Procedure		Worcestershire Acute Hospitals NHS Trust

Procedure for the safe and secure handling of medicines in Theatres

Department / Service:	Theatres WAHT
Originator:	Keith Hinton
Accountable Director:	Rob Glasson
Approved by:	James Hutchinson
Date of approval:	21st February, 2024
Expiry Date:	21st February, 2027
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	Theatres
Target staff categories	All staff working in a theatre environment

Plan Overview:
This document specifically regulates the working practices of Doctors, Nurses, Midwives and Operating Department Practitioners regarding the use of medicines in Theatre areas where anaesthesia and resuscitation are carried out.

Key amendments to this Document:

Date	Amendment	By:
May 2019	Addition of information regarding warmed fluids	K Hinton
September 2020	Additional information regarding warmed fluids including change to expiry date for IV fluids	K Hinton
October 2021	Inclusion of storage requirements for diamorphine PFS	K Hinton
November 2023	Inclusion of statements relating to labelling, use of pre-filled syringes and purchasing for safety	K Hinton

Contents page:

1 SCOPE

This procedure relates to all staff working in situations where anaesthesia and resuscitation interventions are required.

2 INTRODUCTION

The majority of drugs administered in an operating theatre environment are given as an integral part of the anaesthetic plan, and are administered by qualified Anaesthetists. However, certain areas of anaesthetic practice can differ from that described in the WAH NHS Trust Medicines Policy, which is orientated to nurse/midwife delivered care on the wards areas. This document specifically regulates the working practices of medical staff (anaesthetists and surgeons) and other staff such as nurses, midwives and operating department practitioners (ODP), where anaesthesia and resuscitation are carried out.

3 STATEMENT OF INTENT

This procedure defines those areas where practice varies from that set out in the Worcestershire Acute Hospitals NHS Trust Medicines policy and Injectable Medicines Policy. Therefore, the Trust Medicines Policy and Injectable Medicines Policy should be read in conjunction with this procedure.

4 DEFINITIONS

Doctor: A person registered with the General Medical Council and with a license to practice.
Nurse: A Registered Nurse working in Operating Theatres or the Recovery Area.
Registered Practitioner: A Registered Nurse, Midwife, Dentist, Operating Department Practitioner, Pharmacist, or Pharmacy Technician.

5 DUTIES

5.1.1 **Clinical Director for Anaesthetics and Clinical Director for Theatres** will ensure that systems and procedures are in place to monitor and ensure adherence to these procedures and any exceptions are reported through the appropriate clinical governance committee and the Medicines Optimisation Committee where appropriate.

5.1.2 **Clinical Directors for Surgical Specialities** will ensure that all clinical staff, including temporary and new staff are made aware of this procedure.

5.1.3 **Service Delivery Manager, Clinical Director of Anaesthetics, Senior Sisters / Charge Nurses and Junior Sisters / Theatres Team Leader** will assume overall responsibility for compliance with this Procedure within their areas. They will ensure that any non-compliance is recorded via the Trust Incident Reporting System and any required actions taken.

5.1.4 **All staff** working in situations where anaesthetic drugs and resuscitation interventions are administered will comply with this procedure.

5.1.5 **Each Doctor and Registered Practitioner** is accountable for their own practice and must be aware of their legal and professional responsibilities relating to their competence in the ordering, storage, prescribing, administering and recording of drugs.

5.1.6 **All staff** must know the mechanism for reporting adverse drug reactions or incidents relating to medicines, and how to manage them. All errors relating to medicines must be managed according to the MedPolSOP25 Procedure for managing staff involved in medication errors.

5.1.7 Where feasible, following purchasing for safety principles, Pharmacy should supply injectable medicines in a ready to use format e.g. pre-filled syringes or ready diluted ampoules.

6 PROCEDURAL DETAILS

6.1 Security and storage requirements

6.1.1 All Theatre areas have swipe card access control systems in place. Access is restricted under the authorisation of the Theatres matron.

6.1.2 The Appointed HCP in charge of a clinical area is responsible for the safe and secure storage of all medicinal products issued to that clinical area. She/he may delegate access to another appropriate registered professional e.g. a doctor or a registered practitioner, but retains responsibility.

