Trust-wide Document

Great Western Hospitals NHS Foundation Trust

Controlled Drug Policy

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Ratified by	Medicines Assurance Committee	**Date Ratified**	22/08/19
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Status	LIVE		
Target Audience- who does the document apply to and who should be using it. - The target audience has the responsibility to ensure their compliance with this document by: • Ensuring any training required is attended and kept up to date. • Ensuring any competencies required are maintained. • Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.	All employees covered by the Medicine Control and Administration Policy – Acute, who may be involved with Controlled Drugs directly employed by the Trust whether permanent, part-time or temporary (including fixed-term contract). It applies equally to all others working for the Trust, including private-sector, voluntary-sector, bank, agency, locum, and secondees. For simplicity, they are referred to as 'employees' throughout this policy		
Special Cases	Only Registered Nurses directly employed with the Trust can act as the responsible holder of Controlled Drugs (CD) keys.		
Accountable Director	Medical Director		
Author/originator – Any Comments on this document should be addressed to the author	Director of Pharmacy and Medicines Optimisation		
Division and Department	Diagnostics and Outpatients. Pharmacy.		
Implementation Lead	Controlled Drug Accountable Officer		
If developed in partnership with another agency ratification details of the relevant agency	N/A		
Regulatory Position	The Misuse of Drugs Act 1971 (Ref 6). The Misuse of Drugs Regulations (Safe Custody) 1973 (Ref 19). The Misuse of Drugs Regulations 2001 (Ref 20). Controlled Drugs (Supervision of Management and Use) Regulations 2013 (Ref 10).		
Review period. This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.			

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1 Introduction & Purpose

1.1 Introduction & Purpose

The purpose of this policy is to promote the safe and effective use of controlled drugs (CDs) within the Great Western Hospitals NHS Foundation Trust (the Trust). Its aim is to have a robust system for the safe management of CDs that takes into account current legislation and regulations whilst ensuring appropriate and convenient access for patients that require them.

The use and management of CDs falls under legislation including the Misuse of Drugs Act 1971 (Ref 6), the Misuse of Drugs Regulations (Safe Custody) 1973 (Ref 19), the Misuse of Drugs Regulations 2001 (Ref 20) and Controlled Drugs (Supervision of Management and Use) Regulations 2013 (Ref 10). CDs could be prone to misuse, abuse, could cause significant harm or might be obtained illegally. Supply to outside units will be according to the requirements of the Wholesaler Dealers Authority and the Home Office Licence for the Supply of Controlled Drugs (Ref 13). Legislation stipulates how CDs are procured, stored, transported, supplied, prescribed, administered, recorded, disposed of and possessed. CDs are classified into five schedules according to the level of control attributed to each. A summary of these schedules is shown below:

	Schedule 1	Schedule 2	Schedule 3	Schedule 4 (part 1)	Schedule 4 (part 2)	Schedule 5
Designation	CD Lic POM	CD POM	CD no register POM	CD Benz POM	CD Anab POM	CD INV P or CD INV POM
CD Prescription requirements apply	No therapeutic use – Home office license required for use. Use only permitted in clinical trials and in exception circumstances	Yes	Yes	No	No	No
Prescription validity	n/a	28 days	28 days	28 days	28 days	6 months

Supply to outside units will be according to the requirements of the Wholesaler Dealers Authority and the Home Office Licence for the Supply of Controlled Drugs (Ref 13).

Where a CD related activity is required to be witnessed, a ‘witness’ is defined as a registered healthcare professional (HCP), including doctors, pharmacists, nurses, midwives, Operating Department Practitioner (ODPs) and pharmacy technicians (PT).

Other registered healthcare professionals may act as a witness but this is at the discretion of the ward sister/charge nurse.

The ward sister/charge nurse may also authorise a final year student nurse or midwife to act as a witness.

Whenever a witness is required for a CD related activity, the entire process must be witnessed. Whenever the first HCP documents or signs, the witness must counter sign. The witness must directly observe the activity.

1.2 Medicines that Require Higher Level of CD Controls

Some medicines including CDs may be required to meet some of the requirements of a CD schedule of a higher level of control following agreement by the Controlled Drug Accountable Officer (CDAO). The CDAO may use investigational software to monitor controlled drug usage, prescribing and potential risks of unintended use which may be considered during any risk assessments. All employees must follow these higher levels of control as instated by the Great Western Hospital (GWH) CDAO. Medicines may be assigned a higher level of control following a CD incident. 12 month CD audit requirements will apply to all medicines managed as a CD regardless of legal classification.

Table 1: Medicines that require higher level of CD control Trust wide

Drug	Legal Classification	Higher level controls required for all GWH clinical areas
Morphine Sulphate oral solution 10mg/5mL	POM (No full CD prescription requirements)	• Order and supply as a CD • Administer as per CD administration requirements • Record as a CD • Store as a CD
Tramadol **(all preparations)**	CD Schedule (Sch) 3	• Order and supply as CD • Administer as per CD administration • Record as a CD • Store as a CD
Midazolam **(all preparations)**	CD Sch 3	• Order and supply as CD • Administer as per CD administration • Record as a CD • Store as a CD
Potassium Chloride **(Ampoules, 1.5g/10mL)**	POM	• Order and supply as a CD Intensive Therapy Unit (ITU only) • Administer as per CD administration • Record as a CD • Store as a CD
Gabapentin	CD Sch 3	• Order and supply as CD • Administer as per CD administration • Record as a CD • Store as a CD
Pregabalin	CD Sch 3	• Order and supply as CD • Administer as per CD administration • Record as a CD • Store as a CD

1.3 Glossary/Definitions

The following terms and acronyms are used within the document:

%	Percentage
CD	Controlled Drug
CDAO	Controlled Drug Accountable Officer
CDLIN	Controlled Drug Local Intelligence Network
CDRB	Controlled Drug Record Book
DDON	Divisional Director of Nursing
DH&SC	Department of Health & Social Care
EIA	Equality Impact Assessment
EPMA	Electronic Prescribing and Medicine Administration
EVT	Estimated Volume Transferred
GWH	Great Western Hospitals
HCP	Health Care Professional
ITU	Intensive Therapy Unit
mg	Milligrams
mL	Millilitres
MMT	Medicines Management Technician
MSO	Medicines Safety Officer
NHS	National Health Service
ODP	Operating Department Practitioner
PCA	Patient Controlled Analgesia
PCEA	Patient Controlled Epidural Analgesia
PO-CD	Patient's Own Controlled Drug
PO-CDRB	Patients Own Controlled Drug Record Book
POM	Prescription Only Medicine
PT	Pharmacy Technician
RN	Registered Nurse
Sch	Schedule
SCHS	Swindon Community Health Services
SOP	Standard Operating Procedure
SWICC	Swindon Intermediate Care Centre
TTA	To Take Away (meaning for patient to take medication home upon discharge

2 Main Document Requirements

2.1 Safe and Secure Storage of Medicines

Store CDs that fall into Schedule 1, Schedule 2 and Schedule 3 (See section 1.1) under safe custody. The ward/area manager is responsible and accountable for all CDs within their area and their safe and secure storage.

The CDAO must approve all CD cupboard purchases. The ward sister/charge nurse must inform the CDAO prior to any CD cupboard purchase to ensure compliance with legislation.

Where it is not easy to control access to the CD cupboard because of its position in the ward/department, where there are large amounts CD stock, and/or there is not a 24-hour presence, the cupboard must be of a higher standard of security acceptable to the CDAO such as the 'Sold Secure Silver Standard'.

