Title: Medicines Overarching Framework

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Contents

1 Introduction

Medicines prevent, treat, or manage many illnesses or conditions and are the most common intervention in healthcare. Medicines Optimisation underpins the safe and effective use of medicines which directly supports our three goals.

This policy is underpinned by medicines law. The key laws (including subsequent revisions) that are applicable for this document are:

- Misuse of Drugs Act 1971: covers the laws associated with Controlled Drugs (CDs)
- Medicines Act 1968: covers all other medicines and medicinal products prepared for administration to patients. This also includes many diagnostic agents, and medical gases.

The National Institute for Health and Care Excellence (NICE) have best practice guidance on Medicines Optimisation (NG5). The Royal Pharmaceutical Society (RPharmS) also have a good practice guide for Medicines Optimisation. There is a wide range of guidance available from different professions and for specific therapeutic areas which describe how to use medicines safely and effectively. This policy pulls together the medicines requirements within Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV) and signposts to the procedures, protocols and guidelines which define our approach to Medicines Optimisation.

It is recognised that there are challenges faced by colleagues, partners, patients', carers, and families when trying to find the right medicines information at the time it is needed. Lots of guidance is available and our intranet and internet sites can feel complex and difficult to navigate. A Medicines Optimisation – Interactive Guide has been developed to make our guidance easier to find. There are two guides available. One is for TEWV staff and helps to navigate our intranet. The other covers a smaller range of key guidance that we expect to be required by those who are not TEWV staff – this guide helps navigate key documents on our internet site.

To co-create a great experience for our patients, carers, and families, so you will experience:
- **Outstanding** and compassionate care, all of the time.
- **Access** to the care that is right for you.
- **Support** to achieve your goals.
- **Choice** and control.

Medicines Optimisation is about ensuring the safe and effective choices are made with patients at the right time. This may mean not starting a medicine and may mean stopping a medicine, but all should be underpinned by shared decision making (NICE NG197).

To co-create a great experience for our colleagues, so you will be:
- **Proud**, because your work is meaningful.
- **Involved** in decisions that affect you.
- **Well led** and managed.
- That your workplace is **fit for purpose**.

Medicines Optimisation ensures that our medicines are stored and used in a safe and appropriate environment. The associated co-created guidelines ensure that best practice is signposted to ensure they contribute to the most meaningful interventions.

To be a great partner, so we will:
- Have a **shared understanding** of the needs and the strengths of our communities
- Be **working innovatively** across organisational boundaries to improve services.

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• Be **widely recognised** for what we have achieved together.

The effective communication and transfer of medicines across organisational boundaries is vital. Ensuring agreement to standards across the integrated care systems, or at a partnership or place level will reduce risk and maximise relationships to provide the best outcomes for our communities.

2 Why we need this policy

2.1 Purpose

The purpose of this policy is to define the procedures to be followed within the Trust for the prescribing, dispensing, storing, administering and disposal of medicines to protect service users and staff against the risks associated with unsafe use and management of medicines.

2.2 Objectives

The objectives of this policy are to:

- To ensure that people who use our services will have their medicines at the times they need them, and in a safe way by
    - Handling medicines safely, securely, and appropriately
    - Ensuring that medicines are prescribed and given safely
    - Following published guidance about how to use medicines safely and effectively

3 Scope

3.1 Who this policy applies to

- All staff working within the Trust who are involved, in some way, with the use of medicines. It also includes medical, nursing and other staff from other NHS Trusts, the Local Authority or from the private sector, who are contracted to work in TEWV on a sessional basis.

> ⚠️ TEWV staff working within other organisations must follow the medicine policies and procedures relating to that organisation being mindful of their obligation to adhere to their professional codes of conduct and standards of practice.

The implementation of this policy and associated procedures and guidelines is underpinned by our trust values of respect, compassion, and responsibility. This document has been developed in consultation with staff and its contents are informed by patient and staff experience through incidents, complaints, and other forms of feedback.

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Respect
- Listening
- Inclusive
- Working in partnership

Compassion
- Kind
- Supportive
- Recognising and Celebrating

Responsibility
- Honest
- Learning
- Ambitious

3.2 What this policy applies to

For this policy, the term 'medicines', whether for internal or external use, applies to:

• Controlled drugs controlled under the provisions of the Misuse of Drugs Act 1971, with stringent requirements for supply, storage, and administration.
• All other medicines and medicinal products prepared for administration to patients, and which are controlled by the Medicines Act 1968. This also includes many diagnostic agents, and medical gases.
• All complementary medicines e.g., aromatherapy, herbal or homeopathic remedies. These products are used for therapeutic purposes and require the same safeguards as other medicines.
• Medicated dressings and nutritional products.

3.3 Roles and responsibilities

Role	Responsibility
All staff involved with the use of medicines	• Familiarising themselves with the correct procedures contained in this policy framework.
Chief Pharmacist	• The designated senior pharmacist responsible for the organising, monitoring, and reporting of a system for assuring the safe and secure handling of medicines.
Local Authority Staff	• Local Authority staff working in integrated community teams must follow this policy in relation to the safe and secure handling of medicines in addition to complying with their own organisational policy requirements. Staff who have roles in which involvement of medicines has been identified must undertake trust training on safe and secure handling of medicines.
Medical Staffing Department	• Providing a record of appointment and signature of all prescribers (including locum appointments) to the Chief Pharmacist which is updated with any changes in appointments

Medical and non-medical prescribers	Doctors and suitably qualified nurses, pharmacists and other designated healthcare professionals are responsible for: • Having up-to-date clinical, pharmacological, and pharmaceutical knowledge relevant to own area of practice. • Making or reviewing a diagnosis, generating management options for the patient, and following up management • Establishing relationships with patients based on trust and mutual respect. Recognising patients as partners in the consultation using the principles of shared decision making. • Being aware of own limitations and not compromising patient safety. • Ensuring prescribing practice is consistent with scope of practice, organisational, professional, and regulatory standards, guidance, and codes of conduct. • Actively participating in the review and development of prescribing practice to optimise patient outcomes. • Understanding and working within local and national policies, processes and systems that impact on prescribing practice. Seeing how own prescribing impacts on the wider healthcare community. • Knowing how to access relevant information. Being able to use and apply information in practice.
Practitioners/Appointed Practitioner in Charge	• Responsible for the stock of all medicines held and ensuring that policies and procedures to manage the risks associated with the use of medicines are followed. • Maintaining the security of medicines and ensuring that stocks of controlled drugs, if held, correspond with the details shown in the register. • Administration of medicines. • Where administration of medicines is delegated to a Designated Practitioner, the Appointed Practitioner in Charge is responsible for ensuring the Designated Practitioner has received the relevant training and experience before being allowed to take on responsibility for medicine procedures. • Practitioners in training must be given every opportunity to become proficient in medicines related activities under appropriate supervision. Delegation and lines of responsibility should be clearly defined. The supervising Designated Practitioner has responsibility for medicine procedures at such times. • Understanding and working within their scope of practice.
Ward/Department Managers	• Ensuring that their staff, especially new starters, and agency/locum staff, follow these procedures. • Managers who contract services must make it explicit within the written contract that sessional or contracted staff must follow this policy and related procedures.

	• Provide a record showing appointment and signature of all Appointed Practitioners in Charge and qualified staff authorised to request medication to the Chief Pharmacist which is updated with any changes.

