escalation techniques

De-escalation is the use of techniques (including verbal and non-verbal communication skills) aimed at defusing anger and averting aggression. PRN medication can be used as part of a de-escalation strategy but PRN medication used alone is not de-escalation (taken from Violence and Aggression Short Term Management in Mental Health and Community Settings - NICE May 2015). De-escalation techniques should be used prior to the use of RT.

**Tranquilisation:** The administration of medicine(s), orally or parenterally, with the aim of calming or lightly sedating a patient in order to reduce the risk to the patient or others from agitated or aggressive behaviour. The aim is to achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place whilst allowing comprehension and response to spoken messages throughout. Tranquilisation should only be used if non-medicine de-escalation has had inadequate effect.

**Non-urgent tranquilisation:** Tranquilisation using orally administered medicine(s). This should be used in preference to rapid/urgent tranquilisation whenever possible (see below).

**Rapid / urgent tranquilisation:** Tranquilisation using parenterally administered medicine(s). This should only be used if non-urgent tranquillisation is not possible (e.g. due to patient refusal), not appropriate (i.e. urgent need), or has inadequate effect. Please note that, in line with NICE NG10, ***the term rapid tranquilisation no longer incorporates the use of oral medicine(s)*** for the management of agitation or aggression.

**PRN (pro re nata) medication:** Medicines that are used when required. PRN medication can be used as part of de-escalation but medication used alone is not de-escalation.

## 4. Legal Considerations

Staff involved in rapid tranquilisation should be mindful of and take account of the following legal frameworks:

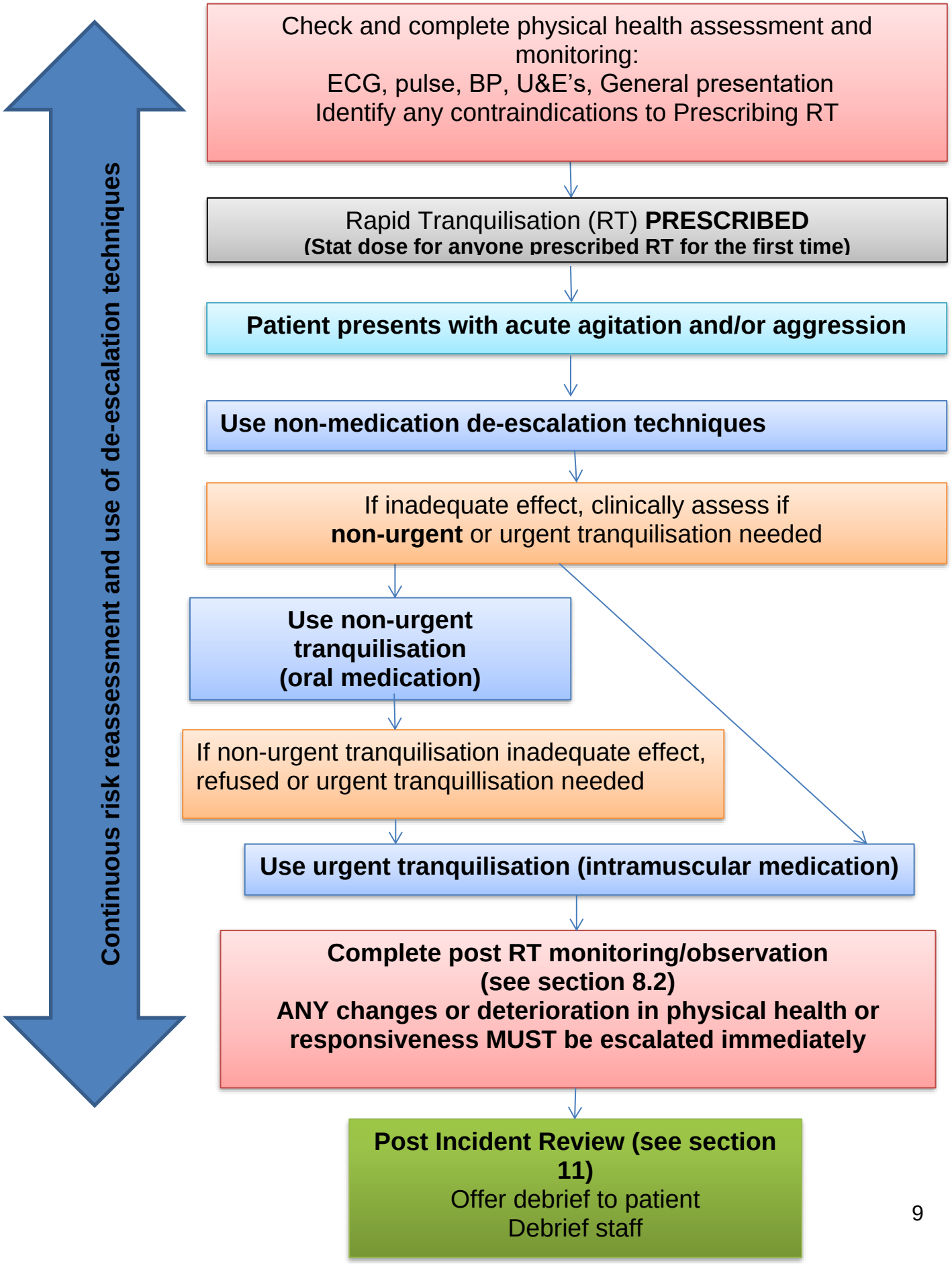
- Relevant sections of the Mental Health Act 1983 and its Code of practice. The principles underlying the common law doctrine of 'necessity', and the requirements of the relevant articles of the European Convention on Human Rights including:
    - Article 2 (right to life)
    - Article 3 (the right to be free from torture or inhuman or degrading treatment or punishment)

- Article 5 (the right to liberty and security of person save in prescribed cases) and
- Article 8 (the right to respect for private and family life), and the principle of ‘proportionality’.

It is also important to ensure that any developing situation or positive intervention takes into account the individuals need of patient related to:

- Protected characteristics (age, disability, gender, gender reassignment, race, religion or belief, sex, sexual orientation, marriage or civil partnership, pregnancy or maternity)
- sensory impairment
- patients with a physical impairment
- patients with a cognitive impairment
- female patients e.g. (are some members of staff who are restraining of the same sex)
- patients with communication difficulties
- frail older patients

## 5. Rapid Tranquilisation Flowchart



## 6.0 Circumstances for Appropriate Use of Rapid Tranquilisation

The need for RT requires careful clinical judgement taking into consideration the following:

- Imminence of violence may be suggested by rapidly increasing verbal aggression or anger, perhaps associated with explicit threats of violence, changes or extremes of behavior, and/or outward signs of inner tension.

- When determining which interventions to employ, clinical need, safety of service users and others, and where possible advance decisions, should be taken into account.

- Where appropriate the patient should be offered oral medication (non-urgent tranquilisation) in the first instance. However if the patient refuses oral medication, or the risks are escalating such that, for safety reasons, the intramuscular (IM) route is deemed necessary, then this route should be used and this RT policy followed.

- The aim of RT is not to treat any underlying illness or disorder. Instead RT should be used as a management strategy to treat acute agitation or aggression.

- Prescribers should aim to ensure that the degree of sedation arising from RT does not compromise the patient's capacity to understand and respond to what is said to them.

- Although not the overt intention, rapid tranquilisation may lead to deep sedation/anesthesia hence the need for comprehensive monitoring.

- RT is potentially hazardous and the risk of adverse events is higher if the patient has taken illicit drugs or alcohol. The duty doctor must be informed that RT has been used as soon as possible and be available for a rapid response for 30 minutes after administration of RT as medical support must be available in case of adverse reactions, over-sedation or the need to administer flumazenil.

- NICE recommends that the doctor should aim to be at the scene within 30 minutes as medical support must be available in case of adverse reactions, over-sedation or the need to administer flumazenil. Therefore if RT is to be attempted out of hours the duty doctor should be contacted.

## 7.0 Physical Health Monitoring

### 7.1 Physical Monitoring Before Rapid Tranquilisation

The prescriber should:

- Review the patients' clinical record with regard to their general medical history and consider the possibility of a physical examination.
- Check for recent ECG, U&E and urine drug screen results, a previous history for severe extrapyramidal side effects or antipsychotic naivety, previous response to RT or other methods of managing imminent violence.
- Review current prescribed medication and recently administered medication,

taking note of administration of PRN prescriptions.

- Mental Health Act Status - consider if a T2/T3 form is in place which lists medications which can be prescribed. A S62 form completed by the Consultant would be needed if RT medicines not included.
- Check baseline NEWS observations.

### 7.2 Physical Monitoring Post Rapid Tranquilisation

Following the administration of RT, the following parameters must be monitored and recorded on the NEWS chart:

- Pulse
- Blood pressure
- Respiratory rate
- Temperature
- Level of hydration
- Level of consciousness

If the patient will not allow the complete NEWS parameters to be monitored discrete visual observations must be undertaken and recorder on the Patients Electronic Record (EPR). The following observations must be included:

- Airway
- Breathing
- Circulation
- Disability
- Exposure

This should only occur in exceptional circumstances when the patient is not compliant with the completion of standard NEWS monitoring. The rationale for using the discrete visual observations must be documented within the EPR, and as soon as the patient becomes compliant monitoring should revert to the standard NEWS chart.

NEWS scores will indicate the escalation level required and the required increase in observations and actions required. Staff MUST always escalate any concerns and seek further clinical advice or support as per the action section on the reverse of the NEWS monitoring form.

As a minimum monitor the above;

- Every 15 minutes for the first hour
- Then every hour for a minimum of 4 hours until the NEWS score is normal and the nurse in charge has no further concerns about their physical health status.

If the patient is unconscious, remains over-sedated or is otherwise unwell they must be reviewed by a Doctor. Immediate escalation and review is required by the Ward Doctor, if not able to attend immediately then 2222 or the duty response team followed by (9)999.

If the patient remains on the ward following clinical review continue to monitor every 15 minutes if the BNF maximum dose has been exceeded (either with one medicine or when regular and ‘prn’ are combined) or the service user:

- Remains over-sedated
- Has sustained a head injury
- Has taken illicit drugs or alcohol
- Has a pre-existing physical health condition
- Has experienced any harm as a result of any restrictive intervention. A clinical review specifically in relation to the harm sustained must be
- undertaken and further observations, reviews or intervention determined to reflect the severity of the injury.

After RT a mental health assessment should be undertaken in conjunction with physical health checks.

## 8.0 Special Circumstances

### 8.1 Rapid Tranquilisation and Seclusion

Particular caution is necessary if combining RT with seclusion and physical intervention. If the service user is secluded, the potential complications of RT should be taken into account.

The service user may be monitored by discrete visual observation by appropriately trained staff. This should only happen if the patient is too agitated to be closely accompanied by a staff member and the rationale for this decision must be clearly documented within the EPR.

### 8.2 Rapid Tranquilisation and Physical Intervention

Medicines for RT, particularly in the context of physical intervention should be used with caution due to the increased risk of the following:

- Loss of consciousness
- Sedation with loss of alertness
- Compromised or loss of airway
- Cardiovascular and respiratory collapse
- Interaction with medicines already prescribed or illicit substances taken (can cause side effects such as akathisia, disinhibition)
- Negative impact on patient-staff relationship
- Underlying pre-existing physical disorder

## 9.0 Medical Equipment

NICE NG10 stipulates that resuscitation equipment must be available if restrictive interventions, including RT, might be used. This consists of an automatic external defibrillator with monitoring ECG pads, a bag valve mask, oxygen, cannulas, fluids, airways, pulse oximeter, vital signs monitor; suction should be available immediately in clinical areas where RT may be used. The equipment should be maintained and checked in accordance with the Trust Resuscitation policy.

## 10.0 Medicines for Tranquilisation

### 10.1 Prescribing Guidelines for Rapid Tranquilisation

This policy describes the use of lorazepam first line and then promethazine and haloperidol second line as RT in line with NICE guidelines (see table 1). When deciding which medication to use, take into account:

- The service user's preferences or advance statements and decisions
- Pre-existing physical health problems or pregnancy
- Any known allergies to medicines
- Possible intoxication or delirium
- Previous response to these medications, including adverse effects
- Potential for interactions with other medications
- The total daily dose of medications prescribed and administered.

The regular medication prescribed to a patient must always be considered to ensure that RT does not duplicate oral medication. Ideally antipsychotic or benzodiazepine polypharmacy should be avoided. If a combination of antipsychotics takes the patient on to a 'high dose' antipsychotic combination then the High Dose Antipsychotic Therapy policy must be followed. If there is insufficient information to guide the choice of medication for RT, or the service user has not taken antipsychotic medication before use IM Lorazepam.

Haloperidol is best avoided in those who are naïve to antipsychotics; have a history of severe extra-pyramidal side effects; have a history of cardiovascular disease or an abnormal ECG; or in whom no ECG has yet been taken due to patient refusal or they are too unwell to have an effective ECG reading. IM Lorazepam should be used instead.

Benzodiazepines are best avoided in those with compromised respiratory function.

If there is a partial response to IM Lorazepam, consider a further dose. If there is no response to IM Lorazepam, consider IM haloperidol combined with IM Promethazine.

If there is partial response to IM Haloperidol combined with IM Promethazine, consider a further dose. If there is no response to IM Haloperidol combined with IM Promethazine, consider IM Lorazepam if this hasn't already been used already during this episode. If IM Lorazepam has already been used, arrange an urgent team meeting to carry out a review and seek a second opinion if needed.

In exceptional circumstances such as contra-indications or product manufacturing issues a Consultant may decide to prescribe an alternative medication for RT. The rationale for this decision must be clearly documented within the patient's notes and appropriate assessment and monitoring followed as per this policy and the BNF.

Aripiprazole is available as an IM injection licensed for RT in patients with schizophrenia or mania. Olanzapine is available as an IM injection licensed for RT in patients with schizophrenia or mania; however it is no longer available in the UK and has to be imported as an unlicensed product. Olanzapine IM cannot be given within 1 hour of IM benzodiazepines.

***Zuclopentixol acetate injection is not recommended for rapid tranquilisation due to its long onset and duration of action. It is only allowed for use in the Trust on the initiation of a consultant psychiatrist with a clear care plan for its use and requires 48 hours of post administration monitoring due to it prolonged half-life.***

When prescribing medication for use in rapid tranquilisation, write the initial prescription as a single 'stat' dose, and do not repeat it until the effect of the initial dose has been reviewed.

It may be necessary to give IM medication through clothing in certain situations. The rationale should be documented in the notes if this occurs.
Note under the Mental Health Act Nurse Associates are not permitted to administer rapid tranquilisation to a patient.

**Table 1: Medicines Used for Management of Acute Agitation or Aggression – their properties, cautions and advice notes**

| Medicine | Route | Pharmacokinetics | Major Adverse effects | Notes |
|---|---|---|---|---|
| **Lorazepam** | Oral or IM | Onset 10 to 30 mins<br>Peak 60 to 90 mins<br>Half-life 12 to 16 hrs | - Respiratory Depression<br>- Disinhibition | - IM absorption is as slow as oral absorption, but is rapid in an active patient.<br>- The injection should be diluted 50:50 with water for injections pre-injection.<br>- There is no accumulation of lorazepam with repeated doses or in impaired liver function<br>- Respiratory depression is readily reversed with the specific antagonist flumazenil.<br>- Paradoxical reactions are more likely to occur in those with organic brain disease, including learning disabilities, the under 18s and the over 65s, and perhaps those with impulse control problems.<br>- Do not give IM lorazepam and IM olanzapine within one hour of each other because there is a risk of excessive sedation, cardiorespiratory depression, and death. |
| **Haloperidol** | Oral | Onset 1 to 2 hrs<br>Peak 4 (2-6) hrs<br>Half-life 24 (15-37)hrs | - EPSE<br>- Hypotension<br>- NMS<br>- Increased QTc or arrhythmias<br>- Seizures<br>- Sudden death | - The bioavailability of both formulations is different and this must be taken into account when considering the total dose per 24 hr period. See conversion table 2.<br>- Note risk of acute dystonia and ensure that an appropriate antimuscarinic is available.<br>- The Summary of Product Characteristics (SPC) for haloperidol specifies that a baseline ECG must be carried out prior to treatment.<br>- Before prescribing haloperidol, there must be documentation on Carenotes of either the QT interval from a recent ECG, or the decision to prescribe haloperidol despite absence of an ECG. |
| | IM | Onset 20 mins<br>Peak 20-40 min<br>Half-life 21(13-36)hrs | | |
| **Olanzapine** | Oral | Onset 5 to 8 hrs<br>Peak 5 to 8 hrs<br>Half-life 32 to 50 hrs | - Hypotension<br>- Bradycardia<br>- Syncope | - Less likely to cause EPSE than haloperidol.<br>- IM administration results in initial maximum plasma concentration 5 times higher than same dose given orally.<br>- IM lorazepam should not be administered until at least 1 hour after IM olanzapine administration.<br>- No more than 3 injections of IM olanzapine should be given in 24 hours and a minimum of two hours should elapse between each |
| | IM | Onset 15 to 45 mins<br>Peak 15 to 45 mins<br>Half-life 30 hrs | | |

| Medicine | Route | Pharmacokinetics | Major Adverse effects | Notes |
|---|---|---|---|---|
| | | | | injection.<br>- Olanzapine IM is intended for short term use, for a maximum of 3 consecutive days. |
| **Promethazine** | IM | Onset 20 mins<br>Peak 2 to 8 hrs<br>Half-life 7 to14 hrs | - Prolonged sedation<br>- Seizures<br>- Cardio-respiratory depression<br>- NMS | - ECG recommended (potential for QT interval prolongation)<br>- Use of IM promethazine for rapid tranquilisation is off-label.<br>- It has a slow onset of action, but is an effective sedative.<br>- Dilution is not required before IM injection.<br>- Smaller doses will be required in severe renal impairment,<br>- Use with caution in hepatic impairment, respiratory disease and congestive heart failure.<br>- As promethazine is **NOT** a benzodiazepine, flumazenil is not an antidote to reverse its effects. |
| **Zuclopenthixol Acetate (Clopixol Acuphase®)** | IM | **Not rapid tranquilisation**<br>Onset 2 to 8 hrs<br>Peak 24 to 36 hrs<br>Half-life 60 hrs | - Sudden death<br>- Cardiac arrest<br>- Arrhythmias<br>- EPSE | - **This is not an appropriate medicine for rapid tranquilisation**<br>- Given by deep IM injection into the gluteal muscle, taking care not to give into a vein, as this can be fatal.<br>- It should not be used in those who are neuroleptic naive, who are struggling, who are sensitive to EPSE, those with cardiac disease, hepatic or renal impairment, or in pregnancy.<br>- Please refer to the latest version of the BNF, SPC, and Maudsley Prescribing Guidelines in Psychiatry when prescribing or administering zuclopenthixol acetate. |

**Table 2: Haloperidol conversion**

| | APPROXIMATE EQUIVALENT DOSES (mg) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Oral Haloperidol** | 0.5 | 1 | 1.5 | 2.5 | 4.2 | 5 | 7.5 | 8.3 | 10 | 12.5 | 16.7 |
| **IM Haloperidol** | 0.3 | 0.6 | 0.9 | 1.5 | 2.5 | 3 | 4.5 | 5 | 6 | 7.5 | 10 |

**Notes:**

- The pharmacokinetics of lorazepam is similar whether given orally or parenterally, therefore the only reason to give lorazepam parenterally is if the patient refuses oral.

- It is recognised that clinicians may decide that the use of medication outside of the manufacturer's Summary of Product Characteristics (SPC) is occasionally justified, bearing in mind the overall risks. However, where the regulatory authorities or manufacturer issues a specific warning that this may result in an increased risk of fatality, the medication should only be used strictly in accordance with the current marketing authorisation.

**Table 3 - Usual and Maximum Doses**

| Medication | Usual Dose | Maximum Dose |
|---|---|---|
| Lorazepam | 0.5-2mg 4-hourly | 4mg/24hours |
| Haloperidol IM | 1-10mg 4- hourly | 20mg/24hours (IM is more potent than PO) |
| Haloperidol oral | 1-10mg 4-hourly | 20mg/24hours |
| Promethazine | 25-50mg | 100mg/24hours (off-label) |
| Aripiprazole IM | 9.75mg | 30mg/24 hours |
| Olanzapine IM | 5-10mg | 20mg/24 hours |

**The maximum doses given are guidelines only.** The dose ranges have been chosen after careful consideration of relevant literature and other guidelines such as the products individual Summary of Product Characteristics (SPC). BNF maximum doses should not be exceeded without careful thought and advice from a Consultant Psychiatrist. The High Dose Antipsychotic Therapy (HDAT) guideline should be followed in this instance.

## 11.0 Management of Adverse Effects and Complications

| Complication | Symptoms / signs | Management |
|---|---|---|
| **Acute Dystonia** | Severe painful muscular stiffness | Procyclidine 5 to 10mg IM |
| **Hypotension** | Fall in blood pressure (orthostatic or <50mmHg diastolic) | Lie patient flat and raise legs - tilt bed head down.<br>Complete physical observation chart every 15 minutes and complete actions |
| **Neuroleptic malignant syndrome** (see appendix 1) | Increasing temperature, fluctuating blood pressure, muscular rigidity, confusion/ altered consciousness | Withhold antipsychotics.<br>Complete physical observation chart every 15 minutes and complete actions.<br>Consider blood test for creatinine kinase level.<br>Liaise with general medical team and consider transfer to acute medical care |
| **Arrhythmias** | Slow (<50/minute) or irregular pulse | Monitor closely and liaise with general medical team immediately |
| **Respiratory Depression** | Reducing respiratory rate, reducing consciousness | Complete physical observation chart every 15 minutes and complete actions.<br><br>If respiratory rate drops below 10/minute in a patient who has received benzodiazepines, then flumazenil should be administered by a doctor:<br><br>1) 200 micrograms IV over 15 seconds.<br>2) If consciousness not resumed within 60 seconds give 100 micrograms over 10 seconds.<br>3) Repeat at 60 second intervals. Maximum dose 1mg/24 hours.<br>4) Contact emergency medical services<br><br>Continue to monitor after respiratory rate returns to normal. Flumazenil has a short duration of action so further doses may be required.<br><br>Patients may become agitated or anxious on wakening. |

## 12.0 Incident Reporting and Post-Incident Reviews

Incidents regarding the administration of parenteral RT should be reported electronically on an Incident Form in accordance with Trust Management of Incident policy. The episode of RT should also be documented in the patient's EPR along with the completed NEWS physical observation forms (available on Lorenzo) and any additional monitoring. Information recorded on the incident form should also include;

- The medication prescribed/administered
- Mental Health Act status

Following the use of RT all staff involved should participate in a staff debrief as soon as possible.

All service users must be offered the opportunity to discuss their experiences and should be provided with a clear explanation of the decision to use RT as opposed to other methods along with any necessary support within 72 hours of the incident. This information may be used to inform amendments to the patient's care plan i.e. how they would like a similar situation to be approached in the future. This discussion should be recorded in their EPR and the service user given an opportunity to record their account of the experience. In doing so, service users should be given the opportunity to be supported by an independent mental health advocacy support worker.

## 13.0 Guidance on Rapid Tranquilisation in Patient Groups

Special consideration must be given to specific patient groups. It may be necessary to refer to colleagues within other clinical specialties to seek advice such as paediatrics.

### 13.1 Guidance on Rapid Tranquilisation in Patients over 65's years of age

1. When dealing with acutely disturbed behaviour in older people non-pharmacological measures, such as de-escalation and distraction should always be attempted first. Remember that if passive restraint is required older people have a higher risk of skin damage.
2. Start with oral medication and remember that in older people lower doses and slower increases are recommended.
3. Risperidone up to 2mg twice a day is licensed for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Generally where a licensed product is available this should be used in preference to that without a license.
4. All antipsychotics should be used with caution in older people with dementia, especially those with a history of cerebrovascular disease and only after discussion with relatives. For older people exhibiting greater risk of acute agitation or aggression, potential management strategies including RT should occur in advance of the likelihood of an alert, e.g. on admission.
5. Older patients will absorb medications more slowly and so there will be a slower onset of action, be sure to take this into consideration before repeating doses.
6. Older patients may also have an effectively larger volume of distribution

which leads to a longer duration of action, this needs to be considered so as to avoid accumulation.

7. There is a higher incidence of adverse effects in older patients; in particular disinhibition is much more likely with benzodiazepines than in working age patients. Be aware that their risk of falls is greatly increased with any sedating medication, consider revising the level of nursing observations. It is important to ensure that all physical monitoring is carried out as per policy so as to be sure to pick up any adverse effects.
8. All antipsychotics should be avoided if possible in Lewy Body Dementia and Parkinson's Disease .
9. All antipsychotics can cause increased cognitive impairment and confusion in patients with dementia.
10. If you think a delirium is the cause of the agitation, NICE advocate haloperidol.

### 13.2 Guidance on Rapid Tranquilisation in Patients under 18s years of age

1. Many drugs are not licensed for use in children and adolescents. Some may be used because over time clinical experience has been built up amongst experts and there is peer support for usage. There is an expectation that in the future drug companies will have to give fuller information on the effects of their drugs on children.
2. Children and adolescents should only be treated with medication (RT) after completing a physical risk assessment and when it has been clearly established that the risks of not treating are greater than the risks of using medication.
3. The weight and pubertal status of the young person needs to be considered in deciding dosages. Over a weight of 40kg dosages up to adult BNF limits may be used. Calculate dosage by weight for those weighing under 40kg.
4. It is unusual to use doses over that given in the BNF for young people as there is no body of evidence to support such usage. In all cases the minimum effective dose of medication should be used. BNF maximum doses should only be exceeded in extreme circumstances and with the advice of a Consultant Child and Adolescent Psychiatrist. Consider involving a SOAD.
5. In the case of young people who are not detained under the mental health act, or who are detained, but under a section of the act which does not authorise treatment, the child/adolescent must be informed that medication is going to be given and must be given the opportunity at any stage to accept oral medication voluntarily. In children/ adolescents who are not Gillick competent, the person with parental responsibility should be informed of the situation and consent sought for such treatment. It is good practice to inform both the child/adolescent and the person with parental responsibility. Rapid tranquilisation can be given in emergency situations under common law, but this should be in exceptional cases only.
6. In the case of young people who are detained under a treatment section of the mental health act, reference must be made to the consent to treatment

documentation (forms T2 or T3). Medication not specifically consented to or authorised by a consent to treatment form can still be given if necessary under section 62 of the mental health act 1930 as amended 2007 ('urgent treatment', subsection (d) [treatment] which (not being irreversible or hazardous) is immediately necessary and represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to himself or others).

7. Before prescribing RT it is necessary to be aware of potential drug naivety, differing pharmacokinetics in children and adolescents, and varying durations of response. Children and adolescents are more sensitive to all side effects of medication, in particular dystonia with antipsychotics and paradoxical excitation with benzodiazepines. Refer to appropriate physical risk assessment documentation whenever possible.
8. The most appropriate medicine for use in RT in children and adolescents is lorazepam; sedating antihistamines may also have a role in specific cases. Medication for naïve young people should be started at low doses which should not be repeated until there has been enough time to assess effect. NICE only recommends lorazepam in under 18s for RT.
9. No parenteral RT medication, even if prescribed on a prn basis, should be given to a child or adolescent without a doctor being informed, ideally prior to administration, but if this is not possible due to the urgency of the situation, then as soon as practical thereafter. Repeated doses should never be given parenterally without medical review.

### 13.3 Use of Medicines for Tranquilisation in People with a Learning Disability

The policy will apply to learning disability using the appropriate guidance to the age of the patient. Special consideration will need to be given to those with cerebral palsy as they may be at risk of postural deformities and hip dislocation. Additionally, there is a higher rate of undetected visual and hearing problems in the learning disability population and findings suggest that a high proportion of people with learning disabilities have an altered pain threshold. Many also carry an increased risk of certain health complications such as cardiac and respiratory disorders, which contribute to potential hazards associated with restraint. The choice between using physical intervention and rapid tranquilisation as a method of managing violent behaviour in those with a learning disability should be part of an overall care plan.

## 14.0 Implementation and Monitoring

### Training

There are four components to the training that will be required for all staff involved in the administration, prescription, and monitoring of service users to whom RT has been administered. They are as follows:

### 14.1 Management of Actual and Potential Aggression (MAPA)

All staff whose need is determined by training needs analysis will receive on- going competency training to recognise anger, potential aggression, antecedents and risk factors of disturbed/violent behaviour

Training will include methods of anticipating, de-escalating or coping with

disturbed/violent behaviour. (Management of Actual and Potential aggression – MAPA Training Strategy).

All inpatient staff should receive training to ensure current use of physical intervention, which adheres to approved national standards.

The training needs analysis will be reviewed annually, as a minimum, to identify those staff groups that require on-going professional training in the recognition, prevention and de-escalation of disturbed/violent behaviour and in physical intervention to manage disturbed/violent behaviour.

### 14.2 Resuscitation

All staff involved in administering or prescribing RT or monitoring service users to whom parenteral rapid tranquilisation has been administered, will receive on-going competency training to a minimum of in–hospital resuscitation (Resuscitation Council UK).

Staff who are involved in physical intervention or seclusion will also be trained to a minimum of Basic Life Support (Resuscitation Council UK).

### 14.3 Use of Medical Equipment

All staff (Band 5 and above) involved in administering or prescribing RT or monitoring service users to whom parenteral rapid use of pulse oximetry, vital signs monitoring and the use of Automated External Defibrillator with monitoring ECG leads in addition to existing training provision for current Resuscitation Equipment. This training will be undertaken in conjunction with the training provided for all other items of medical equipment that are included in resuscitation equipment. This training will be provided within the in- hospital resuscitation Training (Resuscitation Council UK).

### 14.4 Physical Health Training

The Trust Physical Health Day training which includes NEWS must also be completed.