CDs must be stored in a locked cupboard which:

- Is firmly fixed to the wall at all times.
- Has sufficient storage space for the stock level of CDs held by the ward/department and hold stock to cover at least four days' worth of typical use.

- Does not need an external red light or be locked within another cupboard (if the cupboard has a red light already, this must be in working order).
- Must have a unique lock and key to all other locks in the organisation. Security key pads must not be used.
- Must be locked at all times except when a CD is being prepared for administration, a CD check is in progress or a CD is being checked in/out of the CD cupboard.

The CD cupboard is for storage of CDs, including clinical trial CDs and patients own CDs. Some high risk medicines are required to be stored in CD cupboards on the recommendation of National Health Service (NHS) National Patient Safety Alerts and apply to concentrated potassium infusions and epidural infusions. When high risk medicines are to be stored in the CD cupboard, a risk assessment will be undertaken by the Medicines Safety Officer and final authorisation will be given by the CDAO. Anything else other than the items listed above may only be stored in the CD cupboard following formal approval from the CDAO.

Placement of CDs within the cupboard must reduce the risk of errors occurring e.g. mis-selection of the wrong drug or strength for administration.

Place CDs on different shelves where confusion can occur e.g. Oxycodone modified release and Oxycodone plain release.

For areas that stock multiple strength CDs, e.g. Morphine, Diamorphine, or Midazolam, high strength CDs must be stored on separate shelves to help reduce risk. Label the shelf clearly with 'HIGH STRENGTH PREPARATIONS'.

CDs requiring refrigeration must be stored in a locked refrigerator. Epidural bags containing CD's may be stored within the CD cupboard, but different strengths or types must be clearly separated. No other infusion bags can be stored in a CD cupboard.

2.1.1 Controlled Drug Keys and Access to Controlled Drugs

CD keys must:

- Remain on the ward or department at all times except when the areas are temporarily or permanently closed to patients. Safe custody of CD keys must be discussed with a senior pharmacy representative.

- Never be left unattended or accessible to unauthorised persons.

- Be kept by the registered nurse (RN) / midwife / ODP (or delegated deputy) shift coordinator who is responsible for controlling access to the CD cupboard at all times during that shift. This responsibility may be delegated to another RN, midwife or ODP if the coordinator has to leave the ward or department for any reason.

- Only be handled by RN's / midwives / ODPs with a contract of employment with the Trust.

- Be kept on a separate key ring from other drug cupboard keys.

There must only be one set of CD keys per CD cupboard on the ward/clinical area. Patient controlled analgesia / Patient controlled epidural analgesia (PCA /PCEA) / Syringe Driver keys must be kept with CD keys. If CDs are stored in the fridge, the fridge key can remain with the non-CD drug keys.

The CD cupboard must only be accessed by:

- Employees authorised by the ward sister/charge nurse e.g. RN, midwife or ODP.
- All pharmacists and pharmacy technicians (PT) if carrying out CD checks as part of their professional role (except those with restrictions on practice as identified by the CDAO) as

authorised by the CD Accountable Officer and in the presence of a registered nurse for the area.

Only RN's / midwives and ODPs may access CDs for the purpose of administration. The RN / midwife / ODP must return the CD keys back to the coordinator when they have finished using them.

Medical employees must not handle or have direct access to the CD keys and CD cupboard. A nurse, midwife or ODP must accompany medical employees requiring access to the CD cupboard.

2.1.2 Missing or Lost CD Keys

The ward sister / charge nurse or appointed clinical manager and ward pharmacist must be informed immediately if the keys are missing and state if this includes the CD cupboard keys. If keys are missing out of hours, the on-call pharmacist must be contacted who may then seek advice from a senior pharmacist.

Every effort must be made immediately by the designated key holder to find the keys or retrieve them from employees working the previous shift. If an employee finds they have gone off duty with the keys they must inform the ward/department immediately. If the keys are identified as having been taken home by an employee, the employee must be informed that they must return the keys immediately.

If controlled drug keys cannot be accounted for, the equipment team must be contacted and permission given for the lock to be broken. All controlled drugs must be transferred to another controlled drug cupboard under the verbal direction of a pharmacist. They must be checked by two registered people (one of whom can be a pharmacist) and documented in the Controlled Drug Record Book as transferred to another cupboard. On no account should it be assumed that medicines are secure if the medicine keys cannot be accounted for. An incident notification form must be completed immediately and the CDAO informed by the next working day.

2.2 Ordering of Controlled Drugs

The sister/charge nurse is legally responsible for the ordering of CDs for their area even if the task is delegated to another RN, midwife or ODP. When a CD is dispensed from pharmacy it is supplied directly to a ward or department against a ward / departmental requisition in accordance with legislation (Ref 12). Only a RN, midwife or ODP with a contract of employment with the Trust can order CDs for a ward or department.

2.2.1 CD Stock Lists

The Trust's Pharmacy Dispensary Manager in association with the Pharmacy Clinical Lead is responsible for maintaining the pharmacy CD stock list database. The CD stock list for clinical areas storing CDs must:

- Be agreed by the sister/charge nurse/matron, divisional pharmacist (supported by the ward pharmacist) and the pharmacy medicines safety officer.
- Include minimum stock levels for each line.
- Be updated if practices change.
- Be reviewed every 6-12 months by the sister/charge nurse and pharmacist.
- Be accurate, up-to-date and clearly visible inside the CD cupboard.

Amendments (including additions) to CD stock lists must be requested via Pharmacy by the ward pharmacist or technician, approved by a senior pharmacist e.g. divisional pharmacist (or nominated deputy) and authorised by the Pharmacy Medicines Safety Officer. The Pharmacy stores team must make any amendments to the pharmacy electronic system. The local CD stock list must be updated to reflect any changes. All non-stock CD orders need to be ordered against an individual patient and verified by a pharmacist prior to supply.

2.2.2 Authorised CD Signature List for Ordering CDs

Staff ordering CDs must be listed on a CD ordering signature (Appendix D) list which applies to a single ward / clinical area managed by a sister or charge nurse. The list is valid for one year from authorisation by the ward sister/charge nurse. The master CD ordering signature lists must be kept by pharmacy.

If there have been employee changes (e.g. newly employed by the Trust, employees who change wards or departments, or who change their name), the sister/charge nurse/matron must instruct the employee to sign the original CD signature list in pharmacy. It is the ward sisters/charge nurse responsibility to ensure details of employees who no longer work in their clinical area are removed from the CD signature list. Pharmacy will not supply CDs against any CD order if the signature is not on the list held in pharmacy and it is not authorised on the list by the ward sister.

A copy of the ward/department signature list must also be kept in a locked room by the ward sister/charge nurse. For theatre areas, the area manager must keep this list.

2.2.3 Completing a CD Order

CD orders must be clearly written using approved stationary and must include:

- Only one preparation is to be recorded on each page.
- Name of hospital.
- Ward or department.
- Drug name, form and strength.
- Total quantity/volume/ampoule size of preparation.
- Signature and printed name of the (registered nurse) RN / midwife / ODP.
- Date.

Requisitions for CDs can only be signed by a RN/midwife/ODP. Pharmacists, pharmacy technicians and doctors cannot request controlled drugs for a clinical area. For Prospect Hospice CD requisitions completed by a nurse need to be countersigned by a doctor.

An original order must be used to order CD's in urgent situations, however, with prior agreement by phone call with the Pharmacy Dispensary Team Leader, an emailed order to **gwh.pharmacydispensary@nhs.net** for a CD may be sent. The CD will not be released until receipt of the original document. A telephoned verbal order from a doctor for a CD will not be accepted.

