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Title:	<b>High Risk Medicines Policy</b>	
Document Author:	Governance Pharmacist and Medication Safety Officer	
Applicability:	All staff	

## Background

This policy outlines the actions to be followed by all staff when prescribing, administering or dispensing those medicines that are deemed by the Trust to carry a potentially high risk to patient safety.

The need for a high risk medicines policy was identified by review of national patient safety alerts (issued by the NPSA, MRHA or the NHSI) and from Trust clinical practice, clinical incident reporting and audits.

The high risk medicines list will be determined by the Medicine Management Committee and will cover those formulations / medicines deemed to cause a potential high level of risk to patient safety.

## Aim

To minimise the risk of harm from high risk medicines being used inappropriately.

## High Risk Medicines List

This is not a comprehensive list but comprises those medicines most likely to be encountered:

- Injectable Medicines - complex regimes, manipulations and calculations are often required in prescribing, preparing & administering injectable medicines. A list of high risk injectable medicines can be found in the Injectable Medicines Policy.
- Liquid Medicines - formulations do not always have equivalent dosing, often prescribed for children and require weight based dosing adding to the complexity of the calculations required
- Anticoagulants – risk of under / over anticoagulation, variable regimens, interactions, monitoring required & handover between care settings
- Biologic medicines – require pre-administration checks to ensure appropriately prescribed, prescribe by brand, risk of adverse reactions on administration & risk of infection

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- Gentamicin (especially in Neonates) and other medicines requiring routine monitoring - risk of adverse effects or treatment failure due to a narrow therapeutic range
  - Insulins – variety of types & devices and potentially fatal consequences to incorrect doses or timings
  - Intrathecal Medicines – high risk of potentially fatal adverse reactions
  - Loading Doses - risk of dose calculation & administration rate error leading to serious consequences in some medicines
  - Oral anti-cancer drugs – risk of inappropriate use & potentially fatal adverse reactions
  - Oxygen – risk of harm from no / wrong prescription, incorrect flow rates, monitoring not completed or acted upon, confusion of oxygen with medical compressed air, inadvertent disconnection of supply, empty cylinders, faulty or missing equipment
  - Parkinson’s Disease Medicines – omitted doses can lead to patients being unable to swallow (risk of aspiration ) unable to speak, unable to move, increased risk of falls, increased care needs, pain and distress, neuroleptic malignant syndrome or even death
  - Potassium solutions – risk of IV administration of high strength potassium
  - Vaccine Cold Storage – risk of vaccine failure if cold chain storage not adhered to
  - Unfamiliar medicine i.e. any medicine used less than once a week should be considered a high risk
  - **Epilepsy-antiepileptic medication missed or late dose, timing of medication is likely to affect seizures.**

See [appendix A](#) for more detail.

If you are unsure about prescribing, reconstitution or administration contact your ward pharmacist, Medicines Information 55304 or the on-call pharmacist out of hours (via switchboard).

### **Roles & Responsibilities**

All staff involved with prescribing, supplying and administration of medicines must be aware of the high risk medicines policy.

#### **1. Prescribers**

Prescribers need to be aware of the high risk medicines policy, the list of medicines and the information in Appendix A. Prescribers are responsible for ensuring that they are competent to prescribe these medicines before doing so.

It is best practice for patients discharged on high risk medicines to have a note added to Inflex for the GP e.g. ‘Lithium - high risk medicine: requires monitoring’ or ‘Amiodarone – high risk medicine: loading complete, maintenance dose 200mg daily’.

## 2. Nursing Staff

When administering a high risk medicine nursing staff, must ensure that they know the normal doses, that they are only administered as appropriate and in the correct manner (NMC Standards for Medicines Management). Information is available in Appendix A, the BNF and SPCs.

Contact your ward pharmacist, Medicines Information 55304 or the on-call pharmacist (via switchboard) for advice.

## 3. Pharmacists

Pharmacists will aim to prioritise all patients prescribed high risk medicines on a daily basis and screen the prescription for accuracy and appropriateness. Wards will be given further guidance as necessary.

Patients discharged on high risk medicines should have a note added to Infollex for the GP e.g. 'Lithium - high risk medicine: requires monitoring' or 'Amiodarone – high risk medicine: loading complete, maintenance dose 200mg daily'.