Nursing associates (NAs)	• NAs can administer medication via oral, enteral, topical, intramuscular, subcutaneous, inhalation routes and administer enemas and suppositories in line with a valid prescription with the following exceptions/caveats:
	   o administration of insulin
	   o NA can only administer to those titrated/established on depot medication.
	• The only as required (PRN) medication that NAs can administer currently are any that are prescribed within the homely remedies section of the prescription chart

Non-registered practitioners (NRPs) and allied health professionals (AHPs)	• Checking receipt, stock checks, and witnessing administration of controlled drugs with a Designated Practitioner where controlled drug witness training has been completed. • Administering medicines to specific patients in identified circumstance following competency training as detailed in local procedures. • NRPs may assist Practitioners with the administration of sip feeds and non-medicated creams and ointments when directed to do so. Responsibility for correct identification of the patient and administration of the correct preparation remains with the Registered Practitioner. • NRPs and AHPs who have completed the safe and secure handling of medicines training may deliver medication if identified as part of their role in the treatment of patients. • NRPs who have a designated role running clozapine clinics without PocHi machines may be authorised by the Designated Practitioner in Charge to access the medicines cupboard for the sole purpose of issuing clozapine supplies to patients which have been dispensed following a green result.
Pharmacy Staff	• Advising on the safe, effective, and economic use of medicines including advising practitioners on the storage of medicines in clinical areas. • Inspecting the stocks of medicines held on the ward or department at any time to ensure the medicines are in date and stored under the proper legal and environmental conditions.
Clinical Pharmacists	• Advising on and monitoring the safe, effective, and economic use of medicines • Reviewing the medication history of patients

	- Providing a medicine information service for staff, patients, and carers - Advising patients on their use of medicines - Monitoring for medicine interactions/adverse reactions and whether the therapy is achieving the desired therapeutic end points - Reviewing pharmaceutical information on Forms T2/T3 - Monitoring reports of medication incidents - Supporting and undertaking reconciliation of medicines - Clinical pharmacists may annotate the drug prescription and administration record. This annotation should ensure the approved name, dose, route, and precautions are included on the prescription, to guide practitioners when they administer the medicine. - The Appointed Practitioner in Charge should agree with the pharmacist and consultant the arrangements for advising patients about their medicines.
Pharmacy Technicians	- Reviewing ward medicine stocks - Ordering medicines to ensure continuity in supply and prevention of omitted doses - Monitoring medicines to make sure they are safe and securely handled and correctly stored - Assessing patient's requirements for compliance aids - Counselling patients on medication - Replenishing and monitoring emergency drug bags - Assessing patient's own drugs for suitability for use - Processing unwanted medication from wards and departments - Supporting and undertaking reconciliation of medicines - Providing compliance/reminder sheets for patients - Accuracy Checking of dispensed medication - Pharmacy technicians who have undertaken basic clinical and accuracy check of prescription and administration chart competency checks may annotate the drug prescription and administration record chart. This annotation should ensure that mandatory information is complete.
Pharmacy Assistants	- Supplying stocks of medicines to wards and departments and for dispensing medicines for use by individual patients. - Procure medicines - Supply and/or dispense ready to administer medicines - Provide medicines for discharge/leave - Advise on the safe, effective, and economic use of medicines as agreed

	• Ensure safe and secure transport of medicines
	• Providing a ward top up service to designated wards in the Trust
	• Processing unwanted medication from wards and departments
	• Undertaking regular expiry date checks of ward stocks

4 Policy – Medicines framework

4.1 Safe and secure handling of medicines

4.1.1 Prescribing and initiation of treatment

4.1.1.1 Consent to treatment

Policy for Consent to Examination or Treatment

- Before providing care or treatment a health professional should be satisfied that the patient has given their valid consent

- For patients detained under the Mental Health Act 1983, they must only receive medicines that are duly authorised and administered in line with the Mental Health Act 1983 Code of Practice.

- When treating patients who may lack capacity, health professionals should give careful consideration the Mental Capacity Act (MCA) 2005 by completing the MCA1 and MCA2 forms as appropriate

- Capacity to consent continues to be applicable for those patients subject to Mental Health Act 1983.

- Consideration needs to be given to the timely completion of consent to treatment forms (T2 and T3)

- Where it is practicably possible, ensure that the patient is involved in the decision-making process in relation to their treatment. This can be considered in relation to their protected characteristics, where applicable (see appendix 1)

> ⚠ Essential reading associated with this section:
> - Policy for Consent to Examination or Treatment

4.1.1.2 *Initiating pharmacological treatment*

Medicines – Prescribing and initiation of treatment

- **Prescribing & alternatives to prescribing**: A patient's pharmacological treatment is, after a diagnosis, usually initiated either by a patient specific prescription from a prescriber (registered doctor, registered dentist, or other Trust registered prescriber). In some cases, a medication may be initiated via a Patient Group Direction (PGD - see section 4.4) or a protocol which has been approved by the Drug and Therapeutics Committee.

- **Allergies and sensitivities** must always be recorded on the patient's clinical records including all drug administration and prescription records - see Medication Safety Series (MSS) 7

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- **Prescribing via verbal and remote orders** can only be used in restricted situations (see Medicines – Prescribing and initiation of treatment)

- **Medication selection**: Only medicines approved for use by the Drugs and Therapeutics Committee can be prescribed to treat mental health conditions.

  - Prescribers should follow approved local and national guidelines to support prescribing decisions (including assessment of contra-indications, cautions, allergies, and previous adverse drug reactions). Prescribing out with these guidelines should follow agreed processes (see links in interactive guide) and have a supporting entry in the patient's clinical notes, explaining the rationale.

  - The TEWV formulary is titled as the County Durham & Tees Valley Formulary (the area where it was developed) but is applicable across the trust. This link takes you directly to BNF chapter 4 of the formulary.

- **High risk medicine processes and critical medicines**:

  - High risk medicines are identified in terms of their potential for harm. These medicines are identified locally and through the National Reporting and Learning System (NRLS).

  - Critical medicines have been identified as those medicines which may cause harm if they are omitted or delayed.

  - Some medications involve a high-risk process as well as being a critical medicine. Greater care is required with these medicines - specific advice is contained within Medication Safety Series Documents

- **Recording on Paris/CITO**: Standards for prescribing and recording information about prescribed medicines on PARIS/CITO must be followed

- **Prescription and Administration Charts**: The requirements for using and writing drug prescription and administration records must be followed. These charts:

  - Provide a permanent record of the patient's treatment with medicines

  - Indicate the patients' sensitivity to medicines

  - Direct and record the administration of the medicines to the patient

  - All prescriptions must be in black ink and written in block letters to facilitate legible scanning. The administration record lasts for a maximum of 12 weeks for regular medication, after this period treatment must be re-written if it is to be continued.

  - A range of TEWV approved charts are available. In addition, local area palliative care charts can be used as clinically appropriate.

- **As required medications standards - see** Standards for use of 'as required' and rescue medication which promote safe, effective, and appropriate prescribing and administration of "as required" medication. The standards encourage regular review of "as required" prescriptions and discourage unnecessary routine "as required" prescribing. They identify the appropriate prescribing or potentially urgent medical treatment (rescue medication) and have specific age group guides to common frequencies and maximum doses.

- **Controlled Drugs:** Prescribing controlled drugs must comply with legal requirements - see Controlled Drugs Standard Operating Procedures

- **Prescribing for staff, family and friends is <u>not</u> allowed**

- **Prescribing issues identified:** Any health professional identifying prescribing queries / issues relating to a potentially serious error or risk must be alert the prescriber immediately / as soon as practicable

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4.1.2 Medicine reconciliation

[Medicines Reconciliation Procedure](#)

- The purpose of medicines reconciliation is:
  - Provide personalised care through effective use of medicines
  - Manage risks with medicines through effective procedures for prescribing medication and handling information about the patient's medication at all points of care.
  - To reduce medication errors occurring when patients transfer between care settings, particularly at the time of admission.

- The aim of medicines reconciliation is to ensure that the correct medicines are provided to the patient at all transition points between admission and discharge from hospital through a process of checking medicines prescribed against the most recently available lists from reliable sources of prescribing and supply.

- For most admissions, the pharmacy team will perform medicines reconciliation within 48 hours of admission. However, when this is not possible to ensure patient safety non-pharmacy staff must undertake the medicines reconciliation process. [MSS24](#) is available to provide top tips and safety checks, when undertaking medicines reconciliation.

⚠️ Essential reading associated with this section:
- [Medicines Reconciliation Procedure](#)

4.1.3 Ordering and receipting of medicines

[Medicines – ordering, storage, security, transporting and disposal](#)

- **Procurement** of medicines is managed through the pharmacy procurement team and ordered directly from wholesalers and manufacturers through the trust dispensaries.

- Some medicines will be routinely held as a **ward stock.** These are normally the medicines that are commonly prescribed on the ward or medicines that are not regularly used, but where timely access is important. A process of top-up by pharmacy staff will be in place on in-patient wards to avoid over ordering while still maintaining sufficient stocks.