Requests for CDs must be made available to pharmacy before 12 noon during core hours (Monday to Friday 08:45 – 17:30) if needed for the same day. Requests submitted after this time will only be completed if there is an urgent clinical need. **CDs must not be borrowed between wards and departments without pharmacy authorisation. Contact the on-call pharmacist if CDs are required out of hours.** The ward sister/charge nurse or shift coordinator must ensure that CD stocks are adequate to avoid the need to contact the on-call pharmacist unnecessarily outside of pharmacy opening hours.

2.3 Record Keeping

Records of all CDs received onto a ward/department, administered to patients, destroyed or returned to pharmacy must be kept. Controlled Drug Record Books (CDRB) and CD order books must be supplied from Pharmacy and must be stored securely in the CD cupboard. Store all complete CDRB for two years after the last entry / date of use. After two years, CDRB may be placed in the confidential waste. The ward sister / charge nurse must keep all CDRB up to date and in good order. All wards / departments must only have one CDRB or PO-CDRB in use at a time. A small number of areas may need more than one CDRB to be in use but this must be approved by the CDAO. Requests for replacement CDRB or PO-CDRB must be made by filling out a request in the ward / department CD order book and sending to pharmacy for issue. CD order books will be reissued once all requisitions have been made from the book.

Write in blue or black ink (pharmacy employees may use green ink). Only one preparation is to be recorded on each page.

Bracket errors or place a single line through any errors made in the CDRB. Make corrections in the margins or footnotes. The original entry must remain clearly legible.

- Do not cancel/obliterate/alter entries.
- Any corrections must be signed, dated and witnessed.
- Do not use correcting fluid.

Loss or theft of any controlled drug stationary must be reported as soon as possible to the Director of Pharmacy and the CDAO. An incident notification form must be completed immediately.

2.4 Receipt of CDs by Wards and Departments

2.4.1 Collecting and Delivering CD Stock Orders from Pharmacy

- CDs can be collected by any grade of Trust employee including Trust volunteers. Employees that are not registered practitioners who collect and transport CDs are known as CD messengers.
- Employees acting as a CD messenger must ensure their destination is known, be aware of the safe storage and security of CDs and the importance of handing over the CDs to a registered practitioner on delivery to the ward or department.
- All employees collecting CDs must have their relevant identification with them.
- The employee must check the medicine against the requisition for correct name/item, strength, preparation, quantity, requisition number, expiry date.
- Full, sealed original containers do not need to be opened.
- Any discrepancies must be reported to pharmacy immediately by the receiving employee.
- Sign and date the requisition on the accepted for delivery line by the receiving employee.
- Tear out the white copy as this is retained in pharmacy for their records.
- Repeat this for all requests in the order book.
- CDs must be placed in a green pharmacy bag and sealed with a tamper proof tag to be transported to the ward/clinical area.
- The CD messenger must sign the pharmacy green bag collection log.
- The CD messenger is responsible for ensuring the safe delivery of the CDs to the ward or department and handing to a registered practitioner (if they themselves are not one) on arriving on the ward for prompt receipt into the CD register.
- The bag must then be given to a registered practitioner for immediate receipt into the register and CD cupboard.
- Registered practitioners accepting delivery of CDs via the pharmacy CD messenger must check the number on the tamper proof seal matches that written on the CD delivery log.
- They must sign and print their name on the CD delivery log next to their clinical area.

2.4.2 Receipting CDs into Stock

At no time should delivered CDs be left unattended. When CDs are received onto the ward they must be receipted immediately into the register. The registered practitioner must:

- Check the medicine against the requisition for correct name/item, strength, preparation, quantity, requisition number, expiry date.
- Find the correct page for the medicine in the CDRB and make an entry of receipt in the appropriate column.

The following details must be recorded:

- Quantity/Volume received.
- Date received.
- Requisition number.

- Received from pharmacy.
- Two signatures of registered employees.
- Total balance.

The opening of the sealed bag must be completed in the presence of a second registered person. The balance must be checked and certified as correct. Discrepancies that cannot be rectified must be reported to most senior employee on shift and process for dealing with CD discrepancies followed. The stock must then be locked away in the CD cupboard.

2.5 Patient Own Controlled Drugs (PO-CDs)

PO-CDs are the property of the patient and must only be used for that patient. PO-CDs may be used on discharge if there is no change to the prescription and it is appropriately labelled, packaged and in date. RN/ODP/Midwives when handling PO-CDs

Do not:

- Transfer PO-CDs of deceased patients to the mortuary.
- Store in the bedside POD locker.
- Transfer PO-CDs if a patient is transferred between different areas within the GWH without pharmacy support.

It is essential the PO-CDs are signed out of PO-CD register and into the PO-CD register at their new destination.

All PO-CDs must be recorded in the PO-CD register. This will provide a full and complete record of PO-CD received, destroyed or returned. If a patient's own register is not available a page may be allocated at the back of the CD Register and a PO-CD register ordered from pharmacy. A separate page must be used for each medicine and each patient. The following details must be recorded

- Date.
- Patient's name.
- Name of medicine.
- Form of medicine.
- Strength of medicine.
- Quantity received.
- Two signatures of registered employees.

PO-CDs must not be routinely used, however, if it is deemed necessary then it is essential to check the PO-CD is the patient's own, the medicine is within the expiry date and the medicine is clearly identifiable with the name and strength visible. PO-CDs in a dossette box or compliance aid must not be used apart from exceptional circumstances and only following authorisation from a pharmacist or technician who has assisted in medicine identification. Administration of PO-CDs follows the same rigour and process as required for stock CDs.

Where a patient's own CD is no longer required and the patient is still on the ward permission from the patient must be sought before removal and destruction. If a PO-CD is not returned to a patient on discharge it must remain in the CD cupboard and PO-CD register until a pharmacist or technician can remove it.

2.6 CD Stock Checks/Audits on Wards and Departments

The sister/charge nurse is responsible for ensuring that a RN / midwife / ODP witness checks all CDs every 24 hours (minimum). For clinical areas that are not open seven days a week checks need to be completed at least once every 24 hours when the service is operational. In theatre areas balance checks must be completed each morning in each theatre. A further check must be completed at the end of the day and recorded as noted below at the back of the register. The stock check must confirm that only CDs on the stock list or CDs for named patients are stored in the CD cupboard. The ward

sister/charge nurse must aim to rotate this activity regularly through the team to avoid the responsibility falling on one or two individuals.

Ensure the treatment room where the CD check is taking place is free from distraction and the work bench is clear of other medicines**.** The process for checking by the RNs / ODPs / midwifes includes:

- Removing all items from the CD cupboard.
- Each CD should be checked for quantity, expiry date and correct register entry.
- **Check stock balances of liquid medicines by visual inspection**. If there is a noticeable discrepancy, conduct a volume check.
- A physical balance check of CD liquids should take place at the end of each bottle using an oral syringe.
- If the contents and the balance are correct, place the item back in the CD cupboard.
- Add an entry stating "Balance checked and correct" noting the date and the signatures of two registered practitioners. Complete for all stock CDs.

For PO-CDs follow the same procedure as for stocks CDs listed above. PO-CDs must be recorded in the PO-CD register but in exceptional circumstances there may be occasions it is recorded at the back of the stock CD register. Order a new PO-CDR as soon as possible (beginning of next working day) and then immediately transcribe entry into new PO-CDR. For PO-CDs that are no longer required or the patient has been discharged contact a pharmacist or technician who will remove as soon as possible.

If any discrepancies are noted then refer to the section in this policy that deals with discrepancies. Compliancy will be audited as part of the CD six monthly audit carried out by pharmacy.