## 15.0 Duties and Responsibilities

| Roles | Responsibility |
|---|---|
| The Chief Executive | • To ensure that an appropriate and adequate infrastructure exists to support the provision of rapid tranquilisation policy amongst staff and patients throughout the organisation. |
| The Executive Director of Nursing and Quality and Medical Director | • For the strategic and operational management of the rapid tranquilisation policy;<br>• To ensure the implementation of this policy is monitored and appropriate mandatory training is developed and accessed by relevant staff with their areas of responsibility. |
| Deputy Director of Medicines and MACE | • Monitoring safe and appropriate usage of medication. |
| Clinical Directors and Associate Clinical Directors | • To ensure that managers and Trust staff working in services who use RT are aware of the policy and promote good practice;<br>• To ensure staff attend relevant training;<br>• Provide support and guidance regarding resources and the consistent application of the policy and future practice recommendations;<br>• To ensure that safe systems are in place to enable medical and nursing staff to work in accordance with the procedures referred to in the policy;<br>• To implement the policy across their areas of responsibility and monitor the competence of nursing staff in applying the procedures referred to in the policy. |
| Quality Improvement Leads Nurses | • To ensure competency based training and assessment packages are developed and available to inpatient staff and adherence to training is monitoring via the Trust Training information system;<br>• Ensure within the area of responsibility the application of the rapid tranquilisation policy is adhered to and where necessary , action is taken to ensure compliance;<br>• Monitor compliance of staff with training requirements and inclusion of RT in appraisals. |
| Authorised Prescribing staff | • To ensure they are familiar with the policy and be responsible for adhering to the procedures referred to in the policy;<br>• Undertake appropriate mandatory training |

| | |
|---|---|
| | (Royal College of Psychiatry or Trust);<br>• Take responsibility for adhering to the service specific prescribing recommendations in this policy and actions to take in the event of an adverse incident or suspected adverse drug reaction;<br>• To assess the patient and ensure a drug history is available, wherever possible, including ascertaining any past allergies and drug reactions from the clinical notes<br>• To conduct a mental state examination, assessment of physical health (including a ECH when possible), and ascertain a history of any physical health conditions before prescribing and administering any medication;<br>• To always refer to the most recent British National Formulary (BNF) to check recommended drugs and dosages;<br>• To consider any advance decisions/statements before prescribing;<br>• To follow the guidance of the Mental Health Act Code of practice in relation to the use of RT and The mental Capacity Act;<br>• To ensure that the nurse in charge is fully aware of any decisions regarding medication;<br>• To ensure rationale for prescribing is documented within the patients electronic care record;<br>• Must be aware of their responsibility in relation to first response and the use of remedial measures. |
| Registered Nurses | • To ensure they are familiar with the policy and be responsible for adhering to the procedures referred to in the policy;<br>• To ensure mandatory training is undertaken;<br>• Provide support and information to patients, carers and their families with regards to the use of RT;<br>• Adhere to the Trust Policies and the NMC Medicines Management Standards;<br>• To ensure they are competent in all the clinical procedures required to implement this policy including first response training and appropriate use of equipment; |

| | |
|---|---|
| | • To assess risk and implement the policy when they feel it is appropriate;<br>• To ensure that non-pharmacological (de-escalation) methods are tried first;<br>• Monitor vital signs after the use of RT using the appropriate National Early Warning Score 2 (NEWS) guidelines;<br>• To ensure maintenance and monitoring of practice standards and equipment is carried out as recommended;<br>• To follow the guidance of the Mental Health Act Code of practice in relation to the use of RT and The mental Capacity Act;<br>• To complete all relevant Rapid Tranquilisation documentation. |
| Clinical Pharmacy staff | • To ensure medicines for RT are prescribed accurately, unambiguously and compliant with legal requirements and good practice standards;<br>• To ensure medicines for RT and medicines to treat adverse effects are available on wards;<br>• To check if patients prescribed RT have received, or may potentially receive “high dose” antipsychotic therapy;<br>• To check if medicines prescribed for RT interact with any regular medication the patient is taking;<br>• To check that required monitoring is being done following administration of RT. |
| Ward Managers | • To ensure the policy and related procedures are adhered to;<br>• To ensure that adequate training is given to allow staff to safely implement the guidelines;<br>• To ensure compliance is audited;<br>• To ensure Quality Improvement Lead Nurses are informed if the guidelines are not being adhered to appropriately. |

## Appendix 1 - The Neuroleptic Malignant Syndrome (NMS)

### Neuroleptic Malignant Syndrome (NMS)

- Incidence - 0.5% - 1% patients;
- Mortality - (untreated) 20%;
- Onset may be acute or insidious;
- Course may fluctuate;
- May occur out of hospital.

### Signs and symptoms

- Fever / Hyperthermia;
- Hypertension / autonomic instability (Fluctuating B.P);
- Tachycardia;
- Sweating;
- Incontinence / retention / obstruction;
- Muscular rigidity (may be confined to head and neck);
- Confusion / agitation;
- Varying degree of unconsciousness;
- Raised white blood cell count;
- Raised creatinine phosphokinase (CK).

### Risk factors

- Organic brain disease, dementia, alcoholism;
- Hyperthyroidism;
- Parkinson's' disease;
- Dehydration;
- High dose of antipsychotic medication / recent dose increase;
- History of catatonia.

### Treatment

- Withdraw the precipitating medicines immediately- antipsychotics, antidepressants, lithium, promethazine;
- Treat as a medical emergency – arrange emergency transfer to acute medical trust
- Correct dehydration and hyperpyrexia- rehydrate, use ice packs;
- Control agitation with short-acting benzodiazepines;
- Dopamine antagonists: bromocriptine / dantrolene (can only be administered at acute trust);
- Antimuscarinic agents;
- Propranolol;
- General supportive intervention on a medical ward.

**Training Needs Analysis for the policy for the development and management of Trustwide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| Staff Group | ✓ if appropriate | Frequency | Suggested Delivery Method (traditional/ face to face / e-learning/handout) | Is this included in Trustwide learning programme for this staff group (✓ if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |
| Non-clinical non patient contact | | | | |

| Please give any additional information impacting on identified staff group training needs (if applicable) |
|---|
| |

| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |
|---|
| |

| Any other additional information |
|---|
| |

| Completed by | | Date | |
|---|---|---|---|

**Document level: Trust**
**Code: 1.88**
**Issue number: 1**

# High Dose Antipsychotic Therapy Policy

| | |
|---|---|
| Lead executive | Chief Medical Officer |
| Authors details | Principle Clinical Pharmacist<br>Nurse Practitioner |

| | |
|---|---|
| Type of document | Guidance |
| Target audience | All clinical staff |
| Document purpose | For information |

| | | | |
|---|---|---|---|
| Approving meeting | Quality Committee<br>Trust Board | Meeting date | 1st June 2023<br>8th June 2023 |
| Implementation date | 31st July 2019 | Review date | 30th June 2026 |

| Trust documents to be read in conjunction with | |
|---|---|
| | Medicines Policy |
| | Medication Monitoring Policy |
| | Non-formulary, Off-label, and Unlicensed Medicines Policy |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | Clarity around frequency of monitoring.<br>Section referring to Lorenzo.<br>Change from LUNSERS to GASS.<br>References updated.<br>Table of medication – new medications added (appendix 1)<br><br>References updated, clarification of monitoring requirements and expectations. | 1 (As a standalone policy)<br><br>2 | 26.06.2019<br><br>01.03.2023 |
| Appendices / electronic forms | Form unchanged from version already on Lorenzo | | |
| What is the impact of change? | Clarification of guidance and updated to include most recent information | | |

| | |
|---|---|
| Training requirements | None |

| Document consultation |
|---|

| | |
|---|---|
| Directorates | All members of Clinical Effectiveness Group (CEG) |
| Corporate services | N/A |
| External agencies | N/A |

| | |
|---|---|
| Financial resource implications | N/A |

| External references |
|---|
| Royal College of Psychiatry. Consensus statement on high-dose antipsychotic medication. Council Report CR190, November 2014<br><br>Royal College of Psychiatry. The risks and benefits of high-dose antipsychotic medication. College Report CR190, Revised January 2023<br><br>Harrington et al (2002a). The results of a multi-Centre audit of the prescribing of antipsychotic drugs for in-patients in the UK. Psychiatric Bulletin, 26, 414-418<br><br>The Maudsley Prescribing Guidelines in Psychiatry 14th Edition, 2021, D Taylor et al.<br><br>Antipsychotic Dosage Ready Reckoner version 10, 2022, Prescribing Observatory for Mental Health UK and The Royal College of Psychiatrists |

| | |
|---|---|
| Monitoring compliance with the processes outlined within this document | Policy includes a section on audit |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favourable / More favourable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |
| – **Age** (e.g., consider impact on younger people/ older people) | No | |
| – **Disability** (remember to consider physical, mental, and sensory impairments) | No | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | No | |
| – **Gender identity and gender reassignment** (i.e., impact on people who identify as trans, non-binary or gender fluid) | No | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | No | |

| | | |
|---|---|---|
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | No | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay, or bi – whether stated as 'out' or not) | No | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | No | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | | |
| – **Other equality groups?** (May include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | No | |

| | |
|---|---|
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | |
| Enter details here if applicable | |
| If you have identified potential negative impact:<br>- Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | |
| Enter details here if applicable | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | No |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | N/A |
| Enter details here if applicable | |
| Where an adverse, negative, or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | |
| Was a full impact assessment required? | No |
| What is the level of impact? | Low |

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## 1. Introduction

The College Report on high-dose antipsychotic medication (Royal College of Psychiatry Council Report CR190, November 2023 defines high-dose antipsychotics use as:

**A total daily dose of a single antipsychotic which exceeds the upper limit stated in the SPC or BNF with respect to the age of the patient and the indication being treated, and a total daily dose of two or more antipsychotics which exceeds the SPC or BNF maximum using the percentage method.**

Doses above the BNF maximum are more likely to occur with the co-prescribing of depot and oral medication or typical and atypical antipsychotics. It should be noted that the prescribing of 'when required (prn)' antipsychotics may also contribute to high-dose antipsychotic use. It is importance that all prescribing is taken in to consideration, there is a particular risk that GP prescribing of PRN antipsychotics is overlooked.

Past audit of prescribing for in-patients has suggested poor adherence to monitoring recommendations. We also know that in the community there is an even higher risk that monitoring requirements will not be adhered to. **All patients on high-dose antipsychotic treatment must be monitored as per this Policy.** This Policy aims to support the identification of patients on high-dose antipsychotics, factors to be taken into account before making a prescribing decision and the documentation required when antipsychotics are prescribed at high doses

## 2. High Dose Antipsychotic Therapy (HDAT) Policy

All patients on HDAT must be identified in order to properly monitor them. See Appendix 1: Identification of Patients on High Dose Antipsychotic medication.

Consider alternative approaches including clozapine, adjuvant therapy and newer or atypical antipsychotics.

The responsibility to exceed the licensed dose of a single antipsychotic or a combination of more than one lies with the patient's Consultant Psychiatrist. The decision should be discussed with the multidisciplinary team, the patient and/or carer and valid consent obtained. For detained patients, ensure compliance with Part IV of the Mental Health Act for England 1983 specifically Section 58 which deals with the issues of consent in detained patients. If a T2 or T3 form is in use 'high dose' status must be declared on this. The details of the decision-making process should be recorded in the patient's notes including:

- The clinical indication for use of HDAT;
- The patient had been informed of the HDAT, or the reason why they have not been informed.

The use of a medicine at doses that exceed its marketing authorisation is termed off-label or off-license. This applies to the use of HDAT and must be considered and discussed with the patient. Any discussion and decision reached should be documented in the notes including the risks and benefits, the aims of treatment and a plan for when and how the outcomes will be assessed and the medication reviewed (as per the Trust Non-formulary, Off-label and Unlicensed Medicines Policy).

HDAT may be prescribed by Junior Doctors or IPs in an emergency for acute symptoms in inpatients, for example while on-call. This should be discussed with a Consultant Psychiatrist before it is prescribed; if this is not possible the reason must be documented and the treatment reviewed at the next opportunity by the Consultant Psychiatrist or deputising consultant.

Only the Consultant Psychiatrist or another deputising Consultant should make the decision to use regular HDAT. The decision should be documented in the patient's notes. For community patients these patients must then be added to the local register of patients on HDAT, in order that monitoring and follow-up reviews are not missed. For inpatients this should be done at discharge by the community team if the treatment is still ongoing.

Use of HDAT is associated with an increased potential for adverse effects. This may include an association with postural hypotension, sedation, seizures, extrapyramidal side effects (EPSEs), hyperprolactinaemia, tachycardia, neuroleptic malignant syndrome (NMS), cognitive impairment and sudden death. Cardiac arrhythmia is more likely to occur in the presence of electrolyte disturbances, treatment with diuretics, alcohol dependence, renal or liver disease.

<u>Actions for prescribers:</u>

- Indicate in the notes, and for inpatients on the prescription chart that the patient is receiving high-dose antipsychotics, using an identifiable clinical note name

- Consider mental health act status. If a T2/T3 is in place ensure it allows for high dose antipsychotics
- A High-Dose Antipsychotic Monitoring Form (Appendix 3) should be completed for the patient and scanned into the notes under documents with a clearly identifiable title. This form is also available on Lorenzo as Clinical Note template which can be completed.

(a) Consider risk factors such as:

- Cardiac history (particularly MI, arrhythmias, abnormal ECG);
- Hepatic / renal impairment;
- Alcohol use / smoking;
- Old age;
- Obesity.

(b) Consider potential drug interactions**,** specifically to avoid concomitant treatment with:

- diuretics;
- anti-arrhythmics;
- anti-hypertensives;
- tricyclic antidepressants, citalopram or escitalopram;
- high dose methadone (>80mg daily)
- other medicines which might prolong QT interval, or increase blood antipsychotic levels e.g. cimetidine, erythromycin.

(c) Obtain a pre-HDAT baseline ECG if possible. If it is not possible and HDAT is to be prescribed anyway, the decision to start must be adequately documented in the notes. include reason for not obtaining ECG, justification for commencing without ECG and who has been involved in the decision. If a prolonged QT interval is recorded (QTc > 440ms in men or >470ms in women), review treatment and consider cardiology assessment. If it is decided to continue treatment, record the reasons for doing so in patient's notes. For all patients on HDAT repeat the ECG after a few days (within 1 week), then every 1-3 months in the early stages of high dose treatment. If the patient transitions between inpatient and community services these monitoring requirements must be clearly communicated between teams. The ECG should then be repeated as clinically indicated or with further dose increases. Minimum of annually once stable.

(d) Serum urea and electrolytes and liver function should be checked before prescribing HDAT and after 1 month. Then every 3 months in the early stages of high dose treatment and thereafter as clinically indicated to ensure liver or renal failure are not developing. Minimum of annually once stable

(e) Monitoring of patients receiving antipsychotics should follow Trust guidelines and include as a minimum, weight, lipids, glucose, blood pressure, pulse, U&Es, GFR, LFTs and FBC. Minimum of annually.

(f) If high-dose antipsychotic therapy is being prescribed in the setting of rapid tranquillisation or sedation then it is particularly important that the routine monitoring of a sedated patient is carried out, with particular attention to regular checks of pulse, blood pressure, respiration, temperature and hydration (see the Rapid Tranquillisation policy). It is recommended that ECGs should be carried out frequently during dose escalation.

Where possible increase the dose slowly, ideally at intervals of at least one week.

A prescriber should review clinical improvement at least once every 3 months, reducing dose to within the licensed range if inadequate clinical improvement is observed and consider alternatives, e.g. adjuvant therapy and newer or atypical antipsychotics such as clozapine. Patients who remain on HDAT should be seen at least annually by the Consultant Psychiatrist for a medication review. Continued use of high-dose therapy where there is no clinical response must be justified in the case notes. Consultants should consider seeking a second opinion from a colleague. The review outcome must be documented in the patients' notes.

The Royal College of Psychiatrists College Statement recommends monitoring of psychotic symptoms. Improvement in psychotic symptoms could be measured using for example BPRS (Brief Psychiatric Rating Scale) and HoNOS (Health of the Nation Outcome Scales). Side effects should be monitored using GASS (Glasgow Antipsychotic Side-effect Scale). These should be performed at weeks 0, 6 and 12, then for each 3 monthly review

The use of and monitoring of HDAT must continue in secondary care, these patients cannot be discharged from Trust services. . If the GP is being asked to prescribe one or more of the antipsychotics they should be made aware of the high dose status even if only being asked to prescribe one of the medicines. The patient should continue to have their physical health monitored, at least annually, either by the Trust HDAT clinics, Trust locality clinics or the Trust SMI service. This may depend on models of service in different clinical areas and across the ICS.

## 3. HDAT Monitoring - Roles and Responsibilities

### Responsibilities of Medical Staff:

- Record reason for high-dose in clinical notes
- Complete the HDAT Monitoring Form
- Inform patient and record consent in notes
- Order ECGs
- Check U&Es
- Check LFTs
- Check HDAT is mentioned on Form T2/ T3 if applicable
- For inpatients, ensure on patients' discharge that GP and other relevant community mental health personnel are informed of HDAT status and required checks.
- Ensure HDAT guideline is followed.
- Prescriber to conduct quarterly review of medication.
- Consultant to conduct annual medication review and document appropriateness of ongoing HDAT.
- Ensure a system by which the required tests and reviews will be conducted is agreed with the relevant community mental health personnel and / or GP at discharge.
- The decision to use high-dose antipsychotic therapy should only be taken by the Consultant Psychiatrist. A transfer of prescribing to a General Practitioner should be undertaken only in consultation with and with the agreement of the General Practitioner and in accordance with local guidance on sharing of care.

### Responsibilities of Nursing Staff:

- Monitor and record NEWS scores
- Record "high dose" status in nursing notes on lorenzo and on care plans
- If administering high dose antipsychotics check that monitoring sheet is being completed and bring to medical staff attention if checks have not been done
- Ensure that high-dose status is discussed at reviews

### Role of the Pharmacist working in inpatient settings or community teams:

- Identify that a patient is on high dose antipsychotic therapy and record on lorenzo if not already done
- Promote and support the use of the HDAT Monitoring Form
- Complete high-dose details and % BNF max on prescription charts for each medicine
- Complete interacting medicines section
- Contact the prescriber and/ or Consultant Psychiatrist with any concerns about the high-dose status

#### Role of the Pharmacist in the dispensary for outpatients

- If dispensing or reviewing an outpatient prescription check the notes for evidence of HDAT rationale, monitoring and review.
- Contact the prescriber or Consultant Psychiatrist about the HDAT status if the notes are unclear, to ensure this is intentional. The outcome of any discussion should be documented on the prescription along with any advice given.
- Promote monitoring and use of the HDAT form.

## 4. Acknowledgements

High Dose Antipsychotic Therapy Guidelines. Greater Glasgow and Clyde Health Board 2006.

High Dose Antipsychotic Therapy Guideline Pennine Care NHS Trust 2007

**Appendix 1**

## IDENTIFICATION OF PATIENTS ON HIGH-DOSE ANTIPSYCHOTIC MEDICATION

High dose antipsychotic prescribing may arise as a result of EITHER:

A Single antipsychotic drug prescribed at a daily dose above the BNF upper recommended limit (High Dose single drug)

OR

B More than one antipsychotic prescribed concurrently where the sum of doses given expressed as a percentage of the BNF/ SPC maximum of each drug exceeds 100% (High-Dose through the prescribing of multiple drugs).

For example: A patient on zuclopenthixol depot 300mg weekly and olanzapine 15mg daily.
Sum of percentages: 50% + 75% = 125% (>100%, therefore high-dose).

| ANTIPSYCHOTIC | MAXIMUM LICENSED (Adult) DAILY ORAL DOSES i.e. 100% (mg/day) |
|---|---|
| Amisulpride | 1200 |
| Aripiprazole | 30 |
| Asenapine | 20 |
| Cariprazine | 6 |
| Chlorpromazine | 1000 |
| Clozapine | 900 |
| Flupentixol | 18 |
| Haloperidol * | 20 |
| Levomepromazine | 1000 |
| Lurasidone | 148 |
| Olanzapine | 20 |
| Paliperidone | 12 |
| Pericyazine | 300 |
| Perphenazine | 24 |
| Pimozide** | 20 |
| Prochlorperazine | 100 |
| Promazine | 800 |
| Quetiapine | 750 or 800 in mania |
| Risperidone | 16 |
| Sertindole (named patient)* | 24 |
| Sulpiride | 2400 |
| Trifluoperazine | 50 |
| Zotepine* | 300 |
| Zuclopenthixol | 150 |
| | **DEPOTS** |
| Aripiprazole **LAI** | 400 /calendar month |
| Flupentixol **depot** | 400 /week |
| Fluphenazine **depot** | 50 /week |
| Haloperidol **depot** | 75 /week |
| Olanzapine **LAI** | 300 / fortnight |
| Paliperidone **LAI** | 150 / calendar month |
| Risperidone **LAI** | 50 / fortnight |
| Zuclopenthixol **depot** | 600 / week |

Use of “Discretionary” (PRN or “as required”) antipsychotic medication should also be taken into account.
* Subject to regular ECG irrespective of dosage (Consult BNF)
** Subject to annual ECG irrespective of dosage.

**Appendix 2**

## Prescribing Guidance
## The Use of More Than One Antipsychotic Drug at the Same Time.

More than one antipsychotic drug should only be given concurrently as part of a considered treatment plan.

- There is no evidence to support the view that a combination of typical and atypical antipsychotics results in fewer neurological side effects than typicals alone
- Treatment with more than one antipsychotic (polypharmacy) is more complex and potentially more confusing.
- Treatment with more than one antipsychotic can make it difficult to accurately titrate the doses of each drug and to assess their individual effectiveness.
- There are no good RCTs of treatment with more than one antipsychotic. Although this does not mean that certain combination treatments might be appropriate for particular patients, more evidence-based approaches should be considered before resorting to non-evidence based and higher-risk treatments.
- “High dose” can inadvertently occur with combinations. PRN antipsychotics are particularly problematic in this respect.
- Subtle drug interactions can occur with combinations through P450 and other enzyme systems.

Before combination antipsychotics are used, specific care should be taken to ensure that:

- The diagnosis is correct
- Plasma levels (if appropriate) are within the usual therapeutic range
- Medicine compliance is assured.
- Treatment duration has been fully adequate.
- Adverse social and psychological factors are minimised.
- Alternative adjunctive drug therapies have been tried.
- An objective measure of effectiveness of drug therapy on symptomatology is used.

If a combination will result in exceeding 100% BNF maximum dose the high-dose antipsychotic policy should be adhered to.

Appropriate indications for use of combination therapy include:

- Failure to respond to clozapine
- Failure to tolerate clozapine
- Where clozapine had produced a partial response, as augmentation.
- During the switch from one antipsychotic to another
- As a temporary measure during an acute exacerbation of illness.

Inappropriate indications would include:

- Confusing sedative effect with antipsychotic effect.

- Failure to wait an adequate length of time for the first drug to have an antipsychotic effect (at least 6 weeks).
- As a substitute for planning, communicating and completing a switch in antipsychotic therapy.
- Where clinical improvement occurs before a switch is completed. An improvement seen during the switch *may* indicate a trial of the combination if appropriate.
- Where inadequate resources and environment result in the need for more medication at higher doses to compensate.

If multiple antipsychotics are to be used:

- The patient should be informed and consent obtained and recorded.
- The rationale for use should be recorded in the patients' clinical notes.
- The clinical indication for use should be recorded in the patients' clinical notes.
- The use of multiple antipsychotic therapy should be reviewed regularly with regard to the clinical indication and the result of this review recorded.
- If no improvement is seen at review, discontinuation of multiple antipsychotic therapy should be considered.
- More than two regular antipsychotics would indicate the need for a thorough medication review.

**Appendix 3**

# HIGH DOSE ANTIPSYCHOTIC MONITORING FORM

This form must be completed for all high dose therapy patients – preferably prior to commencing treatment.

| Name: | NHS Number: |
|---|---|
| Consultant Psychiatrist: | |

High Dose Therapy Checklist - *please circle as appropriate.*

| PMH – contraindications | | Possible drug interactions | | |
|---|---|---|---|---|
| History of cardiac disorders? Y N<br>*Details:* | | Tricyclic antidepressants? Y N<br>Diuretics? Y N<br>Other: | | |
| | | **Initial tests:** | **Results** | **Date** |
| Hepatic impairment? Y N | | Blood pressure | | |
| Renal impairment? Y N | | Temp. | | |
| Obesity? Y N | | Pulse | | |
| Smoker? Y N | | ECG- QTc interval | | |
| Impaired Glucose metabolism? Y N | | U & Es *(✓if ok)* | | |

| |
|---|
| Has the patient failed to respond to two different classes of antipsychotic at maximum dosage for a suitable time period?<br>Yes ☐ No ☐ |
| Please state the reasons why high-dose therapy is to be initiated. If there are relative contra-indications please outline the risk management plan.<br><br>Signature _____ Print Name: _____ |

Consent

| | |
|---|---|
| Form T2 ☐ Form T3 ☐ | |
| High dose therapy mentioned on Form T2/T3? Yes ☐ No ☐ | |

Prescription Details

| Start Date | Drug(s) | Dosage/ frequency: | % BNF maximum | Total daily % BNF max |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

## HIGH DOSE ANTIPSYCHOTIC MEDICATION MONITORING

| TEST | | No 1 | No 2 | No 3 | No 4 | No 5 | No 6 |
|---|---|---|---|---|---|---|---|
| **ECG (QTc)** | DATE | | | | | | |
| | RESULT | | | | | | |
| **Urea & Electrolytes** ***(✓ if OK)*** | DATE | | | | | | |
| | RESULT | | | | | | |
| **Blood pressure** | DATE | | | | | | |
| | RESULT | | | | | | |
| **Temperature** | DATE | | | | | | |
| | RESULT | | | | | | |
| **Pulse** | DATE | | | | | | |
| | RESULT | | | | | | |
| **Full Blood Count** | DATE | | | | | | |
| | RESULT | | | | | | |
| **LFTs** | DATE | | | | | | |
| | RESULT | | | | | | |

***ABNORMAL RESULTS – PLEASE PROVIDE DETAILS***

| Test/Result | Date | Comment | Action |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**Appendix 4**

## Possible Audit Criteria for Clinical Audit / Medicines Use Evaluation of the Guideline

| Criterion Statement | Standard | Exceptions |
|---|---|---|
| All patients who are prescribed high-dose antipsychotics are identified in the notes | 100% | None |
| Each patient identified as being on high-dose antipsychotics has a completed high-dose antipsychotic monitoring form | 100% | None |
| There is evidence that after initiation of high-dose antipsychotic therapy, there was a repeat ECG within 1 week and then at 1-3 months | 100% | High-dose antipsychotic treatment discontinued.<br><br>Reason(s) for not performing ECG documented in notes. |
| The ECG report can be examined for the presence/absence of:<br>Ischaemic Heart Disease<br>Left Ventricular Hypertrophy in addition to $QT_c$ | 100% | |
| There is evidence that 'prn' antipsychotic medication is under review | 100% | None |
| The patients' notes contain details of the treatment plan incorporating high-dose antipsychotic treatment and a rationale for treatment | 100% | None |
| There is evidence of ongoing monitoring of FBC, U&Es, LFTs, glucose and cholesterol during high-dose antipsychotic treatment | 100% | None |

**Training Needs Analysis for the policy for the development and management of Trustwide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| Staff Group | ✓ if appropriate | Frequency | Suggested Delivery Method (traditional/ face to face / e-learning/handout) | Is this included in Trustwide learning programme for this staff group (✓ if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |
| Non-clinical non patient contact | | | | |

| |
|---|
| Please give any additional information impacting on identified staff group training needs (if applicable) |

| |
|---|
| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |

| |
|---|
| Any other additional information |

| | | | |
|---|---|---|---|
| Completed by | | Date | |

**Document level: Trust**
**Code: 1.95**
**Issue number: .**

# Controlled Drug Policy

| | |
|---|---|
| Lead executive | Interim Chief Medical Officer |
| Authors details | Principal Pharmacist (Operations)<br>Principle Pharmacist (Clinical)<br>Pharmacy Manager<br>ePMA Pharmacist Lead<br>Deputy Director of MACE |

| | |
|---|---|
| Type of document | Policy |
| Target audience | This Policy is **mandatory** for all Trust staff. It also applies to any staff who are contracted to work on a sessional or secondment basis. The Policy should be regarded as a working document and should be referred to when necessary for guidance. |
| Document purpose | For information |

| | | | |
|---|---|---|---|
| Approving meeting | Quality Committee<br>Trust Board | Meeting date | 4th May 2023<br>11th May 2023 |
| Implementation date | 31st May 2023 | Review date | 31st May 2026 |

| Trust documents to be read in conjunction with | |
|---|---|
| 1.03 | Medicines Policy |
| | Non-Medical Prescribing Guidance |
| | Physical Health Policy |
| 1.03f | Issuing of FP10 Prescriptions in Community Settings (Trust SOP) |
| MHA28 | Convert Medication Policy |
| 1.52 | Research Governance and Management Policy |
| 5.01 | Incident Reporting Policy |
| 1.94 | Patient Group Direction Policy |
| | Waste Policy |
| | Best Practice Policy Medicines Administration Swallowing Difficulties |
| 7.07 | Records Management Policy |
| | Inpatient Clerking and Prescribing using the Lorenzo Electronic Prescribing and Medicines Administration (ePMA) system |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | KPMG plus….<br><br>This review takes into the account the relatively new Nursing Associate role and their professions scope of practice. It also | 1.0 | Oct 2019 |

| | | | |
|---|---|---|---|
| | reflects the process changes associated with the adoption of Electronic Prescribing and Medicines Administration (ePMA) within the majority of inpatient areas.<br><br>Further changes include:<br>Section 3 - Further guidance on the appropriate use of key safes.<br><br>Section 4 - the guidance relating to the ordering of controlled stationary has been updated to clarify responsibilities.<br><br>Section 4.4 – details the steps that must be followed when sourcing CD's out of pharmacy opening hours.<br><br>Section 6 – clarifies the roles that are permitted to deliver and receipt CD's.<br><br>9.2 – Details considerations in the situation where a community patient is deceased and CDs remain in their home.<br><br>15 – States that all staff involved in the supply and management of CDs have a responsibility to comply with this Policy, failure to do so may result in disciplinary or legal procedures subject to investigation.<br><br>Appendix 4 changed from Obtaining Methadone/ Buprenorphine when Pharmacy Department Closed to record of controlled drug destruction visit (Stoke Heath). | | |
| Appendices / electronic forms | | | |
| What is the impact of change? | | | |

| | |
|---|---|
| Training requirements | N/A |

| | |
|---|---|
| Document consultation | |
| Directorates | All Directorates and CEG membership |

| | |
|---|---|
| Corporate services | N/A |
| External agencies | N/A |

| | |
|---|---|
| Financial resource implications | N/A |

| External references |
|---|
| • Medicines Ethics and Practice. A Guide for Pharmacists. Royal Pharmaceutical Society of Great Britain. Issue 44. July 2021<br>• Misuse of Drugs Act, 1971<br>• Misuse of Drugs (safe custody) Regulations, 1973<br>• Misuse of Drugs Regulations, 1985<br>• Misuse of Drugs Regulations, 2001<br>• The Safe and Secure Handling of Medicines: A Team Approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists Group of the Royal Pharmaceutical Society of Great Britain March 2005<br>• Safer Management of CDs: Guidance on the Destruction and Disposal of CDs new role for accountable officers, Dept of Health, August 2007<br>• Safer Management of CDs: A guide to good practice in secondary care (England) Dept of Health/Royal Pharmaceutical Society of Great Britain October 2007<br>• Department of Health. Safer Management of Controlled Drugs: (1) Guidance on strengthened governance arrangements. Gateway reference: 6077. 9th March 2006.<br>• Department of Health. Safer Management of Controlled Drugs: Guidance on standard operating procedures for controlled drugs. Gateway reference: 7585. January 2007.<br>• Guidelines for administration of Medicines 2008, Nursing and Midwifery Council.<br>• Records Management: NHS Code of Practice, Department of Health 2006. |

| | |
|---|---|
| Monitoring compliance with the processes outlined within this document | |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favorable / More favorable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |
| – **Age** (e.g. consider impact on younger people/ older people) | No | |
| – **Disability** (remember to consider physical, mental and sensory impairments) | No | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | No | |
| – **Gender identity and gender reassignment** (i.e. impact on people who identify as trans, non-binary or gender fluid) | No | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | No | |

| | | |
|---|---|---|
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | No | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not) | No | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | No | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | No | |
| – **Other equality groups?** (may include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | | |
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | | |
| Enter details here if applicable | | |
| If you have identified potential negative impact:<br>- Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | | |
| Enter details here if applicable | | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | ~~Yes /~~ No | |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | Yes / No | |
| Enter details here if applicable | | |
| Where an adverse, negative or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | | |
| Was a full impact assessment required? | ~~Yes /~~ No | |
| What is the level of impact? | Low / medium / high | |

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# 1. INTRODUCTION TO CONTROLLED DRUGS

## 1.1. Background

Medicines optimisation is a patient centred approach to improving outcomes from medicines. This encompasses: reducing harm from medicines; ensuring medicines' use is as safe as possible; evidence-based use of medicines and embedding good practice(s).