## Supporting Information

Supporting information can be found in [Appendix A](#)

Appendix A

High Risk Drug	Rationale for inclusion
Abasaglar	2. Insulin & 6. Omitted doses
Acencoumarol	4. Anticoagulants, 6. Omitted doses & 7. Medicine requires routine monitoring
Acetylcysteine	5. Loading doses
Actrapid	2. Insulin & 6. Omitted doses
Adalimumab	12. Biologic & Highly Immunomodulating Medicines
Amiodarone	5. Loading doses
Apixaban	4. Anticoagulants
Bevacizumab	12. Biologic & Highly Immunomodulating Medicines
Azathiorine	12. Biologic & Highly Immunomodulating Medicines
Capecitabine	Oral anti-cancer drug
Carbamazepine	6. Omitted doses
Ciclosporin	6. Omitted doses & 7. Medicine requires routine monitoring
Chlorambucil	10. Oral anti-cancer drugs
Ciclosporin	12. Biologic & Highly Immunomodulating Medicines
Co-beneldopa	6. Omitted doses
Co-careldopa	6. Omitted doses
Codeine	20. Codeine in children
Cyclophosphamide	10. Oral anti-cancer drugs
Dabigatran	4. Anticoagulants
Dalteparin	4. Anticoagulants
Desmopressin	6. Omitted doses
Dexamethasone	6. Omitted doses
Diamorphine	9. Potent analgesics
Digoxin	5. Loading doses
Dipotassium phosphate	1. Potassium solutions
Edoxaban	4. Anticoagulants
Enoxaparin	4. Anticoagulants
Entacapone	6. Omitted doses
Epidurals	9. Potent analgesics
Etanercept	12. Biologic & Highly Immunomodulating Medicines
Ethosuximide	6. Omitted doses
Fentanyl	9. Potent analgesics

Gentamicin	7. Medicine requires routine monitoring & 13. Gentamicin in neonates
Heparin	4. Anticoagulants, 5. Loading doses, 6. Omitted doses & 7. Medicine requires routine monitoring
Hydroxycarbamide	10. Oral anti-cancer drugs
Humalog Lispro / Mix 25 / Mix 50	2. Insulin & 6. Omitted doses
Humulin S / M3 / I	2. Insulin & 6. Omitted doses
Hydrocortisone	6. Omitted doses
Hypurin porcine neutral / porcine 30/70 mix / isophane	2. Insulin & 6. Omitted doses
Hypurin bovine neutral / protamine zinc / lente / isophane	2. Insulin & 6. Omitted doses
Infliximab	12. Biologic & Highly Immunomodulating Medicines
Insulatard	2. Insulin & 6. Omitted doses
Insulin detemir	2. Insulin & 6. Omitted doses
Insulin glargine	2. Insulin & 6. Omitted doses
Insuman Rapid / Comb 15 / Comb 25 / Comb 50	2. Insulin & 6. Omitted doses
Ketamine	8. IV sedation outside of ICU, theatres or not used by an anaesthetist & 9. Potent analgesics
Lamotrigine	6. Omitted doses
Lantus	2. Insulin & 6. Omitted doses
Levemir	2. Insulin & 6. Omitted doses
Levetiracetam	6. Omitted doses
Lithium	7. Medicine requires routine monitoring
Melphalan	10. Oral anti-cancer drugs
Mercaptopurine	10. Oral anti-cancer drugs & 12. Biologic & Highly Immunomodulating Medicines
Methotrexate	3. Oral methotrexate, 10. Oral anti-cancer drugs & 12. Biologic & Highly Immunomodulating Medicines
Midazolam	8. IV Sedation Outside of ICU, Theatres or not used by an Anaesthetist
Morphine	9. Potent analgesics
Mycophenolate	6. Omitted doses & 12. Biologic & Highly Immunomodulating Medicines
Novomix 30	2. Insulin & 6. Omitted doses
NovoRapid	2. Insulin & 6. Omitted doses
Oxcarbazepine	6. Omitted doses
Oxycodone	9. Potent analgesics

Phenindione	4. Anticoagulants, 6. Omitted doses & 7. Medicine requires routine monitoring
Phenytoin	5. Loading doses & 6. Omitted doses
Potassium chloride / dipotassium phosphate	1. Potassium solutions
Prednisolone	6. Omitted doses
Propofol	8. IV Sedation Outside of ICU, Theatres or not used by an Anaesthetist
Rituximab	12. Biologic & Highly Immunomodulating Medicines
Rivaroxaban	4. Anticoagulants
Sodium Chloride 0.18% with Glucose 4%	14. Sodium Chloride 0.18% with Glucose 4% in Paediatrics
Sodium valproate	6. Omitted doses
Tacrolimus	6. Omitted doses & 12. Biologic & Highly Immunomodulating Medicines
Temozolamide	Oral anti-cancer drug
Tobramycin	7. Medicine requires routine monitoring
Topiramate	6. Omitted doses
Toujeo	2. Insulin & 6. Omitted doses
Vancomycin	7. Medicine requires routine monitoring
Vinorelbine	Oral anti-cancer drug
Warfarin	4. Anticoagulants, 5. Loading doses, 6. Omitted doses & 7. Medicine requires routine monitoring

## 1. Potassium Solutions

Rapid administration of concentrated potassium solutions causes cardiac arrest and is frequently fatal. Incorrect injection of concentrated potassium has occurred where ampoules have been confused with other drugs or diluents. In October 2002 the NPSA issued a Patient Safety Alert after research in the UK and elsewhere identified a risk to patients from errors occurring during intravenous administration of potassium solutions.