2.7 Key Holding and Access to Controlled Drug Keys

The Ward/Department Manager is responsible for the keys to all CD cupboards though this responsibility may be delegated to a senior RN/ODP/Midwife.

No more than one set of CD keys is to be in use on the ward for each CD cupboard. A spare set may be kept in Pharmacy.

Only one set of CD keys per cupboard will be in use on a Ward/Department. On the Wards / Units where there are separate CD cupboards (such as Maternity, the Emergency Department and Theatres), the keys for these cupboards may be held separately as required by operational situations.

The keys must always be in possession of a registered employee of the Trust, and the Ward Manager must ensure that there are systems in place to ensure that all sets of keys are secure and are accounted for regularly.

CD keys must be on a separate key-ring to the other keys. This makes it easier to ensure only those requiring access to CDs are in possession of the keys and therefore improves the audit trail.

If the CD keys cannot be located the ward manager must complete an electronic incident form a local investigation must be undertaken, and the Matron and Divisional Director of Nursing (DDoN) informed if the keys cannot be located. The CDAO must also be informed. If the key is not found, then Serco must be contacted urgently by the ward manager to change the locks (even when a spare set of keys exists).

2.8 Administration of CDs

Refer to administration of medicines in the 'Trust Medicine Control and Administration Policy – Acute' (Ref 21) for the requirements of administration. Controlled Drugs for continuous intravenous infusion must be prepared immediately prior to administration. Two HCPs must be involved in the entire process. One HCP must be a RN / midwife / ODP. The entire process and all documentation must be witnessed.

The procedure for administration includes:

1. The RN / midwife / ODP and witness must both access the patient's prescription.

2. Removing the prescribed CD from the CD cupboard. Checking the stock balance recorded on the page of the CDRB against the contents of the container. Any discrepancy must follow the discrepancy process detailed in this policy.
3. Preparing the dose to be given against the prescription, carefully checking all details.
    a. **For CD injections**: Only the dose that is intended to be administered should be drawn up and taken to the patient, e.g. if 5 milligrams (mg) is required only 5 mg should be drawn up from a 10mg vial. The remainder must be destroyed.
    b. **For liquid preparations:** Use an appropriate enteral syringe and bottle bung to draw the liquid directly from the bottle to avoid loss of liquid.
4. Documenting in the CDRB:
    - Date and time when dose removed from the CD cupboard.
    - Name of patient.
    - Dose to be administered.
    - Balance left in stock.
5. Returning the remaining CDs and CDRB to the CD cupboard ensuring the new balance is correct. Lock the CD cupboard.
6. The RN / midwife / ODP and witness must attend the patient's bedside for administration of the dose.
7. Ensuring dose is being administered to correct patient by checking patient details, wrist band and prescription prior to administration.
8. Explaining the CD and the administration process to the patient, gaining implied consent.
9. The RN / midwife / ODP caring for the patient will administer the CD in the presence of the witness.
10. The nurse / midwife / ODP and witness must sign (electronically / physically) the prescription chart for administration only once the drug has been administered to the patient.
11. Discarding any medicines prepared and not used, or partly used, in the presence of the second HCP witness into a sharps bin.
12. Making a record of this disposed medicine in the CD register e.g. if the patient is prescribed 5mg of morphine and only a 10mg preparation is available the record should show 5mg administered and 5mg wasted.`

CDs must only be administered by injection in accordance with a signed prescription. Intravenous CDs may only be given by a Medical Practitioner, or ODP, RN or midwife who has a current Insertion and Maintenance of an Intravenous Cannula Competency (Ref 22).

2.9 Transport of Controlled Drugs within and outside of the Hospital

All staff must be aware of how to transport CDs. Transport CDs in a secure tamper evident container except if transferring a CD with a patient as part of a PCA / PCEA / epidural / opiate infusion. Do not transport CDs or CD stationary / paperwork using internal mail or air tube systems. There must be an audit trail to identify who has custody of the CD at any point in the journey. Where a CD moves from the authorised possession of one person to another, signatures for receipt and delivery must be obtained by the person handing over the drug and the person receiving it e.g. on delivery forms or in CDRBs.

An authorised messenger is a person who transports the CD who must:

1. Be a RN, midwife, ODP, nursing assistant, hospital porter, assistant practitioner or any member of ward/department staff authorised by the nurse or midwife in charge of a ward/department.
2. Be a pharmacist, pharmacy technician, pharmacy assistant or some porters authorised by the CDAO to nominated areas e.g. SWICC.
3. Know the end destination for delivery of the CD.
4. Deliver the intact sealed bag to its destination.
5. Hand the CDs to a RN / midwife / ODP immediately on arrival at the destination ward/department.
6. Never leave the CDs unattended.
7. Have a GWH Trust identification badge.
8. Be aware of safe storage and security requirements for CDs.

9. Sign the pharmacy dispensary collection sheet on collection of the CD acknowledging collection of a sealed bag (not taking responsibility for accuracy of what has been supplied).

2.9.1 Transport outside of the Great Western Hospitals Site

1. Taxis are never to be used to transport CDs.
2. Severn freewheelers (SFW) may be used when there has been a break down in usual transport arrangement or in emergencies. For all deliveries of CDs outside of the GWH, collection of the medicines must be from Pharmacy, or in exceptional circumstances, from ED reception where CD medications for off-site delivery are stored within the ED reception CD cupboard and the iRespond 'Transport, Medicines, Equipment, Notes' documented process has been followed (Ref24) . Pharmacy will follow the Standard Operating Procedure (SOP) D-S-D001 (Ref 23).

The authorised messenger must not be the person who ordered the CD.

2.9.2 Transfer of Patients with Patient Controlled Analgesia, Patient Controlled Epidural Analgesia and Opiate Infusions

A RN / midwife / ODP and witness on the transferring ward/department must record the following in the CD register:

1. The estimated volume in the PCA / PCEA or infusion being transferred with the patient in the wasted section. Use the abbreviated estimated volume transferred "EVT". This must be witnessed.
2. Date and time of the transfer and the drug details.
3. Ward department the patient is being transferred to.

A RN / midwife / ODP and witness on the receiving ward must record the following in the PO-CD register:

1. Patient details.
2. Date of the transfer and details of the drug.
3. The estimated volume remaining in the PCA, PCEA or infusion.

If the PCA/PCEA/Infusion being transferred is discontinued prior to the syringe or bag completing, the contents of the syringe/bag must be destroyed immediately (and not left unattended). Record the destruction in the PO-CD register. This must be witnessed.

2.9.3 Transfer of Non-Stock and Patient Own Controlled Drugs if the patient is moving to another GWH ward/department

During pharmacy opening hours, the ward pharmacist or pharmacy technician (under the direction of the pharmacist) will act as witness to the transfer. Out of pharmacy opening hours, contact the on-call pharmacist for authorisation of the transfer. The on-call pharmacist must inform the Divisional Lead Pharmacist by e-mail so the transfer can be checked by a pharmacist/ pharmacy technician within a maximum of 96 hours. If a transfer occurs without authorisation of the on-call pharmacist, complete an incident form. Outside of pharmacy opening hours, a RN/midwife/ODP can act as a witness instead of pharmacy staff.

The process for transfer includes:

1. A RN / midwife / ODP and pharmacist/technician must collect the CD from the ward.
2. The RN / midwife / ODP and a RN / midwife / ODP from the ward that the CD was originally supplied to must sign the CD out of the PO-CDRB together – the pharmacist/technician must witness this.
3. The RN / midwife / ODP and pharmacist/pharmacy technician must take the CD to ward where the patient is.