- **Non-stock / temporary stock medicines** are dispensed to meet the needs of an individual patient and are usually labelled with the patient's name. In most circumstances, these medicines are ordered by pharmacy technicians or pharmacists through the pharmacy dispensing system or on approved stationery. If pharmacy staff are not available, then they should be ordered on the appropriate stationery by a prescriber or by a registered nurse.

- Medicines for **leave and discharge** are supplied for an individual patient who has authorised leave from the ward or who is to be discharged. Only medicines labelled with the patient's

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name and appropriate directions can be given to patients to take home. Ward stock medicines must not be used for this purpose. Supplies for leave and discharge should normally be sent to the ward for issue to patients.

- All medicines must be **delivered** to wards/departments in a secure container.

- The **receipt** of medicines describes the formal activities undertaken when medicines are received by the Trust from any external source or transferred from one location to another within the organisation. Records of receipt must be maintained.

- All medicines received by the Trust for administration to patients (including those brought in by patients - see 4.1.4) must be of a specified quality and suitable for the purpose for which they are intended.

- Processes must be in place which can confirm the suitability of medicines. The ward or department manager must ensure that the environmental and security aspects of transfer conditions and storage locations comply with the guidance.

> ⚠️ Essential reading associated with this section:
> [Medicines – ordering, storage, security, transporting and disposal](#)

4.1.4 Patients own drugs procedure (PODs)

- PODs are defined as medicines that are the legal property of the patient. They have been prescribed for or purchased by the patient prior to admission or whilst on leave.

- PODs can and should be used wherever possible and practical.

- PODs must only be used for the individual patient for whom they have been prescribed.

- Full details of the procedure, including assessment of suitability for use can be found here [Patient Own Drugs (PODs): Procedure for use](#)

> ⚠️ Essential reading associated with this section:
> - [Patient Own Drugs (PODs): Procedure for use](#)

4.1.5 Pharmacy supply and dispensing

- Supply or dispensing of medicines are the activities undertaken in response to formal orders when medicines are issued to the place they will be used or supplied directly to the patient.

- Dispensing is the supply after manipulation of the medicine. Manipulation may include preparation, reconstitution, repackaging, and labelling.

- Supply or dispensing is the responsibility of the pharmacy department and community pharmacies (for FP10s)

- Medicines may be supplied as ward or department stocks or as items for specific patients.

- The dispensing process requires a consideration of all the factors which may endanger the safety, effectiveness, and stability of the preparation plus adherence to legal requirements.

- Standard Operating Procedures (SOPs) will be in place and followed in each dispensary.

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4.1.6 Storage and security of medicines

- The Chief Pharmacist (or appropriate deputy) must be involved at an early stage in any plans to upgrade or build **new medicine storage facilities in healthcare premises** and must approve final plans prior to placing orders for storage systems. Failure to do this may result in the provision of unsafe, inefficient and, potentially, illegal medicine storage solutions. It may also entail costly retrofits.

- Once medicines are **received** onto the ward or department the Appointed Practitioner in Charge is always responsible for ensuring the safekeeping of the medicines which includes both environmental and security aspects.

- All cupboards, closed storage units (i.e., with doors) and fridges in which medicines are stored must be **lockable** and should be locked when not being accessed. Locks for metal cupboards (except patients' drugs cabinets) must comply with BS 3621.

- All medicine cupboard keys are the responsibility of the Appointed Practitioner in Charge. Custody of the medicine cupboard **keys** are the responsibility of the Designated Practitioner in Charge.

- Medicines for Clinical **Emergency** must be readily accessible but stored securely to prevent unauthorised access.

  - There should be appropriate storage of **medical gases** as per Oxygen & other medical gases – administration, prescribing, storage and safety

4.1.6.1 *Staff Personal Medication*
- All staff requiring access to their own **personal medication** whilst at work must ensure that the medication is:
  - In the original container
  - Clearly labelled with the staff name
  - Stored in a secure location (e.g., staff locker)
- To ensure adequate health and safety, to manage risk and to maintain the safety of patients, colleagues, and visitors; if a staff member needs to carry medication on their person for urgent use (e.g., salbutamol inhaler, GTN Spray) they should discuss this with their line manager and agree appropriate precautions.
- For staff working in Forensic Services:
  - Any non-urgent staff medication should be stored in a locker outside of the secure perimeter.
  - Any non-urgent but frequent/regular medication e.g., antibiotics should be stored in a staff locker on the ward.

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o Any medication which may be required for urgent use should be discussed with the relevant ward manager, a risk assessment undertaken, and an appropriate course of action agreed.

4.1.7 Preparation and administration of medicines

- Instructions to administer:

    - Medicines are administered to a patient according to the directions of a prescriber, a patient group direction (PGD) or an approved protocol.

    - Remote orders may be appropriate in limited circumstances. A detailed process is defined in Medicines – Prescribing and initiation of treatment

    - The administration of a number for medicines for the purpose of saving a life is underpinned within schedule 19, Regulation 238 of the Human Medicines Regulations of 2012 which enables them to be administered without a prescription. This practice is supported with the following documents for adrenaline, glucagon, naloxone and oxygen.

- Administration may require the calculation and selection of doses and the preparation of injections or mixtures.

- The administration of medicines is an important aspect of the professional practice of registered nurses. It is not solely a mechanistic task to be performed in strict compliance with the written prescription of a registered prescriber. It requires thought and the exercise of professional judgement.

- Use an oral/enteral syringe to measure oral liquid medicines if a medicine spoon or graduated medicine pot cannot be used. NEVER use IV/IM syringes to administer oral liquid medicines.

- **Administration advice** – The BNF lists advisory labels for medicines which have specific administration requirements. This advice should be followed for inpatients recognising there may be occasions when a clinical decision is taken not to follow this advice. Further support is available via MSS 8: Administration of medicines in relation to food and other special instructions

- **Self-administration of medicines** in hospital by patients allows them to administer their own medicines with the support and education provided by the multi-disciplinary team (MDT).   The process uses this guidance Self-medication procedure

- **Medicine administration record charts procedure (MAR charts):** There are some services within the Trust which receive medical and prescribing services from teams outside the Trust but the administration of medicines is the responsibility of Trust staff. In these circumstances the Medicine Administration Record (MAR) chart - procedure for use will be followed.

- **Covert administration** is a complex issue and involves the administration of a medicine disguised in food or drink to a patient without their knowledge or consent. It should only be considered, within a legal framework, for patients who are deemed to lack capacity, consistently refuse medication and it is deemed in the patient's best interests. Follow the covert administration procedure

- **Administration of Subcutaneous Fluids** is well recognised and commonly used as an appropriate and effective measure to correct mild to moderate dehydration. Follow the subcutaneous fluid administration procedure.

- Percutaneous Endoscopic Gastrostomy (PEG) Feeding - Medicines are not specifically formulated for enteral administration therefore use via this route requires careful consideration and caution to ensure safety and effectiveness. A pharmacist must always be consulted if there is any doubt about administering a medicine via the enteral route.

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4.1.8 Disposal of medicines

- Medicines which are no longer required or no longer suitable for their intended use must be removed for safe disposal or re-used in line with legal requirements and environmental regulations.

- Appropriate records should be made to complete the audit trail of the medicine from purchase or receipt to destruction or re-use.

4.1.9 Management of patient safety (untoward) occurrences

- The way in which medication alerts are handled is covered in this document. Medicines – management of alerts, recalls, reporting
- Medication errors are identified, recorded, and monitored appropriately reported and investigated according to Incident reporting and serious incident review policy
- Pharmacy maintains systems to ensure that patient safety alerts, rapid response reports and patient safety recommendations disseminated by the MHRA and supplier-led recalls which require action are acted upon within required timescales
- Trust staff identifying adverse drug reactions (ADRs) should complete a Yellow Card for appropriate and reportable ADRs
- Loss or theft of prescriptions/controlled stationery must be reported

4.1.10 Controlled drugs

- Controlled drugs must be handled within the constraints of regulatory requirements. Trust procedures cover all aspects of risk management of controlled drugs which include audit trails for ordering, storing, prescribing, recording, supplying, administration and destruction.