The alert set out actions around:

- storage and handling of potassium chloride concentrate and other strong potassium solutions
- preparation of dilute solutions containing potassium
- prescribing of solutions containing potassium
- checking the use of strong potassium solutions in clinical areas

**Prescribing:** Commercially prepared ready-to-use potassium solutions must be prescribed wherever possible.

**Administration:** A second practitioner must always check for correct product, dilution, mixing and labelling during the preparation of, and again prior to administration of solutions prepared from concentrated potassium. Two registered nurses must be involved in these processes, with signatures entered in the relevant sections of the fluid chart, additive label and controlled drug (CD) record book.

**Ordering:** Strong potassium treated as a CD and ordered in the same way.  
Only to be held as stock in the pharmacy department and in those areas where they are needed for urgent use (ICU, CCU and Resus in ED)

**Storage:** CD cupboard.

**Training:** Training in the associated risks of concentrated potassium solutions is part of the Medicines Awareness Course.

## 2. Insulin

In 2010 the NPSA issued a Rapid Response Report on the 'Safer administration of insulin'.

It had been noted that errors in the administration of insulin by clinical staff were common and in certain cases had been severe and had caused a number of deaths. Two common errors were identified for action:

- the inappropriate use of non-insulin (IV) syringes, which are marked in ml and not in insulin units;
- the use of abbreviations such as 'U' or 'IU' for units. When abbreviations are added to the intended dose, the dose may be misread, e.g. 10U is read as 100.

Some of these errors have resulted from insufficient training in the use of insulin by healthcare professionals.

The term 'units' must be used in all contexts; never use abbreviations. To reduce the potential for serious harm the Trust paper drug chart has dedicated insulin prescribing pages. The word 'unit' is pre-populated on the chart to avoid the risk of it being abbreviated.

**Prescribing:** Accurate drug histories are important, use more than one source

Know if the insulin you are prescribing / giving is:

- short acting
- intermediate / long acting
- a combination of the two

**Never** abbreviate the word units

**RIGHT** insulin, **RIGHT** dose, **RIGHT** frequency, **RIGHT** time & **RIGHT** device

**Administration:** All regular and single insulin (bolus) doses should be measured and administered using an insulin syringe, or a commercial insulin pen (never use intravenous syringes)

**Ordering:** Wards are restricted to keeping actrapid as stock and order all other insulins for individual named patients.

Simpson and the EAUs do keep a wider range.

**Storage:** 2-8°C in the medicines fridge. Patient's signed off for self-administration may store their insulin out of sight at the bedside.

**Training:** An eLearning package on 'The Safer use of Insulin' is available on the Hive. All healthcare staff expected to prescribe, prepare and administer insulin should complete this. This will become mandatory for F1s and nursing staff who administer insulin.



### 3. Weekly Methotrexate

Low dose oral / subcutaneous methotrexate for psoriasis or rheumatoid arthritis is prescribed for once a week administration, and care is often shared between GPs and hospital consultants. Prescribing, dispensing and administration errors have led to inappropriate daily dosing, resulting in a number of fatalities. The primary causes of these serious errors are the dose and/or frequency prescribed or dispensed.

In June 2006 a Patient Safety Alert Improving compliance with oral methotrexate guidelines was issued. Patient handheld records were implemented to provide patients with the information they required about their treatment.

- Prescribing:** Care when changing treatment of chronic disease states which is being managed by specialist colleagues.  
Be familiar with the weekly dosing regimen ensuring the dose is clearly prescribed as WEEKLY (6 days of the 7 must be marked with an 'X' and the prescription annotated 'ONCE a WEEK'.  
Take an active role in ensuring patients understand their dose and regimen. Ensure patients are able to recognise the signs of toxicity and the importance of referring themselves to a doctor if these develop.
- Administration:** All staff administering weekly methotrexate should be aware of what condition is being treated and the correct dosage / frequency.
- Ordering:** Order only a single weekly dose at a time and community hospitals to fax a copy of the drug chart to enable dose & frequency verification. Only the 2.5mg strength tablets are stocked in pharmacy.
- Storage:** Labelled for the named patient and stored in the medicines trolley or the locked bedside medicines cupboard.
- Training:** Part of Medicines Awareness Course.

## 4. Anticoagulants

Anticoagulants (including the direct oral anticoagulants, DOACs) are frequently involved in serious medication errors. If warfarin is not monitored properly, the patient's clinical condition changes or concurrent drug therapy changes the potential consequences can be fatal. Safe anticoagulant therapy is a multidisciplinary process involving healthcare professionals in primary and secondary care.