4. The RN / midwife / ODP and pharmacist/pharmacy technician delivering the CD must check the CD into the PO-CDRB on the receiving ward. The RN / midwife / ODP from the receiving ward must witness this.
5. Lock in the CD cupboard.

2.10 Controlled Drug Returns, Disposal and Destruction of Controlled Drugs

CDs must be unrecognisable, unusable as a CD and in a manner that renders them unsalvageable as a CD when discarded or destroyed. CDs must not be returned to pharmacy from wards/departments in a pharmacy green bag, crate or bin*. CDs can only be removed by a pharmacist or a pharmacy technician*. In the absence of a ward based pharmacist or pharmacy technician contact the medicines optimisation lead technician on bleep 1336 to arrange removal. Any CD(s) removed by a pharmacist / pharmacy technician must be witnessed by a ward / department nurse / midwife / ODP and recorded in the appropriate CD register which must include:

1. Date of removal.
2. Quantity being removed.
3. Reason for removal.
4. Signature of the pharmacist/pharmacy technician and appropriate witness.
5. Balance remaining.

Any discrepancies need to follow the discrepancy process in this policy and an incident notification form completed.

The pharmacist/pharmacy technician will also complete an appropriate CD return sheet (Appendix B) which will detail:

1. Controlled drug name, form and strength.
2. Quantity being returned.
3. Pharmacist/Pharmacy Technician name and signature.
4. Nurse/Midwife/ODP name and signature.
5. Destruction register identification.
6. Date returned.
7. Name of person entering into the pharmacy register or destruction book.

Once returned to pharmacy, pharmacy employees will follow the SOP for returning GWH ward/unit CDs to pharmacy for destruction. The relevant SOP will also be followed by Pharmacy employees for the destruction of expired / damaged pharmacy stock.

2.10.1 Denaturing and Disposal of “wasted” or part-use of CDs at Ward / Theatre Level

Only RNs, midwives or ODPs are able to destroy small volumes of “wasted CDs” at ward level. This must be witnessed and recorded in the appropriate CD register. Destruction must take place immediately. Wastage may materialise from:

- A dose/part doses being prepared for administration but not fully administered.
- A dose/part being prepared for administration but not administered at all.
- Discontinuation of an epidural / opiate infusion / syringe driver / PCA / PCEA.

All CDs that require “wasting” must be disposed of in the pharmacy supplied denaturing kits. Once these kits are full they are to be returned to pharmacy for a replacement kit. Any clinical area that regularly disposes of liquid CDs resulting in significant pooling (e.g. areas using and wasting CDs from syringes / PCA / PCEAs / epidurals) in the yellow sharps bin should use “gel vac sachets” (obtained from NHS supplies) to act as an absorbent base to render the CDs irretrievable. An appropriate entry into the register to reflect the waste must be made. CDs must never be discarded down the sinks or drains.

2.11 Prescribing of Controlled Drugs

CDs may be prescribed by registered medical practitioners. Non-medical prescribers who are independent prescribers may also prescribe CDs, and this is detailed in the Non-Medical Prescribing Policy (Ref 8). CD use which is part of the midwives exemption list is described in the Trust Medicines Control and Administration Policy (Ref 21).

If CDs are prescribed for outpatients or for patients to take away (TTA) on discharge, the instructions on the prescription sheet must state in the doctor's or dentist's handwriting, in words and figures, the dose and total quantity of the medicines to be supplied by the Pharmacy. A proforma prescription sheet for CDs is available on the Pharmacy Intranet pages. Prescriptions generated via the Electronic Prescribing and Medicine Administration system (EPMA) will automatically be populated with the appropriate details, but will need to be signed by the prescriber.

The prescribing or use of controlled drugs by supplementary prescribers, independent prescribers and in patient group directions is described in the Trust policies on non-medical prescribing policy and patient group direction policy.

2.12 Managing Controlled Drug Discrepancies and Incidents

Any loss of CD must be reported regardless of volume or quantity. No percentage of “loss” is permitted for CD oral liquids. The balance in the CD record books must tally with the CDs in the cupboard. All CD balance changes in all CD registers that are required as a result of a suspected loss are required to be countersigned by a pharmacist/pharmacy technician. The discrepancy should be reported to the ward/department/theatre manager or the most senior member staff immediately and the ward pharmacist or on-call pharmacist if it is discovered out of hours. An incident notification form and a possible loss of CD form, Appendix C, (if appropriate) must be completed and a thorough investigation must take place within 48 hours of discovery. Missing CD stationary must be treated as a CD incident. Treat any missing CD from boxes that appear sealed as a CD incident.

Discrepancy Discovered

Inform the ward pharmacist (or on-call pharmacist if out of hours who must forward the details to the relevant divisional lead pharmacist)

Two RNs/midwives or ODPs must immediately check that:
All requisitions received have been entered on the correct page of the record book(s)
Administered CDs prescribed for inpatients have been entered into the CD record books
No item has been accidently put in the wrong place or cupboard
All calculations of previous balance checks are correct

Error/omission traced and clear/obvious calculation error

Two RNs, midwives or ODP must:

- Make an entry in the relevant CD register clearly stating the reasons for the entry.
- Correct the balance and sign the entry.
- Report the calculation error via incident reporting.
- Add incident number to entry in the register
- Do not complete a possible Loss of CD Form.

Excess less than 10 per cent (%) noticed in bottle containing CD liquid when balance in register states zero

Two RNs, midwives or ODP must:

- Measure the volume remaining.
- Correct the balance in the register.
- Do not complete a possible Loss of CD Form.
- Report the discrepancy via incident reporting.
- Add incident number to entry in the register

Excess more than 10% noticed in bottle containing CD liquid when balance in register states zero

Two RNs, midwives or ODP must:

- Measure the volume remaining
- Correct the balance in the register
- Follow "**Error/Omission traced but not simple calculation error or error/omission not traced"**

"Error/Omission traced but not simple calculation error or error/omission not traced"

- Two RN's, midwives or ODPs must start the possible Loss of CD Form (Appendix C)
- The ward pharmacist and ward sister/charge nurse, manager (or assigned deputy) must complete a basic investigation and document their findings on the possible Loss of CD Form and report the error via incident reporting. Add incident number to entry in the register.
- Attach the possible Loss of CD Form to the incident.
- The ward pharmacist must forward the possible Loss of CD Form to the Divisional Lead Pharmacist and CDAO via email (gwh.cdaccountable.officer@nhs.net) and include the incident reference number.
- CD incidents of this category must only be closed by the ward sister/charge nurse, manager following investigation from the divisional lead pharmacist. This investigation must be documented on the possible Loss of CD Form.
- The divisional lead pharmacist must escalate any concerns to the CDAO, particularly if no explanation is found for the CD incident and any incident involving the loss of a CD liquid of over 10% of the container it was supplied in.

It is important to remember that any discrepancy may indicate misuse. The Trust's CDAO will report all CD incidents to the Controlled Drug Local Intelligence Network and the Trust Security Lead on a quarterly basis should any serious incidents involving CDs, CDs Storage or CDs stationary occur.

2.13 Incident Review Outcomes

The divisional lead pharmacist and CDAO may review drug use using CD investigational software e.g. ADIOS®. Depending on the incident the CDAO may request a full CD stock check from the ward pharmacist and ward manager. Following an incident review the CDAO may recommend the following:

- An appropriate period of monitoring and review date.
- Any extra controls that are required whilst during the period of monitoring.
- Access to the CD cupboard is reviewed by the ward/department manager.
- Access to the medicines storage area is reviewed by the ward/department manager.
- That the ward manager reviews and sends confirmation to the CDAO that all employees involved in the handling of CDs have read and understand this policy and are deemed competent by the ward manager.
- Daily CD checks may be increased until the monitoring period review date from the CDAO. A database will be maintained of all areas that have extra monitoring requirements. The CDAO will document on the database and communicate with all staff involved when these extra requirements have been lifted.

