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Introduction

The purpose of this policy is to define the minimum standards for Clinicians and Non-Clinicians working in BrisDoc services in the prescribing, administering, dispensing, ordering, and storage of medicines to ensure compliance with best practice and legal requirements.

The aim of a standardised approach is to eliminate error, the risk of harm to patients, and protect staff.

Definitions

Medicine

Any substance or combination of substances presented for treating or preventing disease whose primary mode of action is pharmacological, metabolic, or immunological. Any substance or combination of substances which may be administered with a view to making a medical diagnosis or restoring, correcting, or modifying physiological or psychological functions.

Controlled Drug (CD)

A Controlled Drug (CD) is a drug identified by the Misuse of Drugs Act 1971 and related Regulations as having potential for diversion and misuse. The Regulations divide the CDs into five Schedules with differing levels of control, depending on therapeutic benefit balanced against harm when misused.

Prescribe

To authorise in writing the supply and/or administration of a medicine.

Medical Prescriber

A registered doctor who may prescribe any licensed medicine for any medical condition according to the authorised formulary for their profession, including Controlled Drugs.

Independent Prescribers

Nurse and AHP Independent Prescribers are registered clinicians who are entered on the relevant parts of their professional Register and may prescribe any licensed medicine for any medical condition according to the authorised formulary for their profession, including Controlled Drugs.

An Independent Prescriber must work within their own level of professional competence and expertise.

Supplementary Prescribing

Supplementary Prescribing is defined as a voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement and agreed patient-specific Clinical Management Plan with the agreement of the patient. The key principles of

supplementary prescribing emphasise the importance of communication between the prescribing partners (the patient is treated as a partner in their care) and the need for access to shared patient records.

Prescription Form

Prescription Forms (NHS England) FP10 are secure prescription forms, serially numbered with anti-counterfeiting and anti-forgery features. Prescriptions are controlled stationery therefore must be stored securely, fully accounted for and reported if missing. Prescriptions are ordered via a secure ordering system and distributed free. The range of forms is listed on the Department of Health (DH) and NHS Business Services Authority (NHSBSA) websites. Please note there are no prescription forms currently held for home visiting/outreach at the homeless health service (HHS) as it is deemed too high risk with this patient population.

Administer

To give a medicine by introduction into the body (e.g., orally, rectally, by inhalation or by injection) or by external application (e.g., a cream, ointment, patch).

Supply

To provide a clinically appropriate medicine for a patient for self-administration or administration by another person.

Patient Group Direction (PGD)

A specific written instruction for the supply or administration of named medicines in an identified clinical situation in the absence of a written prescription.

Responsibilities

Medical Director

Responsible for the safe and secure handling of medicines and Accountable Officer for controlled drugs. This is delegated to the Deputy Medical Director for the respective service line in their absence.

Lead Clinicians (GP, Nurse, Allied Health Professionals [AHPs])

Lead clinicians (medical and non-medical), including the Clinical Guardian team, in each service are responsible for prescribing practice and supervision of all prescribers. They will ensure robust prescribing policy and procedure is followed and developed in their service. They will be responsible for the appropriate ordering, storing and stock management of medicines held in BrisDoc premises. A nominated representative from this group will attend and liaise with the respective medicines Management Groups as required.



Facilities Manager and Practice Managers

Practice Managers, in practices and the Facilities Team oversees the management of medicines, stock control and prescriptions pads. They will action appropriate drug alerts, received by the Governance team from the MHRA, arranging for stock to be checked, withdrawn, and replaced as appropriate across services.

Facilities Team weekly medication processes

Bases

Monday – Medication audit – 5 bases.

• A medication audit is carried out every Monday to check usage & expiry dates. The audit book for schedules 3, 4 & 5 CD's is checked and an additional audit is carried out, the audit book is signed & dated. Any discrepancies with CD medications are reported immediately and a learning event submitted. Medication forms are collected to be brought back to Osprey for Justification. This includes mediation forms from bases, cars and hosts.

· Any medication due to expire is removed, this is logged on the audit.

· Once the audit has been completed, it is uploaded to the AHS stock data.

• Any OOD medication is logged and put in the OOD Tradebe clinical waste box, for disposal. This box is kept in a separate locked cupboard.

• Photos of the CD audit books are uploaded to the SDrive.

• The unaccountable report for the previous week is downloaded from the AHS stock data and shared with the Clinical Lead Practitioner to review any trends / patterns.

- Medication issued from stock forms and car medication forms are scanned on the s:drive and saved for auditing purposes

Tuesday – Medication justifications & medication ordering.

• The uploaded medication audit is cross checked against the medication issued from stock forms, driver forms and the CD audit books to ensure there are no discrepancies. Any discrepancies with CD medications are reported immediately and a learning event submitted.

· After the medication has been justified, a medication order is placed in relation to usage.

Thursday – Medication distribution

• Medication ordered on a Tuesday, arrives on a Thursday. Medication is cross checked with delivery notes, added to the AHS stock data, CD medications are added to the audit book (2nd signature required), 'do not split pack' and 'sealed' stickers are added to the boxes of medication, expiry dates are checked and arranged so shortest dates are supplied first, all medications are added to the store cupboard / safe.

Once medication has been packed away, the distribution is carried out. All CD (schedules 3,4 &
5) medication being distributed requires a 2nd witness signature in the audit book and the distributed medication and remaining balances needs to be checked. All medications are

allocated to the correct base delivery box, ready for a Friday delivery to the bases. The boxes are now cable tied sealed shut until Friday morning where they are unsealed and the Class 3,4, and 5 medications are checked against the book.

• An audit is carried out weekly on the distributed medications, remaining stock is cross checked again the AHS stock data to ensure quantities are correct.

Friday – Medication delivery to bases

• The medication delivery boxes are picked up from Osprey, the CD audit book is signed & dated to show they are being removed from Osprey to the bases. Once medication has been delivered to the bases, the medication is added to the medication cabinets. CD medication is also added to the audit books, signed & dated.

Monthly processes

· A full audit is carried out on the medication stock at Osprey Court.

Quarterly processes

• A full audit is carried out and expiry dates checked. A copy of this audit is set to the accounts department.

Cars

Weekly processes

• Every week, 1 car is audited (every visiting car gets a full car audit once a month). A full car audit form is completed, replenishing any medications, used, open or out of date. If there are any discrepancies with any CD medications, this must be reported immediately and a learning event submitted.

· Any missing stock from the cars are restocked from the base and learning events submitted.

Lead Pharmacist and Pharmacy Support

The Lead Pharmacist will provide support for audit, advice on best practice, monitoring prescriptions, provision of reports on medicines used and their cost, medicines supplier and PGD sign off.

Additional Pharmacist support is provided by NHS Bristol, North Somerset, South Gloucestershire (BNNSSG) Integrated Care Board (ICB).

The facilities team

The facilities team is responsible for checking and maintaining stock levels in Treatment Centres, checking expiry dates, managing the withdrawal and replenishment of stock recalled through a drug alert, reconciling medicines supplied from a Treatment Centre or during home visits against the prescription left by the clinician supplying the medicine to the patient, and ordering medicines for stock.

Practice Services

The lead nurse in each service will be responsible for the monitoring, ordering and storage of medication. They will be supported by other members of their team together with the lead Pharmacist. Any concerns will be reported via the learning event process and relevant data/reports will be reviewed at the medicines management committee meetings. Practice services do not accept any patient return of medications.

IUC

The facilities team is responsible for checking, monitoring, and replenishing medicines stocks in all IUC Treatment Centres and cars.

Specific tasks include:

- Assessing medicines stock against minimum levels, determine what replacements are required
- Check expiry dates, rotate stock, tidy medicines stocks
- Collect medicines (which will always be delivered to Osprey Court) from Osprey and store at relevant Treatment Centre
- Maintain records of stock levels
- Reconcile prescriptions for medicines supplied by clinicians against stock lists
- Submit records to the Facilities Team for review and action
- Log a learning event if stocks do not reconcile

Any discrepancies will be alerted to the Facilities Team with regards to any potential over usage of a medicine for review and investigation. All drug orders will be kept for a period of 2 years to ensure any trend analysis can be noted.