- The Accountable Officer for CDs has overall responsibility for all aspects of the safe and secure management of CDs within the organisation. This appointment is a statutory requirement as identified by the Controlled Drugs (Supervision and Management of Use) Regulations 2006. The Accountable Officer for TEWV is the Chief Pharmacist tewv.pharmacycdao@nhs.net
- Any incident involving a CD must be reported immediately to the Accountable Officer (AO). In most instances the completion of a Datix report will meet this requirement and ensure the CD AO is notified, however, any significant unaccounted-for loss of CDs should be escalated by a direct phone call or email to the CD AO.
- In the absence of the CD AO, the Deputy Chief Pharmacist is the deputy AO.

Management of Substance Misuse on Trust Premises

- The following Policy, Procedure & Protocol should be followed
- The Trust's primary aim is to prevent/minimise the use of substance misuse on Trust premises. Posters will be displayed in all clinical areas outlining the Trust's adopted Zero Tolerance policy on the use/possession/dealing of substances and the repercussions of those individuals who disregard the advice given on the notices.
- Patients admitted to hospital for treatment, or a substance misuse problem should have a written agreement or contract as part of their care plan. This should include the checks to be made within treatment e.g., breathalyser or urine samples and the steps to be taken if there is continuing substance use.

> ⚠ Essential reading associated with this section:
> - Controlled Drugs Standard Operating Procedures
> - Managing Substance Misuse on Trust Premises
>   - Policy
>   - Procedure
>   - Protocol

4.1.11 Retention of records

- Pharmaceutical records must be retained for the **minimum** period depending on the record type. These retention periods are defined in Medicines - Retention of Records

> ⚠ Essential reading associated with this section:
> Medicines - Retention of Records

4.1.12 Code of practice for working with the pharmaceutical industry

- Any proposed arrangement complies with all relevant national and local ethical standards, policies and guidance relating to business conduct and always complies with their professional code of conduct.
- Relationships with commercial organisations should be fully declared, transparent and publicly disclosed.
- Any formal agreement must clearly indicate the commitment and obligations of both parties and the anticipated outcomes.

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- The interests of patients are paramount. All decisions and actions that are of a clinical nature must be made and managed by the NHS independently of any input from the collaborating pharmaceutical company.

⚠️ Essential reading associated with this section:
- Conflicts of Interest Policy

4.1.13 Access to medicines and pharmacy services outside of normal working hours

- Outside of normal working hours, the Trust makes provision so that medicines or pharmacy services can be accessed if needed.

⚠️ Essential reading associated with this section:
- Medicines – Access to medicines and pharmacy services outside working hours

4.1.14 Multi-compartmental Compliance aids

- Before there is any agreement to provide medicines in a multi-compartmental compliance aid a full documented assessment of compliance problems should take place by involving a member of the Pharmacy Service.

⚠️ Essential reading associated with this section:
- Medicines – compliance aids

4.1.15 Clinical trials involving pharmaceutical products

- The Trust has strict procedures to assure legal and indemnity issues are complied with when supplying clinical trial materials to patients.

⚠️ Essential reading associated with this section:
- Medicines - clinical trials involving pharmaceutical products

4.2 Clinical procedures

4.2.1 Rapid tranquilisation

- Severe behavioural disturbances will sometimes occur despite all attempts to prevent them. It may become necessary to use pharmacological interventions, alongside physical restraint, to maintain the safety and physical health of an individual.
- The administration of medicines using the parenteral route (usually intramuscular) under restraint to maintain safety is Rapid Tranquillisation (RT).

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- The Rapid tranquillisation (RT) policy is to be followed to ensure safe and consistent age appropriate prescribing in accordance with national guidance and current research evidence.
- The policy gives the required monitoring and action, following administration, if there is a change in condition, including management of side effects and adverse reactions.

> ⚠️ Essential reading associated with this section:
> - Rapid tranquillisation (RT) policy

4.2.2 Taser Electrical Incapacitation Device post exposure aftercare guidance

Electrical Incapacitation Devices (EID) such as Taser are single or multiple shot weapons designed to temporarily incapacitate a subject using an electrical current, which temporarily interferes with the body's neuromuscular system. The decision to deploy an EID will always be made by a trained police officer following a risk assessment made by them of the situation. There is an increased risk of adverse responses where:

- a person has been taking drugs or medicines, including alcohol.
- they have a pre-existing medical condition such as asthma, diabetes, epilepsy, cardiovascular disease.
- they are over-aroused, displaying extreme irrational and violent behaviour towards others.

> ⚠️ Essential reading associated with this section:
> - Taser Electrical Incapacitation Device post exposure aftercare guidance

4.3 Non-medical prescribing

- Guidance is available on both becoming a non-medical prescriber and on good practice for independent and supplementary prescribers and their supervisor
- The selection of appropriate healthcare professionals to train will be based upon local service and patient needs. All individuals selected for prescribing training must have the opportunity to prescribe in the post they will occupy on completion of their training.
- NMP practice will take place within a clinical governance framework and individuals are aware of their legal and professional responsibilities and boundaries

> ⚠️ Essential reading associated with this section:
> - Non-Medical Prescribers (NMPs) Policy and Procedure to Practice
> - Non-Medical Prescribers (NMPs): Procedure to access training

4.4 Patient group directions (PGDs)

- Where a service is using PGDS, it is the responsibility of the Appointed Practitioner in Charge of each ward/department to ensure a valid and current PGD is available to guide practitioners and that the person administering the medicine has signed the PGD and undertaken any required training.
- All aspects of PGD managements are covered in the PGD policy

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⚠️ Essential reading associated with this section:
- [PGD policy](#)

4.5 Homely remedies

- Some medicines do not need a prescription to be supplied. These medicines are defined as P and GSL (Pharmacy Only and General Sales List). Within the trust, these types of medicines may be administered under agreed homely remedy protocols / procedures.
- An agreed protocol / procedure, approved by the Drug & Therapeutics Committee must be in place for these medicines to be administered without a prescription.

4.6 Prescribing guidelines

4.6.1 Managed entry of new drugs

New drugs process

- As part of an effective medicines' optimisation approach, the Trust has a process for the introduction of new drugs.
- New drugs not evaluated by NICE, the Regional Medicines Optimisation Committee (RMOC) or by the Northern Treatment Advisory Group (NTAG) will require an application. The full process is described in this [flow chart](#) which contains the application form.
- All new drug applications will be sent to other stakeholders for comment
- Recommendations from the evaluation group will be taken to the Drug and Therapeutics Committee for approval and implementation.
- Adoption of decisions by all local organisations reduces post-code prescribing and inequalities in access to medication.

⚠️ Essential reading associated with this section:
- [New drugs - Application process for TEWV](#)

4.6.2 Mental health prescribing guidance

- A wide range of prescribing guidance is available for TEWV prescribers. The aim of these guidelines is to encourage safe and efficient prescribing by advising the best evidence-based treatments. All up to date guidance is signposted from the [Medicines Optimisation – Interactive Guide](#).

4.6.3 Guidance for safe transfer of prescribing

- Most medicines prescribed to treat mental health illnesses are covered by NICE guidance. Where prescribing follows NICE recommendations, it is expected that prescribing responsibilities can be transferred from secondary to primary care services once patients are stabilised on treatment. This allows secondary care services to concentrate on the provision of specialist support and increases access to services. It also offers a much more convenient system for patients obtaining their medicines and allows primary care to provide comprehensive management of all a patient's medication.