The June 2007 Patient safety alert 18 'Actions that can make anticoagulant therapy safer' recommended action on policies, competencies, loading monitoring, and communication with colleagues amongst others whilst the July 2010 rapid response report <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2010-NRLS-1270-LMWH-RRR-2010.07.30-v1-1.pdf> looked at reducing treatment dose errors with low molecular weight heparins with the aim of reducing the risk of harm from under dosing (therapeutic failure) and over dosing (risk of bleeding).

Examples:	<b>Acencoumarol</b>	<b>Heparin</b>
	<b>Apixaban</b>	<b>Phenindione</b>
	<b>Dabigatran</b>	<b>Rivaroxaban</b>
	<b>Dalteparin</b>	<b>Warfarin</b>

- Prescribing:** Be aware of local policies and the need for monitoring warfarin when the patient's clinical condition changes or concurrent drug therapy changes. Take care when loading with warfarin. Be familiar with guidelines for over anticoagulation.  
Ensure GP colleagues are informed promptly when patients are started on anticoagulation therapy. Calculate LMWH doses with consideration to a patient's weight, renal function and other appropriate parameters.  
Be aware of differing dose regimens and adjustments e.g. loading, renal function and age for DOACs.
- Administration:** Be aware of local policies and the need for monitoring warfarin when the patient's clinical condition changes or concurrent drug therapy changes.  
Be familiar with guidelines for over anticoagulation.
- Ordering:** Wards keep the commonly used anticoagulants as stock with the newer DOACs requiring ordering for named patients.  
Limited range of heparin products available to avoid confusion.
- Storage:** As normal stock / named medicines.
- Training:** Part of Medicines Awareness Course.

## 5. Loading Doses

Loading doses of medicines can be a high risk area as some medicines have the potential to cause a high degree of harm. There is a Trust guideline on preventing fatalities from medication loading doses [G1453 Preventing Fatalities from Medication Loading Doses.pdf](#) produced after the publication of the safety alert <https://www.sps.nhs.uk/articles/npsa-alert-preventing-fatalities-from-medication-loading-doses-2010/> in November 2010. It notes the importance not only of prescribing, dispensing and administration but also of effective communication between healthcare professionals and healthcare settings.

Examples: **Acetylcysteine**  
**Amiodarone**  
**Digoxin**  
**Heparin**  
**Phenytoin**  
**Warfarin**

**Prescribing:** Be aware of the local policy, if unsure seek advice.  
Note essential information documents linked to the above medicines on the intranet.

**Administration:** Be aware of the local policy, if unsure seek advice.  
Note essential information documents linked to the above medicines on the intranet.

**Ordering:** Order via pharmacy on a requisition.

**Storage:** As normal stock / named medicines.

**Training:** Medicines Awareness Course.

## 6. Omitted Doses

While the omission of all medicines should be avoided, medicines included in the critical list have a much greater risk of significantly harmful outcomes if missed or delayed. In the event that omission of a critical medicine cannot be avoided, the doctor must be informed.

This list addresses the most commonly used critical medicines, and is not exhaustive.

A medication which is not on the list may be considered a critical medicine, when viewed in the context of an individual patient.

**Anti-infectives**

**Anticoagulants**

**Antiepileptics**

**Stat doses**

**Parkinson's drugs See – The Inpatient and Perioperative Care of Patients with Parkinson's Disease (Idiopathic) Guideline [G1754.pdf](#) (Consider all medications essential for neurological function)**

**Analgesia - regular**

**Immunosuppressants for transplant**

**Corticosteroids (oral or IV)**

**Insulin**

**Desmopressin for diabetes insipidus**

**Prescribing:** Timely prescribing is **essential** and the timing of doses can also be crucial. Avoid abrupt withdrawal as for some medicines as it can be life threatening e.g. anti-Parkinson's disease medications. If your patient is unable to take their usual medication seek advice from a pharmacist or senior / specialist colleague.

**Administration:** Omission of some medicines can have life threatening consequences e.g. anti-Parkinson's disease medications, desmopressin. If your patient is unable to take their usual medication contact their doctor urgently. Consider self-administration for your patient.

**Ordering:** Order via pharmacy on a requisition. Stock is available of most anti-Parkinson's medicines on Simpson, Cheetham Hill & the EAUs. Out of hours contact the on call pharmacist via switchboard.

**Storage:** As appropriate to the individual drug.

**Training:** Can be arranged through the Parkinson's Disease Nurse Specialist or other specialist nurses.

## 7. Medicines Requiring Routine Monitoring

Examples: **Acencoumarol**                      **Phenindione**  
**Ciclosporin**                                      **Tobramycin**  
**Gentamicin**                                      **Vancomycin**  
**Lithium**    **Warfarin**

Some medicines require close monitoring of their blood levels because of their narrow therapeutic range. The risk is that treatment will either be sub-therapeutic leading to treatment failure or to toxicity.