The IUC Medicines Management Group reviewed records and data for assurance via a dashboard monthly.

Independent Prescribers

Purpose

This section applies to all qualified independent prescribers employed or contracted by BrisDoc and covers registration, practice, and clinical governance of independent and supplementary prescribing. This includes.

- Nurse and AHP Independent Prescribers
- Supplementary Prescribing

who are eligible via profession registration and qualification standards.

Registration with Professional Body

Any independent prescriber must register as such with the appropriate regulatory body before commencing their prescribing role.

Training Requirements

All independent prescribers must undertake training as determined by their professional body and maintain ongoing competence through continuing professional development. The Scope of Practice Statement outlines the areas that the practitioner will be prescribing in and their methods of achieving competence in that area. This will be completed annually as part of the PDR process and kept in the Practitioner's personal file.

Accountability

Prescribers must act in accordance with the standards set by their registering body for prescribing. Practitioners must act within their own professional competence and expertise when prescribing, seeking advice where they require it and adhere to local prescribing policies.

BrisDoc Contracts

The prescriber and line manager must ensure the individual's job description and contract is updated to reflect their new prescribing responsibilities before prescribing is undertaken. The Lead Clinician responsible for their practice is responsible for ensuring all prescribers are registered with the relevant authorities. For self-employed clinicians' relevant checks of registration and performers lists are conducted prior to working in the service.

Indemnity and Legal Liability

All primary clinical care (delivered under an NHS contract for primary medical services) is covered by NHS Resolution's Clinical Negligence Scheme for GPs (CNSGP). Additionally, BrisDoc provides medical negligence indemnity cover for employed Practitioners for issues not covered by CNSGP. This does not remove a Practitioner's responsibility and accountability for their own prescribing actions, nor does this include professional indemnity provided by a registration authority.

Self-employed clinicians will provide their own medical defence organisation indemnity cover for non-CNSGP covered issues.

Prescribing

All independent prescribers hold individual clinical responsibility for undertaking an appropriate assessment, or critical review of assessment, for all patients for whom they prescribe.

The prescriber must prescribe only for the specific patient. Prescription items are not transferrable.

Controlled drugs must only be prescribed in accordance with the current legislation and best practice where there is a clinical need. Please referred to the controlled drugs section of this policy.



Single Prescribing Competency Framework

To support all independent prescribers in prescribing safely and effectively, a single prescribing competency framework was originally published by the National Prescribing Centre/National Institute for Health and Care Excellence (NICE) in 2012. The current guidance can be found at:

https://www.rpharms.com/resources/frameworks/prescribing-competencyframework/competency-framework

All Clinicians

All clinicians, whether prescribers or not, must comply with legislation, their professional body requirements, and guidelines, and BrisDoc medicines policies and procedures. Clinicians are responsible for their own prescribing practice and accountable for their actions.

Medicines Management Overarching Principles

This section details the principles by which BrisDoc clinicians will manage the administration and supply of medicines in respective services.

Regular medicines management meetings are held to address and monitor matters of medicines e.g. alerts, learnings, prescribing and other medicines management issues. These meetings have minutes recorded and have associated terms of reference.

This policy is intended to protect all BrisDoc staff, patients and the wider public from any harm associated with the use or misuse of CDs, and to enable prompt access to prescribed CDs, especially out of hours.

Ordering Medicines

The governance process for the documentation of medicines orders and receipt, and their reconciliation is essential to secure intelligence and assurance with respect to the probity and accuracy of the ordering process, particularly regarding controlled drugs. Email orders will be sent on a secure network, records kept of orders against stock lists and receipt of medicines delivered will be maintained and saved on the BrisDoc shared drive. The process will be kept under review by the Facilities Manager and Practice Managers and is scrutinised by respective Medicines Management Groups.

Prescriptions

In IUC, prescriptions are generated by Adastra via Electronic Prescribing Service (EPS) and digitally transferred directly to the relevant pharmacy. Hand-written and printed prescriptions in Treatment Centres are provided by exception if the IT system fails or there is another reason preventing the safe use of EPS.

EPS is not possible in the IUC visiting cars. Hand-written prescriptions can be generated at home visits and where necessary will be written legibly, clearly, in indelible ink and include full patient details and the date. The issue of a prescription will be documented in the prescription

log in the car. The visiting clinician may task the Clinical Assessment Service (CAS) to generate an EPS script to go to the patient's chosen pharmacy for collection by a family member/carer.

Pre-printed prescriptions for end-of-life care can be used for home visits. These prescriptions will need to be completed with appropriate doses by the visiting clinician and signed for the community pharmacy to dispense the medication appropriately. Any hand-written prescriptions are recorded by the clinician by logging into Adastra and recording the medicines that have been scripted in the medical record to ensure it includes all the relevant information.

Prescriptions are no longer sent to pharmacies via fax.

In practices, prescriptions are generated by EMIS and may be printed or sent via EPS to the patient's nominated pharmacy. Hand-written prescriptions are provided by exception in business continuity situations or on home visits where EPS is not accessible.

Prescriptions will only ever be in accordance with the clinician's license to prescribe, and will be within BNF and local formulary guidelines, or the departure therefrom will be clearly documented.

Ordering and Monitoring Prescription Pads

Integrated Urgent Care

The ordering of printer and prescription pads for IUC is managed by the Facilities Team. Upon receipt of printable prescriptions, the serial number of each box of prescriptions is recorded, along with the number of the first and last prescription in each box. A central log is maintained of where each box of printable prescriptions is issued to.

For hand-written prescription pads the serial number of each prescription is recorded and a central log is maintained of where each pad is issued to.

Evidence of prescription receipts by a pharmacy is submitted to the ICB by the Prescription Pricing Authority, the details of which are obtained for audit purposes.

A batch of individual prescriptions will be issued to a car and replenished when used and as required. A log of issued prescription form serial numbers and their use will be maintained by the driver and scrutinised by the Facilities Manager.

At the start of each shift the Host/Driver will load the IUC Treatment Centre prescription printers with prescription forms. A log of prescription serial numbers and their use is maintained in each Treatment Centre. When business continuity requires the use of hand-written prescriptions, a log of the prescription number and Adastra case record number will be maintained by each clinician on duty. The Host is responsible for issuing and retrieving the logs and reconciling them with the remaining handwritten prescriptions. These logs are returned to the Facilities Team for audit and re-ordering.

All prescription forms (including those from a car) will be securely locked away in the Treatment Centre by the Host at the end of each shift.



Practice Services

In practices prescriptions are ordered by the Practice Manager from NHS England (NHSE). Upon receipt a record is kept of the prescription numbers. Prescriptions issued to clinicians will be tracked by prescription number.

Security and Safe Handling of Prescriptions

It is the responsibility of the prescriber to always ensure the security of prescriptions and prescription pads. In the event of loss or theft the following procedure should be followed:

- The prescriber must report any loss immediately, with details of approximate number of prescriptions lost and serial numbers if known, to the Shift manager or senior clinician on duty
- The senior clinician will inform Police, NHSE, NHS Business Services Authority and ICB Head of Pharmacy and report the incident in accordance with the Learning Event management policy
- Prescriptions identified as missing through reconciliation of the log will be reported as a learning event and investigated. Missing prescriptions will be reported to NHS England so appropriate alerts may be issued, and if advised by NHS England, to the police.

Repeat Prescriptions

IUC

BrisDoc recognises that there are occasions when a patient will run out of their medicine or may be visiting the local area and have forgotten/lost their medicine. A request for a repeat prescription will therefore be considered on an individual patient basis.

In cases where an IUC clinician recognises that to go without a regular medicine may be to the detriment of symptom control and good health, a clinician may provide a repeat prescription for the relevant medicine for a short duration that gives the patient time to arrange with their own GP to provide their usual repeat prescription and to be reviewed for their long-term condition. EMIS access should be sought to provide confirmation of repeat medicines and when they were last prescribed. Other resources such as summary care record, Connecting Care and the NHS prescription tracker can be used to obtain further information regarding acute/repeat prescriptions.