The Misuse of Drugs Act 1971 controls 'dangerous or otherwise harmful drugs' which are designated as 'Controlled Drugs'. The primary purpose of the Misuse of Drugs Act is to prevent the misuse of Controlled Drugs (CDs) in particular their manufacture, supply and possession. It does this by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by Regulations or by licence from the Secretary of State for Health.

The use of Controlled Drugs is permitted by the Misuse of Drugs Regulations 2001, as amended. These Regulations define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities. Other regulations deal with the safe custody of CDs and with the notification of and supply of drugs to misusers.

The legal framework affecting Controlled Drugs were brought in to sharp focus by issues arising from the Shipman case and the publishing of the Shipman Inquiry's Fourth Report (2004). To implement the recommendations made in the Shipman Report, a number of legal changes were made to the way that CDs are managed in England, Scotland and Wales.

Legislative changes have been made in the form of The Health Act 2006, the accompanying Controlled Drugs (Supervision of Management and Use) Regulations 2006 and amendments to the Misuse of Drugs Regulations 2001.

More recently, changes to the professional use of controlled drugs by pharmacists and nurses relating to independent pharmacist and nurse prescribers, patient group directions and compounding (mixing) came into effect in April 2012. The Department of Health (DH) published additional information about changes to the controlled drugs regulations, which came into effect on 1 April 2013.

In addition the DH and the Royal Pharmaceutical Society of Great Britain (RSPGB) jointly issued 'Safer Management of Controlled Drugs - A guide to good practice in secondary care (England)' in 2007.

The purpose of this policy is to:

- Ensure the Trust complies with the legal requirements of the Misuse of Drugs Regulations (1971), all other relevant Controlled Drugs Legislation and NHS Guidance including National Patient Safety Alerts.
- Provide clear standards and procedures for all staff carrying out their duties involving Controlled Drugs. The aim being to reduce risk, minimise harm and reduce adverse incidents.
- Improve the governance arrangements in place and ensure that any risks associated with the use of controlled drugs are identified and managed.
- Support professionals, encourage good practice and ensure that controlled drugs are available and used when clinically required by patients.

## 1.2. Definition of a controlled drug

In the misuse of drugs regulations (2001) there are five schedules under which medicines are classified. Brief details on each schedule are outlined below:

### Schedule 1 (Controlled Drug License)

This schedule includes the hallucinogenic drugs (e.g. LSD), ecstasy-type substances, raw opium and cannabis (see schedule 2 below). A license from the Home Office is required for production, possession or supply; such licenses are limited to research and other special purposes.

### Schedule 2 (Controlled Drug POM)

This schedule includes the opioids (e.g. diamorphine, morphine, and methadone) the major stimulants (e.g. amphetamines) and quinalbarbitone (secobarbital). They may be supplied by or on the authority of, a pharmacist to a patient on the authority of a prescription in the required form. They may also be supplied by, or on the authority of, a pharmacist to a nurse in charge of a ward/unit on the authority of a requisition in the required form. Full storage, register and destruction requirements apply.

Following the widening of legislation on the 1st of November 2018, defined cannabis-based products for medicinal use can be accessed through restricted routes if prescribed by specialist doctors on the GMC's specialist register for certain indications. See current NICE guidance for further information. These products are not currently on the local formulary and are not licensed for any mental health conditions, so would not normally be initiated in the Trust.

### Schedule 3 (CD No Register POM)

This schedule includes a small number of drugs (such as buprenorphine, gabapentin, midazolam, phenobarbital, pregabalin, tramadol and temazepam) which are either not so likely to be misused as those in Schedule 2 or not so harmful if they are misused. Most drugs in this schedule are to be recorded in the ward CD registers and require safe storage. The requirements include all Schedule 3 patients' own drugs and self-medication supplies. Gabapentin and pregabalin are not entered in the pharmacy or ward CD registers and the safe custody requirements do not apply to both drugs, however prescription requirements still apply. Destruction requirements apply as for Schedule 2 drugs above.

### Schedule 4 (CD Benz POM or CD Anab POM)

Part 1 (CD Benz POM) contains most of the benzodiazepines as well as non-benzodiazepine hypnotics such as zopiclone and zolpidem. Part II (CD Anab POM) contains mostly the anabolic and androgenic steroids. Like all Schedule 2 and 3 drugs, it is now a legal requirement that Schedule 4 Part 1 Controlled Drugs be denatured before being placed into waste containers. Ward staff must ensure that all Part 1 (CD Benz POM) preparations are returned to Pharmacy for denaturing and destruction. Benzodiazepines are not recorded in the pharmacy/ward CD register and stock reconciliation takes place in line with normal procedures for rolling stock checks. As for Schedule 2 and 3 medicines, a prescription for schedule 4 medicines is legally valid for only 28 days.

### Schedule 5 (CD Inv. P or CD Inv. POM)

This schedule contains preparations of certain controlled drugs, such as codeine, pholcodine and morphine, which are exempt from full control when present in medicinal products of low strength. However, for good governance and clinical safety, the Trust requires that morphine

sulfate oral solution 10mg/5ml continue to be treated as a Schedule 2 Controlled Drug.

## 2. POLICY SYNOPSIS

All staff involved in aspects of controlled drug management should be familiar with this policy and associated standard operating procedures and comply with them at all times.

This Policy must be read in conjunction with the Medicines Policy and describes in detail the processes, roles and responsibilities in relation to the management of controlled drugs (CDs), including:

- Stocks, storage and security of CDs at ward / department level
- Ordering and receipt of CDs
- Administration of CDs
- Record keeping in the ward controlled drug record book
- Controlled drug stock checking at ward level
- Disposal and / or return to the Pharmacy Department
- Patient's own CDs
- Prescribing of CDs

All staff working within the Trust who are involved in some way with the supply and management of medicines, must familiarise themselves with and comply with the Trusts' medicines policy.

To monitor compliance with this policy, the pharmacy department will undertake quarterly controlled drug audits on all the inpatient wards (including Summers View and the Darwin centre).

## 3. STORAGE AND SAFE CUSTODY OF CONTROLLED DRUGS

Controlled drugs (CDs) and associated stationary in wards must be stored in a locked controlled drugs cupboard which is firmly fixed to the wards at all times. The CD cupboard and locks/keys must conform to the specification of the Misuse of Drugs (safe custody) regulations 1971. Ward CD cupboards should conform to the British Standard Reference BS2881.

Only controlled drugs and associated stationary may be stored in the controlled drugs cupboard. No other medicines, valuables or items except controlled drugs and other medicines deemed controlled by Trust Policy should be stored in this cupboard. An exception to this is suspected illicit substances, which should be stored in a sealed envelope in the Controlled drug cupboard until such time as they can arrange for disposal by the police. The envelope should be cleared marked as quarantined with the date, printed names and signatures of the two staff involved in quarantining the illicit substance.

If the ward's controlled drug cupboard is found to be defective, this should be reported immediately to Estates. The security of the controlled drugs should be maintained at all times. The ward pharmacist must be contacted for advice during pharmacy working hours or the on-call pharmacist outside of working hours. If it is necessary to re-locate controlled drugs to alternative storage, this must be done on the advice of a pharmacist. On the arrival of Estates, they should be escorted to the controlled drug cupboard by a registered nurse. A registered nurse must remain with the Estates personnel whilst the controlled drug cupboard is fixed. Immediately after the controlled drug cupboard is fixed, a stock check of all controlled drugs should be performed. If the cupboard has been altered in any way during the repairs, it may no longer conform to the regulations specified above. The cupboard must be risk assessed by a senior pharmacist in discussion with the Trust's Accountable Officer to establish if a new

cupboard is required. An incident form must be raised to report all defective controlled drug cupboards.

Controlled drugs cupboards must be kept locked at all times when not in use. The lock to the controlled drug cupboard must not be common to any other lock. Controlled drug cupboard keys must be kept separately to all other keys.

Some wards have a key safe installed for the safe keeping of the controlled drug keys. Key safes must have unique codes that are not easily guessable and that are only known to registered nursing staff working within that clinical area who have the authority to access the controlled drug cupboard. Codes should be change periodically (i.e. a minimum of annually) and when a staff member leaves the Trust or moves from the clinical area in order to ensure controlled access. No other items should be stored alongside the controlled drug keys in the key safe (including other sets of keys) so as to prevent unnecessary access to controlled drug keys.

The most senior registered nurse in charge of a clinical area has overall responsibility for ensuring all controlled drugs are stored, administered, recorded and handled in accordance with the Misuse of Drugs Act 1971 and Misuse of Drugs (Safe Custody) Regulations 1973. This will be the ward/team manager or where the manager is not a registered nurse, the most senior registered nurse. Day to day responsibility can be delegated, for each shift, to a nurse or healthcare practitioner assessed as competent under the trust medicines management competency framework and where this practice is in line with a specific service. However, the ward manager or most senior registered nurse must ensure that the nurse (or healthcare practitioner assessed as competent and authorised) understands and accepts the responsibility associated with controlled drugs and key holding. Legal responsibility remains with the ward manager/most senior registered nurse. Whilst the task can be delegated, the responsibility cannot. The registered nurse in charge must be aware of every time the controlled drug cupboard is opened and must be informed of the reasons when the keys are used and approve of their use. Two registered nurses must be present at all times when the controlled drug cupboard is open – one to carry out the required activity and one to check/witness the activity**.**

**In exceptional circumstances, a final year nursing student, a registered pharmacist or pharmacy technician can act as witness if no other registered nurse available.**

The controlled drug keys must be handled only by registered nurses on the ward. The keys may be handed to a registered pharmacist or pharmacy technician for the purpose of stock checking but there should always be a registered member of the ward staff present if they open the cupboard.

If the controlled drug cupboard keys are missing then urgent effort should be made to retrieve the keys as soon as possible, for example, by contacting staff that have just gone off duty. The ward manager and the site manager must be informed if the keys cannot be found. An incident report must be completed when controlled drug keys cannot be accounted for. If after extensive search the keys cannot be located, the ward manager must contact a senior pharmacist by dialing extension 7304604 during working hours. Out of hours the on-call pharmacist can be contacted via the switchboard. The pharmacist will be able to give advice on action to take including obtaining urgent doses of medicines to continue patient care. If the keys have been taken home by a member of staff, the key must be returned as soon as possible by the staff member. If there is any possibility that the controlled drugs keys have been taken by a non-authorised person, the pharmacist and estates may agree if locks are to

be changed.

All controlled drugs must be stored in the correct original outer packaging carrying the dispensing label from Pharmacy. It is not safe to have loose tablets/capsules/ampoules in the controlled drug cupboard. Where a container maybe damaged, loose tablets/ capsules/ ampoules MUST be returned to Pharmacy as soon as possible ideally within 24 hours so that they are not accidentally lost.

## 4. ORDERING OF CONTROLLED DRUGS AND ASSOCIATED CONTROLLED STATIONARY

### 4.1 Ward Stationary Orders

Controlled drugs and associated stationary can only be obtained by ordering from the pharmacy department. This applies to all schedule 2 and 3 controlled drugs and all preparations containing morphine. Controlled stationary is used to describe controlled drug requisition books, CD registers prescription charts, leave/discharge prescriptions and FP10 prescription pads. The controlled drug register is a legal document used to record all transactions involving controlled drugs. Each ward will be issued with one for stock controlled drugs and one patients' own controlled drug if required. The CD register must be ordered from pharmacy using the requisition book. Wards can use the same register to record both stock and Patient Own Drugs (POD) controlled drugs provided entries are separated appropriately.

Only one controlled drug requisition book and one controlled drug register book per ward/department should be in use (active) at any one time.

The controlled drug requisition book/register MUST be kept in a locked cupboard. When completed, the ward manager must keep them in a locked cupboard on the ward and retained for a minimum of two years from the date of last recorded entry. The cover should be labelled with the time period covered to facilitate accessing records if required. A new CD requisition book can be ordered from the pharmacy using page 95 of the most current requisition book.

In May 2022 the majority of inpatient wards had Lorenzo Electronic Prescribing and Medicines Administration (ePMA) installed and operationalised, replacing the paper based charts. All paper charts have been withdrawn from these areas to prevent risk of medication errors. Where ePMA is not live (i.e. Edward Meyers Unit) ward prescription charts (8 week prescriptions, discharge prescriptions and leave prescriptions) are all on the ward stock list and will be replenished where necessary during the pharmacy weekly stock top-up. Registered nurses on the Edward Myers unit are able to request prescription charts if required before the next top-up. This can be done by emailing the pharmacy department on pharmacyteam.harplands@combined.nhs.uk. Ward prescription charts are delivered to the requesting wards by the normal porter/transport deliveries.

### 4.2 Outpatient Stationary Orders

FP10 prescriptions for outpatient clinics can be obtained from the Pharmacy Department. The requesting prescriber MUST complete the requisition form and sign the relevant sections of the form before it can be supplied from pharmacy. All FP10 requisitions must be completed by the named prescriber. Prescribers new to the Trust must contact the Pharmacy Department to ensure they have their own FP10 pads set up. If a pad is not yet set up the Clinical Directorate may authorise a Prescriber to temporarily use another senior prescriber's pad working within the same service. Pharmacy must be informed of this in writing. FP10 MDA do not have a named prescriber and requisition for these pads can be completed by an authorised member

of staff working for the substance misuse services

All FP10's must be stored in a designated secure location and be accessible only to staff authorised to use it (see Trust SOP issuing of FP10 prescription in community setting).

### 4.3 Ordering Controlled Drugs

A Controlled Drugs requisition book must be used for all requests for controlled drugs and associated stationary required for treatment of patients' on wards and departments. Controlled drugs may only be ordered by registered staff nurses specifically authorised to do so by the appointed ward manager. Agency staff are not authorised to order controlled drugs. An up-to-date list of registered nurses permitted to order controlled drugs must be kept on the ward and a copy sent to the Pharmacy Department (see appendix 3). It is the ward manager's responsibility to ensure that this list is regularly reviewed and accurate. All staff must also provide a sample signature on the sheet in the requisition book to enable pharmacy staff to verify their authority to make the request. Failure to do so may cause delays to supplies being issued against controlled drug requisitions.

When placing an order for a controlled drug, each drug requisition must be on a separate, duplicated, numbered page. A carbon paper must be used to duplicate the order and staff must ensure that it is in the correct place before writing out the order so that the order is clear on both the top copy and the bottom copy. Staff completing the requisition must include the following details:

**Requirements for Stock CD Orders**

- Each item must be ordered on a **separate page**
- Each order must be duplicated using **carbon paper**; the top copy is retained in Pharmacy. Staff should ensure the carbon paper is in place correctly.
- The **name of the ward** must be stated
- The **name of the drug** must be stated
- The **formulation** must be stated (e.g. tablets, injection)
- The **strength/ concentration** required must be stated; where injections where more than one **vial/ ampoule size** is available, this must also be specified.
- The **quantity required** must be clearly stated, and should be expressed in terms of dose units e.g. 56 tablets, not 1 pack; 10 ampoules not 1 pack etc.
- The form must be **signed** by the person preparing the order.
- The person preparing the order must **print their name** next to their signature.
- The order must be **dated**.

Failure to meet all these requirements will result in controlled drug not being dispensed until amended by an authorised member of the ward staff.

It is the responsibility of the registered nurse in charge to ensure adequate controlled drugs are available on the ward for their patients' anticipated requirements. This includes ensuring supplies are available on the ward to cover weekends and bank holidays when the Pharmacy Department is closed.

Most wards do not hold stocks of any schedule 2 or 3 controlled drugs. To order these controlled drugs from pharmacy the page in the CD order book must be endorsed with the initials of the patient that the order is required for (except for Edward Myers from whom a copy of the patients chart will be required). This is to enable the pharmacist to match the order to the patient's electronic medication chart, or paper chart in the case of Edward Myers; and perform a clinical check prior to issue of the controlled drug. This is to ensure that the prescribed controlled drug

is safe and appropriate for the patient. Ward 2 and Edward Myers unit both hold a supply of methadone mixture and buprenorphine tablets and a copy of the inpatient chart is not required before a supply is made to them.

Once a requisition has been completed accurately, the book must be placed inside the ward blue controlled drug box and sent to pharmacy to be processed.

Stock controlled drugs can only be obtained from Pharmacy.

- It is not permitted to transfer stock controlled drugs from one ward to another.
- If a controlled drug is ordered exclusively for administration to one patient and the patient is subsequently transferred to another ward, the controlled drug must be returned to pharmacy. The receiving ward must then order the controlled drug from Pharmacy for use on that ward.
- Only in the case of Patient's Own Drugs (PODs) may CDs be transferred with the patient; these must be signed out of the controlled drug register by a Register Nurse and a suitable witness

### 4.4 Obtaining Controlled drugs outside Pharmacy opening hours

Every effort should be made to ensure that adequate stock levels of controlled drugs are maintained to meet the likely demand

**Stock controlled drugs cannot be borrowed between wards as it is illegal for nurses to supply controlled drugs directly to another nurse or ward/department (as outlined in Misuse of Drugs Act 1971).**

Outside Pharmacy opening hours, if a patient is prescribed a controlled drug but it is not available on the ward, the nurse in charge should contact the on-call pharmacist for advice. The pharmacist will establish if the patient may come to harm as a result of a missed dose of controlled drug and what the options are for obtaining the drug e.g. use of FP10 to obtain a supply from a community pharmacy.

Outside Pharmacy opening hours, **the on-call pharmacist may authorise** obtaining methadone or buprenorphine tablets from the Omnicell® out-of-hours medication cabinet if deemed appropriate. As with all controlled drug transactions, two Registered Nurses registered to use the Omnicell® must attend the unit together and controlled drugs must be obtained in line with the Omnicell® SOP. The attending registered nurses must both have accounts registered with the Omnicell® and at least one of the nurses must have their fingerprint set up against their log in to authenticate access of controlled drugs. Once obtained, the controlled drugs must be entered into the ward controlled drug register and stored securely in the controlled drug cupboard.

In the rare occasion where there is no stock of controlled drug prescribed for a patient in the Omnicell® medication cabinet, **the on-call pharmacist may authorise** the administration of these controlled drugs from another ward if previously supplied to the ward as stock by the Harplands pharmacy. Ideally, the patient should come to the ward that stocks the controlled drug to complete administration. However, should this not be possible due to the patients' physical or mental health presentation, if a dose is required from another ward, the following process must take place:

- Obtain authorisation from the on-call pharmacist
- A registered nurse from the requiring ward should attend the ward holding the stock and

access the patients electronic prescription chart on Lorenzo to see the dose required (Edwards Myers would take the paper chart)

- A registered nurse on the supplying ward should remove the required dose of the controlled drug and sign it out of the register to the patient requiring the dose including the ward they are residing on. The registered nurse from the requesting ward and the registered nurse from the supplying ward should both sign the controlled drug register.
- Both registered nurses should attend the patient and witness the administration of the CD.
- The electronic prescription chart should be accessed by the registered nurse on the requiring ward who will record administration. The nurse who is logged onto Lorenzo will search for the registered nurse from the supplying ward who will then enter their 6 digit Lorenzo PIN to sign as the witness. (except Edward Myers where both registered nurses will sign the paper chart)
- Instructions on how to set up a 6 digit Lorenzo PIN are included here: https://cat.combined.nhs.uk/wp-content/uploads/2022/04/Set-up-a-PIN-to-witness-CD-and-student-nurse-administration.pdf.
- A record should be made in the patient's notes that the dose of CD needed was obtained from another ward and a note left to prompt the ordering of the CD from pharmacy when it is open.

## 5. RECORD KEEPING AND ENTRIES IN CONTROLLED DRUG RECORD BOOKS/REGISTERS

### 5.1 Pharmacy Department

Within the Pharmacy Department records must be kept of all controlled drugs received (e.g. from suppliers or wards) or issued to wards and patients. On the wards, details of each controlled drug product obtained and administered must be recorded in the controlled drug register. Entries in the register must be made at the time of receipt or administration of controlled drugs. It is essential that all order books and controlled drug registers are in good condition and that there are no loose or missing pages. If a register is in a poor state, a new register must be ordered.

### 5.2 Wards

All entries including balance transfers in the controlled drug register must be signed by two registered nurses. In exceptional cases where only one registered nurse on duty, then a final year student nurse, a competent nursing associate or a registered pharmacist or pharmacy technician can countersign entries. In the controlled drug register a separate page should be used for each controlled drug and each page must be clearly headed to indicate the drug, form, strength and ampoule size to which it refers. All entries should be made in indelible black or blue ink and must be clear and unambiguous.

### 5.3 Recording Standards

If an error is made in the controlled drug register, it **must not** be crossed out. Amendments must be in the form of footnotes (i.e. enclose the error with brackets and a note in the margin at the bottom of the page should be made acknowledging the error and this should be signed and dated and countersigned by a witness). The correct entry if appropriate for that page should be made on the next line below. The use of correction fluid is not allowed.

When a page in the controlled drug register is full and a continued record is needed, use consecutive pages where possible. At the bottom of the old page, write the new page number in the "carried over to page" section. On the first line of the new page, write 'Balance transferred from page…..' and sign and date the entry. Enter the balance after it has been confirmed as correct against the actual stock. As with any register entries, this entry and the balance check

should be signed by a witness.

When selecting a new page in the register, it is good practice to leave a reasonably sized section for preparations frequently used so that where possible the records for a particular preparation run on consecutive pages. When a new page is started, the index at the front of the register should be updated with the new page number.

When a new controlled drug register has to be started, the balance of the stock controlled drugs on the ward should be transferred from the old controlled drug register and written into the new register promptly by a registered nurse. The controlled drug stock should be signed out of the old register as 'Transferred to page xxx of new register' and signed, dated and signed as witnessed by another registered practitioner. The stock should be signed into the new register as 'Transferred from old register page xxx', the balance checked against the actual stock recorded and signed, dated and witnessed by another practitioner.

It is good practice to transfer all balances when a new controlled drugs register is started on ward to avoid using two registers at any one time.

When checking ward controlled drug stock balances during the quarterly audit, pharmacists/registered pharmacy technicians must record that the balance has been checked under each drug entry.

### 5.4 Retention of Controlled Drugs Documentation

The recommendations below are based on the following legislations and guidelines:

- Misuse of Drugs Regulations 2001
- Safer Management of Controlled Drugs – A guide to good practice in secondary care (England), Oct 2007
- Recommendations for the Retention of Pharmacy Records - prepared by the East of England NHS Senior Pharmacy Managers 2015

**In addition, the standards given in the Trust Records Management Policy must be followed.**

### Hospital Pharmacy

| | |
|---|---|
| CD register | 2 years from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 years |
| Pharmacy CD destructions register | 7 years |
| Prescriptions (inpatient and outpatient) | 2 years |
| Requisitions, orders, order books, delivery note or other record of receipt | 2 years or 2 years from date of last entry for record books. |
| Extemporaneous CD preparation worksheets | 13 years |

### All Ward or community settings

| | |
|---|---|
| CD register | 2 years from date of last entry |
| Requisitions, orders, order books, delivery note or other record of receipt | 2 years or 2 years from date of last entry for record books. |

Ward registers and controlled drug requisition books are to be retained by the Ward or Nursing Management. They will not be stored in the Pharmacy department.

## 6.0 DELIVERY AND RECEIPT OF CONTROLLED DRUGS

Controlled drugs can be transferred in a number of ways within and outside the hospital and are likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by patients or their representatives from the pharmacy OR ward
- Collection by pharmacy staff from ward
- Delivery by pharmacy staff to ward
- Delivery by Trust employed/contracted porter/driver

A person who transport/conveys a controlled drug acts as a “messenger”, in that they carry a sealed or locked container and is responsible for delivering the intact container. The person acting as the messenger should:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document, and the process by which this should be done.
- Have a valid ID badge

The following staff are authorised to transport/convey controlled drugs:

- Registered Nurses
- Healthcare support workers
- Pharmacists
- Pharmacy technicians/assistants
- Hospital porters
- Trust transport drivers

The messenger must always carry a current Trust identification name badge according to Trust Policy.

The controlled drugs should be transferred in a secure, locked or sealed, tamper-evident container unless collected directly from pharmacy by a patient or their representative. The system must be fully auditable and explicit to who has custody of the controlled drugs at any point in time. **At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the CD and the person receiving it.**

### 6.1 Collection from Pharmacy

The messenger must check that the bag or box containing the controlled drugs is sealed and

that the seal number corresponds to the number recorded on the controlled drug requisition book. The **messenger** must **sign** and date the **'accepted for delivery'** section in the controlled drug requisition book. The white copy of the controlled drug requisition must be retained by the pharmacy for two years.

If the controlled drug requisition is for delivery to external wards by approved pharmacy driver, the Pharmacist or pharmacy technician accuracy checking the requisition must endorse the **'accepted for delivery section'** as sent with transport. The white copy of the requisition must then be taken to be retained by the Pharmacy Department. The controlled drugs and the requisition book must then be placed in the transport bag/box and sealed ready for the driver to collect.

### 6.2 Delivery to Wards

The messenger will deliver controlled drugs in a sealed box/ bag to the ward. On no account should a controlled drug be left unattended, the messenger must be able to identify the appropriate individuals authorised to receive controlled drugs.
When the messenger arrives, the following MUST be carried out immediately:

- Handover personally the CD to an appropriate authorised individual i.e. registered nurse in charge or authorised nurse who.
- The registered nurse must check the box/bag is sealed and that the seal number on the box/bag is the same as the number stated on the top of the page of the ward requisition book.
- When satisfied the registered person receiving the goods must sign the **pink copy** of the numbered requisition page. This must be done in the presence of the messenger. In some cases the messenger and the person accepting the delivery may be the same person (for instance a registered nurse collects the controlled drug from pharmacy and transports to ward). The registered nurse receiving the controlled drug should not be the same nurse who has completed the requisition. However, in exceptional circumstances where only one registered nurse is available to receive the controlled drug and they happened to have written the order they may be permitted to receive and sign the pink copy, this will needed to be documented on the pink copy of the requisition stating the reason.
- The above applies if an approved driver delivers controlled drug orders to external wards.

### 6.3 Receipt on Ward

The registered person receiving the controlled drugs is responsible for their safe custody until the controlled drugs are securely stored in the locked controlled drug cupboard. Immediately after delivery, two registered nurses must check the contents of the sealed box or bag against the order (this includes checking the number ordered and received). If entry is not immediately possible i.e. a second witness is unavailable, the delivery must be stored in the controlled drug cupboard immediately and entered at the earliest opportunity.

After checking the received controlled drugs, the stock should be placed neatly away in the controlled drug cupboard; this process, and that of entering the stock in the register, must be undertaken by two trained staff, one of whom should be a permanent member of NSCHT staff, one of the witnesses may be a student nurse or a registered clinical professional such as registered pharmacist or pharmacy technician if only one registered nurse is available. Both staff members must sign the quantity received as part of the entry and both sign their names in the register. The controlled drug register entry should detail:

- Words 'received from pharmacy'
- Date stock was received

- Quantity received in dose units
- Serial number of the CD order (typically on the top right corner of a requisition order page)
- Signature of the nurse making the entry
- Signature of person witnessing the entry
- Updated running balance.
- Entries must be written in indelible ink

The new balance should be checked against the contents of the cupboard by both registered staff members to ensure the balance in the register matches that in the cupboard.
If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. Under no circumstances should an entry be struck through. This should be signed, dated and witnessed by a second registered nurse or other registered professional. The witness should also sign the correction. No correction fluid may be used.

### 6.4 Discrepancy With an Order

Any discrepancies with the order must be reported immediately to the senior pharmacist on duty in the Harplands Pharmacy Department on extension 7304604 and the discrepancy must be investigated. In the event that the pharmacy is closed at the time of receipt the on-call pharmacist must be contacted immediately to investigate. Items which do not match the order should be 'quarantined' in the controlled drug cupboard until the situation is resolved with Pharmacy.