2.14 Suspicion of Theft or Diversion of a CD

If theft or diversion of a CD by an employee is witnessed or suspected, the senior RN, midwife or ODP in charge of the shift and the matron must be informed immediately to deal with the situation. The ward pharmacist (or on-call pharmacist out of hours) must be informed immediately. The ward or on-call pharmacist must inform the CDAO who will inform security and the relevant duty manager. The need to escalate any concerns to the CDAO is at the discretion of the senior employee involved. Any concerns that are deemed to cause immediate harm to patients/employee/visitors must be escalated to the CDAO.

The CDAO is responsible for informing the police if criminal activity is suspected. Ward employees must not contact the police unless instructed to do so by the CDAO.

In addition if there are any concerns about unusual, excessive or inappropriate prescribing of CDs this must be reported to the Director of Pharmacy / CDAO who will undertake an investigation. Trust employees should not feel that they need to prove any concerns, they only need reasonable belief that something untoward may be happening.

2.15 Suspected Illicit Substances

Suspected Illicit drugs are those preparations where possession is illegal such as Cannabis, Cocaine etc. The procedure for handling these drugs is described in the Security Policy (Ref 4).

Safe storage requirements apply in the interim. Any suspected illicit drug must be stored in the CD cupboard until security and pharmacy are informed. It needs to be entered into the patient's own CD register as "Suspected Illicit Substance". Pharmacy will remove the suspected substance and quarantine it in pharmacy for 30 days after procession and then destroy it.

2.16 Community Nursing

Within Swindon Community health Care Services (SCHS), Registered Community Nurses and Paramedics may administer CDs to a patient in their home environment, the following processes must be observed:

- Registered Community Nurses and Paramedics may administer CDs to a patient in their home environment without a witness. All medication administration must be documented on SystemOne and in the patient's paper notes.

- CD stock balance sheets will be held in the patient's home with the CDs and must be updated every time a CD is administered or received into stock.

- Whenever possible CD medication must be collected by a family member, carer or delivered directly to their home, however in an emergency these may be collected by a registered nurse/paramedic. The CDs must be taken immediately to the patients home and entered into the stock balance sheet.

- Small quantities of CDs may be destroyed in the patient's home in the following circumstances:

    - Remainder of part dose prepared for administration.
    - Contents of a syringe following discontinuation or change of the syringe driver contents. These should be disposed of by emptying onto an absorbent tissue and then placed into the patients yellow sharps bin.

- After a death, the patient's family should be asked to remove any CDs from the house for disposal at a Community Pharmacy. However, in certain circumstances (e.g. patient lives alone and has no family, or there is a risk of misuse) the nurse/paramedic may remove the medication and return to a community pharmacy for disposal as per the relevant SOP. If this occurs out of hours and there is risk of abuse contact the on call pharmacist for advice.

2.17 Private Patients Controlled Drugs

The Misuse of Drugs (Amendment No.2) Regulations 2006 require that private prescriptions for schedule 2 & 3 controlled drugs must be on a pink FP10PCD private prescription form. It is the prescriber's responsibility to obtain the pink prescription pads. The prescriber will need to obtain both the 'Private Controlled Drugs Self-Assessment Form' and the' Mandate for Private Controlled Drug Prescriptions forms(FP10PCDs) for supply of schedule 2 and 3 Controlled Drugs' from NHS England england.southcentral-CD@nhs.net and submit the completed forms back to NHS England . Only then will NHS England process the application for supply of these pink private prescription forms FP10PC directly to the prescriber and issue the prescriber with a six digit prescriber identification number.

The prescriber is responsible for the safe storage of the FP10PCD private prescription forms and for the disposal of unused prescription pads confidentially

The prescriber can obtain further supplies of personalised FP10PCD private prescription pads from Capita pcse.enquiries@nhs.net or http://pcse.england.nhs.uk/supplies/

Dispensing of FP10PCD private prescription forms

Private prescriptions for Schedule 2 or 3 CDs can only be dispensed in community pharmacies on pink FP10PCD prescriptions which have the six digit prescriber identification number.

Stock of Controlled Drugs

Controlled Drugs are not stocked in the Shalbourne outpatient department. The prescriber must not order stock of Controlled Drugs.

Reporting Incidents concerning Controlled Drugs

Controlled Drug incidents must be reported via the Trust incident reporting scheme and also to the CDAO via email gwh.cdaccountable.officer@nhs.net. The prescriber must inform the controlled drug accountable officer of any changes to contact details.

3 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring or audit method	Monitoring responsibility (individual, group or committee)	Frequency of monitoring	Reporting arrangements (committee or group the monitoring results is presented to)	What action will be take if gaps are identified
100% of Ward/Clinical area controlled drug balance checks are completed at least once daily and any discrepancies are recorded and investigated	Senior Sisters/ Charge Nurses/Ward Managers/Midwives review of wards. Part of monthly pharmacy CD checks	CDAO	Monthly pharmacy CD check/audit	Medicines Governance Group	Action via Medicines Advisory Committee
Controlled Drug Incidents are shared with the Local Information Network (CDLIN)	Quarterly reports completed and sent to the Local Information network	CDAO and Medicines Advisory Committee	Part of quarterly CDLIN report	Medicines Advisory Committee	Accountable Officer to share remedial actions with NHS England Accountable Officer
100% of ward/clinical area employees have completed the medicines management training tracker prior to handling controlled drugs.	Senior Sisters/ Charge Nurses/Ward Managers/Midwives review of mandatory training records	Senior Sisters/ Charge Nurses/Ward Managers/Midwives	Monthly mandatory training reviews	Divisional governance meetings	Action via Divisional Tri and escalation to Trust CDAO
Compliance with requirements of CD policy	Senior Sisters/ Charge Nurses/Ward Managers/Midwives review of wards.	CDAO	Annual full clinical area CD audit completed by pharmacy (Appendix E)	Divisional governance meetings	Action via Divisional Tri and escalation to Trust CDAO and Patient Quality Committee

4 Duties and Responsibilities of Individuals and Groups

4.1 Chief Executive

The Chief Executive is ultimately responsible for the implementation of this document.

4.2 Director of Pharmacy and Medicines Optimisation

The Director of Pharmacy and Medicines Optimisation is appointed by the Chief Executive as Controlled Drugs Accountable Officer for the Trust. They are responsible for putting in place controls around the security and use of Controlled Drugs, and the investigation of any discrepancies or incidents. They will liaise with senior colleagues within the Trust, and will be part of, and communicate matters of joint concern with other members of the Controlled Drug Local Information Network.

The Controlled Drugs Accountable Officer is responsible for:

- Ensuring that Trust policy is updated and reflects current guidance and legislation.
- Giving assurance through audit and monitoring that the policy is being followed across the Trust.
- Ensuring that the policy and subsequent updates are implemented across the Trust.
- Monitoring CD usage across the Trust.
- Instigating investigations where necessary into unexplained variances or concerns raised by employees.
- Sharing learning across the Trust and with the CD Local Intelligence Network (CDLIN)
- Attending the CDLIN.
- Providing an annual report to the Trust Patient Quality Committee.
- Reporting any concerns to the CDAO for NHS England.
- Appointing deputy(ies) to ensure suitable cover arrangements when off site and absent.