- An underlying principle of this guidance is that prescribing, and monitoring responsibilities must be clearly defined to ensure safe transfer of prescribing. Advice is available from the General Medical Council (GMC) on shared care prescribing.
- The full process for the safe transfer of prescribing, including the requirements of individual drugs can be found here - Guidance for safe transfer of prescribing

> ⚠️ Essential reading associated with this section:
> - Guidance for safe transfer of prescribing

4.6.4 Psychotropic medication monitoring guidance

- The trust's medication monitoring guidance should be followed to ensure that appropriate patient safety checks (e.g. blood monitoring and physical health checks) are in place when medication is initiated and maintained. The guidance only covers mental health medication and does not cover the overall monitoring and review of the mental health indication. For monitoring of physical health medication, the prescriber should refer to local primary care guidelines, the summary of product characteristics or the British National Formulary.
    - The guidance does not replace clinical judgement. Further tests may be necessary on an individual patient basis. TEWV clinicians should state the rationale for additional tests if requesting from primary care.
    - This guide is intended to be used in conjunction with the TEWV Safe Transfer of Prescribing Guidance and all other TEWV clinical guidelines
- **Antipsychotic monitoring:** additionally the Lester tool provides a framework for screening and intervening when monitoring antipsychotics

> ⚠️ Essential reading associated with this section:
> - Psychotropic medication monitoring guidance
> - Guidance for safe transfer of prescribing

4.6.5 Guidance on the use of High Dose Antipsychotic Treatment

- If high doses are to be used this should only be after evidence-based strategies have failed and as a carefully monitored therapeutic trial.
- The decision should be taken explicitly by a level ST4 doctor or above with membership of the Royal College of Psychiatrists and should involve completion of an individual risk/benefit assessment.
- The decision should involve consultation with the wider clinical team, the patient, any family if relevant or involved in patient consent, and with a patient advocate (if the patient wishes). Patient consent should be gained if they have capacity to provide this; if they do not have capacity, and HDAT is in their best interests, a second opinion should be sought.
- The decision to prescribe HDAT and the associated patient capacity and/or consent should be documented in the case notes, including the assessment of risks and benefits, the aims of treatment and plans for assessment of response and outcome

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4.6.6 Safe Lithium Therapy and Shared Care Guidelines

- Lithium should be initiated in secondary mental health services
- The patient booklet, alert card, and record book (or smartphone app) developed by the NPSA will be made available to all patients on lithium and their use supported by healthcare professionals involved in providing care
- Patients prescribed lithium should receive supplies from secondary mental health services until a shared care arrangement is agreed with their GP. This includes patients discharged from inpatient settings who have been newly initiated on lithium
- A patient's clinical condition must be stabilised before requesting shared care. Once the patient is stabilised on lithium, they should be considered for shared care between mental health services and the GP. This will normally occur following the first 3-month monitoring check
- Prescribing and monitoring tasks for patients prescribed lithium must stay together. Prior to issuing a prescription prescribers must check that blood tests are monitored regularly and that it is safe to issue a prescription.
- Regular checks on lithium levels, renal function and thyroid function are essential for safe prescribing.

⚠️ Essential reading associated with this section:
- [Guidelines on Safe Lithium Prescribing and Shared Care](#)
- [MSS2 Lithium for inpatients](#)

4.6.7 Clozapine treatment guidance for psychosis

- Initiation of clozapine is restricted to consultant psychiatrists registered with the CPMS.
- Clozapine titration can be safely done in the community:
  - Always consider physical health state, patient adherence with oral medication and blood tests, ability to see patient every day during the early titration phase, support for patient to attend team base or with collection/delivery of medicines, team resources and client preference.
  - If you have any concerns regarding the above, consider IHTT or admit to an in-patient area.
- GPs should be aware of clozapine side effects so that physical health problems can be appropriately managed, cardiovascular, and metabolic risk factors reduced and patient safety improved.
- GPs must be made aware of potentially fatal side effects associated with clozapine including constipation

⚠️ Essential reading associated with this section:
- [Processes for prescribing, dispensing, supply and monitoring](#)
- [MSS 4: Clozapine](#) - this document provides an essential overview of clozapine use within TEWV
- [Clozapine and the role of therapeutic drug monitoring](#) (plasma levels)
- [GP information sheet on clozapine](#)

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- Smoking - the impact of smoking is discussed in appendix 1 of Medicines and Smoking Guidance

4.6.8 Medicines and smoking guidance

- A framework for prescribing / providing stop smoking products for inpatients suffering acute nicotine withdrawal but who do not intend to stop smoking or inpatients suffering acute nicotine withdrawal and who are motivated to stop smoking is available here - Medicines and Smoking Guidance
- The process for administering and supplying Nicotine Replacement Therapy as a homely (see section 4.5) remedy is covered in appendix 2 of the guidance

⚠️ Essential reading associated with this section:
- Medicines and Smoking Guidance
- MSS25 Tobacco smoking, smoking cessation & psychotropic drugs

4.6.9 Unlicensed and off-label use of medicines

- These guidelines provide a framework for the prescribing of medicines which do not have a marketing authorisation or are being used outside the terms of the marketing authorisation
- Most medicinal products used within the trust do have the appropriate marketing authorisation.
- However, there are occasions when the treatment of a patient requires:
  - A drug that does not have a marketing authorisation (unlicensed medicine)
  - A drug which has a marketing authorisation but for a condition, at a dose, via a route or for an age that is not listed in the Summary of Product Characteristics for that drug (off-label use)
  - The formulation of a medicine needs to be altered to enable administration via an enteral route (off-label use)
- The choice of treatment requires partnership between patients and healthcare professionals and informed consent should be obtained wherever possible before prescribing any medicines. Patients should be informed of identifiable risks and details of information given should be recorded. A patient information leaflet about unlicensed and off-label use is available to support discussions with patients and carers.

⚠️ Essential reading associated with this section:
- Guidelines for Unlicensed and Off-Label Use of Medicines

4.6.10 Physical Health Prescribing

4.6.10.1 Antibiotic Prescribing

- Antibiotic resistance is linked to the extent and the way in which antibiotics are used. Inappropriate use of antibiotics is the main driver of antibiotic resistance.
- The aim of this procedure is to:
  - promote prudent prescribing and antimicrobial stewardship to improve patient care
  - minimise the emergence of bacterial resistance in the community for the future

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4.6.11 Treatment of other physical health conditions

- Healthcare professionals should follow best practice guidelines, primarily those developed by NICE. TEWV have developed supportive guidelines in some commonly seen conditions.

4.6.12 Herbal Medicines, Essential oils, and complementary medicines

- Only those **complementary medicines** which are approved by the Drug and Therapeutics Committee are practiced
  - A designated complementary therapist must have obtained a recognised qualification and be registered with an accredited body for the therapy.
  - Before any complementary therapy is practised the head of service must ensure the practice is in line with the scope of professional practice and code of conduct of the accreditation body for the therapy.
- A record of the patient's consent must be documented in the patient's care plan. If a patient cannot give consent, it is good practice to tell the family/carer/advocate and document their support.
- The therapist must document within the patient's care plan the therapy practised and an evaluation.
- **Herbal medications / supplements** should not normally be initiated within TEWV. Prescribing of these products should, normally, only be associated with continuing a treatment that the patient wants to continue, has brought in with them and is suitable for use. All herbal medications/supplements for inpatient use should be stored in the patients' medication locker and prescribed on the drug chart before they can be administered.
- Staff caring for patients in Forensic Services should follow the additional points:
  - If a patient would like to commence the use of herbal medicines / supplements, then an individual risk assessment must take place during the next MDT. The assessment should include consideration of patient preference, therapeutic benefit, contra-indications, interactions etc. If the request for herbal medicines/supplements is approved, then the item should be prescribed on the medication chart.
  - Patients will be required to self-fund the elective purchase of herbal medicines / supplements.
  - Herbal medicines/supplements should be purchased whilst the patient is on leave and must fulfil the following criteria on return to Ridgeway:
    - Must be declared and handed to a registered nurse
    - Must be in a sealed, original container
    - Must be accompanied by proof of purchase
  - On receipt of herbal medicines/supplements, the registered nurse should:
    - Ensure the medications fulfil the criteria listed above
    - Add the patient's name and date of receipt to a blank label and apply to each individual container

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- Any herbal medicines / supplements which are brought onto Ridgeway without an appropriate risk assessment being undertaken should be confiscated until discussion can take pace in the next scheduled MDT.