### 6.5 Discharge or Leave Prescriptions Containing Controlled Drug(s)

Discharge or leave prescriptions containing controlled drugs must be collected from the pharmacy by a ward staff (messenger) using the ward blue controlled drug box. When controlled drugs on a discharge/leave prescriptions are dispensed in pharmacy the checking Pharmacist or Technician will contact the ward to inform them when they ready for collection. The person collecting the leave or discharge must sign the 'received on the ward' section of the prescriptions.

For discharge and leave prescriptions, the signed prescription will be photocopied and the copy of the prescription sent back to the ward sealed in the blue controlled drug box. The original copy of the prescriptions MUST be retained in pharmacy. When the messenger arrives on the ward, a registered nurse will check the seal number on the box/bag corresponds to the seal number on the copy of the prescription. If the patient is not leaving the hospital immediately the controlled drugs must be entered into the Patient Own Drug (POD) section of the controlled drug register under the patient's name and stored in the controlled drug cupboard. . One page per patient per drug must be used. This process must be undertaken by two trained staff (as per 6.4), one of whom should be a permanent member of NSCHT staff. The discharge CD drug should be segregated from the ward controlled drug stock, clearly marked and remaining in the named Pharmacy bag.

When given to the patient it must be signed out of the register by two staff. One of these must be a registered nurse and a permanent member of NSCHT staff.
Patients or relatives may only collect discharge, leave medicines or outpatient prescriptions containing controlled drugs from Pharmacy following an agreement with the pharmacy team. When handing out the prescription to the patient or their representatives the pharmacy staff will ask them for a form of identification (e.g. driving license) and record this as seen on the prescription. The patient or their representative will be asked to sign the prescription to confirm they have received the controlled drug. The Pharmacy staff must record in the controlled drug register who has collected the controlled drug and if identification was seen.

## 7. PRESCRIPTION OF CONTROLLED DRUGS

Extra legal requirements apply for the prescribing of controlled drugs. These requirements apply in hospital for the writing of discharge medications, leave medications and FP10 outpatient prescriptions. It is illegal for a prescriber to issue a prescription which does not comply with the requirements of the Misuse of Drugs Act. It is an offence for a pharmacist/person acting under the authority of a pharmacist to dispense such a prescription.

Controlled drugs may only be prescribed by legally authorised practitioners. Independent pharmacist prescribers and independent nurse prescribers are now able to prescribe controlled drugs. All prescriptions for controlled drugs should be written in indelible ink. Pharmacists must be confident that the prescriber is genuine and should ensure as far as is reasonably practical that the prescription is valid and the items are not being prescribed for the purpose of misuse. Prescriber's signatures can be checked by pharmacy staff against signature specimens provided by accessing the relevant folder on the x-drive. In order to support the Pharmacy Department in this role it is essential that prescribers print their surname alongside their signature. Failure to do so may result in a delay in issuing the supply.

Prescriptions for controlled drugs are valid for 28 days after the date the prescription was signed or the indicated start date by the prescriber. This also applies to schedule 4 controlled drugs such as zopiclone and diazepam. Up to a maximum 30 days' supply should be issued at any one time for schedule 2, 3 or 4 controlled drugs.

### 7.1 Clinical Considerations for Prescribing Controlled Drugs

**SPECIAL NOTE**: It is important to recognise reports of adverse incidents in patients receiving unsafe doses of opioid medication. It is essential to ensure safe practice by seeking confirmation of any recent opioid use, the dose, formulation, frequency of administration and any other analgesic medicines prescribed for or used illicitly by the patient. The accumulative effects of opioid medication should be taken into consideration when prescribing opioid substitution treatment. Verification should be sought from the original prescriber or though medication records, when opioids are to be prescribed, dispensed or administered.
When prescribing controlled drugs, prescribers must give consideration to:

- the benefits of the controlled drug for the patient
- the risks of prescribing the controlled drug including overdose/respiratory depression and dependency
- potential interactions with other medication that may potentiate the effect of the opioid e.g. gabapentin
- Patient's current clinical needs and if appropriate, adjust the dose to balance effect versus potential side effects
- Dose conversions when switching between formulations or different opioids. Refer to the relevant section of the BNF and discuss with the ward Pharmacist or dispensary Pharmacist on extension **7304604**. Out of hours advice can be obtained from the on-call Pharmacist via Harplands switch.
- When initiating controlled drugs, document clearly the indication and regimen on the patients' inpatient chart and clinical notes (Lorenzo). Document if this is short term treatment for acute pain or if it is likely to be continued e.g. for chronic pain management. Acute prescriptions should usually be reviewed before the patient is discharged.

### 7.2 In-Patient Prescriptions:

- On both electronic and paper charts the allergy section must be updated and checked before prescribing
- Controlled drugs must be prescribed in the same way as any other medicine on the in-

patient electronic prescription chart (on Edward Myers an 8 week paper prescription chart must be used).

- On the inpatient electronic prescription chart the following fields are mandatory and must be completed: drug name, form, route, dose and frequency. Start date and prescribers signature will be automatically populated and the start date can be amended if appropriate. A duration or review date can also be added if required.
- When a paper chart is in use (Edward Myers only) the written requirements for controlled drugs on these charts are the same as for other medicines i.e. drug name, form, route, dose, frequency, indication, start date, duration (where appropriate) and signature of the prescriber. In addition where paper charts are used, the patients' name, address, unit number/ NHS number and allergy status should clearly be written on the prescription chart.
- If the prescription is for 'when required' opiates, the frequency and maximum dose within 24 hours must be clearly documented in the 'administration instructions' section on the inpatient electronic chart. When a paper chart is in use (Edward Myers only) clear instructions on when to take, dosage, frequency and maximum dose per day must be documented on the paper chart.
- If prescribing the same opiates by different routes, each must be prescribed separately with clear instructions on when each should be used.

### 7.3 Discharge/Leave and Out-Patient Prescriptions

- Prescriptions for controlled drugs for patients going on leave or discharged from the hospital should be prescribed on the leave or discharge section on the electronic prescription chart (except Edward Myers where paper leave/discharge prescriptions will be in use). Outpatient prescriptions must be written on an FP10 prescription.
- When prescribing controlled drugs for leave/ discharge or for an outpatient the prescriber should establish if the patient has an existing supply of suitable controlled drugs at home to ensure patients do not stockpile controlled drugs.
- It is against the law for a pharmacist to dispense a controlled drug prescription that does not comply with the controlled drug regulations.
- When an electronic leave/discharge prescription is generated it will be mandatory for the prescriber to enter the quantity required for supply, the strength and formulation.
- When an electronic discharge prescription is generated the prescriber will be prompted to print the prescription. Discharge prescriptions requiring a supply of controlled drugs must be printed, signed and dated by the prescriber and then brought to pharmacy.
- When an electronic leave prescription is generated the prescriber must create the 'Leave prescription template' in clinical notes and must fill in details on when the supply is needed, how many days to supply and whether a compliance aid is needed or not. When this is completed it must be printed, signed and dated by the prescriber and brought to pharmacy.
- Any paper discharge/ leave and outpatient prescriptions for controlled drugs must be handwritten in the prescriber's handwriting. It is mandatory that the following information is written on the controlled drug prescription:

    - Name and address of the patient (include the ward if in-patient)
    - Generic name of the controlled drug (include brand if brand specific)
    - The form of the preparation (e.g. oral solution, modified release tablets, patch) MUST be included.
    - The strength of the preparation (contact the pharmacy department if unsure of the strength stocked)
    - Dose, route and frequency

- Total quantity in words and figure of the volume or number of dose units to be supplied (see 7.4)
- Signature of the prescriber including name in block capitals
- Date

*An example of an acceptable complete controlled drug prescription*:

| |
|---|
| *Mr Joe Jones X12345 Ward 7*<br>*11 Hospital Lane, Stoke-on-Trent*<br><br>*Morphine Sulfate MR 50mg 12 hourly*<br>*Please supply:*<br>*30mg x 14 (fourteen) capsules*<br>*10mg x 28 (twenty-eight) capsules*<br>*Matthew Smith 30/06/19 Dr Matthew Smith* |

The prescription requirements for dose, form, strength and total quantity in both words and figures do not apply to schedule 4 and 5 controlled drugs. Morphine sulfate 10mg/5ml solution is handled as schedule 2 controlled drug within the Trust and as such will need to meet the prescription requirements.

Out-patient prescriptions are retained for a minimum of 2 years.

### 7.4 Pharmacist Amendments to Prescriptions

All the above requirements for leave/ discharge prescriptions and outpatient prescriptions must be fulfilled for a prescription for a controlled drug to be dispensed. However, pharmacists may supply against and amend prescriptions with minor typographical errors e.g. spelling mistakes or where only the total quantity in either words or figures (but not both) is specified. Any amendments must be signed, dated and made in indelible ink.

## 8. ADMINISTRATION OF CONTROLLED DRUGS

This applies to the administration of all Schedule 2 and 3 controlled drugs (see the Trust's medicines policy). The following checks are required before administering controlled drug:

Check the prescription is clear and legal:

- Confirm that the prescription is for the correct patient
- Check that the allergy section has been completed and the patient does not have any allergy to prescribed medication
- Confirm that the age and weight of any patient younger than 16 years is documented (children's services)
- Check that the weight is documented if the dose of any prescribed medicine is weight-dependent.
- The prescription must specify the drug to be administered using its generic or brand name where appropriate, the form, strength, dose, route and times for administration.
- Ensure that each prescription is signed and dated by the prescriber if a paper chart is used.

Check the prescription is safe for the patient:

- Confirm that the dosage, method of administration, route and timing of administration is appropriate to the patient's condition.

- The administering practitioner must have knowledge of the medicine to be administered and be familiar with its actions and potential side effects.
- Ensure that any dose calculations are checked by a second qualified person e.g. nurse, pharmacist.
- Check all sections of the prescription chart including the once only section, regular and when required section to ensure that dose has not been duplicated.
- Medication must not be administered to a patient if a prescription is illegible, ambiguous, incorrect, incomplete, or if there is any doubt about its clinical appropriateness and safety.

Checking Administration:

- Two practitioners must check the administration of controlled drugs.
- One practitioner will take the lead and administer the medicine and the other must act as a witness to the procedure. The witness must be present at all stages of the process and must independently check:
- The identity of the patient
- The prescription appropriateness
- The medicine being administered
- The expiry date
- The witness can be a competent registered healthcare professional such as a Nurse Associate, Pharmacist, Pharmacy Technician or Doctor if two nurses are not available.

Both practitioners must observe:

- The patient taking an oral formulation, the patch being applied or the injection being administered
- Any surplus drug or used patches being discarded appropriately as per the Trust's Waste Policy and Standard Operating Procedure (SOP).
- The entry in the controlled drug register.

To act as a witness to a controlled drug administration a 6 digit Lorenzo pin must be created. This PIN must be unique to the member of staff and MUST never be shared – See appendix 7

Obtaining and preparing the controlled drug:

- Obtain keys to the controlled drugs cupboard, open the cupboard and remove the required drug. The cupboard must be closed and locked immediately afterwards. The controlled drugs must be supervised at all times. Do not leave the controlled drug cupboard open and unattended. Do not leave controlled drug unattended after removing from the cupboard.
- If there is an interruption in the process of preparing a controlled drug prior to administration to the patient (e.g. in an emergency situation), it must be secured in controlled drug cupboard until the registered nurses are able to return to continue administration as soon as possible.
- Check the formulation, strength, route and expiry date of the selected preparation and confirm it corresponds with the prescription.
- Remove the exact quantity of medication required to fulfil the prescription:
- For tablets, capsules and patches – place the exact number of tablets, capsules or patches into a medicine tot/cup to convey to the patient.
- For liquid preparations – liquid preparations intended for oral administration must be measured using a purple oral syringe or glass measuring cylinder
- For Injections – the exact dose to be administered should be drawn up into an appropriate

size syringe for parenteral administration to take to the patient. Any surplus drug left in the ampoule should be destroyed by expelling contents into the yellow sharps bin for incineration. For example if 5mg is required from a 10mg Morphine 10mg/ml ampoule, then 0.5mls should be drawn up to administer the dose and the remainder should be destroyed by placing into the yellow sharps/ clinical waste bin.

Administer the dose and complete documentation:

- The controlled drug should be administered to the patient in accordance with the specific procedure stated in the Trust's Medicines Policy for the prescribed route.
- The registered practitioner who is leading the administration and is logged into the electronic chart on Lorenzo will enter any relevant details onto the electronic chart, time and date will be automatically populated but can be changed if appropriate. They will then search for the member of staff who is acting as the witness. The second member of staff will then enter their 6 digit Lorenzo PIN to sign as the witness. The leading practitioner will press 'ok' to complete the documentation of the administration.
- If the box stating 'no witness available' is selected the registered practitioner must write in the comment box the name of the person acting as the witness and the reason the 6 digit PIN was not used. This will be monitored and any administrations of a controlled drug with no documented witness will be investigated and an incident raised.
- If a paper chart is in use record the exact time and dose administered in the relevant section of the patient's prescription. Both registered nurses must sign the entry. All entries must be legible and in black ink.
    - Record the administration in the ward controlled drug register:
    - Date and time of administration
    - Name of the patient
    - Dose administered and the amount discarded if relevant
    - Deduct the quantity used from the balance in the running balance column. Reconcile the stated balance with the remaining stock
    - Signature of both registered nurses

Incorrect Balance/ entries in the register:

- If the balance remaining in the cupboard does not correspond exactly to the balance stated in the register, the registered nurses involved must investigate immediately as specified in section 12.
- If an error is made during the entry in the controlled drug register, corrections must be carried out as follows:
    - Enclose the error with brackets and write a note at the foot of the page acknowledging the error, signed and dated by both nurses. <u>Errors must not be scored through</u>
    - The correct entry should be made on the line below the original entry if applicable or the right section of the controlled drug register.

Controlled drugs not administered/ no longer required (individual doses only):
If an individual dose of a controlled drug has been prepared for a patient but not administered (e.g. patient refused) or if the controlled drug is no longer required e.g. removal of a fentanyl/ buprenorphine patch then the doses should be disposed of as follows:

- Tablets/capsules should be placed directly in a yellow sharps bin for incineration.
- Patches should be folded so that the adhesive sides stick together and placed directly in a yellow sharps bin for incineration.
- Liquid doses (including injectables) should be expelled from the container directly into a yellow sharps bin and the empty container also placed into the yellow sharps bin.

Destruction of prepared doses of controlled drugs not administered must be witnessed by two registered staff, one being a registered nurses witnessed by another registered practitioner (i.e. doctor, pharmacist or registered pharmacy technician) if a second registered nurses is unavailable and recorded in the CD registered.

### 8.1 Stoke Heath Exceptions

The service at Stoke Heath prison is provided in partnership with RAPT, Shropshire Community Team and Prison team. Exceptions to our current Medicines Management policy are:-

- Site is set up as 'Medical store' i.e. medicines are obtained via wholesaler on direct order by authorisation of approved medical staff. Supplies are obtained within current legislation i.e. supplier to have relevant Home Office and Wholesaler Dealers licence.
- The prison electronic medication chart (SystmOne) is used to document administration of methadone or buprenorphine.
- Prescribing is recorded on the electronic prescribing / record (SystmOne). This gives access to previous and current medicines prescribed by healthcare team.
- Non nursing staff from Forward Trust or nurses from Shropshire Community Trust team are authorised to occasionally provide second signature for controlled drugs.
- Methasoft device in use to measure methadone and procedure. This device must be calibrated and maintained as per the manufactures instructions.

## 9. MANAGEMENT OF PATIENTS OWN CONTROLLED DRUGS (Including TTOs and Leave)

### 9.1. Patients' Own CDs Brought into the Trust (Inpatient)

Where appropriate registered practitioners may request that relatives take patient's own controlled drug home (e.g. limited storage capacity in controlled drugs cupboard). However, the following must be taken into consideration prior to sending the PODs home

- Whether an accurate medicines reconciliation has been undertaken. This must be recorded before the CDs are sent home.
- If there are sufficient quantities of controlled drugs available on the ward to administer doses until a supply can be obtained from pharmacy. It is not appropriate to send suitable controlled drugs home if the patient will miss a dose of the medication.
- If the relative or carer with the patient is suitable and reliable to take responsibility for the POD controlled drugs. Registered practitioners may need to use own judgement regarding the suitability of relatives to receive controlled drugs.
- Whether the patient is still prescribed the medication and the label is correct, reflecting the patients' current prescription.
- Whether the medication has been stored correctly to ensure safety and efficacy (e.g. tablets that have been popped from foil packaging into an unlabeled container). If the medication is deemed to have been stored incorrectly it must be destroyed as per the policy.

If it is appropriate to send the controlled drugs home, the registered practitioner must document the following in the patient's clinical notes on Lorenzo:

- That the patients' own controlled drugs have been sent home including the time and date
- The name of the person that they were given to and their relation to the patient
- The drug name and strength
- Drug quantity
- The name of the practitioner and witness (usually two registered nurses).

If it is not appropriate to send patient's own controlled drugs home with relative, follow the procedure outlined below:

- There must be a separate patient's own controlled drug register (ward stock controlled drug register must not be used for recording patient's own).
- A record of receipt must be entered into the POD controlled drug register by two registered nurses
- POD controlled drugs must be stored according to safe custody principles as specified in section 3.
- POD controlled drug must be checked as part of the daily controlled drug balance check as specified in section 10.

Controlled drugs can only be returned for use by the patient for whom they were prescribed. They cannot be returned if no longer prescribed, or if the patient has died.

Entries in the controlled drug register

- Two registered nurses must witness the receipt and storage of patient's own controlled drugs.
- A new page must be started for every patient.
- The name of the patient must be entered at the top of the page and in the contents page the patient's name must be recorded with the page number that has been allocated.
- More than one controlled drug POD for a specific patient can be entered on the same page but at least 6 lines must be left in between each drug to allow for entries relating to:
    - Drug administration in the event of insufficient stock on the ward.
    - Returning controlled drugs to patient on discharge
    - Sending controlled drugs to pharmacy for disposal

    The entry in the register must state:
    - The date controlled drugs received
    - The origin of the controlled drugs (e.g. PODs received from patient on admission or PODs received from Pharmacy)
    - Name of the drug
    - Form and strength of the preparation
    - The quantity received must be written in the quantity received column and must be written in the running balance column
    - The signature of the two registered nurses.

    Controlled drug brought into the hospital that are not stored in their original packaging with a pharmacy dispensing label (e.g. loose tablets/ capsules or blister strips) must:
    - Be placed in an envelope labelled with the patient's name and NHS/unit number, drug name, strength, form and quantity.
    - This must also be entered in the POD controlled drug register.
    - The envelope must be sealed and two nurses must sign over the top of the seal.
    - The envelope must then be quarantined in the controlled drug cupboard.
    - Sent to Pharmacy for destruction as soon as possible.

Re-issuing Patient's own controlled drugs back to the patient

- Patient's own controlled drugs can be re-issued back to the patient by the discharging registered nurse when the following has taken place:
    - The discharge prescription must have been clinically screened by a pharmacist.
    - The controlled drugs must have been assessed for suitability for continued use and accuracy against the discharge prescription by the relevant pharmacist/ nursing staff. This includes a product check as well as a dispensing label check.

- An entry must be made in the patient's own controlled drug register stating that the controlled drug has been returned to the patient. Two registered nurses must witness that this has taken place and document and sign the register.

**Note**: if POD controlled drugs are reissued then the discharge prescription is not subject to controlled drug handwriting requirements as it is assumed that the controlled drug has already been dispensed against a legally valid prescription.

Patients Own controlled drugs not suitable for use on discharge

- If the patient is not prescribed the controlled drugs on discharge or if PODs are otherwise not suitable for use, then the controlled drug must be returned to the pharmacy for destruction and supply requested by using a legally valid discharge prescription.

### 9.2. Patient's Own Controlled Drugs (Community)

Controlled drugs are not stored in the community (including resource centres). However, in situations where patients bring in controlled drugs or staff retrieve unwanted controlled drugs from patient's home during a home visit, staff must make an entry in the patient's Electronic Patient Record (EPR) documenting full details of the controlled drugs (including quantities and circumstances surrounding the retrieval of the controlled drug).
In the situation where a patient has died in their home and it is identified that there are controlled drugs on the premises these need to be removed for destruction and disposal in primary care, consider discussing the removal of controlled drugs with a family member or carer. The outcome should be recorded in the patient's EPR detailing the actions taken and the full details of the controlled drugs listed in the person's medical record or notes. It may be advisable to consider:

- having a witness to the removal;
- any requirements for the coroner.
- taking the drugs to a health professional, such as a community pharmacist who is legally allowed to possess controlled drugs, for safe disposal at the earliest opportunity.

The controlled drug must then be taken to a community pharmacy as they are legally allowed to possess controlled drugs for disposal or destruction. It is good practice for the community pharmacy to make an entry of schedule 2 and 3 controlled drugs returned to them for destruction. The community pharmacy will ask for proof of identification from the staff member returning the medicine. Staff returning the controlled drug to the community pharmacy must also make an entry on Lorenzo stating which community pharmacy the controlled drug was taken to so that an audit trail is maintained.

### 9.3 Receipt of Discharge/ Leave Controlled Drugs from Pharmacy

- Discharge/ Leave controlled drugs are collected from pharmacy by an appropriate member of staff in a sealed controlled drug box.
- If the patient is leaving the ward immediately, it is not necessary to record the To Take Out (TTO) supply in the POD controlled drug register. The issue of the controlled drugs must be recorded in the patient's clinical notes on the patient's notes to ensure there is an audit trail. Document the name of the staff handing over the controlled drugs to the patient and witness in the notes as well.
- If the patient is not leaving immediately, the discharge/ leave controlled drugs must be stored in the controlled drug cupboard and entered in the PODs controlled drug register as per section 6.3.

### 9.4 Compliance Aids with Controlled Drugs

Prescriptions requesting compliance aids may include requests for controlled drugs. Controlled drugs may be dispensed into compliance aids where clinically appropriate (pharmacy must

receive a copy of the medicines compliance assessment tool) and where the medicinal product is suitable for such use pharmaceutically (for example, hygroscopic and effervescent products must never be dispensed into compliance aids). Where a controlled drug is dispensed into a compliance aid, it must be labelled in accordance with the dispensing procedure.

Compliance aids (e.g. Nomads) for inpatient use must have the supplementary label, "This Nomad contains a Controlled Drug; please record in your controlled drugs register". Additionally another supplementary label 'Store in a controlled drug cupboard' will be on the pharmacy bag for the information of staff.

It should be noted that dispensing into compliance aids can increase risk of harm from accidental overdose, the patient's needs should be carefully considered.

## 10. STOCK CHECKS OF CONTROLLED DRUGS ON WARDS

The appointed registered nurse in charge is responsible for ensuring that the 24 hourly stock check of controlled drugs is carried out and recorded by staff on the ward.

### 10.1 Frequency of Controlled Drug Stock Checks

- Two registered nurses must perform this check, or if two are not available, one may be a competent Nurse Associate or Pharmacy Technician.
- As stated above, the stock balance for ALL controlled drug (including patient's own controlled drugs) recorded in the controlled drug register and stored in the controlled drug cupboard on a ward must be checked a minimum of once every 24 hours.
- The nurse in charge must designate a time for the 24 hourly controlled drug stock checks to take place.
- A rolling stock balance must be maintained for each individual drug every time the drug is received from pharmacy or a receipt of a POD controlled drug
- A rolling stock balance must be maintained for each individual drug every time the drug is removed from the cupboard for administration to a patient, returning controlled drugs to pharmacy or returning PODs controlled drugs to patient.

### 10.2 How to Carry Out The Stock Check

- Select the page in the controlled drugs register for the individual drug/form/strength
- Check that the running balance for the item is recorded accurately. The registered nurse must be satisfied that the entries in the controlled drug register are accurate and that there are no ambiguities or discrepancies in the recording/ legibility of the entries.
- Count the actual quantity of the item within the controlled drug cupboard and reconcile to the recorded stock level in the register.
- There is no requirement to open packs with intact tamper evident seals for stock checking purposes
- Check the expiry date on every container of the individual controlled drug.
- Repeat the procedure for every controlled drug recorded in the controlled drug register and patients' own controlled drug register.
- Stock balances of opened/unsealed liquid medicines may be estimated by visual inspection. This is to minimise liquid lost by repeated measuring of volumes and ensures that excessive handling does not compromise the integrity of the liquid.
- The actual balance for liquid medicines MUST be confirmed to be correct when the bottle has been finished. **NOTE** – the running balance for the bottle should be zero when the bottle is empty. If the bottle is empty but the running balance states a positive balance this must be investigated a stock discrepancy – ( see section 12 below)

- Controlled drug balances will also be checked by a member of the pharmacy team together with a registered nurse every 3 months. Where appropriate, this will include cross checking inpatient prescriptions to check that the drug has been prescribed.

### 10.3 Stock Check Record Keeping

- Wards must keep a record of all daily controlled drug stock checks. The Ward Manager must designate where the information is to be recorded. The record may be kept at the back of the controlled drug register or in a designated log book.
- The record must show the date and time of each stock check and must be signed and dated by the two registered nurses undertaking the stock check.
- Controlled drug not in use: during the stock check, preparations and strengths of controlled drugs that are no currently in use on the ward or out of date may be identified. Such controlled drugs must be returned to Pharmacy for re-use/disposal. **Note**: some wards are approved to hold limited controlled drug as stocks to preempt potential out-of-hours admissions (e.g. methadone and buprenorphine on ward 2).

## 11. RETURNING CONTROLLED DRUGS TO HARPLANDS PHARMACY

Expired stock or controlled drugs no longer required (including patients' own) must always be returned to Pharmacy in a secure way at the earliest practical opportunity. The following process should be followed:

- The registered nurse in charge of the ward and a second registered nurse must select items to be returned to pharmacy and the corresponding page in the controlled drug register. In the absence of a second registered nurse, a final year student nurse or a pharmacist/ pharmacy technician can act as a witness.
- Count the quantity of drug to be returned to Pharmacy
- On the next available line in the register, record the date, state "returned to Pharmacy", state the quantity returned in the 'quantity used' column and the remaining balance in the running balance column. Check that the remaining balance (if any) corresponds exactly with the quantity of drug to be left on the ward.
- Place the controlled drugs into the blue controlled drug box and seal with the red seal that is inside box.
- The box, along with the controlled drug register must be brought to the Pharmacy dispensary by an appropriate member of staff.
- The Pharmacy staff will handle the returned controlled drugs in accordance with the relevant pharmacy SOP.
- Unwanted patient's own controlled drug in the community should be returned to the nearest community pharmacy in a timely manner and the community pharmacy will be able to dispose appropriately.

## 12. MANAGEMENT OF CONTROLLED DRUG STOCK DISCREPANCIES

If a stock discrepancy is found between the quantity of the controlled drug present in the cupboard and the balance recorded in the register must be investigated immediately. The nurse in charge must immediately carry out an initial investigation to attempt to resolve the discrepancy.

If liquid discrepancy of 5% or less of total volume, the nurse in charge MUST discuss with pharmacy and controlled drug register amended accordingly, documenting clearly and adjusted the balance. Actual balance check and volume adjusted where necessary must be done at the end of a bottle before opening a new bottle.

*For example:* If ward has 105mls recorded in register as volume of Morphine sulfate 10mg/5mls liquid in stock and a patient required a dose. On measuring, there is one unopened/sealed bottle containing 100mls and a bottle in use with 3mls measured (a discrepancy of 2mls – less than 5% of the total volume). The volume recorded in the controlled drug registered should be adjusted as 103mls (actual measurement not estimated) by the nurse in charge and witnessed by another registered nurse or authorised witness. The ward pharmacist must be informed as soon as possible. If any trends in discrepancy are noted, the pharmacist MUST treat as suspicious controlled drug incident and escalate to the accountable officer.

Discrepancy checklist:

- Two registered nurses must re-count the quantity in the cupboard, ensuring that all possible locations have been searched and all possible containers of the drug have been checked.
- Check that ALL quantity calculations are correct when comparing controlled drug receipt and removal from the controlled drug cupboard with the rolling stock balance.
- Check that all requisitions received have been entered into the correct page of the register
- Check that a receipt entry e.g. patients' own controlled drugs has not been entered twice on multiple pages.
- Check that all controlled drug removed from the cupboard for administration/ return/ disposal have been entered into the correct page of the controlled drug record book
- Check that items have not been accidentally stored in a different area of the cupboard
- Check that all controlled drug doses administered on the ward have been entered into the register
- Check if patients' own controlled drugs have been returned to the patient but not recorded accurately in the register.

When a stock discrepancy is resolved on initial investigation:

- If an error or omission is identified the nurse in charge must make an entry in the controlled drug register to explain the discrepancy. The balance must be corrected. This entry should be witnessed by a second registered nurse.
- An incident report must be completed with the full details of the incident including:
    - Date and time when the discrepancy was identified
    - Date and time of the last stock check
    - Name, strength, form and quantity of the drug
    - Remedial action where appropriate
    - A note under the investigation that the stock discrepancy has been resolved
    - The incident number must be included when adjusting balances in the controlled drug register.

When a stock discrepancy is not resolved on initial investigation:

- During Pharmacy opening hours
    - If the above actions fail to resolve the discrepancy, the discrepancy must be reported immediately to the ward pharmacist.
    - The Pharmacist will confirm that all possible sources of error have been investigated including any returns to Pharmacy through unapproved routes (e.g. check unprocessed pharmacy returns)
    - Check that the controlled drugs have not been mistakenly placed in the drug trolley.
    - The Pharmacist will escalate to the **Accountable officer** immediately who will advise on further action after consideration of the facts.

All staff have a responsibility to report the loss, theft or forgery of controlled stationery, which may be used to order controlled drugs immediately, or any lost or stolen controlled drug medication to the registered nurse in charge of the ward/department, site manager, pharmacist and controlled drug Accountable Officer. The police need to be informed in such circumstances and for the incident to be investigated as a Serious Incident. Refer to Appendix 6.

## 13. MANAGEMENT OF CONTROLLED DRUGS FOLLOWING A WARD CLOSURE

When a ward closes permanently, the controlled drugs will need to be returned to the pharmacy for destruction or to be reused. The pharmacy department must be contacted prior to the day the ward is closing to arrange a suitable time for this transfer to occur. The ward controlled drug register and requisition book must be retained and securely stored in a locked cabinet/cupboard by the Directorates senior leadership for a minimum of two years from the date of the last entry. The controlled drug register and requisition book will not be stored in the pharmacy department.