For lithium see the 'Safer lithium therapy' patient safety alert from December 2009 <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2009-NRLS-0921-Safer-lithium-trt-2009.12.01-v1.pdf>

**Prescribing:**            Timing of doses is essential for effective treatment. Indicate when blood levels should be taken and whether to await the results before giving the next dose or not.  
When taking blood for drug level monitoring, ensure clear and accurate documentation of the time when the sample was taken. When interpreting serum levels it is important to confirm when the level was taken as this will impact on the resulting level.  
Be aware of interacting medicines which may affect blood levels.

**Administration:**    Timing of doses is essential for effective treatment.  
Ensure that doses are given on time and only held pending blood levels when indicated. If in doubt seek advice.

**Ordering:**              Order via pharmacy on a requisition.

**Storage:**              As appropriate to the individual drug.

**Training:**              Medicines Awareness Course.

## 8. IV Sedation Outside of ICU, Theatres or not used by an Anaesthetist

The use of iv sedation outside of specialist areas e.g. ICU & theatres or by staff other than anaesthetists has the potential for serious harm. Midazolam is frequently used on the wards in end of life care but the strength of preparation used is much higher than that used for sedation leading to the potential for an unintentional overdose. This was the subject of an NPSA alert in December 2008 <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2008-NRLS-1074A-midazolam-RRR-mation-2008-12-09-v1.pdf>

**Midazolam**                    **or emergency administration of prolonged or serial seizures must be accompanied by a protocol/care plan in the community or on discharge-support see epilepsy nurses.**

**Propofol**

**Prescribing:**            Be aware of the local policies for end of life prescribing and sedation, if unsure seek advice.

**Administration:**    Be aware of the local policy for end of life care and sedation, if unsure seek advice.

**Ordering:**              Order via pharmacy in the CD order book for midazolam. Midazolam 10mg in 2ml (high strength) is used for end of life care. Lower strength midazolam is restricted to specific areas. Ensure flumazenil is available in all areas where midazolam is used. Propofol is restricted to specific areas.

**Storage:**                Midazolam must be stored in the CD cupboard.

**Training:**                Medicines Awareness Course.  
Staff involved in sedation techniques must have the necessary skills / competence.

## 9. Potent Analgesics

**Diamorphine**  
**Epidurals**  
**Fentanyl**

**Ketamine**  
**Morphine**  
**Oxycodone**

Potent analgesics are frequently involved in serious medication errors. A safer practice notice was issued in May 2006 'Ensuring safer practice with high dose ampoules of diamorphine and morphine' <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2006-NRLS-0295-Diamorphine-morne-SPN-2006-05-25-v1.pdf> requiring Trusts to look at procedures for safe prescribing, labelling, supplying, storing, preparing and administering diamorphine and morphine injections. In July 2008 a Rapid Response Report 'Reducing Dosing Errors with Opioid Medicines' was issued <https://www.sps.nhs.uk/wp-content/uploads/2018/02/NRLS-1066A-Opioid-Medicinmation-2008-07-04-v1.pdf> again looking at the prescribing, dispensing and administration of opioids. An alert from March 2007 <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2007-NRLS-0396-Epidural-injectns-PSA-2007-03-28-v1.pdf> looked at safer practice with epidural injections and infusions.

- Prescribing:** Follow local guidelines, seek senior or pain team advice as appropriate. Check if the patient has had opioids previously.  
Ensure an antidote is prescribed / available e.g. naloxone.  
Prescribe oral sustained release opioids by brand name & be aware of differences in potency / bioavailability between agents / formulations and the risks this creates.  
For patients who are addicted to opioids and admitted to hospital see policy <https://Opiod addiction G1417.pdf> and for those patients who are taking strong opioids for benign pain, cancer pain or who are taking opioids for addiction who require surgery see policy <https://Perioperative high dose opioids G0751.pdf>
- Administration:** Ensure all dose calculations, preparation and administration of potent analgesics are double-checked. Be aware of the importance of the correct route of administration especially for epidurals (risk of catastrophic harm).  
Careful monitoring of patients receiving potent analgesics. Correct labelling of epidural bags.  
Check that the right formulation e.g. SR, IR is administered. Giving the incorrect oxycodone preparation is a common error.
- Ordering:** In CD order book.
- Storage:** In the Controlled Drugs Cupboard and limit the range of products available to minimise the risk of confusion
- Training:** Medicines Awareness Course & Trust policies & guidelines

## 10. Oral Anti-Cancer Drugs

Examples:

<b>Abiraterone</b>	<b>Fludarabine</b>	<b>Olaparib</b>
<b>Afatinib</b>	<b>Hydroxycarbamide</b>	<b>Pazopanib</b>
<b>Axitinib</b>	<b>Imatinib</b>	<b>Pomalidomide</b>
<b>Bosutinib</b>	<b>Ibrutinib</b>	<b>Ponatinib</b>
<b>Busulfan</b>	<b>Idarubicin</b>	<b>Procarbazine</b>
<b>Cabozantinib</b>	<b>Idelalisib</b>	<b>Sunitinib</b>
<b>Capecitabine</b>	<b>Lapatinib</b>	<b>Temozolamide</b>
<b>Chorambucil</b>	<b>Lenalidomide</b>	<b>Trametinib</b>
<b>Cyclophosphamide</b>	<b>Lomustine</b>	<b>Trifluridine/tipiracil (Lonsurf)</b>
<b>Dabrafenib</b>	<b>Melphalan</b>	<b>Treosulfan</b>
<b>Enzalutamide</b>	<b>Mercaptopurine</b>	<b>Venetoclax</b>
<b>Erlotinib</b>	<b>Methotrexate</b>	<b>Vemurafenib</b>
<b>Etoposide</b>	<b>Nirapanib</b>	<b>Vinorelbine</b>

No oral chemotherapy medicines are to be held as stock on the wards except for hydroxycarbamide on Turner ward. The acute oncology service must be notified of all patients admitted on oral anti-cancer drugs, either directly or via pharmacy.

**Prescribing:** Oral chemotherapy should only be prescribed by an Oncology / Haematology consultant or Registrar. Best practice is to **not** prescribe oral chemotherapy for patients on admission.

**Administration:** Wear gloves  
Women of child bearing potential to avoid handling.  
Seek advice

**Ordering:** Individual drugs must be ordered on a named patient basis.

**Storage:** As appropriate to the individual drug.

**Training:** Medicines Awareness Course & Trust policies & guidelines.



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## 11. Intravenous Anti-Cancer Therapy

All staff involved in the prescribing, clinical checking, preparation and administration of intravenous anti-cancer therapy must have undergone the appropriate training.

## 12. Biologic & Highly Immunomodulating Medicines

Biologic medicines are made from proteins and other substances produced by the body.

Injectable antineoplastic and highly immunomodulating agents are prepared by pharmacy others are prepared by the nursing staff in clinical areas.

Examples: **Adalimumab**    **Azathioprine**  
**Infliximab**        **Ciclosporin**  
**Etanercept**       **Mercaptopurine**  
**Bevacizumab**    **Mycophenolate**  
**ranibizumab**    **Methotrexate**  
**Rituximab**        **Tacrolimus**

**Prescribing:**        Seek advice from a pharmacist or senior / specialist colleague when prescribing especially for biologic medicines.

Ensure timely and accurate prescribing of immunomodulating medicines prescribed for prevention of organ transplant rejection.

**Administration:**    As appropriate to the individual drug.

**Ordering:**            Individual drugs must be ordered on a named patient basis.

**Storage:**             As appropriate to the individual drug.

**Training:**            Medicines Awareness Course & Trust policies & guidelines.

See Injectable Medicines Policy. ([Ref 1923](#))

### 13. Gentamicin in Neonates

Patient safety incidents have been reported nationally involving administration of gentamicin in neonates as highlighted by the Patient Safety Alert from February 2010 'Safer use of intravenous gentamicin for neonates'. Prescribing errors, incorrect administration times and issues relating to blood levels have all played a part in the reported incidents.

**Prescribing:** Be aware of the local neonatal gentamicin protocol and care bundle which incorporates

- 24 hour clock for administration times & blocking out unused time slots at the time of prescribing

**Administration:** Be aware of the local neonatal gentamicin protocol and care bundle which incorporates

- 24 hour clock for administration times & blocking out unused time slots at the time of prescribing
- Minimise interruptions during preparation & administration
- Using a double checking prompt during preparation & administration
- Ensuring dose given within **one** hour of the prescribed time

**Ordering:** Order via pharmacy on a requisition

**Storage:** In stock cupboard

**Training:** All staff involved in prescribing & administration of gentamicin to neonates must have training relating to its use

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**14. Sodium Chloride 0.18% with Glucose 4% in Paediatrics**

A patient safety alert was issued in 2007 on 'Reducing the Risk of Hyponatraemia When Administering IV Infusions to Children'.

Sodium Chloride 0.18% with Glucose 4% must not be prescribed for children.

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## 15. Intrathecal Medicines

See 'Intrathecal Chemotherapy'

[https://icon.torbayandsouthdevon.nhs.uk/corp\\_doc\\_mgmt/Clinical%20Effectiveness/G0456.pdf](https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G0456.pdf)

Specific 1:1 training must be undertaken with the Cancer Service Pharmacist to enable annual validation to prescribe or administer,

## 16. Oxygen

Oxygen is one of the most commonly used medicines in the hospital setting. It is indicated in many critical conditions and can save lives by preventing severe hypoxia. However, there is a potential for serious harm and even death if it is not administered and managed appropriately.