5 Definitions

Term	Definition
Administration	Giving a medicine by the introduction into the body orally or by injection or by external application e.g., cream or ointment.
Allied Health Professionals (AHPs)	Professions allied to medicines who are regulated by a professional body e.g., physiotherapists, occupational therapists, dietitians.
Appointed Practitioner in Charge	The senior nursing appointment for the ward or department e.g., ward manager, community nurse or team manager with 24-hour responsibility for that ward, team, or department.
Controlled Drug	Any medicine regulated by the Misuse of Drugs Act 1971. This may also include any locally agreed substances that it would be appropriate to monitor.
Controlled Stationery	All stationery, which in the wrong hands, could be used to obtain medicines fraudulently e.g., pharmacy requisition books, Trust prescription forms and FP10 prescription forms.
Designated Practitioner in Charge	The senior nurse on duty for the ward or department who has been identified as the nurse in charge for a particular span of duty.
Designated Practitioner	Any registered nurse who has been identified by the Appointed Practitioner in Charge as competent and appropriate to perform a specific function
Dietitian	A dietitian with a current registration with the Health Professions Council
Dispensing	To prepare a clinically appropriate medicine for a patient for self-administration or administration by another. The act of dispensing includes supply and encompasses several other cognitive and practical functions which are usually performed under the supervision of a pharmacist.
Illicit Substance	A substance covered by the Misuse of Drugs Act or other legislation, which is not lawfully held in accordance with the relevant legislation.
Licensed Medicines	Medicines which hold a UK Marketing Authorisation and are being used in accordance with the terms of the marketing authorisation.
Non-Medical Independent Prescribers	Staff who have completed Non-Medical Prescribing training and are authorised to prescribe any licensed medicine for any

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	medical condition within their competence and as defined in their approval to practice form
Non-Medical Supplementary Prescribers	Staff who have completed Non-Medical Prescribing training and are authorised to prescribe medicines specified within a clinical management plan.
Non-Registered Practitioners	Health care assistants and support workers who are not registered or regulated by a professional body.
Patient Group Direction (PGD)	A specific written instruction, authorised by a doctor and a pharmacist, for the supply and/or administration of a named medicine in a specified clinical situation in the absence of a written prescription.
Pharmacist	A pharmacist with a current registration with the General Pharmaceutical Council (GPhC).
Pharmacy Assistant	A member of the pharmacy staff who performs ward stock top up orders and/or issues original packs of medicines to a ward or department against a list, under the supervision of a pharmacy technician and/or pharmacist.
Pharmacy Technician	A Medical Technical officer having achieved an NVQ3 qualification in Pharmacy with BTEC underpinning knowledge in pharmaceutical sciences or equivalent with a current registration with the General Pharmaceutical Council (GPhC). Pharmacy Technicians work under the supervision of a registered Pharmacist.
Senior Pharmacy Technician	A Pharmacy Technician with a current registration with the General Pharmaceutical Council (GPhC) who has successfully undergone further training to undertake additional specified medicines management duties at ward/department level.
Practitioners in Training	Student nurses
Prescribers	Doctors and suitably qualified nurses, pharmacists, and other designated healthcare professionals.
Supply	To supply a medicine to a ward or patient/carer for administration
Supplementary Prescribers	Nurses, pharmacists, and other designated healthcare professionals who have completed Non-Medical Prescribing training and are authorised to prescribe within the scope of a clinical management plan agreed with the patient and the doctor who has clinical responsibility for the patient.
Trust Pharmacy Staff	Pharmacists, Pharmacy Technicians and Pharmacy Assistants employed by the Trust and working within the Pharmacy Service providing medicine related advice and support.

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6 Related documents

Related documents are linked, in the relevant sections, throughout this framework.

The easiest way to access related documents is by using our Medicines Optimisation – Interactive Guide to [navigate our intranet](#).

7 How this policy will be implemented

- This policy will be published on the Trust's intranet and external website.
- Line managers will disseminate this policy to all Trust employees through a line management briefing.
- Pharmacy will be responsible for monitoring and reviewing this policy and its associated documents on behalf of the Drug & Therapeutics Committee

7.1 Training needs analysis

Training needs are also identified in individual procedures

Staff/Professional Group	Type of Training	Duration	Frequency of Training
Registered Nurses	Annual Medicines Optimisation eLearning	40 mins	Annually
Registered Nurses (inpatient staff only)	Annual inpatient medicines module	40 mins	Annually
Registered Nurses	Controlled drugs eLearning (Separate community and Inpatient modules)	Inpatient 1 hour Community 30 mins	3 yearly
Registered Nurses (For inpatient and crisis team staff only)	Rapid Tranquillisation eLearning	2 Hours	3 yearly
Registered Nurses	Face to Face medication assessment	1.5 – 2 hours	2 yearly
Registered Nurses (crisis teams only)	PGD training	Initial session face to face then 3 yearly eLearning module	3 yearly

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Registered Nurses (if using PGDs)	PGD theory eLearning	1 hour	Annually for flu fighters and as and when for appraisal or action plans
Preceptorship Nurses	Preceptorship day	Full day	One off for all newly qualified practitioners or if requested
HCA (in-patient only)	Rapid Tranquillisation eLearning	1 hour	3 yearly (inpatient and Crisis team staff only)
Medics	Rapid Tranquillisation eLearning	2 hours	3 yearly
HCA (only if required)	Witness to Controlled drugs eLearning	2 hours	3 yearly
HCA	Safe and secure Handling of medication eLearning	1 hour	One off
TNA	Medicines management – general mental health medicines/side effects, injections techniques	1 day	One off at commencement of TNA training

8   How the implementation of this policy will be monitored

	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Medicines Management Assessments - 10 key medicines management standards for in-patient units	Monthly (or less often if achieved) / ward visit / Chief Pharmacist via Pharmacy Technicians	Care Group Quality Assurance & Improvement Group
2	Clinical Pharmacy Audit Programme - identified	Deputy Chief Pharmacist (Governance)	Clinical Audit Group

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	priority areas will be chosen on a 1-2 yearly basis		
3	As identified in the procedures sitting under this framework	Identified in procedures	Identified in procedures

9   References

Underpinning legislation, information and guidance:

Relevant evidence-based guidance and alerts about medicines management and good practice published by appropriate expert and professional bodies, including:

National Institute for Health and Care Excellence

Medicines and Healthcare products Regulatory Agency

Department of Health and Social Care

NHS England

Royal Pharmaceutical Society (RPS)

10 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval	20 July 2022
Next review date	01 August 2025
This document replaces	Medicines Overarching Framework PHARM-0002-v7.2
This document was approved by	Drug & Therapeutics Committee
This document was approved	26 May 2022
This document was ratified by	Management Group
This document was ratified	20 July 2022
An equality analysis was completed on this policy on	17 June 2022
Document type	Public
FOI Clause (Private documents only)	N/A

Change record

Version	Date	Amendment details	Status
6.1	February 2015	Added Self administration guidance for crisis house and recovery staff at section 3.1.4	Superseded
6.2	September 2015	Updated hyperlink to Influenza vaccine to PGD 16-7 at 3.4.5	Superseded
7	15/3/18	Format changed from tabular to bullet points Essential reading guides added throughout Some details removed from within this framework, but are maintained in the procedures noted beneath this framework Sections 4.1.71., 4.5, 4.6.4, 4.6.11 & 4.6.12 are new to this document but previously agreed through D&T	Superseded
7.1	22/11/18	Page 9 – line added to enable the use of palliative care charts from other organisations	Superseded
7.2	26/9/19 (for publishing on 4/11/19)	Minor amendments: Added Nursing Associates to roles & responsibilities (page 6) Removal of reference to contracted pharmacies (pages 8, 11 & 24)	Superseded
8	20 July 2022	Hyperlinks & readability updated throughout	Ratified

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		References to crisis and recovery house (former section 4.1.4.1) removed	
		References to injectable meds on Birch removed from section 4.1.7	
		Section 4.7.2 & 4.7.11 – removed tables of links to guidelines and replaced with MO-Interactive Guide	
		Refreshed text throughout.	
		Appendix 1 added - Considerations made with regards to a patient's protected characteristics when administering medication	

11 Appendix 1: Considerations made with regards to a patient's protected characteristics when administering medication

Patients protected characteristics are considered as part of the considerations to administer medication. Whilst some examples and considerations are listed below, this is not an exhaustive list.

11.1 Race

Genetic differences between different ethnic and racial groups may affect the metabolism, efficacy, and side effect profiles of different medicines. This can be checked against the individual medicine's summary of product characteristics (SPC).