**Entries in the Ward Controlled Drugs Record Book**

The pharmacist and nurse in charge/authorised deputy should do a final check of controlled drug stock against the quantities in the ward controlled drugs register.

For each item the record should be:

- Annotated with the date and time of stock check
- Signed out “stock level checked and X (number of dose units) returned to the pharmacy prior to ward closure”
- The new stock level should be recorded as zero and signed by the pharmacist and nurse in charge closing the register.
- If a pharmacist is unable to perform this duty on ward level, then two registered nurses must sign the controlled drugs out of the register.
- All controlled drugs should then be placed in the blue controlled drug transport box and secured using a red seal.
- The sealed box and the ward controlled drug register should then be sent to the pharmacy department.

## 14. DESTRUCTION OF CONTROLLED DRUGS

The destruction of controlled drug stocks are primarily governed by the Misuse of Drugs Act 1971, the Misuse of Drugs Regulations 2001, and the Misuse of Drugs and Misuse of Drugs (Safe Custody) (amendment) Regulations 2007

### General Principles

Controlled drug destruction must occur in such a way that the drug is denatured or dissipated so that it is incapable of being retrieved, reconstituted or used. Destruction must occur in a timely fashion so that excessive quantities are not stored awaiting destruction.

### Controlled Drug Destruction within NSCHT

The Trust’s Medical Director is the Controlled Drugs Accountable Officer (CDAO) within Combined Health Care. The CDAO is responsible for ensuring legal and statutory duties are met and that appropriate governance structures underpin these duties.

### 14.1. Expired/Unwanted Stock

Items for destruction should under no circumstances be sent back to pharmacy in a ward bag. Expired or unwanted controlled drugs must be signed out of the ward controlled drug register by a registered nurse. This must be witnessed by another registered nurse. The unwanted will be returned to pharmacy using the blue controlled drug box and secured using a red seal. The sealed box containing the unwanted controlled drug should be sent to Pharmacy with the controlled record book.
If the stock is unsuitable for reuse, it should be entered into the Pharmacy controlled drug destruction register and stored in the designated pharmacy controlled drug cupboard for later destruction by an authorised witness. The frequency of destruction will depend on the quantity of material for destruction and the storage area available. The controlled drugs will be destroyed in accordance with Pharmacy SOP for controlled drug destruction and as detailed in appendix 4.

If the stock is suitable for reuse, it should be returned to Pharmacy stock in the controlled drug cupboard and re-entered into the pharmacy controlled drug registers according to Pharmacy Department SOP.

### 14.2. Controlled Drugs Returned by Patients

Patients own drugs are the property of the patient. On the inpatient wards patients' own controlled drugs may be returned to the patient on discharge or the patient may request for them to be destroyed on their behalf by the Trust. If this is the case these drugs must be clearly segregated and stored within the secure controlled drug cupboard until arrangements have been made to return these medicines to pharmacy for destruction.
Should the patient or a representative wish to return controlled drug to an out-patient clinic staff should refer or escort the patient to a local community pharmacy as they will be able to carry out the destruction on the patient's behalf. If this does not appear to be an appropriate option staff must contact the Pharmacy Team at Harplands before accepting these drugs and they will advise on how to store, record and return to the Pharmacy. Authorised Witnesses would not be typically be asked to destroy patient own controlled drugs.

### 14.3. Authorised Witness

Any person required by the Misuse of Drugs Regulations 2001 to keep records of Schedule 1 or 2 Controlled Drugs may only destroy obsolete, expired and unwanted Schedule 1 and 2 CDs in the presence of an Authorised Witness (AW). The General Pharmaceutical Council (GPhC) guidance indicates that for Schedule 3 controlled drugs (such as buprenorphine, midazolam, phenobarbital, tramadol, temazepam, gabapentin, pregabalin) it is best practice to have another member of staff witness the denaturing, this is the approach the Trust has adopted for all schedules 2 and 3 controlled drugs. (except pregabalin and gabapentin)
An amendment to the Misuse of Drugs Regulations 2001 which came into force in August 2007 allows Controlled Drug Accountable Officers (CDAO) to authorise people or groups of people (the Authorised Witness) to witness the destruction of controlled drugs to render them irretrievable. Previously the witnessing of destruction of controlled drugs was only undertaken by the police chemist inspection officers, GPhC inspectors, and the Home Office inspectors. The establishment of appointed Authorised Witness was in acknowledgement of the significant volume of controlled drugs that required destruction across large geographically areas by a small number of individuals and that failure to carry out destruction within a reasonably timeframe presented a greater risk of controlled drugs being misused. For that reason the

authorised witness is a person who must not be involved in the day-to-day handling of controlled drugs and who has been appointed by the CDAO to oversee the management and governance of activities related to controlled drugs.

There is no requirement in the 2001 regulations that the disposal of date-expired medicines in Schedules 3, 4, and 5 needs to be witnessed or recorded. Nevertheless, the Trust has adopted a good practice approach and ensures a witness is present, this does not need to be an Authorised Witness for pregabalin, gabapentin, all schedule 4 and schedule 5 controlled drugs.

### Practicalities of the Authorised Witness role

Persons authorised to witness destruction by a CDAO continue to be subject to a professional code of ethics, they will receive appropriate training and must remain independent of day-to-day use or management of CDs whilst undertaking the role as AW. Authorisation to act as an AW is valid for 2 years. Should the AW's role or responsibilities change within this 2 year period they must inform the CDAO.

- Authorised Witness must familiarise themselves with the Trusts Controlled Drug Policy
- The Authorised Witness will receive training on how to destroy CDs appropriately from the Pharmacy Team
- The Authorised Witness must contact the CDAO if their role or responsibility changes as this may deem the AW unsuitable to continue to carry out this role
- The CDAO will keep a register of AW's within the Trust and will review at a minimum of every 2 years
- The Pharmacy Team will contact the AW to inform them of any stock requiring destruction and arrange an appropriate time to carry this out
- Particulars of the date of destruction and the quantity destroyed must be entered in the controlled drug register and signed by the AW in whose presence the drug is destroyed
- The AW will provide a report of the destruction of controlled drugs with the Pharmacy Team to retain a log of destruction
- If the AW is unsure which Schedule a drug falls under they must contact the Pharmacy Team before attempting destruction
- If the AW notes a discrepancy in the controlled drug register, this must be investigated immediately and if it cannot be resolved they must inform the Deputy Director of Medicines and Clinical Effectiveness (MACE) as soon as possible. If the CDAO or Deputy Director MACE cannot be reached, the AW must contact the Pharmacy Team and inform a senior member of staff
- If the AW has any concerns in relation to controlled drug they must inform the CDAO.

## 14.4. Permitted Disposal on Wards/ Clinical Areas

This includes: part doses for individual patients, used patches, doses prepared but not given and unused dose units (e.g. dropped tablets).
An Authorised Witness is not required for controlled drug destruction in ward/ clinical areas.

Full details must be recorded in the controlled drug record book by a registered nurse and witnessed by another registered nurse, pharmacist or pharmacy technician. The controlled drugs must be destroyed as follows:

- Solid dosage forms (e.g. tablets and capsules) should be placed directly in a yellow

sharps bin for incineration.

- Patches (e.g. fentanyl) should be folded so the adhesive sides stick to each other and placed directly in a yellow sharps bin for incineration.
- Volumes of less than 10mls should be expelled into a yellow sharps bin together with the empty ampoule/ syringe for incineration

Dropped/ broken ampoules or bottles must be carefully cleaned up according to ward/ clinical area procedures. An incident report must be completed on the Trust Incident Reporting System and the action must be witnessed and recorded in the controlled drugs register (including the incident number) by the registered nurse involved and countersigned by the witness who must be a registered nurse.

### 14.5. Method of Destruction - Pharmacy Department Only (see Appendix 1)

- Wherever possible the out of date controlled drugs will be disposed of using the approved controlled drug denaturing kit. This will then be disposed of as pharmaceutical waste.
- All controlled drug destruction will be done in line with the Pharmaceutical Waste SOP and the Pharmacy controlled drug Disposal SOP.
- Patches will be destroyed by removing the backing and folding the patch over itself. The patch will then be placed in the denaturing kit.
- All entries should be checked and enough denaturing kits available to ensure safe and effective destruction of the controlled drugs. Following destruction of the controlled drugs, the relevant sections in the destructions register should be signed by both the authorised witness and the pharmacist/pharmacy technician or another senior member of Trust staff carrying out the destruction.
- Patient's own controlled drugs, ward/pharmacy stock of Benzodiazepines, Z drugs, gabapentin and pregabalin may be destroyed in Pharmacy by a pharmacist or pharmacy technician, and witnessed by a pharmacist or pharmacy technician. (One of the two members of staff involved must be a pharmacist

## 15. DUTIES

- The Executive Medical Director and Deputy Director of MACE are responsible for setting the standards by which all staff are expected to act with respect to medicines. Further to this, the Executive Medical Director is accountable for the performance of all Medical Staff and the Deputy Director of MACE is accountable for the performance of all Pharmacy Department staff.

- The Executive Medical Director is also the Trust's Controlled Drugs Accountable Officer and has a statutory responsibility for advising the Trust on, and putting in place systems to ensure the safe use of Controlled Drugs. The Medication Safety Officer has a statutory responsibility for advising the Trust on, and putting in place systems to ensure the safe use of medicines and continuous learning to improve medication safety.

- Directorate senior management teams are responsible for the performance of their services with respect to all aspects of this policy.

- Quality Improvement Leads Nurses and managers of clinical areas in conjunction with Directorate and Trust level managers have additional responsibilities for ensuring that staff, working in areas that they are responsible for, are adhering to the standards laid down in this document.

- All managers of clinical areas are responsible for ensuring that their staff, especially new starters and temporary staff members (as practices may differ between organisations), are aware of the content of this document, and practice accordingly.

- All members of staff working in the Trust who are involved in the handling of medicines in any way are responsible for ensuring that they are aware of the contents of this document, and practice accordingly.

- If any staff member suspects misappropriation of controlled drugs by a member of staff they have a duty to report their concerns to the Controlled Drug Accountable Officer or Deputy Director of MACE. Concerns may occur which do not involve specific incidents or near misses but include healthcare matters, such as suspected mistreatment of patients and/or issues relating to the quality of care given, concerns about professional/clinical practice and concerns relating to the competence of staff. Concerns regarding increased or abnormal usage of controlled drugs may also be identified following a review of prescription monitoring data. Any concerns must be reported to the Trust CDAO and any specific concerns relating to staff must also be reported in line with the Trust Whistle Blowing policy

- Failure to adhere to this Policy may result in disciplinary or legal procedures subject to investigation.

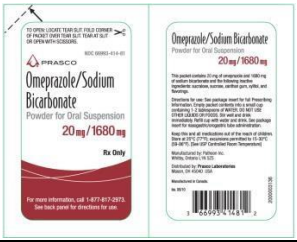
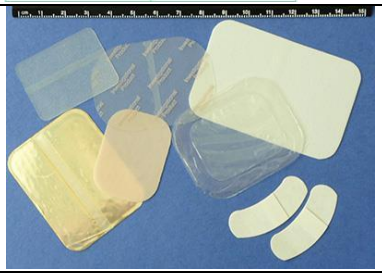
## 16. TRAINING AND IMPLEMENTATION

Implementation of the Controlled Drugs Policy is the responsibility of all staff members who are involved in any aspect of the handling of controlled drugs and controlled stationary. The Pharmacy Department will provide training to support clinical areas in implementing this policy.

NHS North Staffordshire Combined Healthcare NHS Trust

**Appendix 1**

# CD Destruction Process

| Type of Medication | Examples of what they may look like | How they should be destroyed |
|---|---|---|
| Solid Dose Formulations |  | • Tablets and capsules are to be removed from their outer packaging, removed from blister packaging and placed in a CD denaturing kit. |
| Powder Sachets |  | • As much of the powder content as possible must be emptied directly into the CD denaturing kit.<br>• The opened sachet must also be added to the kit. |
| Transdermal Patches |  | • The patch backing is to be removed and the patch folded over on itself. The active ingredient in the patches is thus rendered irretrievable.<br>• The folded patch must be placed into the CD denaturing kit. |
| Lollipops |  | • Scissors are used to cut the lollipop stick and discarded.<br>• The lollipop section containing the active ingredient is to be placed into the CD denaturing kit. |

| Type of Medication | Examples of what they may look like | How they should be destroyed |
|---|---|---|
| Aerosol Formulations |  | • A facemask should be worn by staff undertaking this activity.<br>• Prior to this destruction process beginning, the area where the destruction takes place must be well ventilated.<br>• Aerosol formulations should be expelled into water – this is to prevent droplets of drug entering the air.<br>• The resulting solution should be poured into the CD denaturing kit where it will mix with the other waste materials, thus rendering it irretrievable |

| | | |
|---|---|---|
| Parenteral Formulations |  <br>  <br>  | • Liquid ampoules should be opened and as much of the content as possible emptied directly into the CD denaturing kit. The opened glass ampoule should also be added to the kit.<br>• Vials containing the CD in a powder form should not be discarded with powder still insitu. There are two options available to empty items contained with these vials:<br>**Option 1:** Water should be added via a needle and syringe to dissolve the powder and the resultant mixture is then to be drawn up into the syringe and poured into the CD denaturing kit. The vial and syringe should be rinsed with water and placed in the DOOP bin. The needle must be dispensed into a sharps box.<br>**Option 2:** The metal part of the vial removed and the contents of the vial including the vial placed in the denaturing kit. |
| Oral Liquid Formulations |  | • CD liquids should be poured into the CD denaturing kit where it will mix with the other waste materials, thus rendering it irretrievable.<br>• The bottle should be rinsed with a small amount of water, which should then be added to the denaturing kit. |

Once all products for destruction have been added to the denaturing kit, water should be added (if necessary) according to the instructions accompanying the pack. Where appropriate, the volume of CD liquid added to the kit should be taken into account. The kit should then be well shaken to ensure that the contents are well mixed.
The used kit should be locked in the CD cabinet for a minimum period of time as per the kits instructions (typically 24 hours) to allow the inactivation process to complete. The CDs are now deemed to be “irretrievable” and may be disposed of in the pharmaceutical waste.

***The kit contents will turn into gel within a few minutes and may become hot initially but the full activation process may take up to 24 hours. Once denatured, the denaturing kit must be put into the normal pharmacy DOOP bins.***

**Appendix 2**

# SUSPECTED ILLICIT SUBSTANCES

This section outlines the procedures for dealing with suspected illicit substances handed in by or found on a Client.

**Guiding principles**
Clients with mental health problems co-morbid with substance misuse form a substantial and significant proportion of inpatients. The principle underlying this policy is to engage clients in treatment and harm reduction rather than into the criminal justice system.

Illicit substances handed in by/found on a patient will be disposed of in accordance with Trust policy.

The Misuse of Drugs Act 1971 allows exemption from prosecution for possession of these substances, as long as possession is for the purpose of destruction or handing over to the police.

Supply is against the law, therefore any suspected illicit substance **must not** be returned to the person once they have surrendered it.

**Procedure**
If a substance handed in by/found on a patient is thought to be a suspected illicit substance it should be dealt with on the ward by two members of staff as follows:

1. Wear disposal gloves

2. Retain the substance – exceptions are syringes which must be disposed of in the sharps bin immediately

3. Place item in a sealed bag labelled with the following details
    - Found by:
    - Found in possession of:
    - Ward:
    - Date …… Time…..….

4. Inform the nurse in charge of the ward

5. Nurse in charge to complete ‘Suspected Illicit Drug Confiscation Form’.

**For small quantities**
Quarantine the substance in the ward controlled drugs cupboard.

In the Controlled Drugs register designate a page for suspected illicit substances and enter the necessary details. The item should be referred to as ‘suspected illicit substance’ in the controlled drugs registers, and without using the chemical, ‘street’ name or description of the substance.

Inform the Hospital Manager bleep holder who will then inform the police if necessary (e.g. large quantities / class A drugs).

**For larger quantities**

- Seal in a designated container and hand over to the police for storage or disposal
- Police and Bleep holder to sign confiscation form.
- The police will take possession of the suspected illicit substance.

A balance between treatment and pursuit of criminal prosecution should be made clear in the care plan. It may be necessary to convene a Care Plan Agreement (CPA) meeting to determine the most appropriate course of action.

Inform the Trust Controlled Drug Accountable Officer or Deputy Director of MACE at the earliest opportunity.

Copies of the confiscation form will be handed over to the police (where they have been contacted) or the Unit Manager, and the ward will retain a copy.
Complete the relevant Health and Safety incident form.

# Suspected Illicit Drug Confiscation Form

Date: Time Found:

Name of Patient or Visitor: Patient's Hospital Number:

Ward / Department:

**Details of suspected illicit substance and circumstances surrounding incident:**

Signature of Staff Member (1)……

Print Name:……..

Signature of Staff Member (2)……..….

Print Name:……

**Details of disposal:**

Signature of person destroying the substance:

……

Witnessed by:……..

(Senior Nurse on duty) and authorised person

**To be completed by manager / person in charge**
Date and time police contacted (If applicable):……..

Handed to police by (signature / print name):…….

Receiving police officer (signature / print name):……...

Copy: (please circle) Ward / team / CSM / Accountable Officer / Audit

**Appendix 3**

# Nurses Authorised to Order Medicines and Controlled Drugs

The Pharmacy Department needs a current list of names and signatures of Nurses authorised to order medicines and controlled drugs to validate that orders are from duly authorised staff. Please complete this form in **BLACK INK** and forward a copy to the pharmacy department as soon as possible.

**Note:** The Ward Manager will need to review and update this list periodically **(minimum every three months)**

| **Ward/Department** | | | | | |
|---|---|---|---|---|---|
| **Ward/ Dept Manager** | | | | | |
| **Nurse name** | **Signature and initials** | **Role** | **Authorised to order medicines** | **Authorised to order controlled drugs**<br>Amend as appropriate | **Ward manager sign/date** |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |
| | | | Yes | Yes/No | |

**Please retain list on the ward**

If you have any queries please contact the Pharmacy Team on extension 7304604

**Appendix 4**

# Record of Controlled Drug Destruction Visit

# (HMP Stoke Heath only)

| | |
|---|---|
| **Service/Team Name:** | |
| **Address:** | |
| **Telephone Number:** | **Email Address:** |
| **Contact Name:** | |
| **Date & Time of Visit:** | |

**Controlled Drug (CD) Pre- Destruction Checklist**

1. Denaturing kits of a suitable size
2. Safety equipment as required e.g. gloves, dust mask, syringe with needle, pestle and mortar

**Drugs Destroyed**

| | Drug | Expiry Date | Strength | Form | Quantity | Sign on Destruction |
|---|---|---|---|---|---|---|
| **1** | | | | | | |
| **2** | | | | | | |
| **3** | | | | | | |
| **4** | | | | | | |
| **5** | | | | | | |
| **6** | | | | | | |
| **7** | | | | | | |
| **8** | | | | | | |
| **9** | | | | | | |
| **10** | | | | | | |
| **11** | | | | | | |
| **12** | | | | | | |
| **13** | | | | | | |
| **14** | | | | | | |
| **15** | | | | | | |
| **16** | | | | | | |

Expired stock must be stored securely in the CD cabinet. It should be clearly labelled as out of date and segregated to prevent dispensing errors. The stock must continue to be included in the running balance in the CD register until it has been destroyed.

| **Prior to the visit please ask the team to make sure you have conducted a recent CD balance check.**<br>**Details below to be inserted by Authorised Witness at destruction visit** | | | |
|---|---|---|---|
| Name and role of person destroying drugs | | | |
| Authorised witness | | | |
| | **Response** | **Advice provided by AW** | **For Action by:** |
| Where was the CD key? On the authorised person? | | | |
| Frequency of balance checks | Usual frequency:<br><br>Date of last balance check: | | |
| Have there been any CD related incidents or concerns within the past 6 months. If yes, please give a brief summary. | | | |
| Is the overage of liquids adequately recorded | | | |
| Is expired stock kept in the running balance until destroyed | | | |
| How frequently are patient returned drugs destroyed | | | |

| | | | |
|---|---|---|---|
| Are similar strength drug/ strengths appropriately separated | | | |
| **Additional Notes/Actions** (other CD issues observed or discussed during the visit, photos taken) | | | |
| **Follow up** (e.g. What advice did you give and what do you/they need to do to carry out the advice. Do we need to check that recommendations have been implemented?) | | | |

Signed by person doing destruction:……..

Signed by Authorised Witness:……...

Date:……

**Please return the completed form to the Pharmacy via email -**
pharmacyteam.harplands@combined.nhs.uk.

**Training Needs Analysis for the policy for the development and management of Trustwide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br><br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br><br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| Staff Group | ✓ if appropriate | Frequency | Suggested Delivery Method (traditional/ face to face / e-learning/handout) | Is this included in Trustwide learning programme for this staff group (✓ if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered | | | | |

| | | | | |
|---|---|---|---|---|
| Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |
| Non-clinical non patient contact | | | | |

| |
|---|
| Please give any additional information impacting on identified staff group training needs (if applicable) |

| |
|---|
| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |

| | | | |
|---|---|---|---|
| Completed by | | Date | |

**Document level:** Trust
**Code:** 1.98
**Issue number:** 2

# Non-Formulary, Off-Label and Unlicensed Medicines Policy

| | |
|---|---|
| Lead Executive | Interim Chief Medical Officer |
| Authors details | Principal Pharmacist (Clinical) |

| | |
|---|---|
| Type of document | Guidance |
| Target audience | All clinical staff |
| Document purpose | For information |

| | | | |
|---|---|---|---|
| Approving meeting | Quality Committee<br>Trust Board | Meeting date | 1st December 2022<br>13th January 2023 |
| Implementation date | 31st January 2023 | Review date | 31st January 2026 |

| Trust documents to be read in conjunction with | |
|---|---|
| | Medicines Policy |
| | Medication Monitoring Guideline |
| | High Dose Antipsychotic Therapy Policy |

| Document change history | | Version | Date |
|---|---|---|---|
| What is different? | New changes are:<br>• Addition of Deputy Clinical Directors as authorisers- new role<br>• Removal of 'Goldfax' no longer in use<br>• Change from APC to IMOC as authorising body across the ICB<br>• Updated link to 'Medicines for Children' leaflet | 2 | 26.10.22 |
| | • New formulary website link<br>• Addition of responsibilities for Clinical Directors<br>• Addition of how to complete forms in Lorenzo<br>• Addition of Independent Prescribers leading patient's care, Associate Specialists and Staff Grade Doctors as alternative to Consultant as a requestor<br>• New patient leaflets | 1 (as a stand alone policy) | 26.06.19 |

| | | | |
|---|---|---|---|
| | • Change to section on pre-authorised Unlicensed medicines, allowing CEG to review these if situation changes | | |
| Appendices / electronic forms | Appendix 1- Model Patient Information Leaflet for Unlicensed Medicines<br>Appendix 2- Request for a Non-Formulary, Off-label, or Unlicensed Medicine Form (this form is available electronically on Lorenzo, in clinical notes section). | | |
| What is the impact of change? | Easier access to medicines as forms available on Lorenzo and more prescribers can request medicines. Addition of deputy clinical directors as authorisers also improves access. | | |

| | |
|---|---|
| Training requirements | None |

| Document consultation | |
|---|---|
| Directorates | All members of Clinical Effectiveness Group (CEG) |
| Corporate services | N/A |
| External agencies | N/A |

| | |
|---|---|
| Financial resource implications | None |

| External references |
|---|
| 1. North Staffordshire Joint Formulary, available at: http://www.northstaffordshirejointformulary.nhs.uk/<br>2. Royal College of Paediatrics and Child Health leaflet available at: https://www.medicinesforchildren.org.uk/wp-content/uploads/sites/8/2021/10/Unlicensed-medicines.pdf |

| | |
|---|---|
| Monitoring compliance with the processes outlined within this document | Pharmacy will collate forms received authorising these medicines and present them as CEG, as described in the policy. |

| **Equality Impact Assessment (EIA) - Initial assessment** | **Yes/No** | **Less favourable / More favourable / Mixed impact** |
|---|---|---|
| Does this document affect one or more group(s) less or more favorably than another (see list)? | | |

| | | |
|---|---|---|
| – **Age** (e.g. consider impact on younger people/ older people) | No | |
| – **Disability** (remember to consider physical, mental and sensory impairments) | No | |
| – **Sex/Gender** (any particular M/F gender impact; also consider impact on those responsible for childcare) | No | |
| – **Gender identity and gender reassignment** (i.e. impact on people who identify as trans, non-binary or gender fluid) | No | |
| – **Race / ethnicity / ethnic communities / cultural groups** (include those with foreign language needs, including European countries, Roma/travelling communities) | No | |
| – **Pregnancy and maternity, including adoption** (i.e. impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples) | No | |
| – **Sexual Orientation** (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not) | No | |
| – **Marriage and/or Civil Partnership** (including heterosexual and same sex marriage) | No | |
| – **Religion and/or Belief** (includes those with religion and /or belief and those with none) | | |
| – **Other equality groups?** (may include groups like those living in poverty, sex workers, asylum seekers, people with substance misuse issues, prison and (ex) offending population, Roma/travelling communities, and any other groups who may be disadvantaged in some way, who may or may not be part of the groups above equality groups) | No | |
| If you answered yes to any of the above, please provide details below, including evidence supporting differential experience or impact. | | |
| Enter details here if applicable | | |
| If you have identified potential negative impact:<br>- Can this impact be avoided?<br>- What alternatives are there to achieving the document without the impact?<br>Can the impact be reduced by taking different action? | | |
| Enter details here if applicable | | |
| Do any differences identified above amount to discrimination and the potential for adverse impact in this policy? | ~~Yes /~~ **No** | |
| If YES could it still be justifiable e.g. on grounds of promoting equality of opportunity for one group? Or any other reason | ~~Yes /~~ **No** | |
| Enter details here if applicable | | |
| Where an adverse, negative or potentially discriminatory impact on one or more equality groups has been identified above, a full EIA should be undertaken. Please refer this to the Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid or reduce this impact.<br><br>For advice in relation to any aspect of completing the EIA assessment, please contact the Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk | | |
| Was a full impact assessment required? | ~~Yes /~~ **No** | |
| What is the level of impact? | **Low** ~~/ medium / high~~ | |

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## 1. INTRODUCTION TO THE NON-FORMULARY, OFF- LABEL AND UNLICENSED MEDICINES PROCESS

Medicines management is an essential part of the safe use of medicines by the Trust. As such the Clinical Effectiveness Group exists to ensure the safe, effective and appropriate use of medicines within the Trust. There are a number of situations where prescribing of medicines can be of particularly high risk to the Trust:

- Prescribing of Unlicensed (UL) products
- Prescribing of licensed medicines outside of the conditions of their product License, Off-Label (OL)
- Prescribing of medicines not on the North Staffordshire Joint formulary, Non-Formulary (NF)

Prescribing of medicines that have no UK product license or outside of their licensed indication transfers liability onto the prescriber if any adverse event occurs, risking litigation. Therefore any prescribing outside of product license needs to be approved by the Clinical Effectiveness Group of the Trust. They would then share liability if approval has been given and the prescribing is deemed appropriate.

The Trust is bound by our commissioners to prescribe medicines that are on the North Staffordshire Joint Formulary. Prescribing outside of this could affect the reimbursement received from our commissioners and therefore any prescribing outside of the formulary must also be approved by the Clinical Effectiveness Group.

**It is the responsibility of all prescribers to be familiar with the NF/OL/UL process and to seek approval of any prescribing that falls within the above categories. If an approved form has not been received for a medicine that falls within these categories the Trust pharmacy will notify the prescriber that the NF/OL/UL process must be initiated and this may delay the supply of the medicine.**

# 2. POLICY ON THE PRESCRIBING, SUPPLY AND USE OF UNLICENSED MEDICINES

## 2.1 TRUST STATEMENT

This document describes the Trust's Policy on the prescribing, supply and use of unlicensed medicines.

2.1.1 Unlicensed medicines must only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time that the patient requires it. Such uses are informed and guided by respectable and responsible bodies or professional opinion. Products are considered pharmaceutically equivalent if they contain the same amount (or concentration) of the same active substance in the same dosage form, and meet the same or comparable standards considered in the light of clinical needs of the patient at the time of its use.

## 2.2 INTRODUCTION

2.2.1 For various reasons it is sometimes necessary to prescribe or use unlicensed medicines. Unlicensed medicines are defined as those not having a Product License (PL) in the United Kingdom (UK). Such unlicensed medicines include:

- Imported items having PL equivalents in other countries imported due to non-availability of the formulation in the UK e.g. levomepromazine suspension, olanzapine IM injection, Ritalin SR and naltrexone implants
- Imported items having PL equivalents in other countries, imported due to non-availability of the medicine in the UK e.g. pirenzepine
- Imported items without licenses, for example, certain melatonin preparations
- Items prepared in the UK by manufacturers holding a "Specials" license

2.2.2 This Policy is NOT intended to cover:

- Medicines used in Clinical Trials
- Medicines which are prepared extemporaneously in response to a prescription
- Products prepared under Sections 9, 10 or 11 of the Medicines Act 1968

2.2.3 All unlicensed medicines used by the Trust will be procured, received, stored and supplied by the Pharmacy department in accordance with the 'Policy on the Use of Unlicensed Medicines' of UHNM Pharmacy and this Policy.

## 2.3. CONSENT OF PATIENTS OR CARERS

2.3.1 The prescriber must explain fully the anticipated benefits and potential risks of the unlicensed medicine to the patient stating that the medicines is not licensed in the UK and make a record of this discussion and the information provided. The rationale for its use should be clearly explained, particularly if the use of the medicine is not recommended by guidelines such as NICE.

2.3.2 Healthcare professionals must respect the rights of patients and carers to participate in discussions regarding the health of the patient and to seek to ensure that these decisions are properly informed.

2.3.3 Adult out-patients and patients being discharged should receive a Patient Information Leaflet (PIL), a model of which is given in Appendix 1, from the Trust Pharmacy department that explains why it is necessary to prescribe unlicensed medicines.

2.3.4 Children and their carers should receive a copy of a Patient Information Leaflet (PIL) published by the Royal College of Paediatrics and Child Health, from the Trust Pharmacy Department. The link to this is: https://www.medicinesforchildren.org.uk/wp-content/uploads/sites/8/2021/10/Unlicensed-medicines.pdf

2.3.5 In-patient's medicines which are unlicensed because they are not available in the UK should be named on Form T2/T3 when in use, with a specified maximum dose and indication as they do not appear in the British National Formulary (BNF).