6.1.3 Medicines must be stored in a way that prevents unauthorised access while taking into account the need to obtain medicines in an emergency. This may necessitate that anaesthetic room drug cupboards (excluding those containing controlled drugs) remain unlocked when the anaesthetic room is unoccupied and the operating theatre is in use. The anaesthetic room must remain visible to staff in the theatre.

6.1.4 All medicines must be secured and drug cupboards locked when the anaesthetic room and operating theatre are unoccupied.

6.1.5 Medicine cupboard keys must be kept separate from other keys and carried on the person of a trained nurse, midwife, ODP, or other qualified person designated by the Appointed HCP-in-Charge. A key safe with a combination lock may be used provided the combination is changed regularly. CD cupboard keys may only be stored in a key-safe with access control, e.g. restricted access.

6.1.6 The responsible person must ensure outdated medicines are marked “Expired” and returned to the Pharmacy.

6.1.7 Pharmacists and pharmacy staff visiting wards and departments will advise on storage conditions. The place of storage will be inspected at intervals of not more than 3 months by a designated member of the pharmacy staff.

6.1.8 A pharmacist must be consulted whenever changes to existing medicines storage facilities are planned or new cupboards are proposed.

6.1.9 All local anaesthetic infusions are stored separately from intravenous infusion solutions and other safe segregation practices are used, e.g. epidural preparations and penicillins.

6.1.10 Where diamorphine pre-filled syringes (PFS) are available these must be stored in a dedicated refrigerator which must remain locked when not in use and the keys held by the registered practitioner as per the Medicines Policy.

6.1.11 Medicines for spinal, epidural or for nerve block injection are presented as prefilled syringes wherever possible and are clearly identifiable (e.g. as different coloured lines, bags and labels). Appropriate connectors are used for epidural, intrathecal and nerve block infusions.

6.2 Fluids

6.2.1 Secure storage areas are required for fluids with restricted access when not in use.
6.2.2 Fluid wrappers are only removed at the point of use.
6.2.3 Fluid warmers:

- Fluids placed in warmers must be labelled with the date of insertion
- Warmed solution temperatures should not exceed $40^{O}C$
- Once warmed, Tisept sachets must be discarded after 24 hours
- Once warmed, Hartmanns solution and sodium chloride 0.9% 500ml and 1000ml bags should be discarded if unused after 14 days.
- Once warmed Baxter irrigation solutions (1l Water, 3l water and 3l glycine) should be discarded if unused after 14 days.
- Warmed fluid should not be returned to room temperature storage

6.3 Administration of Medicines

6.3.1 Medicines (excluding IV fluids) should not be routinely prepared (i.e. drawn up / reconstituted) by a Registered Practitioner before the start of the operating list unless the Registered Practitioner is in receipt of a valid prescription chart and/or a verbal instruction from the administering Anaesthetist.

6.3.2 If medicines are drawn up and labelled in a theatre setting ideally this is done by the person who will administer them at the time of preparation.

6.3.2 Drugs that are drawn up before the start of the operation list, or in advance of the patient arriving in the anaesthetic room in an emergency situation, must be labelled and those in syringes sealed with a 5 micron filter needle or specific syringe cap. The preparation and labelling must be double checked when prepared by a Registered Practitioner. The vial or ampoule used to prepare the medications is kept with the prepared preparation until a second check is performed or the preparation is administered. In obstetrics, the emergency medications drawn up in advance of the patient arriving in the anaesthetic room will be fully labelled, second checked and placed in a plastic box provided for this purpose. The box must then be labelled with the date and time of preparation and the signature of the registered professional that prepared the medicines.

6.3.3 Emergency drugs prepared in advance of a case should accompany the patient from the anaesthetic room into the operating theatre and disposed of appropriately if not used.

6.3.4 Only a doctor will administer medication as part of an anaesthetic and this administration must be recorded on the Anaesthetic Chart. In an emergency, a Registered Practitioner can deliver anaesthetic medicine, but only under the immediate and precise instructions of an accompanying Anaesthetist, who will assume full responsibility for its administration, use and effect.