The CDAO deputy is the Deputy Director of Pharmacy.

The CDAO may deputise part of this activity to a deputy, but remain accountable for all parts of the above activity.

4.3 Ward / Department Manager

The clinical manager of a ward / department, who is a RN, midwife (or Operating Department Practitioner) must:-

- Ensure the safe and secure management of Controlled Drugs in their area. They may delegate control of access (‘key holding’) or other tasks to another registered employee, but they remain responsible for the implementation of this policy.
- Ensure that the employees they manage have read and been trained in this policy before carrying out duties involving CDs.

In areas where the manager is not a registered practitioner as described above, the responsibility for management of CDs may be delegated to an appropriately registered and experienced employee.

4.4 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

4.5 Target Audience – As indicated on the Cover Page of this Document

The target audience has the responsibility to ensure their compliance with this document by:

- Ensuring any training required is attended and kept up to date.
- Ensuring any competencies required are maintained.
- Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.

4.6 The Medicines Governance Group

This group will review this policy. It will also review the number of CD incidents as a standing item at each meeting. Resolution and further investigation of incidents will then be pursued and reported back by the Divisional representatives at the group.

4.7 The Trust Medicines Advisory Committee

This Committee will ratify this Policy and will also review the quarterly Controlled Drug Occurrence report sent to the CDLIN.

5 Further Reading, Consultation and Glossary

5.1 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	Ward and Department Based Epidural Analgesia (Non-Obstetric) for Adult and Children over 16 Policy	T:\Trust-wide Documents
2	NMC List of Midwifery Exemptions	WWW.NMC-UK.org
3	Medicine Control and Administration Policy	T:\Trust-wide Documents
4	Security Policy	T:\Trust-wide Documents
6	Misuse of Drugs Act 1971 and Revisions	www. Legislation.gov.uk
7	Patient Group Direction Policy	T:\Trust-wide Documents
8	Non-Medical Prescribing Policy	T:\Trust-wide Documents
9	Management of Patient Controlled Analgesia (Morphine) (for Adults) Policy	T:\Trust-wide Documents
10	Controlled Drugs Regulations	www.legislation.gov.uk
11	Safer Management of Controlled Drugs: a guide to good practice in secondary care (England) October 2007	www.england.nhs
12	The Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England Single Operating Model	www.Gov.uk
13	Wholesaler Distribution Authorisation	www.gov.uk
14	Home Office Licence for the Supply of Controlled Drugs	www.gov.uk
15	Prescribing, Storage and Administration of Potassium	T:\Trust-wide Documents
16	British Standards	www.BSIgroup.com
17	Safe Handling and Disposal of Sharps Policy - Trust wide	T:\Trust-wide Documents
18	Waste Policy	T:\Trust-wide Documents
19	The Misuse of Drugs Regulations (Safe Custody) 1973	www.gov.uk
20	Misuse of Drugs Regulations 2001	www.gov.uk
21	Trust Medicines Control and Administration Policy	T:\Trust-wide Documents
22	Insertion and Maintenance of Intravenous Cannula Competency	T:\Trust-wide Documents
23	Pharmacy SOP D-S-D001	Pharmacy Department

24	iRespond – Transport, Medicines, Equipment, Notes 00:013b version 2	iRespond

5.2 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

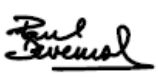
Job Title / Department	Date Consultee Agreed Document Contents
Deputy Director of Pharmacy	14/08/19
Divisional Lead Pharmacist	24/05/19
Matron, Gastroenterology and Respiratory	14/05/19
Non-medical Workforce Transformation Lead	10/05/19
Community Services Quality Lead	17/09/19

6 Equality Impact Assessment

An Equality Impact Assessment (EIA) has been completed for this document and can be found at Appendix A.

Appendix A - STAGE 1: Initial Screening For Equality Impact Assessment

At this stage, the following questions need to be considered:			
1	What is the name of the policy, strategy or project? Controlled Drugs Policy		
2.	Briefly describe the aim of the policy, strategy, and project. What needs or duty is it designed to meet? The purpose of this policy is to promote the safe and effective use of controlled drugs (CDs) within the Great Western Hospitals NHS Foundation Trust (the Trust). Its aim is to have a robust system for the safe management of CDs that takes into account current legislation and regulations whilst ensuring appropriate and convenient access for patients that require them.		
3.	Is there any evidence or reason to believe that the policy, strategy or project could have an adverse or negative impact on any of the nine protected characteristics (as per Appendix A)?		**No**
4.	Is there evidence or other reason to believe that anyone with one or more of the nine protected characteristics have different needs and experiences that this policy is likely to assist i.e. there might be a *relative* adverse effect on other groups?		**No**
5.	Has prior consultation taken place with organisations or groups of persons with one or more of the nine protected characteristics of which has indicated a pre-existing problem which this policy, strategy, service redesign or project is likely to address?		**No**

Signed by the manager undertaking the assessment	 Paul Devenish
Date completed	14/08/2019
Job Title	Director of Pharmacy

On completion of Stage 1 required if you have answered YES to one or more of questions 3, 4 and 5 above you need to complete a STAGE 2 - Full Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

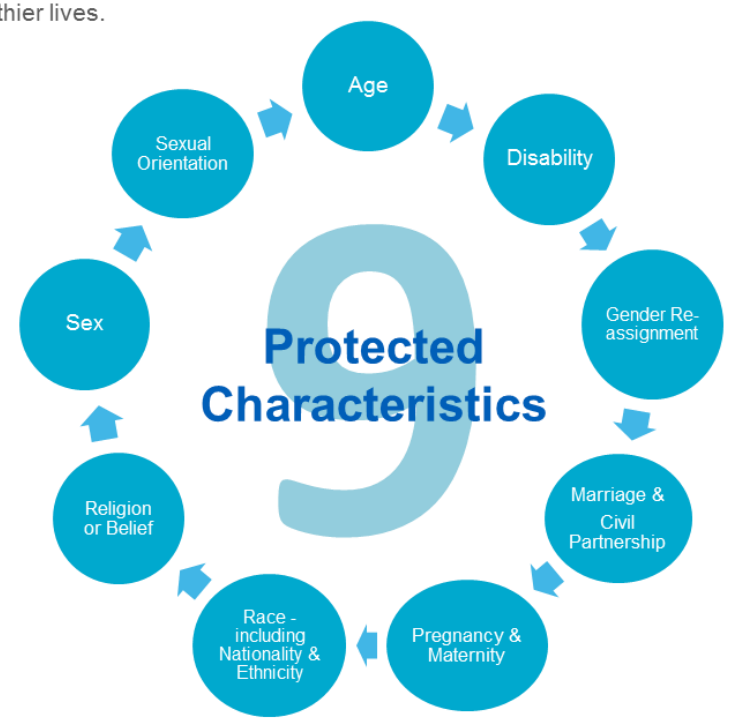
If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



Appendix B: Controlled Drug Returns – Patients Own

All CDs returned from the wards must be logged on this form and witnessed by another person on the ward (RN, MMT or ward Pharmacist), in order to create an audit trail. This sheet should be placed in the bag with the CD returns, and remain with the items until they are destroyed.

Ward:
Date returned:
Name & Signature of pharmacist/MMT: **Witnessed on ward by (name and signature):**

Drug name, strength and form	Quantity	Destruction Register Identification	Comments

Entered into destruction register by:
Date processed:

Appendix B: Controlled Drug Returns - Ward Stock

All CDs returned from the wards must be logged on this form and witnessed by another person on the ward (RN, MMT or ward Pharmacist), in order to create an audit trail. This sheet should be placed in the bag with the CD returns, and remain with the items until they are destroyed.