## 2.4. RESPONSIBILITY OF PRESCRIBERS

2.4.1 Prescribers of unlicensed medicines carry their own responsibility and are professionally accountable for their judgment in doing so.

2.4.2 Junior medical staff AND junior non-medical prescribers are NOT permitted to initiate the prescription of unlicensed medicines EXCEPT with the documented permission of a Consultant, Associate Specialist, Staff Grade Doctor or NMP managing patient's care.

2.4.3 Prescribers are responsible for seeking consent from the patient as described above and clearly documenting this discussion along with any information given to the patient. This should include a planned review date for the medication.

2.4.4 Prescribers must ensure that they adhere to this policy and that where prescribing necessitates a NF/OL/UL form, this must be completed and

reviewed by the Clinical Director or Deputy Clinical Director (who must be a Medical Doctor) before a prescription is written. This from may be completed on paper, or directly onto the patient's Lorenzo Clinical Notes section. There is a clinical note template available for this purpose.

2.4.5 For unlicensed medicines, prescribers have a responsibility to discuss availability, cost and rationale with the Trust Pharmacy Department.

2.4.6 Documentation supporting a decision to prescribe an unlicensed medicine should be made in the Patients Electronic Record (EPR) by the Consultant or NMP managing patient's care, and the same information conveyed to the patient's GP. The GP may not wish to participate in prescribing of unlicensed medicines and the additional burden of the Trust maintaining this prescribing must be considered as part of the initial decision making process.

## 2.5. RESPONSIBILITY OF PHARMACISTS

2.5.1 The Principal Pharmacist (Operations) has overall responsibility for controlling the procurement and supply of unlicensed medicines within the Trust Pharmacy department.

2.5.2 Pharmacists working in the Trust will be responsible for ensuring that prescribers are aware that a medicine that they have requested is only available as an unlicensed product. As part of this discussion pharmacists should discuss the rationale for prescribing to ensure that all licensed options have been considered.

2.5.3 Pharmacists working in the Trust will ensure that all the controls specified in this Policy are applied including the keeping of appropriate records.

2.5.4 It is likely that within the Trust several pharmacists may be involved in the decision making process around the use of an unlicensed medicine, for example, the Principal Pharmacist (clinical), the Principal Pharmacist (Operations) and the Chief Pharmacist. All pharmacists involved should ensure there is clear communication to others who may need to be involved, e.g. the pharmacist covering a ward where a medicine has been requested.

2.5.5 The Principal Pharmacist (Operations) will maintain records of all requests to prescribe unlicensed medicines and all associated paperwork in the dispensary and electronically.

## 2.6. RESPONSIBILITY OF CLINICAL DIRECTORS

2.6.1 The Clinical Director or Deputy Clinical Director within a Directorate is responsible for reviewing UL/OL/NF request forms and either authorising or rejecting the request. Where this person is not a medical Doctor this should be

passed on to another CD or DCD who is. A copy of the completed form should be returned to the requestor and also to the Trust Pharmacy Department. The review must be completed in a timely fashion.

2.6.2 As part of this the reasons for the application should be scrutinized, this should include a review of which other licensed/ formulary medicines have already been tried. If this information is unclear from the form this information must be sought from the applicant.

2.6.3 The Clinical Director or Deputy has a responsibility to challenge the rationale for prescribing which goes against guidelines or outside of the formulary. They must be assured that use of medicines which are UL/OL/NF is appropriate in each case. They must also consider any additional burden which may be placed upon the Trust, including financial if the UL or NF product is a high cost item. Also the cost and time to the Trust if the patient's GP will not take on the ongoing prescribing of an item.

2.6.4 If the Clinical Director or Deputy is not a specialist in the area of prescribing concerned, they should seek guidance from colleagues working in that clinical area where necessary.

2.6.5 If the Clinical Director or Deputy for a Directorate is not available then another Clinical Director, or Deputy, or the Medical Director will be expected to review the application to prevent any delay.

## 2.7. AUTHORISATION

2.7.1 A Consultant, Associate Specialist, Staff Grade Doctor or NMP managing patient's care wishing to prescribe an unlicensed medicine should contact the Pharmacy department in the first instance, stating the reason for the request and appropriate clinical details.

2.7.2 The responsible Pharmacist will ensure the application for use of an unlicensed medicine (NF/OL/UL form) (Appendix 2) has been completed in full by the consultant or NMP managing the patient's care and then discuss each application with a Principal Pharmacist.

2.7.3 The Pharmacist will review the clinical data and take a view on the likelihood of supply chain difficulties, the possibility of interruption to patient treatment and any other consequences of starting treatment with an unlicensed medicine. The UHNM Pharmacy department may be involved in this discussion as the wholesaler of medication to the Trust.

2.7.4 A response to the Doctor or NMP will be made as soon as is practicable.

2.7.5 Where permission is required to prescribe an unlicensed medicine not already

in use by the Trust the response will include details on the completion of the Unlicensed Medicines request form of the UHNM Pharmacy department. A copy of this form will be sent directly to the designated Pharmacist in that Pharmacy department by our Trust Pharmacist.

## 2.8. RESPONSIBILITY OF THE CLINICAL EFFECTIVENESS GROUP

2.8.1 The Clinical Effectiveness Group (CEG) is responsible for the approval for use of unlicensed medicines in the Trust, through the Directorate Clinical Directors.

2.8.2 When considering a request to approve use of an unlicensed medicine, the CEG must be certain that there is no suitable licensed alternative available.

2.8.3 Ratification of initial approval by the Clinical Director will occur at the next CEG meeting.

2.8.4 A list of unlicensed medicines that have been approved for use and details of usage will be maintained by the Chief Pharmacist.

## 2.9. EVALUATION OF UNLICENSED MEDICINES

2.9.1 The Principal Pharmacist (operations) will have a monitoring role in the use of unlicensed medicines and will keep a record of the use of unlicensed medicines within the Trust.

2.9.2 The CEG will review the list of unlicensed medicines in use at each meeting. If they feel usage is of concern they may request a review, which will include a re-assessment of the original clinical data, any new clinical data and any newly licensed products that may be more appropriate for use.

## 2.10. ADVERSE DRUG REACTIONS

2.10.1 Adverse drug reactions to unlicensed medicines are handled in the same way as licensed medicines. All clinicians should report adverse drug reactions to the Medicines and Healthcare Regulatory Agency (MHRA) using the Yellow Card System. Copies of Yellow Cards are available in the BNF and reports may also be submitted electronically at: https://yellowcard.mhra.gov.uk/

2.10.2 Copies of ALL adverse drug reaction reports (Yellow Cards) to UNLICENSED MEDICINES should be submitted to the CEG via the Chief Pharmacist or their deputy.

## 2.11. DEFECTIVE PRODUCTS

2.11.1 Reporting a defective unlicensed medicine is handled in the same way as a licensed medicine. Suspected defects should be reported to the Pharmacy

department of the Trust.

## 2.12. CONTINUING SUPPLIES OF UNLICENSED MEDICINES

2.12.1 There is no expectation that General Practitioners will continue the prescribing of unlicensed medicines for discharged patients or out-patients. Agreement may be sought on a case by case basis. Where a patient is admitted to hospital on an unlicensed product the prescriber may continue this if they are happy to do so. They will still need to contact pharmacy and complete a form as soon as practicable although treatment should not be interrupted where a supply of the medication is available in the Trust or from the Patient's home.

## 2.13. CURRENT PRE-APPROVED UNLICENSED MEDICINES

2.13.1 Authorisation by Clinical Director/ Deputy Clinical Director / Medical Director for individual patients is not currently required for the following medicines. However, the process of completion of a form must still be followed for each individual patient prior to dispensing.

2.13.2 It is the right of CEG to ask for this preferential status to be reviewed at any time if evidence or procurement issues change the situation.

| **Medicines** | **Indication and Restrictions** |
|---|---|
| Methohexitone/ Methohexital injection | Induction of anaesthesia during ECT when propofol is not effective |
| Lorazepam injection | All areas when licensed product unavailable |

# 3. POLICY ON THE USE OF LICENSED MEDICINES OUTSIDE THE CONDITIONS OF THEIR PRODUCT LICENCE

## 3.1 INTRODUCTION

3.1.1 In the UK the Medicines and Healthcare products Regulatory Agency (MHRA) operates a system of licensing for certain indications, medicines which it considers to have been demonstrated as being safe and effective for those uses.

3.1.2 The application for a Product License (PL) for a particular product is generally made by a pharmaceutical company with a commercial interest in that product.

3.1.3 The applicant for the license provides extensive clinical trial, and other data, after scrutiny of which the MHRA decides whether to award a PL or otherwise.

3.1.4 The process must be repeated for alterations or extensions of the original license.

3.1.5 Products which DO NOT have a PL are termed ‘unlicensed products’, and their use is dealt with in section 2.

3.1.6 The Product License defines the therapeutic or diagnostic purposes (the clinical indications) for which a product may be marketed. The manufacturer may then promote and sell the product for these purposes. The clinical indications are based on data submitted by the manufacturer as part of the Product License application.

3.1.7 In psychiatry it is not uncommon for licensed medicines to be used outside the terms of their product licenses. In child and adolescent psychiatry it is recognised that informed use of licensed medicines for unlicensed indications is often necessary. In many cases such use is well-supported by evidence and experience, and under such circumstances the absence of support for such use in the product license ought not to be regarded as an impediment.

3.1.8 The use of licensed products outside the conditions of their license (e.g. for different indications, at different doses, in different patient groups, for different lengths of time, in different forms or by different routes) is often termed ‘off-label’ (OL) prescribing, and will be so termed in this document.

3.1.9 If a prescriber uses a licensed medicine for an unlicensed indication (i.e. outside the terms of its Product License) then the manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the harm is directly attributable to a defect in it, rather than the way it was prescribed.

## 3.2 'OFF-LABEL' PRESCRIBING OF LICENSED MEDICINES FOR UNLICENSED USES

Certain unlicensed use of licensed medicines is well established in clinical practice and widely supported in the medical literature whilst some use is less well supported in the literature. Within the Trust such practice may be considered to fall into the following three categories

### 3.2.1 Category 1

'Off-Label' use of a licensed medicine with accepted, or supported evidence of, efficacy and/or associated with low risk or similar risk to the patient than comparable licensed treatment. The treatment may be recommended for off-label use in national guidelines or the BNFC for Children.

In addition to following the usual good prescribing practices, the prescriber is advised to:

- Obtain informed consent from the patient or their legal carer if under 16 years old, or from the young person if they have capacity, or to document why this is not possible
- Be particularly clear in documenting the intended purpose and the effects of treatment
- Follow any relevant guidelines with regard to biochemical and other side effect monitoring

Examples are given in Table 1. The list of examples is not intended to be exhaustive. The list will be reviewed should a need arise. Difficulties with the definition of the categories and list of examples are acknowledged, but it is hoped they will be useful.

### 3.2.2 Category 2

'Off-Label' use of a licensed medicine with less evidence of efficacy and/or associated with moderate risk or greater risk to patient than comparable licensed treatments.

As Category 1, but the prescriber is advised to:

- Obtain informed consent from the patient or their legal carer if under 16 years old, or from the young person if they have capacity, or to document why this is not possible
- Consider the use of reliable rating scales to assess ongoing efficacy
- Consider seeking (and documenting) a second opinion from a colleague
- Complete a NF/OL/UL request form for off-label use, either on paper, or directly onto Lorenzo Clinical Notes section.

  Examples are given in Table 2. The list of examples is not intended to be exhaustive. The list will be reviewed should a need arise. Difficulties with the

definition of the categories and list of examples are acknowledged, but it is hoped they will be useful.

3.2.3 Category 3

'Off-Label' use of a licensed medicine barely or un-supported and/or associated with relatively high risk of adverse events

As Category 2, but the prescriber is advised that:

- A second opinion is essential (this may be a referral from a tertiary centre or a local colleague)
- Consider initiation of treatment under particularly close in-patient supervision. Prior discussion with a Pharmacist about such use is recommended
- Complete a NF/OL/UL request form for off-label use

Examples of such use are given in Table 3. The list of examples is not intended to be exhaustive. The list will be reviewed should a need arise. Difficulties with the definition of the categories and list of examples are acknowledged, but it is hoped they will be useful.

**3.3 PRESCRIBING OF LICENSED MEDICINES FOR UNLICENSED INDICATIONS ('OFF-LABEL') WITHIN THE TRUST**

3.4.1 Prescribers wishing to prescribe a licensed medicine for an unlicensed indication should ensure that they follow the advice given in 3.1 and 3.2.

3.4.2 Particular attention is drawn to the duty of the Prescriber to record clearly in the medical notes the details of any unlicensed use of a medicine (such as the rationale for, review date of, discussions with patients about).

3.4.3 Common unlicensed uses include:

- Prescribing of doses above the Summary of Product Characteristics (SPC) limits
- Prescribing for longer than SPC time limits
- Prescribing for conditions other than specified in the SPC
- Prescribing a drug by a route not given in the SPC
- Prescribing an altered dose form e.g. crushed tablet or opened capsule

3.4.4 Prescribers of medicines for use outside their product licenses have responsibility for that prescribing. Junior Medical Staff and junior non-medical prescribers are NOT permitted to initiate 'category 2 or 3' off-label medicines EXCEPT with the permission of the Consultant, Associate Specialist, Staff Grade Doctor or the NMP managing a patient's care. Please see prescriber

responsibilities in section 2.

3.4.5 For a category 2 or 3 request the consultant or NMP managing the patient's care must complete an off-label request form (appendix 2). This form must then be sent to the directorate Clinical Director or Deputy Clinical Director for consideration, or another Clinical Director, Deputy or Medical Director if they are unavailable. They will then consider and approve or decline the application and forward the form to pharmacy to allow the medicine to be ordered. A separate application must be made for each individual patient who is to be prescribed a category 2 or 3 off-label medicine on a case by case basis. This form is also available on Lorenzo as a clinical note which can be completed directly.

3.4.6 Where it has been agreed as suitable for prescribing to be transferred from secondary care to primary care, full information around the decision to prescribe off-label should be relayed to the GP in writing.

3.4.7 The Principal Pharmacist (operations) will maintain records of all requests to prescribe category 2 or 3 off-label medicines and all associated paperwork in the dispensary.

3.4.8 The Clinical Effectiveness Group (CEG) is responsible for the oversight for use of off-label medicines in the Trust. Ratification of initial approval by the Directorate Clinical Director will occur at the next CEG meeting.

## Table 1 - Examples of Category 1 'off label' prescribing

| Medicine | Unlicensed Indication |
|---|---|
| Sodium Valproate including M/R | Acute mania/prophylaxis of Bipolar Affective Disorder, Behavioural disturbance in dementia |
| Semisodium Valproate | Prophylaxis of Bipolar Affective Disorder |
| Haloperidol | Control of disturbed behaviour/Rapid Tranquilisation |
| Lorazepam | Control of disturbed behaviour/Rapid Tranquilisation |
| Clonazepam | Control of disturbed behaviour |
| Antipsychotics (except clozapine) | Psychotic depression, non-schizophrenic psychosis |
| Propranolol | Akathisia |
| Lamotrigine | Depression in Bipolar Affective Disorder |
| Mirtazapine in combination with an SSRI | Resistant depression (as per NICE) |
| Anticholinesterase inhibitors **or** memantine | Lewy Body Dementia & vascular dementia |
| Antidepressants | Behavioural disturbance in dementia |
| Medicines for children as referenced in the Children's BNF | All indications referenced in the Children's BNF |
| Antipsychotics (except Clozapine) | Schizoaffective Disorder/Delusional Disorder |
| Mood Stabilisers e.g. Lithium, Sodium Valproate | Cyclothymia |
| Antipsychotics (except Clozapine) | Severe Personality Disorder |
| Lamotrigine | Treatment Resistant Depression |
| Circadin (Melatonin) | For insomnia in those below the age of 18 (although still non-formulary) **no form needed for children** |

**This list is not intended to be exhaustive and is open to debate.**

**It reflects current thinking and will be updated in the future.**

**Table 2 - Examples of Category 2 'off label' prescribing**

| Medicine | Unlicensed Indication |
|---|---|
| Antipsychotics | All doses above those in SPC. |
| Aripiprazole | Raised prolactin, in combination with another antipsychotic |
| Buproprion | Treatment Resistant Depression |
| Clonidine | ADHD, tic disorders, opioid withdrawal |
| Zopiclone | Insomnia for longer than 4 weeks continuous duration |
| Mirtazapine in combination with an SNRI | Resistant depression |
| Melatonin CR 'Circadin' | Insomnia in adult patients under 55 years or for longer than 21 days continuous duration |

**This list of examples is not intended to be exhaustive and is open to debate. It reflects current thinking and will be updated in the future.**

**Table 3 - Examples of Category 3 'off label' prescribing**

| Medicine | Unlicensed Indication |
|---|---|
| MAOIs | With other antidepressants in Treatment Resistant Depression |
| Clozapine | Any indication other than that contained in SPC (For example, schizoaffective psychosis, Bipolar Affective Disorder), or via the IM route |
| Sodium Valproate | Use in women of childbearing potential |

**This list of examples is not intended to be exhaustive and is open to debate. It reflects current thinking and will be updated in the future.**

# 4. POLICY ON THE PRESCRIBING OF MEDICATION NOT ON THE NORTH STAFFORDSHIRE JOINT FORMULARY

## 4.1. INTRODUCTION

North Staffs Combined Healthcare Trust functions as part of the North Staffordshire health economy. Therefore medicines management is in part determined by our commissioners and the new Integrated Medicines Optimisation Committee (IMOC). They in turn are guided by regional bodies and national organisations e.g. MTRAC and NICE.

All medication approved for use in North Staffordshire is listed on the North Staffordshire Joint Formulary. All medication on the formulary has been through an approval process whereby the evidence for effectiveness, place in therapy and cost-effectiveness has been reviewed.

The North Staffordshire Joint Formulary is available online:

http://www.northstaffordshirejointformulary.nhs.uk/

Each approved drug is listed by BNF category for its licensed indication. The formulary website also includes a link to all of the formulary reviews where the evidence underlying the decision process can be read in greater detail.

Any newly launched medication must be added to the formulary before it is available to be prescribed in North Staffordshire. This may occur automatically if it is approved by NICE. Otherwise, the medication will only be considered for approval if an application is submitted to the New Medicines Committee by a Consultant who wishes to prescribe the product. They must then address the Committee and put forward the case for the new medicine to be used and its place in therapy.

Prescription of a medicine not listed on the formulary should not be a routine occurrence or part of a regularly used treatment pathway. However all patients are individuals, and it is recognised that there will be some situations where prescribing outside the formulary may be necessary if other medicines are not tolerated or have not been effective.

## 4.2. PROCEDURE FOR INITIATION OF A NON-FORMULARY MEDICINE

4.2.1 If prescription of a non-formulary medicine is being considered, the prescriber should contact the Trust Pharmacy department to discuss the rationale and to ensure all reasonable alternatives have been explored. The discussion should

also include a consideration of any possible delay before a non-formulary medicine may become available due to the time taken to have approval forms signed and then for the medication to be ordered.

4.2.2 Junior medical staff and junior non-medical prescribers are NOT permitted to initiate non-formulary medicines EXCEPT with the permission of the Consultant, Associate Specialist, Staff Grade Doctor or the NMP managing the patient's care.

4.2.3 The Doctor or NMP must complete the NF/UL/OL form (Appendix 2), either on paper on directly onto Lorenzo Clinical Notes section. This form must then be sent to the Directorate Clinical Director or Deputy Clinical Director for consideration, or another Clinical Director or Medical Director if they are unavailable. They will then consider and approve or decline the application and forward the form to pharmacy to allow the medicine to be ordered. A separate application must be made for each individual patient who is to be prescribed a non-formulary medicine on a case by case basis. This form is also available on Lorenzo as a clinical note which can be completed directly.

4.2.4 Full information around the decision to prescribe should be relayed to the GP in writing.

4.2.5 The Principal Pharmacist (operations) will maintain records of all requests to prescribe non-formulary medicines and all associated paperwork in the dispensary.

4.2.6 The Clinical Effectiveness Group is responsible for the oversight of use of non-formulary medicines in the Trust. Ratification of initial approval by the Directorate Clinical Director will occur at the next CEG meeting.

### 4.3. PROCEDURE FOR PRESRIBING A NON-FORMULARY MEDICINE FOR A PATIENT ALREADY INITIATED ON IT

4.3.1 If a patient is admitted to Trust services already established on a non-formulary medication the circumstances should be investigated to form a plan of action. If the medication was started previously and approved within our Trust then the previous approval form is still valid and the medication can be ordered.

4.3.2 If the non-formulary medicine was initiated in another locality or by a GP it may be necessary to continue the medicine at least in the short-term. However a non-formulary request form must still be completed within the pharmacy department and filed for our records. Certain low risk items may not be stocked by the Pharmacy department who may advise an immediate

switch to a safe alternative or for the patient to bring in a supply from home, e.g. topical NSAIDs, indigestion remedies.

4.3.3 Patients admitted to the Trust for a period of time should have their medication reviewed by the Pharmacy department and as a part of this the reason for a non-formulary prescription should be investigated. If there is an opportunity to safely switch to a formulary equivalent then this should be considered, ideally in consultation with the patient's GP.

**Appendix 1**

## PATIENT INFORMATION LEAFLET FOR UNLICENSED MEDICINES

**You have been given a supply of:**

Medication:

Dose:

**To help with:**

### What is this leaflet about?

Sometimes a medicine is prescribed in a way that is not covered by its UK marketing licence. This does not mean that it is unsafe for this use. This leaflet explains in more detail what 'unlicensed' means and why some medicines are used in this way. You may wish to discuss this further with your prescriber or pharmacist.

### What is a licence?

A drug company must have a product licence to advertise and sell a medicine. This will state which illness the medicine can be used for, the ages of the patients it can be used for, how much to give and how to give it. It is obtained from a government organisation called the MHRA (Medicines and Healthcare products Regulatory Agency).

### How does a drug company get a licence?

To get a licence, the drug company must prove that the drug works for the illness to be treated and is safe to use. This is done by trying it first in clinical trials, usually in adults aged 18-65 years. Information from the clinical trials is then given to the MHRA when the drug company applies for a licence. The drug company cannot advertise or make any recommendations about using a medicine outside the terms of its licence. The licensing process and clinical trials are very expensive. Once a drug is on the market, the company may decide, on cost grounds, not to try getting the original licence extended.

### What is 'Off-Label' use of medication?

'Off-label' use means that the manufacturer of the medicine has not applied for a

license for it to be used to treat your condition. In other words, the medicine has not undergone clinical trials to see if it is effective and safe in treating your condition.

**Unlicensed medications**

An unlicensed medicine is one that does not have a product license at all in the UK.

**Why do some medicines not have a license?**

There are a number of reasons why a medicine may be unlicensed in the UK.

- It may be waiting for a license to be granted by the MHRA
- It may still be undergoing testing in a clinical trial
- The need for the medicine may be so limited that it is not economic for the manufacturers to apply for a license(which is an expensive process)
- The medicine may be licensed in another country, and needs to be imported to the UK
- The medicine needs to be made up as a 'special product' because it is not readily available (this is often the case for liquid formulations of medicines which only have a license for the tablet form)

**What are the reasons for an Unlicensed and/or Off-Label medicine to be used?**

To ensure that you have the best possible treatment for your condition, it may sometimes be necessary for unlicensed medicines to be prescribed.

- Clinical trials and research may have shown that the unlicensed medicine is the best treatment for your condition, but the manufacturer has not yet applied for a license, or they may be in the process of having a license granted
- There may be no other effective treatment available
- The medicine may be a special formulation such as a liquid which needs to be manufactured specifically for you.
- Many medicines are only tested with adult volunteers. Therefore, they will not have a license for use in children. There are local processes in place to review medicines and decide on what is best to treat children and younger people
- Syringe pumps are often used to deliver medication subcutaneously to control symptoms. Mixing medicines within the syringe pump makes the resulting

mixture unlicensed. This does not mean that they are unsafe.

**Are Unlicensed and /or Off-Label medicines safe to use?**

Your prescriber will consider all medical evidence available before prescribing an unlicensed medication. No medicine is completely free of side-effects and your prescriber will balance any risk of these against any benefits you may get, in consultation with you.

**Should I be worried about taking unlicensed and /or Off-Label medicines?**

Your prescriber will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your prescriber or pharmacist about your concerns. They may be able to give you further information or help to put you in touch with a support group for your illness or condition.

If you experience any unpleasant or unexpected effects whilst taking the medicine, you should discuss this with the person responsible for prescribing your medicine or the pharmacy which dispenses it for you.

**What else do I need to know?**

Sometimes it will take longer for the pharmacy to order and receive an unlicensed medicine, so you should allow one or two weeks for the pharmacy to obtain further supplies of your medicine. You should bear this in mind if you need to get a repeat prescription. Please remember that using a medication outside of its license may be the best way for you to get maximum benefit from medication with minimum unwanted effects.

**General Advice**

Most of your questions should have been answered by this leaflet, but remember that this is only a starting point for discussion with the healthcare team.

**Consent to treatment**

Before any doctor, nurse or therapist examines or treats you, they must seek your consent or permission. In order to make a decision, you need to have information from health professionals about the treatment or investigation which is being offered to you. You should always ask them more questions if you do not understand or if you want more information.

The information you receive should be about your condition, the alternatives available to you, and whether it carries risks as well as the benefits. What is

important is that your consent is genuine or *valid*. That means:

- you must be able to give your consent
- you must be given enough information to enable you to make a decision
- you must be acting under your own free will and not under the strong influence of another person

**How to obtain a further supply**

If you require a further supply of this medicine and if you do NOT have a further hospital appointment, please:-

 ***Go to your GP to obtain a prescription and take it to your local pharmacy (chemist) along with this leaflet.***

**(OR)**

 ***Return to the hospital pharmacy for a further supply***

**You will probably need to give the Pharmacist one or two weeks' notice to obtain the supply for you, so it is important that you do not let your supply run out before going to the G.P.**

**Appendix 2**

| **REQUEST FOR USE OF NON-FORMULARY, OFF-LABEL OR UNLICENSED MEDICATION** | |
|---|---|
| **Patient and Prescriber Details** | |
| Name: | Unit/NHS number: |
| DOB: | Ward/Unit: |
| Consultant/Prescriber: | Date: |
| Contact number: | Division: |
| **Medicine Details:** | |
| Medicine and Preparation (including strength and formulation): | |
| Indication: | |
| Dosage (including dose and frequency): | |
| **Please tick**<br>**NON-FORMULARY** ☐<br>**OFF-LABEL** ☐<br>**UNLICENSED** ☐ | **For an unlicensed product please also complete the 'unlicensed medicine clinical risk assessment' form if not already available** |
| **Reason for using this medication**- | |
| Medicines already tried including dose and course length used | |
| Allergies or contraindications to other treatments: | |
| **Evidence for use of off-label indication / unlicensed / non formulary medicine** | |
| Please attach supporting literature/ reference/ referral from tertiary centre etc. | |
| **Prescribing an unlicensed or off-label medication may have medico-legal implications**<br>• Section 9 of the Medicines Act (1968) permits the use by prescribers of unlicensed medicines on a 'named patient' basis. A prescriber prescribing an unlicensed medicine or outside the licensed terms does so entirely on their own responsibility, carrying the total burden for the patient's welfare, and may be called upon to justify | |

their actions in the event of an adverse reaction.

- The manufacturer is only likely to be found liable if harm results from a defect in the product. The manufacturer carries no legal liability for an unlicensed indication putting the responsibility on the individual prescriber and the Trust. The ultimate responsibility for prescribing any drug lies with the prescriber who signs the prescription and the prescriber is professionally accountable for their judgment. It is the responsibility of the prescriber to ensure all persons involved with the use of a medicine (patients and staff) are aware of its status e.g. off-label.

**Declaration by the prescribing Consultant/ NMP:**

- I am registering my wish to use this product for the reasons detailed and will await confirmation prior to prescribing the medication.
- I will initiate each prescription and obtain informed patient consent
- I accept full responsibility for informing all staff involved with the use of this medication of the fact that the medicine is currently unlicensed / off-label / non-formulary for the indication it is prescribed.
- I accept responsibility for fully informing any patients prescribed this medication of the fact that the prescribed medicine is currently unlicensed / off- label for the indication it is prescribed.

| **Consultant/ NMP's signature for UNLICENSED/ OFF-LABEL / NON FORMULARY request & declaration** | | |
|---|---|---|
| **Name** | **Signature** | **Date** |
| | | |

| **Clinical Director / Medical Director Review:**<br>***Where a Clinical Director or Medical Director request use of UNLICENSED/ OFF-LABEL / NON FORMULARY medicine the request must be reviewed and authorised by another Clinical Director / Medical Director*** | | |
|---|---|---|
| Supply of preparation (Please tick **)** | **APPROVED** ☐<br>**DECLINED** ☐ | |
| **Name** | **Signature** | **Date** |
| Return form to requesting Consultant/ NMP by secure fax or NHS email, if declined please state reason. | | |
| **Reason why request declined** | | |
| **Once completed** | | |
| **1) Send paper copy or by email to Harplands Pharmacy Team** | | |
| Date of receipt in Pharmacy: | Signature & name | |
| **2) File a copy of this form in patient's notes** | | |
| Date filed in notes | Signature & name | |
| | | |

| | |
|---|---|
| | |

**Training Needs Analysis for the policy for the development and management of Trustwide procedural / approved documents**

Please tick as appropriate

| | |
|---|---|
| There **is no** specific training requirements- awareness for relevant staff required, disseminated via appropriate channels<br>(Do not continue to complete this form-no formal training needs analysis required) | ✓ |
| There **is** specific training requirements for staff groups<br>(Please complete the remainder of the form-formal training needs analysis required-link with learning and development department. | |

| Staff Group | ✓ if appropriate | Frequency | Suggested Delivery Method (traditional/ face to face / e-learning/handout) | Is this included in Trustwide learning programme for this staff group (✓ if yes) |
|---|---|---|---|---|
| Career Grade Doctor | | | | |
| Training Grade Doctor | | | | |
| Locum medical staff | | | | |
| Inpatient Registered Nurse | | | | |
| Inpatient Non-registered Nurse | | | | |
| Community Registered Nurse | | | | |
| Community Non Registered Nurse / Care Assistant | | | | |
| Psychologist / Pharmacist | | | | |
| Therapist | | | | |
| Clinical bank staff regular worker | | | | |
| Clinical bank staff infrequent worker | | | | |
| Non-clinical patient contact | | | | |
| Non-clinical non patient contact | | | | |

| |
|---|
| Please give any additional information impacting on identified staff group training needs (if applicable) |

| |
|---|
| Please give the source that has informed the training requirement outlined within the policy i.e. National Confidential Inquiry/NICE guidance etc. |

| |
|---|
| Any other additional information |

| | | | |
|---|---|---|---|
| Completed by | | Date | |

**STANDARD OPERATING PROCEDURE (SOP)**

North Staffordshire Combined Healthcare NHS Trust

**Applicable to:** Trustwide, Stoke Community, North Staffordshire Community, Specialist Care, Urgent & In-patient Care

**SOP Title** The Management of Depot / Long-Acting Injections (LAI) within Community Mental Health Services

**SOP Number** **1.03c**

**Effective Date:** **30th November 2020**

**Review Date:** **30th November 2023**

| SOP version | Effective Date | Significant Changes | Previous SOP version |
|---|---|---|---|
| 01 | 01.08.2019 | New document | N/A |
| 02 | 30.11.2020 | Updated | 1.03c V1 |
| | | | |

## 1. Purpose

Medicines play a significant role in the care of the people who use our services and creating an effective system for managing medicines in an appropriate and timely manner is key to giving patients the best possible care, positive outcomes and reducing incidents of harm.