6.3.5 A Registered Practitioner can administer medicines that are prescribed on a valid WAHT prescription chart.

6.3.6 Any doctor or Registered Practitioner administering a medicine to a patient or checking the administration will be satisfied that she or he knows the therapeutic uses of the medicine, its normal dosage, side effects, precautions and contra-indications.

6.3.7 Medical students may administer intravenous medication under the immediate and direct supervision of an Anaesthetist, who will record the administration on the Anaesthetic/Prescription Chart.

6.3.8 In accordance with the Trust Medicines Policy, the person administering a medicine or beginning an anaesthetic will:

1. Check the identity of the patient, by asking the patient to state his/her name (where possible), and then cross check the name and NHS/hospital number with clinical notes, identification band and printed operating theatre list.

2. Check the patient identification band, drug charts and preoperative documentation for any recorded and known drug allergies, drug sensitivities or adverse effects.

6.3.9 All drugs from glass ampoules must be drawn up using a 5micron filter needle.

6.3.10 All syringes used to draw drugs from ampoules or reconstituted vials will be clearly labelled, using the generic classification Syringe labelling 2022 v1.1.pdf . Infusions must be labelled utilising a drug additive label where appropriate.

6.3.11 Syringes should be labelled immediately after filling and before leaving the operator's hand; the label should be matched with the ampoule; this should be done one medication at a time[12].

6.3.12 The use of colours is intended only as an aid in the identification of medication groups and does not absolve the user from the duty of reading the label and correctly identifying the medication prior to use

6.3.13 If the drug has been diluted, the new concentration must be written clearly on the label. Where emergency and routine medications are drawn up ready for administration during a procedure they must be stored separately to avoid emergency medication being given in error[13].

6.3.14 Intravenous infusions must be labelled with date and time prepared, using drug additive labels as necessary.

6.3.15 Any CD that has been prepared for patient use must not be left unattended under any circumstances.

6.3.16 In the event of a medicine not being administered due to non-availability the pharmacy should be informed as soon as practically possible.

6.3.17 When administering non-anaesthetic drugs (e.g. antibiotics, analgesia, steroid supplementation, anticoagulants or pro coagulants), the Anaesthetist or Registered Practitioner will:

1. Check that the patient is not known to be allergic to the drug.
2. Check that the medicine has not already been administered.
3. Double check drug identity and dose against the prescription or verbal instruction(1)
4. Check the expiry date of the medicine on the label.
5. Calculate the dose if appropriate.
6. Check any “when required” doses are within maximum daily dosage.
7. Record and initial the administration on the prescription chart. If the prescription includes variable doses, the total amount administered must be recorded.
8. Destroy any medication or remainder not administered immediately.

6.3.17 Injectable medicines must be drawn directly from their original ampoule or container into syringes. Use of ‘open systems’ e.g. galley pots must not be used with the single exception of the embolization procedures. This is due to the risk of death or severe harm posed by unidentifiable solutions.

6.4 Recording of Medicines

6.4.1 Each Registered Practitioner or Doctor must record ALL administrations of ALL medicines given by themselves on the In-patient Medication Chart or Anaesthetic Chart.

6.4.2 ALL antibiotic doses administered in the theatre environment should follow the Trust Antibiotic Policy and will be recorded on the STAT dose section of the In-patient Medication Chart (or Day Case Prescription for day case surgical patients).

6.5 Disposal of Individual Doses of Unwanted or Discarded Medicines

6.5.1 Drugs should not otherwise be removed from container/packaging unless for anticipated administration.

6.5.2 The Anaesthetist is personally responsible for safely disposing of any unused medicine in an open ampoule or in a syringe.

6.5.3 The quantity of wasted of controlled drug must be witnessed and recorded in the controlled drug register.

6.5.4 Discarded drugs must be disposed of via the appropriate waste container in line with the Trust's Waste Management Policy.