For example, individuals from certain ethnic populations, who are otherwise healthy and not prone to repeated or severe infections, commonly demonstrate recurrent low absolute neutrophil counts. This phenomenon is commonly defined as benign ethnic neutropenia (BEN), or benign familial neutropenia. Benign ethnic neutropenia (BEN) is the most common cause of chronic neutropenia seen in individuals of African, Middle Eastern and West Indian descent and studies report unidentified BEN as a key reason for clozapine underutilisation and early discontinuation in the black and ethnic minority communities in the UK. To mitigate this risk, clinicians need to be aware of these genetic factors in their clinical decision making.

Stigma and discrimination with mental health can affect how a person engages with treatment. For example, some communities, such as the Gypsy Romany Traveller community, may prevent people from accessing healthcare altogether or receiving and complying with treatment offered.

Practitioners need to consider cultural beliefs about medication and the importance of building trust, co- production of treatment plans and ensuring the voice of the patient is heard.

References:

[Influence of race or ethnicity on pharmacokinetics of drugs - PubMed (nih.gov)](link)

[Benign ethnic neutropenia: an analysis of prevalence, timing, and identification accuracy in two large inner-city NHS hospitals](link)

11.2 Sex

Patients differ in their body composition and physiology (hormonal influences during the menstrual cycle, menopause, and pregnancy) and they present differences in drug pharmacokinetics (absorption, distribution, metabolism, and excretion) and pharmacodynamics. Clinicians need to understand sex-specific differences in drug efficacy and safety. The physical health monitoring and treatment offered to patients are accessible regardless of gender.

11.3 Disability

Prescribing of medication needs to take into consideration a patient's learning, physical or mental health disabilities.

Many disabled people, and especially older people, may not have access to the internet or may have difficulties using it when seeking medication information. The telephone can be a very important method of communication for these groups

Large print leaflets (BILL-XL) are available for patients with sight impairment on the Choice and Medication Website. Patients can also access medication information and request/ listen to medication information leaflets by ringing emc accessible on 0800 198 5000. Patients can also request leaflets in large/ clear print, in braille and on audio CD. This line is open 24 hours a day 7 days a week.

11.3.1 Learning disability

There are ongoing concerns that psychotropic drugs are used inappropriately in people with an intellectual disability. It is recommended that there is clear rationale for prescribing of psychotropic medication, however recording of diagnoses can be problematic in patients who are unable to give a clear verbal account of their symptoms.

Medications are effective at the same doses as for those without an intellectual disability and there is no clear evidence that they have more side-effects. However, compliance with prescribed treatment, side-effects and potential drug interactions should be monitored carefully, particularly in those with more severe degrees of intellectual disability. The negative impact that side effects and missed doses can have on the mental health of these patients should also be considered.

The prescribing clinician explains the proposed treatment to patients, their families, and carers. Clinicians address any concerns or negative thoughts or feelings that patients and their families have towards taking psychotropic medication.

This can involve providing information in an easy-to-read format (available on the Choice and Medication website as very easy read (VERA) leaflets), making reasonable adjustments and involving independent advocates.

There should be a record of the patient's consent and capacity, any best-interests decisions taken in patients lacking capacity, timeframes for reviews and the tapering off or stopping of drugs that are ineffective.

References:

[Stopping Over-Medication of People with a Learning Disability, Autism or Both](#)

[Psychotropic medicines in people with learning disabilities whose behaviour challenges](#)

[Psychotropic drug prescribing for people with intellectual disability, mental health problems and/or behaviours that challenge: practice guideline](#)

11.4 Sexual orientation

Gay, lesbian, bisexual and transgender (LGBTQ+) patients have unique and different health needs to the heterosexual patient. LGBTQ+ patients should be offered evidence-based treatment irrespective of their sexuality. Real or perceived stigma and discrimination within healthcare may impact transgender people's desire and ability to access appropriate care.

References:

Barriers to Health Care for Transgender Individuals

Bockting W, Robinson B, Benner A, Scheltema K. Patient satisfaction with transgender health services. *Journal of Sex & Marital Therapy.* 2004;30:277–294.

11.5 Religion or Belief

It may be possible that religion and spirituality can have a positive and negative effect on mental health. The experience of illness can be akin to a spiritual event for many psychiatric patients, which may have a negative effect on taking medication to treat a psychiatric condition.

Religious laws do not usually forbid the use of psychotropic medication, but many do forbid the consumption of animal-based derivatives of blood, bovine and/or porcine origin (e.g., gelatin, lactose and stearic acid) such as are found in many medicines which should be considered when prescribing treatment. This could affect patients who follow Judaism, Islam, Hinduism, Buddhism and Seventh Day Adventism. Certain religions forbid the consumption of alcohol, which may be contained in certain liquid/ injectable formulations.

Vegetarian and vegan patients may also request plant-based alternatives to their prescribed treatment. Information relating to excipients can be found in the Summary of product characteristics for each individual medicine.

References:

Religious constraints on prescribing medication

11.5.1 Islam

Prescribers and patients should contact the manufacturers of pharmaceutical products to ascertain their constituents and the process of preparation to determine if they are suitable for a halal diet.

As a broad guide: if a medication contains alcohol or pig products, then it should not be taken orally, where possible, an alternative treatment should be sought. Parenteral or external application of these ingredients is probably permitted but the consent of the patient should be sought. Injections through the skin, muscles, veins, or joints (except for vitamins) and Covid19 vaccinations are permitted.

The use of medication for life- threatening illness is permitted- the preservation of life takes priority in these situations. The use of porcine-derived material for life-threatening illness may become temporarily exempt from the dietary laws, but the decision requires discussion with religious leaders or Imams.

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Medicines and Ramadan: Ramadan fasting is required of healthy adults. Exemptions (omitting the fast) are made for the ill (physically and mentally), travellers, pregnancy/ breastfeeding, old age/frailty/ dementia, where the fast is threatening to life or if the patient is compelled to break the fast. These days must be made up later. If the patient is too unwell to observe the fast, they are not accountable, and the priority is for their treatment and health.

Some patients may find that fasting improves their mental health as their spiritual needs are being met. If someone is taking regular medication, they should discuss with their doctor if the timings of the medications can be changed to outside daylight times. For example, if the patient is prescribed medication that needs to be taken with food, consideration can be made as to whether the time of administration can be amended to the adjusted mealtimes during Ramadan.

Local imams may not have the same understanding of medical terms and can be discouraging of mental health treatment- it is important that they assess if the patient has capacity to make the decision about whether to fast. Patients should seek advice from a local Imam, Sheikh or Muslim Chaplin along with their doctor about the decision to fast.

Useful resources:

Handy fact sheet: Ramadan and mental health medicines,

Chaplaincy advice about Ramadan,

What factors to consider when advising on medicines suitable for a Halal diet?

11.5.2 Judaism

There are no restrictions or prohibitions on the injection or administration by other parenteral methods of non-kosher products such as porcine insulin. However, a rabbi must be consulted in matters pertaining to consumption of non-kosher medication by someone who is unwell but able to carry on with activities of daily living. Kosher gelatin has been formulated, or patients can request medication in a different form

Useful resource: List of kosher medicines 2021

11.5.3 Christianity

Christians, except for Seventh Day Adventists, are generally permitted to consume all animals, including pork, as well as any drug excipients derived from animals. Practising Roman Catholics are also more likely to observe fasting on holy days and specified periods of the church year, such as Lent. Seventh-day Adventists are encouraged to eat a vegetarian diet and have prohibitions on pork, alcohol, coffee, and tea.

Jehovah's witnesses generally accept medication and medical treatment but reject blood transfusions and health treatments or procedures that include occult practices. It is a personal choice, and Jehovah's witnesses are free to accept or reject medical treatments (See consent to examination or treatment policy).

Useful resource: Do Jehovah's Witnesses Accept Medical Treatment? | FAQ (jw.org)

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11.5.4 Sikhism

Vegetarian Sikhs are prohibited from consuming animal-derived ingredients such as gelatin, certain thickeners (e.g., chitin) and animal-based lecithin emulsifiers.