Administering medicines to people should not to be regarded as just a mechanical task to be carried out in line with the instructions of the prescriber, it requires thought, application and the exercise of professional judgement; it is a core component of medicines management and encompasses many areas for potential error.

Objectives:

- To comply with Care Quality Commission's fundamental standards / Key Lines of Enquiry (KLOE) for quality and safety that requires NHS providers to establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.
- To define the process and procedures to be followed within North Staffordshire Combined Healthcare Trust for the prescribing, monitoring and administration of depots / Long-Acting Injections (LAI) medication within the Community and to ensure the highest standards of medicines management and minimise risks associated with the use of Depot injection.
- To promote a consistent and best practice approach to the safe administration of Depot injection, aligning practices across community teams.
- To ensure the safe and secure ordering, storage and transportation of Depot / Long Acting Injection.

## 2. Scope

The scope of this Standard Operating Procedure (SOP) is to ensure that all staff dealing with Depots / Long Acting Injections (LAI's) follow safe practice in the prescribing, requisition, storage, administration and control of medicinal products. It applies to all individuals employed or contracted by North Staffordshire Combined Healthcare Trust

including all locum and agency staff and to all activities relating to depot medicines use within in-patient, out-patient, community and any residential facilities.

This SOP should also we read in conjunction with the following documents:

- Medicines Prescribing Policy
- Non-Medical Prescribing Policy
- Incident Reporting Policy
- Physical Health Monitoring policy
- Medicines Observation Policy
- Medicines Security SOP
- HDAT Policy
- Infection Control Policy
- Resuscitation Policy
- Polarspeed Direct Delivery of Risperidone and Paliperidone Long Acting
- Tutela Monitoring and Recording of Ambient (Room) and Refrigerator Temperatures SOP

## 3. Procedure

### The Supply and Ordering of Depots/LAI's

Each team should have a Registered Nurse who is responsible for ordering Depot injections. Orders should be in a permanent record, and any stock order forms/FP10s kept in a locked cupboard / area. These records should be retained for minimum standard of two years.

The Pharmacy will ensure that depot / LAI medication is only supplied on the instruction of an authorised person (i.e. by confirming signatures). Each team will have an up to date authorised signature list for the purpose of ordering and auditing purposes.

### The Storage and Security of Depot / LAI

- All Depot / LAI's should be stored within Pharmacy approved lockable cupboards. The medication cupboards should be kept locked when not in use and not left unattended whilst unlocked.

- The injections should be stored in accordance with the product licence.

- Quality Improvement Leads will coordinate regular quarterly audits of medicines cupboards in accordance with locally agreed procedures and the pharmacy team will conduct the annual storage audits.

- All medicine cupboard keys must be kept separate from other department / team base keys. They must be clearly identified and kept together within a locked key box or safe. The key box or safe must be attached to a permanent fixture in a safe location within the team base.

- Access to medicine cupboard keys, medicines cupboards and refrigerators is restricted to registered nursing staff, medical staff, Team Managers, Clinical Leads and Pharmacy personnel.

**Loss of Keys**

Any other breaches in security involving medication storage should be formally raised through the Ulysses incident reporting system and reported to the Pharmacy team and the Local Security Management Specialist and investigated accordingly.

Refer to the Trust's Incident Reporting Policy and Security Policy for further guidance.

**Stock Control**

- Depot injections that are delivered to the clinical base should be checked against the requisition by a designated registered nurse and signed in and recorded on the back of the patient's depot card, ensuring that the stock balance is correct.

- The delivery receipts should be retained and be accessible for stock queries and for auditing purposes for a two year period from the date of receipt.

- Any unused stock should be returned to the medicines cupboard and placed in the appropriate box containing the correct batch number and expiry date.

- All stock no longer required should be returned to Pharmacy.

- Any out of date depot stock should be recorded and disposed of in the relevant disposal bin.

- Any Clinician discovering a discrepancy should inform the Team Manager / Deputy Team Manager and this should be reported through the Ulysses incident reporting system.

**Care plan**

- The decision to administer a depot/LAI antipsychotic injection should be part of a comprehensive care plan, which should be accessible in the clinical records
- There should be documented evidence that the patient was involved in the generation of their care plan, and the patient's relapse "signature" signs and symptoms should be documented in their care plan
- The care plan should also include a crisis plan, and a clinical plan for response to default from treatment, i.e. if a patient fails to attend an appointment for administration of their depot/LAI antipsychotic medication or declines their injection

**Prescribing of Depots / LAI's**

The prescription for IM Depot injections for a patient in the Community must be written on the Trust approved Depot / Long Acting Antipsychotic Administration Card (See Appendix 1).

A clear rationale for initiating a depot/ LAI injectable antipsychotic medication should be documented in the clinical records

Review of antipsychotic medication should be conducted at least annually by the prescriber/psychiatrist in the responsible clinical team

Medication review should include consideration of therapeutic responsea

Guidance on prescription writing provided in the BNF should be followed at all times.

The Depot / LAI prescription must**:**

- Be appropriate, complete, unambiguous and legible.
- Be in black ink.
- Be signed and dated appropriately. Each prescription item must be validated by the full signature of a registered medical practitioner or authorised prescriber. The signature should be legible and the printed name of the prescriber should be written next to the signature. Initials or abbreviated signatures are not an adequate means of identification of a prescriber or serve as authorisation of a prescription.
- It is the responsibility of medical staffing to send specimen signatures of all authorised prescribers in the Trust, including locums, on appointment, to the Pharmacy department and Community team managers.
- It is the responsibility of the Independent Prescribing Lead to collate and send specimen signatures of all authorised Non-Medical Prescribers within the Trust, on appointment, to the Pharmacy department and Community team managers.
- Adhere to legal, formulary and Trust policy requirements.
- Bear the full name, address, Date of Birth and NHS number of the patient (Patient information sticker can be used)
- Only use Trust approved abbreviations:- I.M for Intramuscular
- The prescriber to ensure that arrangements are in place for all test doses of Depot / LAI's to be administered on Trust premises that have access to emergency life support equipment.

Patients in the community who are on a Supervised Community Treatment Order (CTO) must have the corresponding documents to support administration in the community. They are:

**Form CTO12** (certificate to confirm community patient has capacity to consent and has done so)

**Form CTO11** (certificate of appropriateness of treatment to be given to community patient).

A copy of the **T2 / T3 / S62** must also be kept with the prescription and administration

chart.

It is the administering nurse's responsibility to challenge any queries / concerns relating to the prescription and raise with the Prescriber or a member of the Consultant medical team. This should be escalated as soon as possible to avoid any unnecessary delays in Patient care.

**The Depot / Long Acting Injection Prescription must include:**

- Name of the Medicine
- The full generic form e.g. zuclopenthixol decanoate.
- The interval expressed using the 'every' (e.g. every 3 weeks; this can be abbreviated to every 3/52)
- The prescription dose should include appropriate use of decimal points.
- The date prescribed and the next due date if appropriate.
- Explicit dosage instructions, including route should be stated. Use of the phrase 'as directed' is not acceptable.
- Abbreviations of units should always be written in the singular, e.g. 10mg, not 10mgs.

**Validity of Community Prescriptions for Depots / LAI**

- The Depot / LAI prescription will remain valid for a maximum of 6 months. After this 6 month period, the prescription will be invalid.

- Verbal orders / prescriptions cannot be accepted for Depot / LAI's.

- Prior to the rewriting of the Depot / Long Acting Antipsychotic Administration Card, the prescriber will check the Patients Electronic Record (EPR).

- The prescriber must ensure that the patient has had a face to face medical review within a maximum period of no more than 12 months.

- If the patient is new to community services and is being discharged from secondary care the inpatient team must contact the community team promptly to arrange for the transfer of care. If there is insufficient time for this to be processed through the Lorenzo system verbal confirmation must made and any agreement should be documented on the EPR.

- The Depot / Long Acting Antipsychotic Administration Card should be completed on discharge by community team using the discharge summary and medication ordered in readiness for the patient appointment.

- It is the responsibility of prescribers to inform the patients CPN / Care coordinator or Depot clinic nurse of any changes to the prescribed Depot / Long Acting Injection and re-write the Community Depot / Long Acting Injection Prescription and Administration Card at the earliest opportunity.

- The prescriber will personally terminate the previous Depot / Long Acting Antipsychotic Administration Card and issue a new card prior to the change of IM Depot / Long Acting Injection being administered.

**Documentation of Allergies/Hypersensitivities**

- All prescription forms must specify whether or not the patient has any allergies / hypersensitivities information (i.e. allergy details or "No known drug allergy" NKDA) on the prescription sheet, along with the source of information identified.

**Prescribing Incidents**

All prescribing incidents must be reported via the Trust Ulysses Incident Reporting System (refer to Incident Reporting Policy). The Patient Duty of Candor notification and processes must be applied where appropriate.

**Initiation of Depots / LIA's**

Care should be taken to ensure that a test dose of Depot injection is prescribed where appropriate. This is not a requirement for Long Acting Injections (see Appendix 5) .

A test dose of Depot Injection should only be administered to inpatients or patients within a Depot / LAI clinic.

**Monitoring of Depot / Long Acting Injections**

Any noted deterioration in a patient's mental or physical health should be escalated to the Responsible Clinician and, where deemed appropriate, medically reviewed at the earliest possibility by the relevant consultant medical team.

All Patients who are receiving Depot / LAI's will be offered an annual physical health check from Planned Care.

Refer to the Physical Health Policy, Medicines Observation Policy and HDAT Policy for further information.

**Monitoring side-effects / Adverse Drug Reactions**

- Prescribers must fully inform patients of possible side-effects / adverse drug reactions that could be caused by the injection prior to prescribing it and should be offered patient information leaflet: https://www.choiceandmedication.org/combined/.

- During every contact, the doctor, registered nurse or a nurse in training (under the direct supervision of a registered nurse) must actively ask patients about side-effects / adverse drug reactions that the patient may be experiencing.

- If the doctor, registered nurse or a nurse in training (under the direct supervision of a registered nurse) becomes aware of or observes any adverse drug reaction following the administration of the Depot / LAI, they should contact the relevant

medical team without delay.

- Details of any serious adverse effects relating to or suspected to relate to the administration of Depot / LAIs should be recorded in the patient's record and this information should be related to the prescriber. A yellow card should be filled in and sent to the MHRA. Yellow forms are available in the back of the BNF or at www.yellowcard.gov.uk. This should also be recorded on the Trust Ulysses Incident Reporting System.

**Medical Reviews of Patients on Depot / Long Acting Injections**

- Prior to the completion or rewriting of a Depot / LAI prescription, the prescriber must ensure that the patient has had a face to face medical review within a maximum period of 12 months.

**The Administration of Depot / Long Acting Injections**

- Depot / LAIs must only be administered with a valid, clearly written and unambiguous prescription, using the generic name of the injection, on the Trust approved community Depot / Long Acting Injection prescription and administration Card.

- IM Depot / Long Acting Injection must be administered by a registered nurse, doctor or a nurse in training (under the direct supervision of a registered nurse).

- The registered nurse, doctor or a nurse in training (under the direct supervision of a registered nurse) must ensure the following is in place prior to administering the Depot / Long Acting Injection:

  - Valid prescription
  - Correct patient
  - Correct depot/long-acting injection
  - Correct date
  - Correct dose

- Verification of this information should be sought by checking the EPR and with the patient to ensure that no transcribing errors have occurred or to identify any changes to the prescribed drug/dose/form since the last administration.

- The person who administers a medicine is responsible and accountable for their action / omission.

- The registered nurse responsible for the administration of the IM injection must ensure that any required calculation is correct. A second practitioner must check the calculation in order to minimise the risk of error.

- Registered nurses responsible for the administration of the IM injection in a patient own home (or outside of the Depot / LAI clinic) are exempt from the

second checking requirements due to the nature of the role and the safeguards in place.

- Wherever possible, the depot / LAI will be administered by the patient's care coordinator.

- If there is any doubt about the content or clarity of a prescription the registered nurse, doctor or a nurse in training (under the direct supervision of a registered nurse) must contact the prescriber or pharmacy team before proceeding to administer the Depot / LAI.

- In an emergency, if the prescriber is unable to attend, the registered nurse, medical officer or nurse in training under the direct supervision of a registered nurse may defer the administration of the injection until further clarification is obtained.

When a community patient is admitted to a Mental Health inpatient ward, the ward staff should notify the community team of the patient's admission as soon as possible:

- A copy of the Depot / LA Antipsychotic Administration Card should be scanned or emailed to the inpatient unit to confirm the due and last date of administration. The Depot / LA Antipsychotic Administration Card should then be discontinued and filed in the notes.

- Patients will receive their Depot / LAI on the ward and **not** within a community Depot clinic.

In the event of a community patient being admitted to a general hospital ward, the following actions should be taken:

- An identified team clinician will inform the patient's community RC who will confirm if the IM depot / LAI should continue during the general hospital admission.

- The identified team clinician will ensure a faxed copy of the Depot / LA Antipsychotic Administration Card is forwarded to the general hospital ward for clarification of the injection.

- The identified team clinician will liaise with the general hospital ward accordingly and agree who will administer the Depot/ Long Acting Injection for the Patient whilst they remain on the ward.

**The Recording of Depot / Long Acting Injection Administration**

Each written entry should include the standards as outlined within the Trust clinical record keeping policy and NMC record keeping guidelines.

Each entry should include:

- Prescribed injection administered
- Patient consent

- Concordance and compliance
- Mental health presentation
- Expressed or observed adverse effects
- Next due date of administration
- Any other concerns voiced or noted within the consultation
- Completion of the Depot/LA Antipsychotic Administration Card including consent.

All Depot / LA Antipsychotic Administration Cards for patient's on Community Treatment Orders (CTO) should have the forms CTO 11/12 attached to the treatment card and the form should then be removed if the CTO is discontinued.

All Depot / LA Antipsychotic Administration Cards that are full, should be scored with a single diagonal line through the card and scanned on to the EPR and saved under Documents and titled 'Completed depot card insert date'.

Records should be completed immediately or at the earliest opportunity not exceeding 24 hours after the injection is administered, or if a dose is refused or wasted, this must also be recorded, signed and dated.

Patient contact must be recorded electronically on all relevant IT systems within 3 working days as per Trust policy.

**Specimen Signatures / Initials**

Each Community Mental Health Team should have an up to date nurse specimen signature list that is reviewed on a quarterly basis.

A copy of this list should be forwarded to Pharmacy and a copy available within the team clinic / treatment rooms.

It is the responsibility of the Team Manager / Deputy to review and update the specimen signature list on a quarterly basis.

**Retention of Trust approved Community Treatment cards**

All old copies of Community Treatment cards must be permanently scanned into notes which are retained according to nationally defined minimum periods.

**Refusal of Depot/ Long Acting Injection**

In general, patients have a right to refuse medicines. Reasons for refusal must be documented and escalated to the relevant consultant medical team immediately and advice sought.

**Patients who Did Not Attend (DNA)**

Clear process guidelines should be followed in accordance with DNA flowchart

(**Appendix 3**) and letter (**Appendix 4**), ensuring actions and outcomes are recorded on the Electronic Patient Record. For further information on managing DNA refer to the Admission, Discharge and Transfer Policy.

**Depot / LAI Clinics**

The treatment / clinic room should;

- Be accessible with disabled access.
- Have appropriate and adequate waiting areas that maintain privacy and dignity.
- Be a safe and clean environment and infection control compliant.
- Contain emergency life support equipment and medical equipment.
- Have a panic alarm system.
- Have access to Lorenzo
- Refer to clinic checklist (Appendix 2)

**The Transportation of Depot / Long Acting Injections within Home Visits**

When carrying medicines within the community, these medicines become the responsibility of registered nurse to whom they are issued.

All medicines carried by the CPN should be prescribed as a specific dose for a named patient by an authorised prescriber for the purpose of administering the injection to the Patient.

Each Depot/ LAI carried should be accompanied by the written prescription on the relevant Community Treatment Card.

CPN's should only carry Depot / LAI's in Trust approved secure medicines bags/ cases (see picture below) to ensure security and infection control compliance.

The Trust approved secure medicines bag / case should contain an appropriate sharps disposal bin and all other necessary equipment for the administration of Depot / LAI's.


Where it is necessary for a CPN to take the medicines bag / case home overnight, the

bag / case should not be left in the car unsupervised and should be stored securely within their home.

**Monitoring / Review of this Procedure**

In the event of planned change in the process(es) described within this document or an incident involving the described process(es) within the review cycle, this Guidance will be reviewed and revised as necessary to maintain its accuracy and effectiveness.

Depot / Long Acting Antipsychotic Administration Card **Appendix 1**

| | | | | |
|---|---|---|---|---|
| **Surname:** | **First Name(s):** | | **Allergies / previous serious drug reactions:** | |
| **Address:** | | | **NHS Number:** | **Date of birth:** |
| **Consultant:** | **Team:** | **Care co-ordinator:** | **GP:** | |
| **Contact Telephone numbers** | **Client:** | **Carer / Relative:** | | |
| **Side effect monitoring Details / Date completed** | **Date due :** | **Date Completed** | **Next due:** | **Date Completed:** |
| **Blood test review (At least annually)** | **Date due:** | **Date Completed** | **Next due:** | **Date Completed:** |
| **Mental Health Act Section:** | **Consent to Treatment T2/T3 date due:** | | **CTO11/CTO12/Sec 64 copy attached: Yes / N/A *(delete one)*** | |

# Medication Authorisation to Administer

**(Delete row when not applicable e.g. dosage changed)**

| Medication Name | Dose | Site/Route | Interval | Prescribers signature | Prescriber print name | Date completed |
|---|---|---|---|---|---|---|
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Injection can be given up to …….days before and / or ……..days after due date

**If medication not administered within above timeframe – complete an incident form**

**Clients must be reviewed every six months with new FP10 prescription.**

**For new medication prepare new administration card with new FP10 prescription.**

Depot / Long Acting Antipsychotic Administration Card **Appendix 1**

| **Client Name:** | **Date of birth:** | **NHS Number:** | **Indication:** |
|---|---|---|---|
| | | | |

# Administration Record **If medication not administered within above timeframe – complete an incident form**

| Date due | Date given | Medicine | Dose | Side (R/L) | Print & Sign | Comments / omission codes | Stock remaining |
|---|---|---|---|---|---|---|---|
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Omission Codes **DNA** – did not attend, **R** – Refused, **N** – no access, **H** – client holiday, **O** – other must be specified

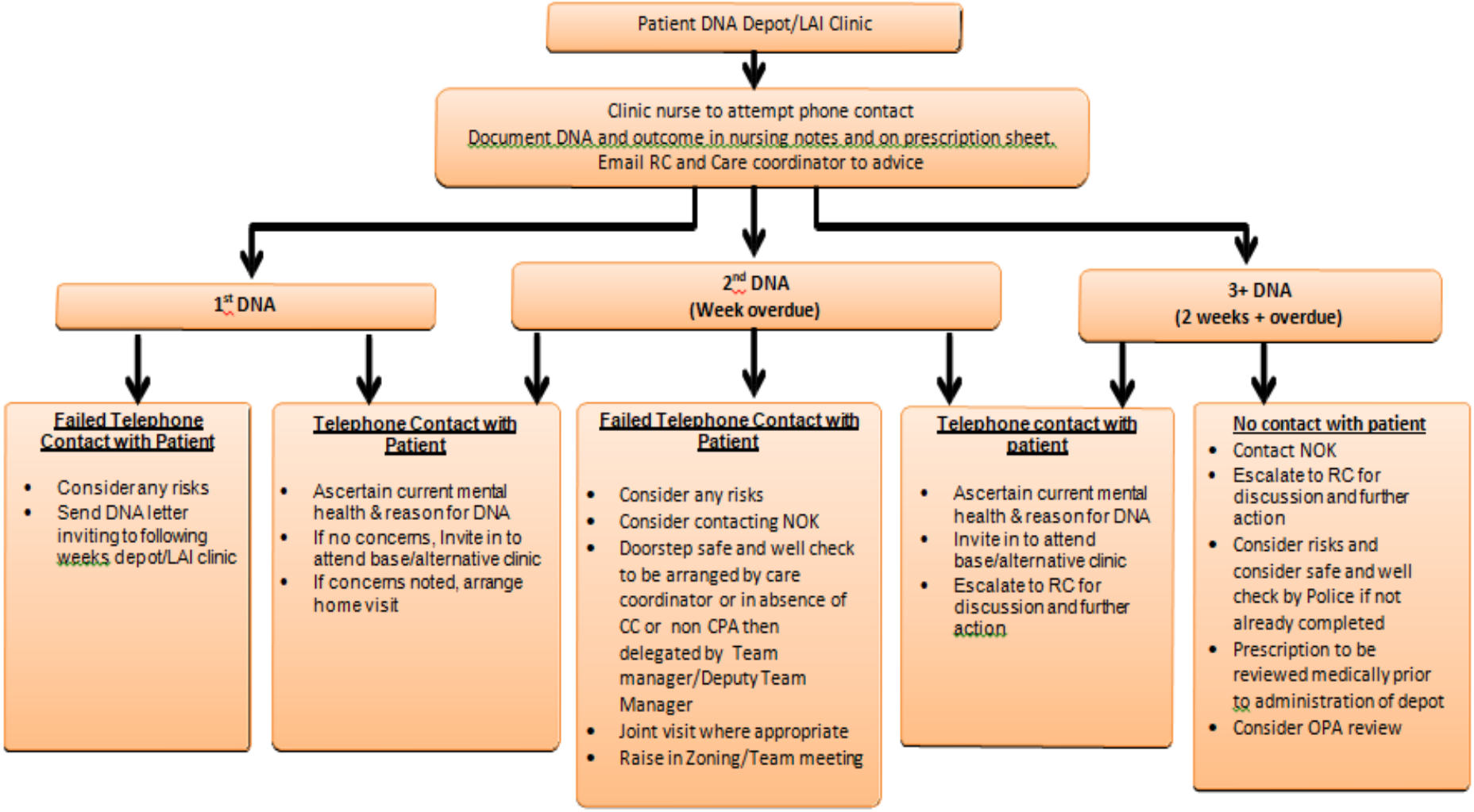
Community Depot / LAI Clinic Checklist Appendix 2

| | |
|---|---|
| PRIOR TO DEPOT / LAI CLINIC | |
| Ensure Community Treatment Card rewrites have been completed and are ready for Depot / LAI Clinic | |
| Prepare and ensure all named Patient Depot/ Long Acting Injections are available | |
| Ensure all Patient notes / case record booklets are available | |
| Ensure that yellow top sharps bins are available for disposal of sharps during depot / LAI clinic | |
| ONGOING ACTIONS | |
| Ensure allergies are documented prior to administration of Depot / Long Acting Injections | |
| Ensure prescription sheets have attached labels and up to date Patient contact details and demographic details | |
| Ensure Risperdal Consta injections reach room temperature prior to administration (recommended 15 minutes) | |
| DNA'S | |
| Adhere to DNA Flowchart for reference | |
| FOLLOWING DEPOT / LAI CLINIC | |
| Ensure all sharps bins are disposed of in accordance with Trust policies | |
| Prepare the following clinics folder | |
| Check for rewrites for the following week | |
| Order any Olanzapine/Aripiprazole injections that have been used on the day (via Harplands Dispensary) | |
| Order any Risperidone consta/Palperidone injections that have been suspended/newly prescribed (via Polarspeed) | |
| Ensure adequate Depot stocks are available / requirement to order stocks communicated to relevant staff member | |
| Ensure transport logistics allow for depot to be received in time for the next administration | |
| E mail clinic list to whoever is doing clinic the following week | |
| Ensure filing cabinet and folders are left in an alphabetical and orderly manner | |
| Tidy Clinic Area and leave it the way you'd wish to find it | |

Signed……

Dated……

Community Depot / LAI Clinic Checklist Appendix 2



Community Depot / LAI Clinic Checklist Appendix 2

Depot / LAI Clinic Letter for Non Attendance

Community Base Address

Tel:
Fax:

Our ref: DNA/
NHS Number:

Date:

NAME
ADDRESS

Dear

**Re: Non-attendance to Depot / Long Acting Injection (LAI) Clinic**

We note that you did not attend Depot / LAI clinic for your depot injection on <<DATE>>.

Could you please attend the next available clinic, which is held as follows:

<<Treatment team name and address>>

**<<Day of week>>** **<<Time of Day>>**

If you are having difficulties in attending the Clinic, please contact your CPN / Care Co-Ordinator or the Duty Worker within the team on <<xxxxxxxx>> to discuss other possible ways of supporting you with this.

Yours sincerely

**Depot / LAI Clinic Nurse**
**XXXXXXXX**

Community Depot / LAI Clinic Checklist Appendix 2

| **Medicine** | **Recommended first-line route(s)** | **Test dose**[1] | **Maintenance dose** | **Maximum dose** | **Storage** | **Pharmaco-kinetics(Bazire)** | **Examples of volumes** [3] | **Comments** |
|---|---|---|---|---|---|---|---|---|
| Aripiprazole (Maintena®) | Deep IM into the ventrogluteal, dorsogluteal or deltoid muscle. | No Test dose (Oral used) | **400mg** monthly<br><br>Can be reduced to **300mg** monthly | **400mg** (no sooner than 26 days after the previous injection). | | PK = 5-7 days (at SS)<br>T1/2 = 46.5 days (400mg) and 29.9 days (300mg) | **400 mg = 2.0 ml** of 200mg/mL<br>**300 mg = 1.5 ml** of 200mg/mL<br>**200 mg = 1.0 ml** of 200mg/mL<br>**160 mg = 0.8 ml** of 200mg/mL | See specific Trust guidance.<br>Vertically shake the syringe vigorously for 20 seconds until the reconstituted suspension appears uniform. inject immediately after reconstitution |
| Flupentixol decanoate (Depixol®) | Deep IM into the ventrogluteal or Dorsogluteal muscle. | **20mg** (allow 1 wk before re administrating) | **50mg** every 4wks to **300mg** every 2 wks | **400mg** weekly | | DOA = 3-4 wks<br>PK = 7-10 days<br>T1/2 = 8 days (single) 17 days (multiple)<br>SS = 10-12 wks | **20mg** = **1ml** of 20mg/ml<br>**40mg** = **2ml** of 20mg/ml (2ml vial)<br>**50mg** = **0.5ml** of 100mg/ml (0.5ml vial)<br>**100mg** = **1ml** of 100mg/ml<br>**200mg** = **2ml** of 100mg/ml<br>**400mg** = **2ml** of 200mg/ml | > 65 years half to quarter of the dose.<br>Can be mixed with other Depixol formulations |
| Haloperidol decanoate (Haldol®) | Deep IM into the ventrogluteal or Dorsogluteal muscle. | **50mg**<br>**12.5-25mg** (>65 yrs) | **50 mg** to **300 mg** every four weeks | **300mg** every 4 weeks | Below $25^{O}C$ | DOA = 6 wks<br>PK = 3-9 days<br>T1/2 = 18-21 (single + multiple)<br>SS = 10-12 wks at monthly dosing | **50mg** = **1ml** of 50mg/ml<br>**100mg** = **1ml** of 100mg/ml<br>**200mg** = **2ml** of 100mg/ml<br>**300mg** = **3ml** of 100mg/ml | |
| Olanzapine pamoate monohydrate (Zypadhera®) | Deep IM into the ventrogluteal or dorsogluteal muscle. | <u>Initially</u><br>**210mg** every 2 weeks or **405mg** every 4 weeks for 2 months **(PO Olanzapine 10mg).**<br><br>**300mg** every 2 weeks for 2 months **(PO Olanzapine 15** | <u>After 2 months</u><br>**150mg** every 2 weeks or **300mg** every 4 weeks **(PO Olanzapine 10mg).**<br><br>**210mg** every 2 weeks or **405mg** every 4 weeks **(PO Olanzapine 15mg).** | **300mg** every 2 weeks or **405mg** every 4 weeks | Do not refrigerate or freeze. | DOA = 1 day – 4weeks<br>T1/2 = 30 days<br>SS = 5-6 months<br>EP = 6-8 months | **150mg** = **1.0mL** of the 210mg vial<br>**210mg = 1.4mL** of the 210mg vial<br>**300mg = 2.0mL** of the 300mg vial<br>**405mg = 2.7mL** of the 405mg vial | See specific Trust guidance.<br><br>Shake the vial vigorously until the suspension appears smooth and is consistent in colour and texture. The suspended product will be yellow and opaque. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | **or 20mg)** | **300mg** every 2 weeks **(PO Olanzapine 20mg** | | | | | |
| Paliperidone (Xeplion ®) | First 2 doses into the deltoid (in order to attain therapeutic concentrations rapidly).<br><br>Maintenance doses can be administered in either the deltoid or gluteal muscle. | No Test dose (Oral used)<br><br><u>Initially</u><br>150 mg on day 1 and<br>100 mg one week later (day 8).<br><br>No loading doses required if currently prescribed a depot (See SPC for further information | Maintenance dose is range = **25- 150mg** monthly usually 75mg.<br><br>Patients who are overweight or obese may require doses in the upper range. | **150mg** monthly | Do not store above 30°C. | DOA = 1 day – 4 months PK = 13 days<br>T1/2 = 25-49 days | In standard syringes | See specific Trust guidance.<br><br>Shake the syringe vigorously for a minimum of 10 seconds to ensure a homogeneous suspension. |

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|---|---|---|---|---|---|---|---|---|
| Paliperidone (Trevicta ®) | Injected slowly, deep into the deltoid or gluteal muscle.<br>Recommended Injection rate is 10 secs per mL. | No test dose required.<br>Only in adult patients who are clinically stable on 1-monthly paliperidone. See trust guidance<br>Initiated on the next schedule 1-monthly dose. | Doses<br>**175mg, 263mg, 350mg or 525mg** every 3 months (± 2 weeks)<br>NB The dose is 3.5 folder higher than the monthly dose. | **525mg** every 3 months (± 2 weeks) | | DOA = 1day -18months<br>PK = 30-33 days<br>T1/2 = 84-95 days (deltoid) and 118-139 days (gluteal). | | It is important to shake the syringe vigorously with the tip up and a loose wrist for at least 15 seconds to ensure a homogeneous suspension. It should be administered within 5 minutes after shaking. |
| Risperidone (Risperdal Consta®) | Deep IM into the ventrogluteal, dorsogluteal or deltoid muscle. | No Test dose (Oral used) | **25-50mg** every 2 wks<br>(For starting doses consider 25mg LAI if on<br><4mg oral risperidone and 37.5mg LAI if on<br>>4mg oral risperidone) | **50 mg** every two weeks. **25 mg** every two weeks in (>65 years of age) | Store at $2^{o}C$ to $8^{o}C$ (fridge) [2] | PK = 4-6 wks<br>EP = 7-8 wks<br>(data sheet) | Whole vial used for each strength | See specific Trust guidance.<br>25 mg to 37.5 mg or<br>from 37.5 mg to 50 mg should be considered after a minimum of four weeks after the previous dose adjustment. **NB the trust standard is to increase after six weeks.**<br>Continuing to hold down the plunger rod,<br>shake vigorously for at least 10 seconds. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Zuclopenthixol decanaote (Clopixol®) | Deep IM into the ventrogluteal (if trained) or otherwise dorsogluteal<br>(nb. lateral thigh is a licensed route but is not<br>recommended first-line) | **100 mg**<br>(half to quarter dose >65 yrs) | **200-500 mg** every one to four weeks | **600 mg** per week. | Store at or below 25°C | DOA = 2-4 wks<br>PK = 4-9 days<br>T1/2 = 17-21 days (multiple)<br>SS = 10-12 wks | **100mg** = **0.5ml** of 200mg/ml<br>**200mg** = **1ml** of 200mg/ml<br>**300mg** = **1.5ml** of 200mg/ml<br>**400mg** = **2ml** of 200mg/ml<br>**500mg** = **1ml** of 500mg/ml<br>**600mg** = **1ml** of 500mg/ml + **1ml** of 100mg/ml | This product may be mixed in the same syringe with other products in the Clopixol Injection range, including Clopixol Acuphase Injection (zuclopenthixol acetate 50 mg/ml). |

**Applicable to:** Stoke Community, North Staffordshire Community

**SOP Title** Supply of Clozapine to Patients Registered with a PocHi Clinic

**SOP Number** NEW

**Effective Date:** September 2022

**Review Date:** 1st October 2025

| SOP version | Effective Date | Significant Changes | Previous SOP version |
|---|---|---|---|
| NEW | September 2022 | | N/A |
| | | | |
| | | | |
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## 1. Purpose

This procedure aims to provide guidance on the supply of Clozapine from Harplands Hospital Pharmacy to outpatient clozapine clinics within Combined Healthcare Trust who are registered for Point of Care Haematology (PocHi) testing so that the sampling results can be verified via the Clozapine Patient Monitoring Service (CPMS) within a few minutes. It does not cover supplies to inpatient units or units/ patients where blood samples are sent to external labs for processing.