Ward:
Date returned:
Name of pharmacist/MMT: **Witnessed on ward by:**

Drug name, strength and form	Quantity	Destruction Register ID	Comments

Entered into destruction register by:
Date processed:

Great Western Hospitals NHS Foundation Trust

Appendix C: Possible Loss of Controlled Drug

(To be completed within 24 hours of loss or discrepancy being discovered or suspected)

PLEASE COMPLETE THE FORM IN BLOCK CAPITALS AND BLACK INK

ATTACH TO incident notification form

Email to: **gwh.cdaccountable.officer@nhs.net**

Division	
Specialty	
Date Senior Pharmacist Informed:	
Incident Number	Number:
Date DDON or professional lead unformed:	Date:
Date Director of Pharmacy/CDAO informed	Date:

Section One: To be completed by Clinical Area
Section Two: To be completed by Pharmacist/Pharmacy Technician
Section Three: To be completed by CDAO and/or Medicines Safety Officer (MSO)

SECTION ONE: To be completed by Clinical Area

Loss Discovered by:	NAME:
Reported to (Senior Nurse/ODP/Midwife)	NAME:
Time of Discrepancy	TIME:
Date of Discrepancy	DATE:
Details of Loss	
Quantity according to CD register	
Actual amount in stock	
Apparent Discrepancy	
DATE of last balance check in CD book	DATE:
Have all calculations in the register been reviewed for the CD in question	
Are there any calculation errors noted for the CD	
For liquid drugs is a purple bung in place	
Are ALL administrations recorded in the register	
Have any CDs been borrowed by another ward recently	

SECTION TWO: To be completed by a pharmacist/pharmacy technician.

Report of Pharmacy Investigation into Loss:
Pharmacy Recommendations for further actions:
Investigation reviewed by senior pharmacist: **Signature:** **Date:** **Name and position**

Section Three: Form to be returned to the CDAO **gwh.cdaccountable.officer@nhs.net**

Copy of possible loss of CD sent to:

- Deputy Chief Nurse.
- DDON for divisional team.
- MSO.

Comments from CDAO:

CDAO Signature:

Date:

Appendix D: Controlled Drugs Authorised Signature List

Ward/Clinical Area: _____

- The names and signatures of staff that are authorised to order controlled drugs for the ward/clinical area above must be provided in the table below.
- Controlled drugs will only be supplied against requisitions from those listed below.
- Staff members that are required to order controlled drugs must sign this signature list kept in Pharmacy.

Staff Name	PiN/Registration Number	Job Title/Role	Signature	Date

Appendix E: Full Clinical Area CD Audit

FULL CLINICAL AREA CONTROLLED DRUG AUDIT BY PHARMACY

Division:	Ward/Clinical Area:	Date:
Pharmacist/ Pharmacy Technician :	Nurse/Midwife/ODP:	

List actions to be completed after last stock check

Evidence of actions completed

Outstanding actions (and reasons not completed)

Audit Criteria	**Compliant with Trust Standards Y/N**	**Record any details required or discrepancies found in this column**
CD Stock list		
Is the CD stock list readily available on the ward?	Y / N	
Has the CD stock list been reviewed with the ward manager in the last 12 months?	Y / N	Date reviewed……
Is naloxone on the ward stock list? Is it in stock and in date?	Y / N	
If the ward stocks midazolam: is flumazenil injection on the ward stock list? Is it in stock and in date?	Y / N	
Have high strength controlled drug preparations been segregated from other stock.		
Actions (including by whom and by when)		
List of authorised signatories for the clinical area		
Does the Ward Manager have a list of signatories for the clinical area?	Y / N	
Is the list stored securely in the Ward Manager's office (the list must not be stored with the CD registers)	Y / N	
Have only registered		

nurses/midwives or Operating Department Practitioners (ODP) signed the signature list?	Y / N	

Review the list of signatories with ward manager to confirm all authorised to order CDs. Remove staff no longer working on the ward or without the authority to order CDs. Identify if any employees need adding to the list		
Actions (including by whom and by when)		
Stock Drugs		
Are only CDs from the list available on the ward as stock?	Y / N	
Is the packaging of all drugs in good condition?	Y / partial / N	
Are all drugs in date? Remove out of date drugs	Y / N	
Actions (including by whom and by when)		
CD Record Book		
Is there only one CD record book in use on the ward for each CD cupboard (unless ward is authorised to keep more than one CD record book per cupboard)?	Y / N	
Are old CD record books stored securely for at least two years on the ward?	Y / N	
Has a pharmacist participated in the transfer from old to new record book?	Y / N	
Have all the in use pages and details been transferred correctly from the old to the new record book?	Y / N	
Have CD requisitions been entered and receipted into the CD record book correctly ** Check 5 requisitions in Cd record book ***		
In Use pages of Record book – check every page		
Are all pages titled with the drug name, form and strength?	Y / partial / N	
Are all entries legible, signed and		

completed in all relevant columns?	Y / partial / N	
Are all cancellations or corrections bracketed with a single line through? There must be no crossing out of entries, blank lines or use of white paper fluid corrector (tippex).	Y / partial / N	
Do drugs transferred to a new page have 'transferred to page …' written on the old page?	Y / partial / N	
Do drugs transferred to a new page have the correct balance recorded at the top of the new page and the number of the old page?	Y / partial / N	
Do part used ampoules/tablets have x mg given/y mg discarded written in the record book?	Y / partial / N	
Working through the record book check the balance in the record book against the balance in the cupboard for all active pages. Write in green pen on the next available line 'Balance check – correct' sign & date and time		
For each liquid drug in the cupboard check the balance in the record book against the approximate balance in the bottle. Write in green pen on the next available line 'Balance check – appears correct' sign & date and time		
Is every drug entered in the register accounted for in the cupboard?	Y / N	
Are stock checks being carried out daily?	Y / N	
There has been no exceptional use of controlled drugs identified. Report to the Ward Manager and Divisional Lead Pharmacist if there has been exceptional use.	Y / N	
Actions (including by whom and by when)		
Patients Own CDs		
Are all Patients' Own Controlled Drugs being recorded in the Patients Own CD Record Book?	Y / N	
Are only Patients' Own Controlled Drugs being recorded in the POCDRB?	Y / N	
Check every active page is completed correctly	Y / partial / N	
Check every 5th inactive page is completed correctly	Y / partial / N	

Is a daily check of the sealed tag numbers is occurring?	Y / N	
Where a Patients' Own Controlled Drug is in use – are daily checks of the balance occurring?	Y / N	
If a patient returns from theatres with a PCA/Epidural have these been recorded?	Y / N	
Are CDs that are not in use returned to patient/transferred or returned to pharmacy	Y / N	

Actions (including by whom and by when)

Summary of Actions to be completed:

Action	**By whom**	**By when**
Completed check list copied to Ward Manager and Divisional Lead Pharmacist/Pharmacy Clinical Services Manager		Signature
Ward CD Balance check and Full CD audit Record Sheet updated	Signature	Date
Scanned audit sheet hyperlinked to Ward CD Balance check and Full CD audit Record Sheet	Signature	Date

CHECK LIST CONTROLLED DRUG CHECKS WHEN TRANSFERRING TO A NEW REGISTER.
TO BE COMPLETED BY A THE WARD MANAGER (OR NOMINEE) AND A PHARMACIST OR THE WARD MANAGER AND A NURSE/MIDWIFE/ODP AND THEN CHECKED BY A PHARMACIST (WITHIN ONE WEEK OF TRANSFER).