Prescribing repeat medication will be in line with local formulary and guidance

As a rule, no more than three days' supply should be prescribed. Prior to prescribing EMIS and Adastra should be checked for other occurrences of repeat prescription requests from the patient to determine if there were a pattern that would affect a decision to prescribe and inform the content of the Post Event Message to the patient's own GP.

Repeat prescriptions will not be issued where the patient's practice is linked to a Pharmacy participating in the Pharmacy Repeat Prescribing Local Enhanced Service (LES) with BNSSG. Where this is known, the patient should be redirected to go to that Pharmacy.

IUC does not issue repeat prescriptions for patients who are under the care of a private service or provider.

For patients visiting from abroad who have run out of their usual medication, IUC can issue a repeat prescription for the shortest period (e.g., until they can temporally register with a local GP). The prescriber must ensure they have proof of the medication(s) and a correct up to date list. The prescriber can refuse to prescribe any medication they deem unsuitable/unsafe/inappropriate.

Practices

GP Practices have an established process for the routine review of patients who are on long term/repeat medication, see Repeat Prescribing SOP. Practice and PCN Pharmacists play a key role in reviewing and supporting these patients, and there is close liaison between the practice and a patient's nominated pharmacy for the management of prescriptions.

A clear record in EMIS of repeat medicines lists and medicines review is important to informing ongoing care.

Homeless Health Service (HHS)

The overriding principle of prescribing at the homeless health service is managing risk. This includes mitigating risks against overdose, patients selling their medication and/or losing their medication. Prescribing small amounts of medication at one time helps reduce these risks. Risk needs to be assessed holistically for patients depending on their individual vulnerabilities. If there is reasonable evidence of script diversion, then prescribing for that patient will immediately stop.

- For uncontrolled substances and medication/products at low risk of diversion this will usually be supplies for one or two weeks only
- Pharmacy notes for "Supervised consumption on pharmacy premises" can be used for any drug and can improve compliance as well as mitigate risks
- Use of EPS whenever possible for audit purposes and to reduce the number of scripts lost

As many patients accessing the HHS only hold temporary registration it is essential to use all data-sharing available including EMIS, SCR, Connecting Care, BSDAS, Theseus and others to access accurate and real-time information. This avoids any possibility of duplicate prescribing or other prescribing errors. Patients who do not consent to data sharing cannot receive treatment from HHS and should be directed back to the GP where they hold full registration.

PGD Use

Non-prescribing clinicians will be able to issue emergency medication via the use of a PGD. The PGDs are produced by BrisDoc's Medicines Management Group and usage is monitored by Clinical Guardian.

There will be a stock of all drugs that are available via PGD at each Treatment Centre and visiting car.

- PGD users will have training prior to being able to issue drugs
- PGD users will be assessed as competent by a Prescriber prior to issuing drugs under PGD
- PGD users will sign to indicate they are able to undertake usage of PGDs

- The clinician will issue medication under the PGD from the Treatment Centre or car stock.
- The Clinician will record the drug given and identify that it was given under PGD in the patient notes.
- Usage will be monitored by the Stock Control Officer and Head of IUC Nursing and AHPs.
- Clinical Guardian will be used to audit the clinical consultations, use of the PGD drug and its appropriateness

Unlicensed Medicines and Unlicensed Uses

Examples of unlicensed drugs are those made by Specials Manufacturers. Some medicines may be used in ways that lie outside their marketing authorisations (formerly product licences). This is particularly so for medicines which are used in palliative care.

Patients should usually be informed if a medicine supplied to them is unlicensed or used in an unlicensed way, and any implications, e.g., that the medicine may not have been assessed by the licensing authority against the criteria of safety, quality, and efficacy. It is the professional responsibility of the prescriber to decide whether it is appropriate for a patient to be supplied with a medicine for an indication outside its marketing authorisation.

In addition, sometimes a medicine may be used outside its licensed route. The prescriber must carefully weigh the likely benefits against the anticipated risks and wherever possible discuss these with the patient before agreeing the most appropriate treatment.

Prescribers and pharmacists should work together to ensure that unlicensed medicines are only supplied when the patient has a special clinical need that cannot be met by an available licensed medicine. This special clinical need does not include reasons of cost, convenience, or operational need. Every reasonable effort should be made by prescribers (with support from pharmacists) to identify a UK licensed medicine, or a licensed medicine in a similar class, that meets the patient's special clinical needs.

Where medicines are prescribed for unlicensed indications, it must be recorded on the patient's supply record.

Further guidance is available as below:

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/tool kit/professional-standards---prescribing-specials.pdf

Amber and Red Drugs

Prescriptions will not be issued for any "AMBER" or "RED" drugs (hospital/specialist only) unless specifically specified in a relevant SOP.

Administration of Medicines

IUC

The occasions when an IUC clinician may be required to administer a medicine will be by exception and typically in an urgent situation or medical emergency. These will be stat doses in the following circumstances:

- the immediate control and management of symptoms
- resuscitation where the clinician makes a judgement that immediate intervention is needed
- providing a window of watchful waiting that then allows for more considered advice and/or treatment from the clinician.

The medicine, dose and route, batch number and expiry date will be documented in the case record. An entry in the dispensing log will be generated for the medicine supplied and left in the Treatment Centre so the Stock Control Officer can reconcile supply against stock levels and reorder stock. A medicine administered from car stock will be recorded in the driver's log.

The clinician administering a medicine in the Treatment Centre or at a patient's home is responsible for undertaking any monitoring required to assess the effect of the medicine or any adverse reactions and recording the effects in the case record.

Practice Services

In practice services, medicines are not routinely stocked (except vaccines and emergency medicines) and any available will be part of the practice's resuscitation equipment and the GP visiting bag (refer to Resuscitation policy for medicines contents by practice). Practices will also stock emergency drugs as per CQC requirements. Any drug(s) that are administered will be documented in the patient's EMIS record and relevant consultation notes. Drug stock is checked regularly, and records are kept reflecting each time the stock is checked and the stocks administrator must sign and date that they have rotated the stock.

Where a medicine that is not held in stock is to be administered in a surgery the patient will be issued a prescription for that medicine and will be asked to bring it to their appointment for administration. Appropriate records will also be recorded in the patients EMIS notes.

HHS

At HHS a supply of non-controlled oral, topical and medications for inhalation are routinely stocked. These are medications for issue to patients who are experiencing significant and complex challenges that may prevent them from attending a pharmacy or commencing a medication in a timely way. This should be clearly documented in the notes and supplied by the prescriber. The prescription should be left in the treatment drugs cabinet so the costs can be reclaimed. The stock list is reviewed and agreed upon by the Lead nurse and lead GP. Stock control is regularly monitored.

Homeless Health will assess on an individual basis as to whether a patient could be reasonably expected to collect and bring their medications. Considering the patients mental health, vulnerabilities, organisational skills, drug taking history and the nature of the drug for administration. Patients who cannot be reasonably expected to collect their medications will

have their medication collected for them from the pharmacy and stored on site in a secure locked cabinet. This will be recorded in the 'patient's own' chapter of the drug record book and signed out for administration.

Supplying Medicines

Supplying a medicine from stock should be by exception in IUC. Medicines may be supplied by a clinician from stock held at a Treatment Centre or in a car when it is not appropriate to provide a prescription e.g., when there is no open Pharmacy, or it is unrealistic to expect the patient to travel to the nearest open Pharmacy.

In instances where a medicine is supplied the clinician should clearly document the medicine and administration instructions in the case record including batch number and expiry date. An entry in the dispensing log will be generated for the medicine supplied and left in the Treatment Centre so the Stock Control Officer can reconcile supply against stock levels and re-order stock. A medicine administered from car stock will be recorded in the driver's log.