11.5.5 Scientology

Scientologists consider drugs as causing extremely damaging effects on a person—physically, mentally, and spiritually. Scientologists do use prescribed medical drugs when physically ill e.g., antibiotics and rely on the advice and treatment of medical doctors, but do not take psychotropic medication. (Refer to the Consent to Examine or Treatment Policy)

11.6 Age

The pharmacokinetics and pharmacodynamics of different medicines change with age, resulting in dose differences between the elderly and the general population. These can be found in the Summary of product characteristics for each individual medicine. In addition, the elderly sometimes have concurrent illnesses, resulting in polypharmacy, consideration needs to be given to drug-drug interactions.

Children differ to adults in their response to medicines. Neonates (the first 28 days of life) are at greater risk of toxicity due to reduced drug clearance and differing target organ sensitivity. Where possible, medicines for children should be prescribed within the terms of the marketing authorisation (product licence). However, many children may require medicines not specifically licensed for paediatric use (unlicensed or off-label use of medicines). The prescribing of medicines for children should follow a discussion of the benefits and risks and different treatment options with both the child and the child's carer. Children should also be involved in decisions about taking medicines and encouraged to take responsibility for using them correctly. The degree of such involvement will depend on the child's age, their understanding and personal circumstances

Useful resources: http://www.medicinesforchildren.org.uk/

BNF for children:

Guidance on Unlicensed and Off- Label Use of Medicines

Summary of product characteristics (SPC)

11.7 Gender reassignment

Clinicians may not always be aware that a patient is transgender or is undergoing treatment for gender reassignment. Clinicians rely on patients to disclose any medical treatment of gender reassignment that may affect prescribing decisions. Prescribing processes should ensure that there is no negative impact for these patients, and ensure steps are taken to minimise the impact

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should it occur. For example, the pregnancy prevention programme should be offered to all patients of child- bearing age taking valproate, regardless of gender.

Transgender patients are known to have worse health outcomes and a higher burden of disease than cisgender patients. Ultimately, we should endeavour to provide the most individualised patient-centred care possible to all patients, but we must pay particular attention to marginalised groups such as trans patients to help minimise associated health inequalities.

Hormone therapy affects serum creatinine and lean body mass in a way consistent with a transgender patient's gender identity, and after 6 months of hormone therapy it is prudent to calculate creatinine clearance and ideal body weight according to gender identity. Consistently using the appropriate creatinine clearance and ideal body weight calculations for each patient ensures safe and effective care. Additional studies are needed to confirm the effect of hormone therapy on renal clearance and lean body mass.

There is limited data available on the impact of long-term hormone therapy on how transgender people handle medication. These hormones change the composition of fat and muscle in patients, which will impact on the distribution of drugs. The change in muscle mass will alter creatinine levels and thus estimation of patients' renal function and how drugs are cleared, which may need to be considered when prescribing for these patients.

11.8 Pregnancy and maternity

When a medicine is licensed, there is often limited information on effects from use in pregnancy and breastfeeding. Medicines should be prescribed in pregnancy only if the expected benefit is thought to be greater than the risk to both the mother and foetus. Potential risks of drugs include major malformations, neonatal toxicity, longer term neurobehavioural effects and increased risk of physical health problems in adult life.

For example, valproate should not be prescribed to people of childbearing potential or pregnant patients unless other treatments are ineffective or not tolerated. This is because of the high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases) in children exposed to valproate in utero. If valproate treatment is continued during the pregnancy, specialised prenatal monitoring is advised to monitor the development of the unborn, including the possible occurrence of neural tube defects and other malformations

The decision to start, stop, continue, or change a medicine before or during pregnancy should be made together with the patient and healthcare professional following a discussion of the benefits and risks of treatment. Maternal drug doses may require adjustment during pregnancy due to changes in maternal physiology.

Breastfeeding patients may require medication for acute or chronic health conditions. For some people, this need for medication can become a barrier to breastfeeding, despite most medicines being considered compactible with lactation. The main areas of concern are a lack of information about medication safety, lack of support in decision- making and maintaining breastfeeding which lead to early cessation of breastfeeding. Tailored interventions are required that adopt a non-

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judgmental and person-centred approach to support decision-making regarding infant feeding, providing people with information that can best enable them to make infant feeding choices.

Useful resources: [BUMPS](#) (Best use of medicines in pregnancy)

Choice and medication leaflets on [drugs in pregnancy](#)

[Why does the need for medication become a barrier to breastfeeding? A narrative review](#)

[Knowledge, attitudes and practices of health professionals and women towards medication use in breastfeeding: A review](#)

[MHRA Drug safety update: Medicines related to valproate: risk of abnormal pregnancy outcomes](#)

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Appendix 2 - Equality Analysis Screening Form

Please note: The Equality Analysis Policy and Equality Analysis Guidance can be found on the policy pages of the intranet

You must contact the EDHR team if you identify a negative impact - email tewv.eandd@nhs.net

Section 1	Scope
Name of service area/directorate/department	Pharmacy
Title	Pharmacy Equality Analysis Screening form
Type	Policy
Geographical area covered	Trustwide
Aims and objectives	Tees, Esk and Wear Valleys NHS Foundation Trust is committed to actively recognising and promoting equality and diversity. The Trust believes in making every effort to be a fair and unbiased organisation. Further to this, the Trust aspires to be an organisation that embraces and values people, recognising the benefits that diversity brings to the Trust both as an employer and in the delivery of services. It is essential to consider the impact of Pharmacy policies or guidance on people with different protected characteristics
Start date of Equality Analysis Screening	01/11/2021
End date of Equality Analysis Screening	17/06/2022

Section 2	Impacts

Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?	All service users and clinicians
Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups?	• **Race** (including Gypsy and Traveller) **No** • **Disability** (includes physical, learning, mental health, sensory and medical disabilities) **No** • **Sex** (Men, women and gender neutral etc.) **No** • **Gender reassignment** (Transgender and gender identity) **No** • **Sexual Orientation** (Lesbian, Gay, Bisexual and Heterosexual etc.) **No** • **Age** (includes, young people, older people – people of all ages) **No** • **Religion or Belief** (includes faith groups, atheism and philosophical beliefs) **No** • **Pregnancy and Maternity** (includes pregnancy, women who are breastfeeding and women on maternity leave) **No** • **Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners) **No**
Describe any negative impacts	Patients protected characteristics are considered as part of the considerations to administer medication however there may be times where decisions are made in the best interests of the patient. Every attempt to reduce or remove negative impact will however be sought where practicably possible.
Describe any positive impacts	Involving the patient in the decision-making process where practicably possible ensures that patients protected characteristics can be considered when administering treatment.

Section 3	Research and involvement
What sources of information have you considered? (e.g. legislation, codes of practice,	MHRA drug safety alerts Choice and medication website

best practice, nice guidelines, CQC reports or feedback etc.)	Best use of medicines in pregnancy (BUMPS) BNF/ BNF for children Summary of product characteristics (SPC) Trust guidance on Unlicensed and Off- Label Use of Medicines Trust chaplaincy advice about Ramadan Stopping Over-Medication of People with a Learning Disability, Autism or Both References as states above
Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the protected groups?	Yes
If you answered Yes above, describe the engagement and involvement that has taken place	Trust chaplain/ Imam Ibraheem Meah Service user involvement through D&T committee
If you answered No above, describe future plans that you may have to engage and involve people from different groups	

Section 4	Training needs
As part of this equality analysis have any training needs/service needs been identified?	No
Describe any training needs for Trust staff	
Describe any training needs for patients	
Describe any training needs for contractors or other outside agencies	

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Appendix 3 – Approval checklist

<mark>To be completed by lead and attached to any document which guides practice when submitted to the appropriate committee/group for consideration and approval.</mark>

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Are people involved in the development identified?	Yes	
	Has relevant expertise has been sought/used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
	Have any related documents or documents that are impacted by this change been identified and updated?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Training**		
	Have training needs been considered?	Yes	
	Are training needs included in the document?	Yes	
7.	**Implementation and monitoring**		

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	Title of document being reviewed:	Yes/No/ Not applicable	Comments
	Does the document identify how it will be implemented and monitored?	Yes	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	Yes	
	Have Equality and Diversity reviewed and approved the equality analysis?	Yes	
9.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
10.	**Publication**		
	Has the policy been reviewed for harm?	Yes	
	Does the document identify whether it is private or public?	Yes	
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	