## 2. Scope

This procedure applies to Stoke Community and North Staffordshire Community Directorates within North Staffordshire Combined Healthcare NHS Trust.

## 3. Specific procedure

### 3.1 Introduction

Clozapine is licensed for the management of treatment resistant schizophrenia; schizophrenia in patients who have severe, untreatable neurological adverse reactions to other antipsychotics; and psychotic disorders occurring during the course of Parkinson's disease which cannot be treated effectively with other antipsychotics.

The initiation of Clozapine is restricted to Consultants registered with the Clozaril Monitoring Service (CPMS) and following a stabilisation period these service users

are referred to the Community Mental Health Team (CMHT) for ongoing prescribing and long term management. The CMHTs will have a dedicated Clozapine Clinic that supports with the collection and testing of blood samples, conveyance of clozapine supplies; and the provision of advice in relation to medication, physical health and health lifestyle. Patients must be registered with a Point of Care Haematology (PocHi) clinic before they can have their bloods analysed there.

Clozapine may cause a significant drop in the white blood cells and neutrophils in the blood which can be life threatening. This means it is necessary to carry out blood tests and ensure these blood cell levels are at acceptable levels (green results) before further supplies of Clozapine can be provided to service users. The frequency of blood tests and length of supply is as follows:

| Monitoring Frequency | Sample Due Day | Usual quantity of supply | Maximum quantity of supply | Clozapine Prohibited on |
|---|---|---|---|---|
| Weekly | Every 7 days | 7 days | 10 days from last blood test | Day 11 |
| Every 2 weeks | Every 14 days | 14 days | 21 days from last blood test | Day 22 |
| Every 4 weeks | Every 28 days | 28 days | 42 days from last blood test | Day 43 |

*Note – the day on which the sample was collected will be considered as Day 0, and Day 1 would be the following day.

### 3.2 Clozapine Clinics

The aim of the clinics is to ensure service users prescribed clozapine are monitored physically and mentally in accordance with CPMS and Trust Medicines Monitoring requirements. The clinics are able to offer a comprehensive service within a safe and consistent environment. The overall aim is to promote safety and concordance while reducing the risks associated with poor/non-compliance. Clozapine clinics are currently held weekly at Lymebrook, Sutherland, Greenfield and Ashcombe Mental Health Resource Centres. The clinics provide blood tests and physical healthcare checks as well as mental health support for patients.

### 3.3 Blood Testing

Owing to the risk of life threatening adverse effects of Clozapine, blood monitoring is required for patients whilst on treatment and for 4 weeks after stopping clozapine. The frequency of this is as follows:

| | |
|---|---|
| Initiation to 18 weeks of treatment; | Weekly |
| Week 19 to week 52; | Fortnightly |
| Week 52 onwards; | Four-weekly |

A Point of Care Haematology (PocHi) machine is used within the clinics to provide prompt analysis of blood samples enabling a “one-stop” clinic to service users. This analyser is connected to the CPMS website which provides blood test results immediately after processing. This is then available for both clinic and pharmacy staff to access on the CPMS website.

### 3.4. Clozapine Dispensing

A Clozapine repeat prescription (FP10) must be used to prescribe and supply clozapine for all out-patients managed by the Clozapine Clinics. This is kept within the pharmacy department and attached to a dispensing record sheet.

Clozapine is supplied from the dispensary at Harplands Pharmacy to the clinics using a valid prescription held at the dispensary with a copy available to the Clozapine Clinic scanned onto the Lorenzo notes.

To facilitate a “one-stop” service, each clinic will provide to the dispensary a list of service users to attend clinic one week prior to clinic date. Medication for these services users must be delivered to clinic for storage at least one day before the clinic date to ensure service users can receive medication during their clinic visit.

The current timetable for Clinic days and deliveries is:

| Centre | Patient list sent to pharmacy Day | Medication Delivery Day | Clinic Day |
|---|---|---|---|
| Ashcombe | Previous Monday | Friday | Monday |
| Lymebrook | Previous Tuesday | Monday | Tuesday |
| Sutherland | Previous Tuesday | Monday | Tuesday |
| Greenfield | Previous Thursday | Wednesday | Thursday |

On the occasion of a bank holiday weekend should the normal clinic day or delivery day be affected the CMHT staff must contact the pharmacy at least two weeks in advance to agree arrangements to accommodate the bank holiday. The pharmacy team will typically arrange for transport to deliver the medication to the clinic on the last working day before the clinic date. Clinic staff should take into account any

adjustments to supplies that might need to be made, this is particularly pertinent to patients on weekly blood monitoring.

Medication sent for the Point of Care Haematology (PocHi) clinic should be kept separately from other medicines in a “quarantined” area where it is clearly marked with an orange sticker, it cannot be given out without a blood result. Once the blood result is available this should clearly be written by clinic staff onto the sticker. Pharmacy may also supply clozapine for service users who already have a blood result, such as those on four weekly monitoring who have two weekly NOMAD packs. These should not be stored with the Point of Care Haematology (PocHi) clinic supplies.

### 3.5. Blood Results

Clozapine licensing stipulates treatment must only be continued after valid blood results are confirmed by the monitoring service. Service users must only be supplied with the Clozapine at the clinic when a green or amber result is confirmed.

It is the responsibility of clinic staff to check the blood status and medicines provided before handing them over and they must complete the supply record forms to indicate date and quantity of supply made.

A counter checking procedure by the dispensary must be in place to ensure at the end of each clinic date all service users dispensed medication have permitted blood results. If any service users have not got a valid green or amber result the pharmacy must contact the clinic to check the medicine has not been given out to the service user.

### 3.6 Errors, Prescription changes and unwanted stock

Any dispensing errors or prescription changes must be returned to the pharmacy for re-dispensing. Any errors must be incident reported as per Trust Policy. In the event of medication having to be returned, the clinic staff must make arrangements with pharmacy for the patient or a staff member to collect a new supply.

At the end of the clinic a copy of the completed clinic list must be emailed to Pharmacy. Any leftover medication must be re-stored in the “quarantined” area until the service user’s bloods can be obtained or the medication can be returned to pharmacy.

Amendments and changes to prescriptions by prescribers must be communicated to the pharmacy as soon as possible to ensure updates are made. Out of date prescriptions must be scored through and filed to prevent errors. If a prescription has expired medication cannot be supplied by pharmacy. Any new prescription needs to

be received by pharmacy one week before the clinic date for supply to be guaranteed.
After the clinic has finished the clinic staff should email over a copy of the completed clinic list to pharmacy. Next to each patient they should confirm the patient attended, the results received and that medication has been given out as per prescription.

If a patient does not attend the clinic as scheduled the staff must contact the patient to arrange for them to come in as soon as possible for their blood test. Patients usually have enough supply to last until Thursday or Friday, so if they can come in by those days for their tests they can then be given the medication as normal. If they do not attend by Friday the quarantined medication must be returned to pharmacy until contact with the patient is made, the quantity would need to be reduced and an enquiry made about if a treatment break has occurred.

Pharmacy must be informed of the plan for any patients who have 'DNA'd'.

### 3.7 Training

Providing a 'one-stop' service entails supply of quarantined pre-dispensed Clozapine to service users on obtaining valid blood results, all clinic staff must undergo training to be certified/accredited by Viatris (PocHi equipment provider) before performing duties at the Clozapine clinics. Two nominated staff members will attend a two day formal training session provided by Viatris; this training must then cascade to colleagues at the CMHT clinic site. The CMHT must keep a log of all staff trained to operate the Point of Care Haematology (PocHi) machine. If one or both of the two individuals certified by Viatris ceases to work at the CMHT they should inform Viatris so that the attendance of a further nominee(s) to the formal Viatris training can be arranged at the soonest opportunity.

Staff involved with patients undertaking treatment with clozapine must have the following training:

| SUBJECT | WHO NEEDS IT | FROM | UPDATE |
|---|---|---|---|
| Actions, uses and side effects of Clozapine | All staff involved with service users taking Clozapine | Patient information leaflet: https://www.medicines.org.uk/emc/files/pil.10290.pdf<br>Choice and Medication: https://www.choiceandmedication.org/combined/<br>Manufacturers SPC: https://www.medicines.org.uk/emc/product/10290/smpc | Ongoing, when assigned Clozapine service |

| | | | |
|---|---|---|---|
| | | GASS-C scale use- available on lorenzo forms | |
| Monitoring requirements | Medical, pharmacy and clinic staff. | As above, also Clozapine Policy, Medication Monitoring Guidelines and CPMS website access https://www.clozaril.co.uk/scrlogon.asp | |
| Point of care blood analyser (PocHi) | Clozapine clinic nurses | Viatris 2-day residential course, or cascaded from certified user. | If coming back after a break in Clozapine care. |

### 3.8 Hazard Control Measures and Limitations

| CATEGORY | INFORMATION |
|---|---|
| Health Hazards | None |
| Fire Hazards | None |
| Storage Precautions | Clozapine must be stored in a locked medicines cupboard and must only be issued once a green or amber result has been confirmed |
| Handling/ Use Precautions | None |
| Disposal Precautions | Following local procedures return to pharmacy to be disposed of as pharmaceutical waste |
| Emergency Action | When RED blood result is obtained, Clozapine clinic, consultant psychiatrist and patient to be contacted to stop use of Clozapine and the need for urgent blood test. |
| Additional Information | Follow advice provided by CPMS |

### 4.0 Responsibilities

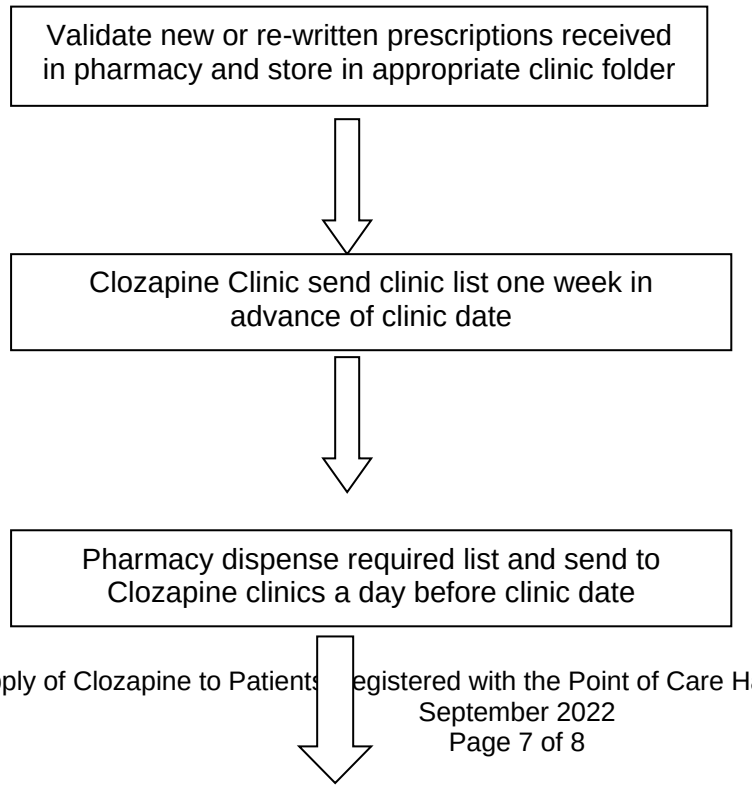
It is the responsibility of the pharmacy department to ensure clozapine supply is made in accordance to the outlined procedure.

Checking blood results to ensure permission to supply medications is the responsibility of CPMS/Viatris Certified users and trained personnel. Counter

checking of all supplied medication against dispensed list is the responsibility of the dispensary manager.

Safe storage of any medication not issued due to patient non-attendance or a red result is the responsibility of the clozapine clinic staff. This medication must be stored separately from other medicines in a “quarantined” area.

## 5.0 Procedural Steps (Recommended SOP Outline)



Service User attends clinic, blood test performed and medication supplied if permitted. Unwanted and excess stock quarantined or returned to pharmacy

This document was produced by:

Claire Ault - Principal Pharmacist (Clinical)

North Staffordshire Combined Healthcare NHS Trust

**SOP Title** **Olanzapine Long-Acting Injection(Olanzapine Pamoate- ZYPADHERA)**

**SOP Number** **1.03g**

**Effective Date:** **13th February 2020**

**Review Date:** **28th February 2023**

| SOP version | Effective Date | Significant Changes | Previous SOP version |
|---|---|---|---|
| 1 | 13.02.20 | New Standard Operating Procedure | N/A |
| | | | |

# Olanzapine Long-Acting Injection(Olanzapine Pamoate- ZYPADHERA)

## 1. Indications

Olanzapine long acting injection (OLAI) is indicated for maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine. It may be an effective treatment option in patients who have shown an initial treatment response to oral olanzapine but for whom concordance with oral medication is a problem. Reflecting the 2009 NICE guidance, it may be offered as a treatment option alongside other long acting antipsychotic injections (depots).

## 2. Commencing treatment with Olanzapine LAI: Request process

**Before the request can be approved, the following criteria must be met and confirmed.**

The current SPC states that olanzapine LAI is only licensed in patients previously stabilised on oral olanzapine. Therefore, patients due to initiate on olanzapine LAI should not be started if olanzapine naïve. The dose equivalencies are detailed below. Olanzapine LAI may only be given by deep intra-muscular gluteal injection.

- **ALL** service users **MUST** have been on oral olanzapine for at least 2-4 weeks before the injection is started to establish tolerability and response.
- **ALL** service users **MUST** have a documented proven response and tolerability to oral olanzapine before Olanzapine LAI is prescribed.

- The patient has been assessed as having significant adherence problems with oral Olanzapine therapy that may compromise on -going therapeutic benefits

- Before prescribing, patients must be advised of the risk of post-injection syndrome and the need for them to be observed on healthcare premises for three hours after each injection for as long as they remain on the medication(consent should be obtained)

- Long-term arrangements have been made, (and agreed with the patient), for every injection to be administered in healthcare premises and for appropriately qualified personnel to be available to observe the patient on site for a minimum of three hours after every injection.

**Training requirements**-

- 1. All nurses and doctors who will be administering the injection have undergone, or will be undergoing, specific training on product administration. https://www.zypadhera.co.uk
- 2. All appropriately qualified personnel who will be providing the three-hour post-injection observation of the patient have undergone, or will be undergoing, specific training on the identification and management of post-injection syndrome.

- The **annual purchase cost** of olanzapine LAI is between £3000 and £6000 per patient year and initiating it without long term monitoring arrangements in place there is a potential waste of resources.

**To identify the starting dose of Olanzapine LAI consult the table below: (Recommended dose scheme)**

| **Target oral olanzapine dose** | **Recommended starting dose of Olanzapine LAI** | **Olanzapine LAI maintenance dose (after 2 months of treatment)** |
|---|---|---|
| 10mg daily | 210mg every 2 weeks or 405mg every 4 weeks | 150mg every 2 weeks or 300mg every 4 weeks |
| 15mg daily | 300mg every 2 weeks | 210mg every 2 weeks or 405mg every 4 weeks |
| 20mg daily | 300mg every 2 weeks | 300mg every 2 weeks |

- The maximum licensed dose of olanzapine LAI is 300 mg 2 -weekly or 405 mg 4 weekly.

- Patients must be monitored carefully for signs of relapse during the first one to two months of treatment with Olanzapine LAI and the dose should be adjusted according to the individual clinical status.

**3**. **Other Dosing Recommendations /Considerations:**

- **The elderly**: Olanzapine LAI has not been systematically studied in elderly patients (>65 years) and therefore is **not recommended** for treatment population unless a well-tolerated and effective dose regimen using oral olanzapine has been established. A lower starting dose (150 mg/4 weeks) is not routinely indicated, but should be considered for those 65 and over when clinical factors warrant. Olanzapine LAI is not recommended to be started in patients >75 years of age.
- **Children & Adolescents**: Olanzapine LAI is not licensed for use in patients aged less than 18 years of age ♣
- **Renal and/or hepatic impairment:** A lower starting dose (150 mg every 4 weeks) should be considered. In cases of moderate hepatic insufficiency (cirrhosis, Child-Pugh class A or B), the starting dose should be 150 mg every 4 weeks and only increased with caution.
- **Plasma half-life**: The plasma half-life of olanzapine after administration of the LAI is **30 days**. (The half-life after oral administration is 30 hours). Clinicians should note that while plasma levels have usually diminished considerably after 8 to 12 weeks, elimination of olanzapine may not be complete until 6 to 8 months after the last injection.

**4. Location for monitoring**

- If the patient can be monitored at the resource centre where they usually attend then this will be the preferred location for the patient to receive the injection.
- If the resource centre is unable to provide the observation the prescribing team will liaise with the crisis care centre manager to arrange for the patient to be observed at this location. The care coordinator will be required to wait with the patient. This will need to be arranged with the crisis care centre manager.

**5. Administration**

**The following conditions apply to every injection of olanzapine LAI. It is essential to ensure that long-term plans for administration and observation are in place before prescribing / administering this product**.

- Olanzapine LAI may only be administered by a doctor or member of the registered nursing team who has received training in the appropriate injection technique.

- The olanzapine LAI will only be supplied from the drug manufacturer to the pharmacy department when both medical and registered nursing staff complete the required on-line training.

- The training involves reading through a PowerPoint slide presentation and at the conclusion acknowledging this by pressing the appropriate link and obtaining an e-certificate of completion. This only needs to be completed once by any individual.

- Detailed, step by step instructions are available for the preparation and administration of olanzapine LAI. These are included in each pack of the injection and must always be available at the time of administration.

- Olanzapine LAI may only be administered in healthcare premises where 3 hours of observation of the patient by appropriately qualified personnel specifically trained to identify post-injection syndrome can be assured.

- Rapid access to medical (or paramedical) care, if needed, (to include dialling 999 if a doctor is not on the premises) must be available throughout the observation period.

- During the time following administration and particularly prior to the patient leaving the unit / clinic, it must be confirmed that the patient is alert, orientated and absent of any signs and symptoms of olanzapine overdose. If overdose is suspected, close medical supervision and monitoring must continue until examination indicates that signs and symptoms have resolved. Alternatively, if a doctor is not available, an ambulance must be called.

- If a patient deemed to have capacity later chooses to leave before the 3 hours are up then they cannot be forced to stay. Any patient refusing to stay for 3 hours should be reassessed by their clinical team for their suitability to remain on the Olanzapine PRI treatment in future due to the risks involved in improper monitoring.

**Post-injection syndrome**

Post-injection syndrome is related to excessive olanzapine plasma concentrations, perhaps caused by injection close to a blood vessel. In clinical trials post-injection syndrome occurred in 0.07% of injections given (approx. 2% of patients). The symptoms of this are those seen in olanzapine overdose including:

- Delirium: including confusion, disorientation, agitation, ataxia, dysarthria, anxiety or other cognitive impairment
- Sedation: ranging from mild in severity up to coma (lasting up to 12 hours in one case)

- Other symptoms may include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, tachycardia, weakness, hypertension and convulsions

It typically begins with milder symptoms which progress in severity and/or number Presentation can appear similar to alcohol intoxication. 80% of patients show symptoms within the first hour of having the injections, with 20% taking 1-3 hours to become unwell. Less than 5% have presented more than 3 hours post-injection.

If overdose is suspected, close medical supervision and monitoring must continue until examination indicates that signs and symptoms have resolved. Alternatively, if a doctor is not available, an ambulance must be called.

**If Post Injection Syndrome Occurs**

- Immediately call for medical assistance
- Dial 999
- Give supportive care

After the injection, observation should be as follows:

| | |
|---|---|
| **0-1 Hour** | **Every 15 Minutes**<br>• Ensure patient is fully alert and ambulatory<br>• Observe for signs of sedation of delirium<br><br>NB. There is no need to measure any physical parameters(BP,Pulse,temperature) unless clinically indicated by the patient's condition |
| **1-3 Hours**<br><br>**>3 hours** | **Every 60 Minutes**; as above<br><br>**Extended observation** period if signs or symptoms of overdose and clinically appropriate to do so. |

- All patients should be fully informed of the symptoms of post-injection syndrome and be given a Zypadhera patient information card.

- After 3 hours confirm that the patient is alert, oriented, and without signs or symptoms of a post injection syndrome event. Advise patients to be vigilant for symptoms of a post injection syndrome event for the remainder of the day and be able to obtain assistance if needed. Community or out patients may be allowed home after three hours, but they must not drive or operate machinery

for the rest of the day. They should not travel alone to their post-injection destination.

## 6. Storage conditions

Olanzapine LAI should be stored at room temperature not exceeding 25$^{o}$C and should not be refrigerated. Once reconstituted in the vial the product is stable for 24 hours. If not used immediately it should be shaken vigorously to re-suspend. Once drawn into the syringe the suspension should be used immediately.

## 7. Responsibilities

### Prescribing clinical team

- CHECK ZYPADHERA -The prescriber and/or administer must complete the pharmaceutical company's on-line training and print a copy of the certificate for their records. https://www.zypadhera.co.uk/zypadhera/templates/loginTemplate.jsp?page=74

- It is the responsibility of the medical team to complete the referral paperwork for each of their patients on Olanzapine LAI If the initiating team is an inpatient team then discussion should have taken place with the expected long term prescriber and agreement reached on the use of Olanzapine LAI and long term arrangements have been made (and agreed with the patient)for every injection to be administered in health care premises and for appropriately qualified personnel to be available to observe the patient on site for minimum 3 hours after every injection.

- An objective assessment (such as BPRS or PANSS) should be undertaken before treatment is commenced and at 6 months after initiation. The initial assessment should be shared with the long-term prescriber and the long-term prescriber will normally be expected to repeat and review after six months.

- To objectively assess side effects experienced by the patient e.g. using the GASS rating scale before treatment is commenced and then six months after initiation. The initial assessment should be shared with the long-term prescriber and the long-term prescriber will normally be expected to repeat and review after six months.

- 

## 8. Cost comparison of Antipsychotics

| Preparation | Dose | Cost per 28 days |
|---|---|---|

| | | |
|---|---|---|
| **OlanzapineLAI (Zypadhera)** | **150mg 2-weekly**<br>**300mg 4-weekly**<br>**210mg 2-weekly**<br>**405mg 4-weekly**<br>**300mg 2-weekly** | **£285 (2 x 210mg packs)**<br>**£223 (1 x 300mg pack)**<br>**£285 (2 x 210mg packs)**<br>**£285 (1 x 405mg pack)**<br>**£446 (2 x 300mg packs)** |
| **Aripiprazole LAI** | **300mg monthly**<br>**400mg monthly** | **£220 – per month**<br>**£220 – per month** |
| **Paliperidone LAI** | **25mg monthly**<br>**50mg monthly**<br>**75mg monthly**<br>**100mg monthly**<br>**150mg monthly** | **£184 – per month**<br>**£184 – per month**<br>**£245 – per month**<br>**£314 – per month**<br>**£393 – per month** |
| **Risperidone LAI** | **25mg 2-weekly**<br>**37.5mg 2-weekly**<br>**50mg 2-weekly** | **£160**<br>**£222**<br>**£285** |
| **Flupentixol depot injection** | 200mg 2-weekly | £36 |
| **Fluphenazine depot injection** | 100mg 2-weekly | £18 |
| **Haloperidol depot injection** | 200mg 4-weekly | £10 |
| **Zulclopenthixol depot injection** | 500mg 2-weekly | £14 |
| | | |

## References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Appendix 1

# Olanzapine LAI injection - Post Injection Syndrome monitoring

**All observations must be recorded in the monitoring sheet**

• All patients should be fully informed of the symptoms of post-injection syndrome

• After 3 hours, post-injection syndrome is exceedingly unlikely to occur

- . Community or out-patients may be allowed home after 3 hours, but they must be advised not drive or operate machinery for the remainder of the day. They should be vigilant for signs of post-injection syndrome (see below) and should be aware of who to contact for assistance if required.

• It should only be administered by deep intramuscular gluteal injection by a healthcare professional trained in the appropriate injection technique and in locations where post-injection observation and access to appropriate medical care in the case of overdose can be assured.

• After each injection, patients should be observed in a healthcare facility by appropriately qualified personnel for at least 3 hours for signs and symptoms consistent with olanzapine overdose.

• The patient should be located in an area where they can be constantly in eyesight during the 3 hours in case they faint and at least hourly, a close check must be done to look for signs or symptoms of a post injection syndrome event.

After the injection, **close recorded observations should be as follows**:

- **Every 15 minutes in the first hour post injection and then at one hour, two hours and three hours** –
- Ensure patient is fully alert and ambulatory
- Observe for signs of sedation or delirium
- NB. There is no need to measure any physical parameters

**If post-injection syndrome occurs**:

- Immediately call for medical assistance or if not immediately available;
- Dial 999
- Give supportive care

**Post-injection syndrome**:

- Post-injection syndrome is probably caused by unintended partial intravascular injection (3) This occurs in a small number of people, even with appropriate injection technique
- The risk of post-injection syndrome is 0.07% (about one in 1400 injections) (1,4)
- Median time to onset of symptoms is 25 minutes and Post-injection syndrome is seen within one hour of injection in 80% of cases
- If post-injection syndrome is not evident within one hour, the risk of it emerging 1-3 hours after the injection is 0.014% (or about 1 in 7000 injections) (4)

**Symptoms of post-injection syndrome typically include**: (4)

- Sedation
- Delirium (disorientation and cognitive impairment)
- Confusion
- Dysarthria (slurred speech)
- Ataxia
- Agitation
- Anxiety

## Appendix 2

## Monitoring Record for Patients Treated with Olanzapine LAI

Name of patient_____

Date of birth_____ NHS number_____

Patient address _____
_____

Consultant _____

Ward/ Team _____

Date of Administration_____ Time of administration_____

Administered by _____ Administered by (Designation)_____

### 0 – 3 hours Post Injection Monitoring:

### Routine Observations:

Ensure patient is fully alert and ambulatory and observe for signs of post-injection syndrome (sedation, delirium, confusion, slurred speech, ataxia, agitation, anxiety)

| | Baseline | 15 minutes | 30 minutes | 45 minutes | 1 hour | 2 hour | 3 hour |
|---|---|---|---|---|---|---|---|
| Routine Observations* (tick) | | | | | | | |
| Completed by:<br><br>Sign and date | | | | | | | |

This form should be scanned into the patient's case notes in Lorenzo