The clinician and host will retrieve the medicine from the storeroom and check the medicine against the case record and issue it to the patient with administration instructions and safety netting advice. The clinician must label the medication box(es) with the patient's name and dosing instructions and make up suspension by adding required volume of water.

When supplying medicines from IUC stock only a complete box of medication should be issued for the patient to take away. It should be labelled with the patient's name, directions for use and date of issue. The medication should be in its original packaging with the PIL.

Spoons and oral syringes

For liquid medicines and especially medicines for children, the supplier should provide a 5ml, 10ml, 50mls spoon, or an oral syringe. Both should comply with BS3321: Part 7 1995. An oral syringe should be supplied when an oral liquid medicine is prescribed in a dose other than 5ml or multiples of 5ml, 10ml, 50mls. The syringe is marked in 0.5-ml divisions from 1 to 5ml to measure doses of less than 5ml and is provided with an adaptor and an instruction leaflet for the patient or carer on its use.

Shelf-life

Medicines for supply must have a sufficient shelf life to cover the intended period of treatment for the patient to whom it is supplied. Some medicines needing reconstitution prior to supply (e.g., oral antibiotic suspensions) have a limited shelf life once reconstituted. Anyone supplying a medicine of this type must ensure that supplied quantities allow for this. Patients requiring treatment courses which exceed the shelf-life of the reconstituted medicine will need appropriate arrangements put in place for further supplies. Whichever arrangement is put in place, the procedure for the supply of completed courses should be discussed and agreed with the patient or their carer.

Accuracy checking

No one is free from the potential to make errors so careful checking and documentation is essential.

Returned Medicines

BrisDoc does not accept returned medicines (the only exception to this is at HHS). Patients or a family member should be instructed to return un-used, out of date, or no longer required medicines to their local pharmacy.

The HHS may accept illicit and prescribed medications from their service users or found by staff on site where their continued circulation may cause harm and where the service user cannot reasonably be expected to return it to a pharmacy. These substances should be immediately disposed of in a CD denaturing kit.

Special Patient Notes

IUC

Special Patient Notes are the mechanism within Adastra that allow Clinicians working in hours to leave explicit information, advice and instructions about their patient's care and treatment plans. These will often have been made in partnership with the patient and family, especially for end-of-life care. Where such a plan exists BrisDoc clinicians will review it in the Adastra case record and make every endeavour to respect and comply with it. Should the note be felt to be out of date, a request should be made to the patient's own GP, via the Shift Manager and Practice Liaison Team, to update it.

The need for a Special Patient Note has been superseded, to a degree, by EMIS access which should be utilised whenever possible. In EMIS, care plans set out the management plan agreed between patients and their GP which provide information to colleagues for any ongoing management. These care plans may be emailed to BrisDoc for inclusion as a special patient note.

Handling Adverse Drug Reactions, Clinical Incidents and Recalls

All adverse drug reactions (ADR) should be reported in accordance with Medicines Healthcare Regulatory Authority (MHRA) Yellow Card system (available in BNF or reporting online at <u>www.mhra.gov.uk</u>) as well as through BrisDoc's learning event reporting portal. All ADRs should be recorded in the patient clinical record.

Any notification comes through the Brisdoc Governance email address, and the relevant clinical lead and Facilities Manager will review the detail and action if necessary.

Audit

Practitioners should audit their own practice as part of their ongoing review of CPD needs.

Prescribing by all clinicians is monitored by the Medicines Management Group at the ICB, Clinical Guardian audit, peer review, individual clinician review by line managers and audit.



Documentation and Record Keeping

All prescribers are required to keep contemporaneous records which are accurate, unambiguous, and legible in line with requirements of the registering body's standards for record keeping. Records must comply with organisational policies for Records Management and Data Protection, Confidentiality and Disclosure.

Prescriptions may be hand-written, or computer generated and must be signed and dated by the prescriber. EPS must be the preferred method of issuing a prescription.

Any item prescribed by a designated independent prescriber must be entered into all patient records at the time of prescription. Where it is not possible to enter details into records directly the information should be passed on to the appropriate person.

Medicines and Stores Management

This section details processes for monitoring, storage and return of all medicines which are not considered as controlled drugs.

Palliative Care Patients

IUC recognises the importance of Clinicians being good partners in supporting patients to follow their end-of-life wishes. Where these exist IUC will respect those wishes and the treatment plan agreed with the patient's usual clinicians.

To this end IUC clinicians will support the prescribing, administration, and supply of end-of-life care medicines in accordance with the BNSSG anticipatory prescribing guidelines and the use of "Just in Case" boxes and medicines.

Palliative Care advice, guidelines and documentation is included in the Palliative Care Pack in each car and with the Clinical Coordinator and on the toolkit guidance.

Safe Storage of Oxygen

Oxygen cylinders are stored in a locked storage room. The room has hazard warnings on the door. The cylinders are stored in trolleys whilst in use and in an appropriate static and fixed unit when not in use. (Refer to policy in BrisDoc's Health and Safety Manual).

Packing Down

Medicines

Part packs of medicines MUST NOT be supplied to a patient from stock, with no exceptions of any medication.

If there are concerns about giving a patient a full pack e.g., opiate-based analgesia, a prescription must be issued. If prompt pain control is required when there is no pharmacy open analgesia may be administered as a stat dose at the treatment centre or during the home visit. The patient must source their ongoing analgesia when a pharmacy next opens.

Diazepam

IUC recognises that there will be rare occasions when diazepam must be supplied to a patient. To respect individual patient management plans the patient's own GP may have in place, and to reduce the risk of dependency, IUC clinicians will supply a maximum of 28 x 2mg tablets of diazepam on one occasion only.

Diazepam is provided by the Supplier in packs of 28 tablets. To supply appropriate quantities, and where appropriate please issue a prescription:

Medication must not be packed down and a reduced dose MUST NOT be given to the patient.

Oxygen

Oxygen is supplied by BOC Medical. HX cylinders hold 2,300 litres of oxygen and CD cylinders hold 460 litres.

HX Cylinders should be re-ordered when the dial indicates a quarter full to ensure that a replacement is in place when needed.

CD Cylinders will be returned to base as soon as the dial shows empty (each vehicle carries 2 cylinders, and the empty cylinder will be replaced from stock).

Supply

Re-ordering Arrangements

Cylinders can be ordered by contacting BOC on 0800 111 333 and ordered using the account name of Broadmead Medical Centre, Homeless Health Service, or Charlotte Keel Medical Practice. In IUC, cylinders can be ordered by contacting the Shift Manager who will highlight on the shift report and will liaise with the Facilities Manager to replace stock.

Delivery can take 24-48 hours so please be aware of this.

Safety

All locations where oxygen is stored must have gas cylinder signs displayed. Cylinders must be in a safe and secure environment.

Oxygen cylinders must be included in COSHH and fire risk assessments.

All spare and in-use cylinders should be adequately restrained on a trolley or suitable racking and should not be left free standing. If necessary additional trolleys/racking can be purchased from BOC.

Where more than one cylinder is available, they should be clearly identified with appropriate labels: FULL, IN-USE or EMPTY. Staff should ensure cylinders are used in strict rotation, so that cylinders on trolleys and with the earliest filling date are used first.



All medical gas cylinders must be kept clean, dry, and stored away from any sources of heat or ignition. Cylinders should be handled with care, never knocked violently, or allowed to fall over. Never roll cylinders along the ground. Additional cylinders or empty cylinders should be restrained to a wall by a safety chain or on an oxygen trolley/racking when not in use. Full and empty cylinders will be separated on the racking and each stack will be correctly labelled.

When using medical gas cylinders, it is important that no part of the cylinder valve or equipment is either lubricated or contaminated with oil or grease. Special care is also needed with the use of oil or petroleum-based hand creams as these could provide sufficient contamination to the medical cylinder valve surface when handling the cylinder to cause an ignition when the valve is turned on.

The application of paraffin-based skin products to patients e.g., diprobase ointment, emulsifying ointment, white soft paraffin causes an additional fire hazard when administering oxygen to them.