**Prescribing:** See appropriate section of the PMAR / supplementary chart (does not cover ICU or children less than 16 years of age).

**Administration:** See appropriate section of the PMAR / supplementary chart (does not cover ICU or children less than 16 years of age).  
Pulse oximetry must be available in all areas where oxygen is administered.

**Ordering:** Order via the porters.

**Storage:** Use of piped oxygen is best practice and the use of cylinders should be minimised.  
Cylinders must be stored in the correct racking or an appropriate trolley away from sources of heat or ignition.

**Training:** Medicines Awareness Course.

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## 17. Vaccine Cold Storage

See the 'Cold Chain Policy for Medicines and Vaccines'

[https://icon.torbayandsouthdevon.nhs.uk/corp\\_doc\\_mgmt/Clinical%20Effectiveness/G1913.pdf](https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G1913.pdf)

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## 18. Injectable Medicines

See the 'Injectable Medicines Policy'. ([Ref 1923](#))

Codeine should only be used to relieve acute moderate pain in children older than 12 years and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen alone. Furthermore, a significant risk of serious and life-threatening adverse reactions has been identified in children with obstructive sleep apnoea who received codeine after tonsillectomy or adenoidectomy (or both). Codeine is now contraindicated in all children younger than 18 years who undergo these procedures for obstructive sleep apnoea.



## 19. Liquid Medicines

The Patient Safety Alert on 'Promoting safer measurement and administration of liquid medicines via oral and other enteral routes' came out in March 2007. Action centred around:

1. Design, supply and use of oral/enteral syringes
  - only use labelled oral/enteral syringes that cannot be connected to intravenous catheters or ports to measure and administer oral liquid medicines
  - do not use intravenous syringes to measure and administer oral liquid medicines
  - make sure stocks of oral/enteral syringes are available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe
  - when patients or carers need to administer oral liquid medicines with a syringe, supply them with oral or enteral syringes.
  
2. Design, supply and use of enteral feeding systems
  - enteral feeding systems should not contain ports that can be connected to intravenous syringes or that have end connectors that can be connected to intravenous or other parenteral lines
  - enteral feeding systems should be labelled to indicate the route of administration
  - three-way taps and syringe tip adaptors should not be used in enteral feeding systems because connection design safeguards can be bypassed.
  
3. Organisational procedures, training and audit
  - medicines and enteral feeding policies and procedures should identify and manage the risk of administering oral liquid medicines by the wrong route;
  - these procedures should be part of the organisation's training and competency assessment programmes;
  - annual medicines management audits should include a review of the measurement and administration of oral liquid medicines to ensure compliance with local policies and procedures.

See policy [Administration of Medicine via Enteral Feeding Tubes G1826.pdf](#)

(The term 'oral liquid medicine' will mean liquid medicine, including soluble tablets once dissolved and feeds or flushes to be administered by oral and other enteral routes, including rectal administration).

## 20. Codeine in Children

Codeine should only be used to relieve acute moderate pain in children older than 12 years and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen alone. Furthermore, a significant risk of serious and life-threatening adverse reactions has been identified in children with obstructive sleep apnoea who received codeine after tonsillectomy or adenoidectomy (or both). Codeine is now contraindicated in all children younger than 18 years who undergo these procedures for obstructive sleep apnoea.

See MHRA Alert <https://www.gov.uk/drug-safety-update/codeine-for-analgesia-restricted-use-in-children-because-of-reports-of-morphine-toxicity>

## Document Control Information

*This is a controlled document and should not be altered in any way without the express permission of the author or their representative.*

*Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.*

*If printed, this document is only valid for the day of printing.*

*This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.*

<b>Ref No:</b>	2378		
<b>Document title:</b>	High Risk Medicines Policy		
<b>Purpose of document:</b>	To minimise the risk of harm from high risk medicines being used inappropriately.		
<b>Date of issue:</b>	29 April 2019	<b>Next review date:</b>	29 April 2022
<b>Version:</b>	1	<b>Last review date:</b>	
<b>Author:</b>	Governance Pharmacist and Medication Safety Officer		
<b>Directorate:</b>	Medical Services		
<b>Equality Impact:</b>	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
<b>Committee(s) approving the document:</b>	Medicines Management Committee Care and Clinical Policies Group Chief Nurse Medical Services		
<b>Date approved:</b>	24 April 2019		
<b>Links or overlaps with other policies:</b>	1754 - Parkinson's Disease (Ideopathic) - The inpatient and perioperative care of patients with 1417 - Opioid addiction; Management of patients with admitted to Torbay Hospital 0751 - Perioperative High Dose Opioids 0456 – Intrathecal Chemotherapy 1913 – Cold Chain Policy 1923 - Injectable Medicines Policy for Registered Professionals 1826 - Administration of Medicine via Enteral Feeding Tubes		