6.5.5 Unused controlled drug must be discarded in a way that results in the dose being irretrievable as per MedPol SOP7.

6.5.6 Single `stray´ ampoules if discovered should be thrown away and not replaced into boxes.

6.6 Controlled Drugs in Theatres

6.6.1 CDs must be ordered, received, recorded, checked, administered and disposed of in accordance with the Worcestershire Acute Hospitals NHS Trust Medicines Policy and associated standard operating procedures (SOP).

6.6.2 Each Anaesthetic room has a Theatre CD Register. This will show issue, receipt, form of administration and vials or part vials returned or disposed of. Issue of the CD from the CD cupboard is carried out by a Registered Practitioner who writes all the required details in the CD Register (see 6.4.3), performs a rolling stock check and signs the CD Register to confirm the balance is correct. The rolling stock balance will be recorded only once, on the supply line for issue or receipt.

6.6.3 When issuing a CD, the Registered Practitioner will record the:

- Date
- patient's name and hospital or NHS number
- amount supplied (S)
- time issued in the CD Register
- and sign the register as the witness and record the stock balance.

Patient details may be recorded in the register using an addressograph sticker providing it is attached within the given space and cannot be removed.

The anaesthetist must sign the CD Register for each case and perform a rolling stock check, confirming by this signature that the stock balance and physical stock are both correct.

6.6.4 When administering a CD, the Doctor confirms drug identity and dose prior to administration, draws up the appropriate amount into a syringe and labels the syringe. The amount(s) administered (A) to the patient will be recorded on the anaesthetic chart. At the end of the operation, the Doctor/Anaesthetist, witnessed by a Registered Practitioner, will dispose of the syringe, along with any volume left in the syringe (discarded) according to current waste policy. The actual dose administered (A) and the amount discarded (D) will be recorded in the CD Register by the Doctor/Anaesthetist, who will sign the register. The Registered Practitioner will also sign the CD Register as a witness for the disposal of the syringe and any volume wasted only.

6.6.5 Where an opioid containing epidural infusion or intravenous infusion is started in theatre, the CD register will be annotated (on the line for amount administered) with

"In situ, transferred to xxxx", where xxxx refers to the ward the patient is being transferred to after recovery.

6.6.6 For continuous administration (e.g. via intravenous infusion) there must be a record of those involved in setting-up the medication. The Anaesthetist concerned must sign for the medicines received in the CD Register, record the amount of medicine administered on the anaesthetic record in the patient's notes and record the actual dose administered in the CD Register, along with a witness signature as detailed in Section 6.5.4.

6.6.7 The recording of the actual doses administered and any amount wasted must be recorded in the CD Register, signed and witnessed as above, before the next case is brought to theatre.

6.6.8 CD stock balance checks must be carried out every 24 hours and recorded in the CD Register by two Registered Practitioners. If the theatre has not been used in any 24 hour period it is good practice to record this information. If a discrepancy is found a full cupboard check must be performed and further investigations carried out according to the procedure detailed in the Medicines Policy.

6.6.9 If a new page of the CD Register is required, the Registered Practitioner must transfer the record to another page of the register. This transfer must be witnessed and the page number in the Index up-dated.

6.6.10 The transfer of the record of CDs from an old CD Register to a new one is to be carried out by two Registered Practitioners. The record in the new CD Register must detail the page number in the old CD Register from which the record was transferred.

6.6.11 Controlled Drugs that are no longer required or expired, must be handed to a pharmacist to return to the pharmacy. This return must be recorded in the CD register and the entry witnessed by the Assigned Nurse, Midwife or ODP in charge.

6.6.12 Controlled drugs that require refrigeration storage i.e. diamorphine 0.5mg pre-filled syringes (PFS) may only be stocked in limited Theatre areas. These areas are Recovery, CEPOD, and Delivery Theatres. Any additional theatres requiring diamorphine PFS must obtain from Theatre Recovery prior to the case. The medicine fridge must remain locked when not in use and the keys held by the registered practitioner as per the Medicines Policy.

7 TRAINING

There is no mandatory training associated with this policy. Ad hoc training sessions based on an individuals training needs as defined within their annual appraisal or job plan.