On no account must staff transport oxygen in their own motor vehicles.

Storage

Broadmead Medical Centre

Cylinders are stored are Rooms 1 and 3 downstairs and the upstairs Treatment Room. Each room has a fire door for safety. Empty cylinders should be treated in the same way as full and in-use. Cylinders should be transported to the Boots basement using the transportation trolleys or a Boots cage. Empty cylinders should NOT be stored alongside full ones and should be taken to the basement for collection as soon as they are empty.

Homeless Health Service

An HX oxygen cylinder in kept in the nurses' clinic room and the grab bag, kept in the same room, includes a CD cylinder. Empty cylinders are kept in the administration office until they are collected.

Charlotte Keel Medical Practice

HX cylinder of oxygen is kept in treatment room 1. on a portable oxygen trolley, with a safety chain attached to the wall. 2. Spare HX cylinders are kept in the treatment room sluice room, secured with a safety chain. A CD oxygen cylinder is kept in a green bag for emergencies next to the resuscitation kit in the central area of the treatment room. A spare CD cylinder is kept next to the resuscitation bag.

Integrated Urgent Care

Empty cylinders are placed within the racking. Empty HX Cylinders at Knowle are exchanged for a full one on the trolley and the empty cylinder is placed on racking in the drug cupboard.

Treatment Centre Storage Locations

Markbury Road

- CD and HX cylinders stored in Medication Cupboard (larger stock as this is the main exchange base). In use HX stored on a trolley, empty chained to wall. CD stored in racking.
- Car stock 2 X CD held in separate oxygen bags.

Cossham

- CD and HX cylinders stored in Hospital Gas storage room, HX delivered to our operation area at the beginning of our shifts on a trolley. 2 X spare CD always kept in storage room.
- Car stock 2 X CD held in separate oxygen bags.

Newcourt

- HX cylinder always stored on trolley in consulting room
- 1 X CD stored in cupboard as spare.
- Car stock 2 X CD held in separate oxygen bags.

Clevedon

- HX cylinder always stored on trolley in consulting room
- 1 X CD stored in Resus bag in our cupboard

Greenway

- HX cylinder always stored on trolley in consulting room
- 1 X CD stored in Resus bag in our cupboard.

Oxygen Administration

Oxygen is a medical gas which is a licensed medicine and as such is subject to the Medicines Act and must be treated in the same way as any other medicine.

The National Patient Safety Agency (2009) reports the potential for serious harm if oxygen is not administered or handled properly. The main safety concerns relate to underuse and overuse of oxygen:

- Underuse of oxygen is extremely dangerous as it exposes critically ill patients to the risk of hypoxic organ damage.
- Overuse of oxygen can also be harmful, especially for patients with chronic obstructive pulmonary disease (COPD).

The concentration of oxygen required depends on the condition being treated. The administration of an inappropriate concentration of oxygen can have serious or even fatal consequences and constitutes a drug error which must be reported in accordance with the Incident Management Policy.

Current prescribing guidelines on oxygen therapy can be accessed via the current edition of the British National Formulary. The administration of oxygen must be recorded in the case record.

Oxygen is generally only used as an emergency medicine and should only be administered by a clinical member of staff that has undertaken the First Response basic life support course.

Face Masks

Simple oxygen face masks are supplied for single patient use. The oxygen mask is placed over the patient's nose and mouth with the elastic strap over the ears and to the back of the head. Adjust the length of the strap to ensure the mask fits securely.

Monitoring

Pulse Oximeters should be available on each resuscitation trolley and every vehicle. The oxygen saturation levels of all patients receiving oxygen should be checked and documented in the case record.

Audit

Oxygen cylinders are checked daily by a nominated individual to ensure there is sufficient supply. These logs will be checked regularly to ensure that the process is being carried out routinely before the logs are filed. Compliance audits are undertaken.

Training records will be maintained by the Workforce Department at BrisDoc.

Oxygen cylinders will be included in the audit of resuscitation equipment.

In The Event of Fire

- Operate the fire drill
- Notify the fire services, warning them of the presence of medical gas cylinders
- Evacuate the immediate area
- Once the immediate actions have been taken and provided it is safe to do so:
- move the cylinders close the cylinder valve to stop flow of product and move away from source of heat.

Unless staff are trained in the use of either fire extinguishers or fire hoses do not attempt to fight a fire in which cylinders are directly involved. If staff have had appropriate training, endeavour to keep the cylinder cool by using a fire hose from a protected position. Do not take any undue risks.

After The Fire

Cylinders which have been involved in a fire should be identified and segregated from all other cylinders. Under no circumstances should their contents be used. Immediately inform BOC Healthcare that the cylinders have been involved in a fire.

The cylinder(s) will be collected as quickly as possible and returned for examination.

Medicines Temperature Management

Principles

- Any medicine stored outside the temperature range specified by the manufacturer is no longer a licensed product
- Extreme hot and cold temperatures can damage medicines and therefore they must be stored according to manufacturers' recommendations i.e., within 15°C-25°C for ambient storage or within 2°C-8°C for fridge storage
- All vaccines have a predetermined shelf life, and the potency of vaccines is guaranteed by the manufacturers up to the expiry date as stated on the product, if stored within the safe temperature range of between 2°C and 8°C
- The term cold chain refers to the system of transporting and storing vaccines within a safe temperature range of between 2°C and 8°C. Breaks in the cold chain can result in loss of vaccine potency and may lead to vaccine failure
- Successful immunisation programmes depend on administering effective vaccines
- It is essential to maintain an unbroken cold chain for the vaccines from the point of manufacture, during transport and storage in a suitable refrigerator until they are used
- Vaccines should not be stored in the door of the refrigerator, as the temperature is warmer than in the main body of the refrigerator
- **DO NOT FREEZE VACCINES.** Freezing may inactivate the liquid vaccines and can cause glass ampoules to crack. Any vaccine subjected to temperatures of 0°C and below must be discarded
- Vaccines should be kept away from the freezing compartment, cooling element or panel where ice may form or direct contact with frozen cool packs
- If it is necessary to transport any vaccines between BrisDoc sites, the Cold Chain must be maintained. Vaccines should be transported in a suitable cold store box with cool packs and for the minimal amount of time to maintain the correct temperature throughout the transit period
- Patients will not be asked to store vaccines for their own use

Environmental Monitoring Procedure

A calibrated max / min thermometer must be kept in all rooms where medication is to be stored. This is used to monitor ambient room temperature. The thermometer must be kept next to the medication. If medication is also stored in a fridge there must be a separate fridge thermometer used to monitor that storage temperature.

This procedure refers to a temperature recording chart found in Appendix One. If a digital temperature recording system is in place and working well, this can continue to be used instead of the chart in appendix one.



Vaccine Delivery and Transportation

At each BrisDoc site where vaccines are stored, a suitably trained member of staff will be responsible for checking the vaccines and looking after the refrigerator. There will be at least one deputy assigned to cover times of absence. Any other staff who may be involved with vaccines must also be trained appropriately in the handling of vaccines and Cold Chain management.

Reception staff receiving vaccine deliveries will be made aware of the importance of ensuring that vaccine deliveries are handed over to the person responsible for their safe storage and handling as soon as possible. Reception staff will also know what action to take if that person (or their deputy) is unavailable.

The designated person who receives the vaccine delivery must observe the manufacturers storage recommendations. Upon receipt all vaccines will be examined for signs of leakage or other damage and immediately placed under the required storage conditions in the vaccine refrigerator.

Damaged vaccine stock must not be accepted and returned to the pharmacy or manufacturer. The date, time, delivery number, where returned to, and any other relevant details must be recorded in the "Drug Stock Record" specific to that BrisDoc site.

Suitable rigid containers should be always used during transportation to reduce damage to vaccines during transit and maintain temperature. Domestic cool bags should not be used to store, distribute, or transport vaccines.

Individual manufacturers' instructions should be strictly adhered to.