<b>Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.</b>	Yes <input type="checkbox"/>	
	Please select Yes                  No	
<b>Does this document have implications regarding the Care Act? If yes please state:</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Does this document have training implications?</b> <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Does this document have financial implications?</b> <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Is this document a direct replacement for another?</b> <i>If yes please state which documents are being replaced:</i>	<input type="checkbox"/>	<input type="checkbox"/>

### Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
29 April 2019	1	New	Care and Clinical Policies Group Medicines Management Committee Chief Nurse Medical Director

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## The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

**“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)**

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

[http://icare/Operations/mental\\_capacity\\_act/Pages/default.aspx](http://icare/Operations/mental_capacity_act/Pages/default.aspx)

## Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

**Rapid (E)quality Impact Assessment (EqIA) (for use when writing policies)**

<b>Policy Title</b> (and number)		<b>Version and Date</b>	
<b>Policy Author</b>			
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.			
<b>Who may be affected by this document?</b>			
Patients/ Service Users <input type="checkbox"/>		Staff <input type="checkbox"/>	Other, please state... <input type="checkbox"/>
<b>Could the policy treat people from protected groups less favourably than the general population?</b> <i>PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below</i>			
Age	Yes <input type="checkbox"/> No <input type="checkbox"/>	Gender Reassignment	Yes <input type="checkbox"/> No <input type="checkbox"/>
Race	Yes <input type="checkbox"/> No <input type="checkbox"/>	Disability	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gender	Yes <input type="checkbox"/> No <input type="checkbox"/>	Pregnancy/Maternity	Yes <input type="checkbox"/> No <input type="checkbox"/>
Sexual Orientation			Yes <input type="checkbox"/> No <input type="checkbox"/>
Religion/Belief (non)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Marriage/ Civil Partnership			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population?</b> (substance misuse; teenage mums; carers <sup>1</sup> ; travellers <sup>2</sup> ; homeless <sup>3</sup> ; convictions; social isolation <sup>4</sup> ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Please provide details for each protected group where you have indicated 'Yes'.</b>			
<b>VISION AND VALUES:</b> Policies must aim to remove unintentional barriers and promote inclusion			
Is inclusive language <sup>5</sup> used throughout?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible <sup>6</sup> ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Does the policy encourage individualised and person-centred care?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Could there be an adverse impact on an individual's independence or autonomy <sup>7</sup> ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
<b>EXTERNAL FACTORS</b>			
<b>Is the policy a result of national legislation which cannot be modified in any way?</b>			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>What is the reason for writing this policy?</b> (Is it a result in a change of legislation/ national research?)			
<b>Who was consulted when drafting this policy?</b>			
Patients/ Service Users <input type="checkbox"/>	Trade Unions <input type="checkbox"/>	Protected Groups (including Trust Equality Groups)	<input type="checkbox"/>
Staff <input type="checkbox"/>	General Public <input type="checkbox"/>	Other, please state...	<input type="checkbox"/>
<b>What were the recommendations/suggestions?</b>			
<b>Does this document require a service redesign or substantial amendments to an existing process?</b> <i>PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below</i>			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>ACTION PLAN:</b> Please list all actions identified to address any impacts			
<b>Action</b>	<b>Person responsible</b>	<b>Completion date</b>	

**AUTHORISATION:**

By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

<b>Name of person completing the form</b>		<b>Signature</b>	
<b>Validated by (line manager)</b>		<b>Signature</b>	

**Please contact the Equalities team for guidance:**

For South Devon & Torbay CCG, please call 01803 652476 or email [marisa.cockfield@nhs.net](mailto:marisa.cockfield@nhs.net)

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email [pdf.sdht@nhs.net](mailto:pdf.sdht@nhs.net)

**This form should be published with the policy and a signed copy sent to your relevant organisation.**

- <sup>1</sup> Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
- <sup>2</sup> Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
- <sup>3</sup> Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
- <sup>4</sup> Consider how someone will be aware of (or access) a service if socially or geographically isolated
- <sup>5</sup> Language must be relevant and appropriate, for example referring to partners, not husbands or wives
- <sup>6</sup> Consider both physical access to services and how information/ communication is available in an accessible format
- <sup>7</sup> Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

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## Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes  No

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our [GDPR](#) page on ICON (intranet).

For more information:

- Contact the Data Access and Disclosure Office on [dataprotection.tsdf@nhs.net](mailto:dataprotection.tsdf@nhs.net),
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [Data Protection](#) site on the public internet.