Awareness of the existence of this procedure will be published via various communication processes, including departmental meetings and e-mail cascade through Clinical Directors.

References:

1. National Patient Safety Agency. Promoting safer use of injectable medicines. Patient Safety Alert 20, 2007; (March 28). www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=2269 (accessed 6th October 2016)
2. NHS England. Patient Safety Alert – Risk of death or severe harm due to inadvertent injection of skin preparation solution. www.england.nhs.uk/2015/05/psa-skin-prep solution/ (accessed 6th October 2016)
3. British Society for Interventional Radiology. www.bsirqi.org/site_media/editoruploads/injectables%20advice%20080216SC.pf (accessed 6th October 2016)
4. Professional Guidance for Safe and Secure Handling of Medicines. RPSGB, London 2018
5. Storage of drugs in anaesthetic rooms. Guidance on best practice from the RCoA and AAGBI. The Royal College of Anaesthetists (RCoA) and Association of Anaesthetists of Great Britain and Ireland (AAGBI) 2016. https://www.rcoa.ac.uk/system/files/STORAGE-DRUGS-2016.pdf (accessed 8.10.2016)
6. Royal College of Anaesthetists. (2018). Guidelines for the Provision of Anaesthesia Services for Intra-operative care
7. College of Operating Department Practitioners. (2009). Scope of Practice.
8. NHS Health Building Note 14-02 – Medicines storage in clinical areas. https://www.england.nhs.uk/wp-content/uploads/2021/05/HBN-14-02-Medicines-storage-in-clinical-areas.pdf
9. Kinsella et al. Handling injectable medications in anaesthesia. Guidelines from the Association of Anaesthetists. Anaesthesia 2023.
10. Royal Pharmaceutical Society. Professional guidance on the safe and secure handling of medicines. Appendix C: Operating theatres - supplementary guidance, 2018. https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines (accessed 25/09/2023)
11. Guidelines Syringe labelling in anaesthesia and critical care areas: review 2022. Association of Anaesthetists. September 2022.
12. Whitaker D, Brattenbø G, Trenkler et al. The European Board of Anaesthesiology recommendations for safe medication practice. European Journal of Anaesthesiology 2017; 34: 4-7.
13. International Organization for Standardization. ISO26825:2020. Anaesthetic and respiratory equipment – user applied labels for syringes containing drugs used during anaesthesia – colours, design and performance. 2020. https://www.iso.org/standard/76678.html (accessed 10/11/2023)

Monitoring Tool

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
3	Ward storage audit	Audit	Annual	Clinical team Lead Pharmacist for Theatres or designated deputy	Clinical theatre manager Director of Pharmacy and Medicines Optimisation Director of Anaesthetics Anaesthetic clinical governance	Annual
3	Controlled drug audit	Audit	Quarterly	Clinical team Lead Pharmacist for Theatres or designated deputy	Clinical theatre manager Director of Pharmacy and Medicines Optimisation Director of Anaesthetics Anaesthetic clinical governance	Quarterly

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation	
Rob Glasson	Clinical Director (Anaesthetics)
James Hutchinson	Consultant anaesthetist & clinical governance lead

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Anaesthetic and Critical Care Divisional Governance meeting

Supporting Document 1 - Equality Impact Assessment Tool
To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	✓	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Keith Hinton	Pharmacist	Keith.hinton1@nhs.net
Date assessment completed	29.04.2022		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Procedure			
What is the aim, purpose and/or intended outcomes of this Activity?	Procedure for the safe and secure handling of medicines in theatres			
Who will be affected by the	✓	Service User	✓	Staff

development & implementation of this activity?	❑ ❑	Patient Carers Visitors	❑ ❑ ❑	Communities Other _____
Is this:	✓ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	See references			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)				
Summary of relevant findings				

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		✓		
Disability		✓		
Gender Reassignment		✓		
Marriage & Civil Partnerships		✓		
Pregnancy & Maternity		✓		
Race including Traveling Communities		✓		
Religion & Belief		✓		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sex		✓		
Sexual Orientation		✓		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		✓		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		✓		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Keith Hinton
Date signed	11/05/2022
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	