Vaccines should be kept in the original packaging and placed into a cool box with cool packs wrapped in bubble wrap or as recommended by the manufacturers' instructions. This will prevent direct contact between the vaccine and cool packs and will protect the vaccine from damage, such as being frozen.

Space within the container must be loosely filled to minimise circulating air.

Cool boxes and packing material should be stored at the lowest temperature possible prior to packing with the vaccine load and vaccine should be loaded as late as possible before departure to minimise exposure time out of the fridge.

Temperature monitoring

- 1. At the beginning of each month start a new recording chart. Write the month and year in the appropriate space
- 2. Check the temperature shown on the thermometer(s) daily and record max and min temperatures onto the chart. Sign in the appropriate space
- 3. Reset the thermometer according to the operational instructions
- 4. If daily recording is not possible, enter the details as frequently as possible
- 5. Min/max thermometers will keep a record of the minimum and maximum temperature reached until it is reset
- 6. During extreme (hot/cold) weather conditions the temperature should be monitored more frequently
- 7. At the end of each month the completed monitoring record form must be signed by a senior team member who must first check that no unreported deviation has occurred
- 8. All records must be kept in a folder along with the thermometers calibration certificate.

These records will be requested during an inspection

Refrigerators

All vaccines are Prescription Only Medicines (POM) and must be stored under locked conditions. Refrigerators used by BrisDoc are designed specifically for storage of pharmaceuticals and vaccines. Refrigerators must be reserved exclusively for the storage of vaccines and other drugs that need storage between 2°C to 8°C.

Food, milk, drinks, or specimens will not be stores in the vaccine refrigerator.

The refrigerator should be large enough to hold the necessary stock and allow sufficient space around individual vaccine packages for air to circulate, thus enabling the temperature to remain constant.

If large quantities of vaccine are required, (e.g., during the flu season), it may be necessary to increase the frequency of ordering, rather than the quantity ordered, to avoid receiving more stock than can be stored safely.

Vaccine refrigerators should be wired into switchless sockets to avoid them being switched off accidentally. Where this is not possible, tape will be placed over the plug and labelled with a cautionary notice not to switch off.

Defrost the refrigerator regularly, every 6 to 8 weeks, to prevent build-up of ice, which can cause the temperature to drop below 0°C, unless the refrigerator is self-defrosting.

Transfer the vaccines to another refrigerator or a cool box with pre-cooled cool packs whilst any defrosting takes place and continue to monitor the temperature to maintain the cold chain.

Replace vaccines back into the refrigerator when the temperature is restored. Dates of defrosting should be recorded on the temperature record log by writing *"defrosted"* next to the signature box.

Fridge Malfunctions or Power Failure

Advice should be sought when:

- The thermometer is reading a current temperature above 8°C which has not returned to the correct range within an hour
- The thermometer is reading a maximum temperature above 8°C when the fridge has not been opened
- Any temperature reading below 2°C
- A temperature reading greater than 8°C at the end or start of a day

If the temperature rises above 8°C or falls below 2°C, ascertain, if possible, how long it has been outside the range and seek advice on whether the vaccines can still be used. It may be necessary to contact the vaccine manufacturers. The vaccines from this fridge must not be utilised until advice this has been sought. The vaccines may be transferred to a working fridge but should be labelled "*not for use.*"

The reason for the fridge malfunction must be established. It may be possible to return the temperature to within range by making a small adjustment to the temperature control.

Contact an engineer if the fridge appears to be faulty. The fridge should be monitored to check it is operating correctly or at least 24 hours before any vaccines are returned to it.

Unless advised otherwise by Public Health England (PHE), remove the vaccines from the fridge and place in vaccine cool boxes with ice packs (wrapped in bubble wrap or cloth). Place an external thermometer probe in a vaccine box and record the temperatures every 10 mins to ensure stays at recommended 2-8 degree centigrade.

Responding to an alarm or a temperature deviation

- 1. The alarms on the thermometer must be set to go off if the temperature reaches the boundaries of the desired range i.e., 15°C-25°C or 2°C-8°C
- 2. If the alarms go off, action must be taken to try to ensure that the room or fridge remains within the desired range open / close windows, install portable fan / heater to cool / heat the room, close fridge door, contact engineer to service fridge
- 3. Once these measures have been taken, ensure that the temperature record has been recorded, then reset the thermometer to silence the alarm
- 4. If the temperature has varied outside of the required range, inform the lead pharmacist or the medicines information department at the local trust. They will need to know the temperature reached, an estimate of how long the temperature has been out of range and the details of any medication stored there
- 5. Log a learning event in accordance with the learning event policy
- 6. If fridge outside of temp range for <20mins and reason known, then reset fridge temp only.
- 7. If unknown how long outside of temperature range, quarantine vaccines (clearly label not for use and put in alternate fridge that is in recommended temperature range)
- 8. Download data logger to determine how long out of range. If <20minutes, reset fridge temperatures and data loggers and record on fridge temperature log. Return vaccines to fridge. No further action needed.
- 9. If temp is out of range for more than 20 minutes but due to stock check or restock, follow step 6.
- 10. If temp is out of range for more than 20 minutes but it was during a fridge stock check or restock, then note min/max and current temps after 1hr of finishing stock check, reset temps and log on the recording chart.
- 11. Download data logger results and note that any temperature excursion was due to fridge stock check. A temperature excursion in these circumstances can be excepted and does not need to be logged as a vaccine fridge temperature breach and a learning event form does not need to be completed. Attach the following document from PHE to the temperatures logged on teamnet. Y:\Equipment\Equipment calibration checks\Fridge Temp Records\Data logger results\Fridge temp excursion exceptions.docx
- 12. In cases where the fridge was out of temperature range for more than 20mins contact the Screening and Immunisations team for advice, email query to https://teamnet.clarity.co.uk/DAV/1a020945-51c5-40c1-acd6-ab4a00c49cb6/1/4/2655/Documents/Library/Files/england.southwestscrimms@nhs.net england.swscreeningandimms@nhs.net, 01138 249540 Monday to Friday (9-5). Outside these hours you can contact the health protection team on 03003038162 and press option 1.
- 13. Please do not contact the manufacturer until the above has been done. Support from the Screening and Imms team will then be available at investigating and assessing the risk so a full and accurate picture can be obtained before involving the manufacturers. The Screening and Imms team will contact the vaccines manufacturers, all the other vaccines (travel vaccines etc not from Immform), the practice will need to contact the manufacturers for advice if the vaccines can still be used on or off label.

- 14. Complete a learning event form, the Screening and Imms team will send you a form to complete and return, you only need to inform Immform if any of their vaccines need to be destroyed.
- 15. Complete a spreadsheet with the names of the vaccines involved in the excursion in the fridge/vaccine folder.
- 16. Label each vaccine involved with the date and time of the excursion if they can still be used.

Stock Management

Keep all vaccines in their original packaging during storage as this will have the expiry date and batch number. Packaging also protects the vaccine from light and damage and contains a patient information leaflet or a summary of product characteristics which has relevant drug information. Routine checks should check for any damage to the packing and ampoules.

Vaccines have short shelf lives and expiry dates, therefore do not over-order or stockpile.

Rotate stock regularly so that those with the shortest expiry date are used first.

Undertake weekly checks and remove expired vaccines. Dispose of these vaccines by returning to a pharmacy for appropriate destruction.

To minimise the length of time the fridge door is kept open looking for vaccines, designate specific shelves for different vaccines.

Ensure a list is kept on the outside of the fridge for easy reference.

Maintain a stock information system that supports monitoring and re-ordering of stock. Ensure vaccine ordering planning takes account of bank holidays.

Maintenance of the Cold Chain during Clinic Sessions

Vaccines kept for prolonged periods at high temperatures are rendered ineffective and may develop dangerous toxins. It is the cumulative effect of exposure to temperatures above those recommended by the manufacturer that reduces potency. Numerous short occasions at high temperatures are as bad as one long one.

Vaccines should never be left out of the fridge; they should be removed from the fridge just prior to use. If a busy session is anticipated, then vaccines can be transferred to a cool box to prevent the frequent opening of the refrigerator door.

Only take out the required number of doses for one session at a time.

Mark any unused vaccines that have NOT been removed from the cool box as "use first" plus the date and time before returning them to the refrigerator. These vaccines should then be used as soon as possible before other stock.

Data logger instructions for use

Set Up (first time use only)

- 1. Put data logger into USB port in computer.
- 2. Click 'set up and start data logger'
- 3. Name the USB data logger e.g., Room 7 Fridge 1
- 4. Select temp scale: C
- 5. Select frequency: 10 mins

- 6. Select display functions: LCD on for 30 seconds after button press
- 7. Select how logger should perform when full: Logger stops
- 8. Select alarms and set temperatures: high 8, low 2
- 9. Select number of high alarms and low alarms: 2

To download data

- 10. Before taking logger out of fridge, download software from this website: https://www.lascarelectronics.com/software/easylog-software/easylog-usb/
- 11. Put data logger into USB port in computer.
- 12. Open 'EasyLog' programme on desktop
- 13. Click 'Stop the USB data logger and download data'. Click 'yes' and 'ok'
- 14. Save the data.
- 15. A graph will pop up, on ribbon at top, click on 'Export' and choose 'excel data & graph' (Can minimise the 'EasyLog' page).
- 16. Click 'save as'. Save in same folder to set up the data logger after downloading
- 17. After downloading data, click on 'set up and start data logger' to start recording data again.
- 18. Click through the first 4 pages, as settings are saved.
- 19. On the fifth page, when asks when to start recording, click on 'Delay the start of the data logger' add 30 minutes on to the time (make it an even time e.g., 09.30.00). This will give time for data logger to be placed back in fridge and cooled down before beginning to record.
- 20. Click finish, click ok. Remove data logger and put back into the fridge.
- 21. The data logger will automatically start recording, you don't need to press any buttons on the logger, it is all set up and ready to record.

To upload files to Team Net Upload both files to TeamNet

https://teamnet.clarity.co.uk/L81015 Menu- Management- Fridge monitor under the correct fridge

Charlotte Keel file storage: (P Drive-Equipment- Equipment Calibration checks – Fridge temp records – Data logger results- month) and save as the same file name (e.g., TR Fridge 1 dd.mm.yy 12.00).

Controlled Drugs

BrisDoc has adopted the BNSSG ICB Policy for Controlled Drugs (CDs) and works in accordance with NICE guidelines, NHS England, the Misuse of Drugs Regulations 2001, and Controlled Drugs (Supervision of Management and Use) Regulations 2013.

CDs are held in stock by BrisDoc practices and IUC. Only Buccal Midazolam and Rectal Diazepam are stocked in practices as part of the emergency drug list within practice. The Homeless Health Service has a suite of SOPs specific to managing the needs of their patients in relation to drugs of an addictive nature.

IUC has SOPs to ensure the safe management and storage of CDs.

Any application for a CD licence or actions related to ongoing management of CD licencing must be raised to the Director of Nursing, AHPs and Governance. Actions must be taken to remain compliant with Home Office licensing requirements.

Principles

The key principles of this policy are that:

- CDs will be managed and used safely and effectively
- Patients should have timely access to the CDs prescribed for them
- Opportunities for CDs to be abused or diverted are minimised/prevented
- Good practice will be shared, and concerns identified promptly and rectified as soon as practical

Responsibilities

BrisDoc staff will comply with appropriate legislation relating to the prescribing, supply, documentation, safe custody, and administration of CDs. This involves not holding Controlled Drugs at any premises until the Home Office have granted a CD Licence.

BrisDoc's Controlled Drugs Accountable Officer (CDAO) is responsible for the safe and effective use and management of CDs within the organisation. They must ensure monitoring and auditing of the management and use of CDs, record and investigate concerns, ensure adequate SOPs are in place and ensure relevant individuals receive appropriate information, education and training. There is a requirement that the CDAO shares concerns and information with police, counter fraud, security, regulators and HSEI CDAO when applicable.

Registered Clinicians must:

- act within the legislation and professional responsibilities relating to controlled drugs
- ensure they consider themselves competent to act in accordance with the medicines management policy
- be familiar with, and always follow, their own professional code of practice in relation to medicines
- use tools that support safe and appropriate prescribing of CDs
- document via indelible route, primarily EPS or written prescription and give information to the person taking the CD or the carer administering it including for example:
- The patient's full name, address, and date of birth
- o The name and form of the drug, even if only one form exists
- how to use sustained and immediate-release formulations when prescribed together,
- o dose, frequency, and duration,
- o the total quantity to be supplied in words and figures
- o side effects,
- o efficacy,
- what the CD has been prescribed for,
- o how to safely dispose of unused, unwanted CDs,
- \circ that the CD is for use only by the person it has been prescribed for.

• The prescription must be signed by the prescriber with his/her usual signature and dated by him/her (a date stamp can be used)

All Clinicians are accountable for their actions and omissions. In all actions involving CDs they must exercise their professional judgement and apply their knowledge and skill in each situation.

The failure of staff to comply with this policy may result in disciplinary action.

It is imperative that all new colleagues that will handle and be involved in the record keeping of controlled drugs are trained in the following information and are aware of regulations and the protocol around controlled drugs.

Ordering Controlled Drugs

Requisitions

By law, a prescriber must produce a written requisition to purchase Schedule 2 and 3 CDs from wholesalers or pharmacies for use or stock purposes. The requisition form FP10CDF should be used when ordering stock CDs from a community pharmacy.

NBT pharmacy holds a list of approved clinicians able to order CDs required for BrisDoc use.

A designated Clinician will liaise with IUC Head of Nursing & AHPs and order CDs. The CD requisition form will be sent to Southmead Pharmacy by Facilities. Ordered CDs will be collected from Southmead Pharmacy by authorised clinicians who will receive a signed requisition from Southmead Pharmacy with the number of drugs ordered and a date and time stamp which is to be given to Facilities.

A member of the operation team and the authorised clinician will then collect the controlled drugs from Southmead hospital and are responsible for their safe transportation to the Treatment Centre. This must be undertaken in a BrisDoc vehicle with a CD safe and the CD Register must be updated in accordance with audit procedure.

Retention of signed orders, requisitions, and invoices

All signed orders and requisitions for CDs must be kept for 2 years. Invoices, which must be retained for 7 years, are sent direct to the ICB Head of Pharmacy by the Facilities Manager.

Storage of Controlled Drugs

CD Cupboards

In accordance with good practice guidelines (Misuse of Drugs (Safe Custody) Regulations 1973), CDs will be stored in accordance with the following criteria:

• Kept in a locked, secure metal safe within a locked drug store cupboard which is fixed securely to a wall – the hinges must be protected and the safe is of suitable thickness for purpose.

- The room containing the CD cupboard is lockable. This cupboard and keys are not open to public access.
- All combination codes to locks must be changed every 6 months.
- The room containing the CD cupboard is tidy around the cupboard to avoid drugs being misplaced.
- Nothing is displayed outside to indicate that CDs are kept within the cupboard.
- The number of sets of keys to the locked CD cupboard, and who holds them is always known.
- One designated person (host) within the premises takes overall responsibility for the keys. The cupboard will only be opened by the designated person concerned, or person authorized by them to do so. The keys / access codes will be stored securely.
- The CD storage cabinet must be locked after each entry into the cupboard.
- There is a designated person remains ultimately accountable for the management of the CDs.
- Stock is kept to a minimum, governed by clinical need.
- Other drugs, such as lower strength CDs that are liable to misuse will be locked in the CD cupboard if deemed appropriate by the member of staff with overall responsibility for CDs.
- Items other than CDs, such as money and paperwork, will not be stored in the CD cupboard.
- The CD register is stored safely outside the CD cupboard in an appropriate location within the drug store cupboard.

Medication	Class	Schedule
Codeine	В	5
Diazepam	С	4
Lorazepam	С	4
Midazolam	С	3
Oral morphine	С	5
Morphine	A	2
Oxycodone	A	2

- All the medications above have daily stock checks
- The only CDs held by GP practices are Midazolam and Diazepam and whilst exempt from safe custody regulations, regular stock checks are still undertaken and recorded accordingly.

Recording of Schedule 2 CDs kept as stock

Records for Schedule 2 CDs must be kept in a CD register. Registers are not a legal requirement for Schedules 3, 4 or 5 drugs.

Format of CD register

To comply with legislation all CD registers are:

- bound (not loose leaved)
- Contain individual sections for each strength and form of a drug
- Have the name, strength and form of the drug specified at the top of each page

- Have the entries in chronological order and made on the day of the transaction or the next day
- Have the entries made in ink or otherwise indelible form
- Not have cancellations, obliterations, or alterations
- Have corrections made by a signed and dated entry in the margin or at the bottom of the page
- Be kept at each location to which it relates and be available for inspection at any time.
- Be kept for a minimum of two years after the date of the last entry, once completed
- Not used for any other purpose

For CDs received into stock, the following details will be recorded in the CD register:

- Date on which CD was received
- Order Requisition number
- Name and address of supplier (e.g., pharmacy)
- Quantity received
- Name, form, and strength in which the drug was received
- Signed as correct by two persons, one of which must be a clinician

For CDs supplied to patients via prescriptions, the following details will be recorded in the CD register:

- Date on which supply was made
- Name and call number of patient
- The authority of person who prescribed CD
- Quantity supplied
- Form and strength in which drug supplied
- Signed as correct by two persons, one of which must be a clinician
- The register will be completed only after the CD has been collected by the patient representative or healthcare professional
- The medicine will only be dispensed once the patient is present at the base

Recording of Schedule 3,4 and 5 CDs kept as stock

Records of these drugs are maintained in a separate register and will form part of daily stock checks. This register is kept in the drug store cupboard. The principles for managing this register will be same as for schedule 2 CDs.

Maintaining CDs at Treatment Centres

In accordance with good practice guidelines, identified members of staff have responsibility for carrying out daily stock checks of CD balances. These checks will be made by a clinician at the commencement of each shift at 6pm on weekdays and at 8am at the conclusion of the night shift. The Host is responsible to ensure clinicians in each Treatment Centre complete this task.

Daily Reconciliation of CDs

Checks of the expiry date of all stock CDs are completed as part of daily checks – if any are out of date and awaiting destruction, they are still included in the running balance.

Checks include reconciling actual stock against the running balance in the register.

Confirm the balance by signing and dating it in the register by both members of staff from each clinician and staff member involved in the checking of CDs is kept in the back of each CD register for reference.

The car contains a supply of schedule 3,4 and 5 controlled drugs. These will be checked daily using the audit book. This will be done by the Driver and a clinician. Further information can be found in the Drivers Handbook. Please refer to SOP in Appendices Operations Management of CDs in Bases and Cars.

The accountability for maintaining the correct balance of CD stock lies with the IUC Head of Nursing and AHPs and not with the person to whom they may delegate the day-to-day responsibility. It is the responsibility of the people performing the check to inform the Shift Manager of low stock level which will be cascaded to the Facilities and Head of Nursing & AHP and learning event to be completed.

Daily Oramorph Reconciliation

The entire Oramorph stock will be measured in millilitres. Any open bottles will be visually checked for volumes each day. If there is a discrepancy then the bottle contents should be measured. If there are any discrepancies these will be reported as a Learning Event and investigated.

Monthly reconciliation of CDs

Stock levels and expiry dates are monitored monthly, a member of the Service Delivery Team at the start of each month asks the shift manager to complete the "Monthly Controlled Drugs Count" (See below)

	COSSHAM	MARKSBURY RD	NEWCOURT
Number of Oxycodone			
Earliest expiry date			
How many expire on this date:			
Number of Morphine Sulphate			
Earliest expiry date			
How many expire on this date:			

This is completed at the beginning of each month and reviewed by the Head of Nursing & AHPs at the monthly medication's management meeting. The usage patterns will create an overview

of volumes of available and usage levels to ensure appropriate volumes are ordered in the future.



Errors in CD Drug Register

If an erroneous entry is made in the CD Drug register, draw a line through the entry, ensuring the entry is still legible. Asterisk the entry and make a note at the bottom of the page explaining the entry and error. Please sign and date the entry. If in doubt, complete a Learning Event for best practice.

Transportation of CDs

All health care professionals in legal possession of a CD have a professional duty of care to take all reasonable steps to always maintain safe custody of that CD.

Nurses, midwives, doctors, pharmacists, pharmacy staff and other health care professionals, formal carers, and patients' representatives, are legally allowed to transport CDs to a patient, provided the CDs have been prescribed, by an appropriate prescriber, for that patient. Transportation of drugs requires a clinician (as stated above), who is legally responsible for the CDs) and a witness (i.e. a driver) in the car to follow process of signing in and out CDs.

Checking In and Out of CDs to Cars

Where a Clinician is undertaking a visit and expects to have to administer a single dose of any CD, it will be transferred to the car safe as below:

- The controlled drug/s will be signed out of the treatment CD cupboard. This will be recorded in the CD register held at the treatment center. This will be completed by the clinician and the driver or host.
- The drugs will be transported from the base to the car in a diagnostic bag. Do not carry controlled drugs in your hands.
- The controlled drugs will be signed into the car and locked into the car safe. This will be recorded in the car CD Register. This will be completed by the clinician and the driver.
- The drugs will be placed in the safe and they will be the responsibility of the Clinician
- If the drugs are used, normal documentation applies, checking in and out of the car CD book, totals adjusted and signed by both the Driver and the Clinician
- When returning to base any unopened CDs will be checked out of the car safe and into the Treatment Centre CD Cupboard in accordance with protocol above.
- Any issues (e.g., broken ampoules, missing drugs) will be reported to the Shift Manager and a learning event completed.
- Please refer to SOP The Destruction of Schedule 2 Controlled Drugs for breakages / waste.
- Please refer to SOP in Appendices Operations Management of CDs in Bases and Cars.

Transporting CDs from base to base for stock adjustment

Medication may need to be transferred from one base to another base to ensure distribution of stock across bases. This will be done by designated clinicians.

- medication is signed out of CD book in treatment centre following usual process (clinician and host/driver)
- medication is transferred into car in a secure receptacle and then into the car safe
- The medication always remains responsibility of the clinician whilst in the car.
- The CD Register in the car is updated and counter signed by driver
- The medication will then be added to the destination Treatment Centre stock and follow Recording of Schedule 2 CDs as Stock.

Car Safes

At no time will a CD be left in a car that is unattended during the day or overnight or left for a long period of time. Midazolam does not need to be kept in the car safe because it is a schedule 3 CD exempt from safe custody arrangements. However, it is good practice for this to be kept in the safe.

Prescribing Controlled Drugs

CD Prescribing Points

- CD prescriptions for Schedule 2 and 3 drugs are currently valid for 28 days
- It is good practice to prescribe no more than three days' supply for CDs schedule 2, 3 and 4 in the IUC setting.
- If more is prescribed, the clinical reason for a greater supply should be documented in the patient's electronic notes.
- When supplying long term pain relief on repeat prescription the prescriber will check EMIS first, supply no more than three days and ensure that patients are not over-ordering their medicines by advising the patient's GP to highlight areas of concern.
- It is good practice to generate all CD prescriptions via computer electronic records where possible to enable a clear audit trail. If handwriting the prescription is unavoidable, make a record of the medicines prescribed in the patient's electronic records and record the prescription number in the IUC prescription record log and on the patient record.
- Good practice requirements and professional codes of ethics make it clear that it is inappropriate for a prescriber to prescribe or administer CDs for personal use, or for family members, at any time.
- Lost or stolen controlled drug prescriptions will not be replaced except under exceptional circumstances with a police crime number at the prescribers' discretion. If medications are claimed to have been lost the greatest care must be taken to verify this. This includes looking on Connecting Care to see where the script has been issued and phoning that pharmacy. Medicines that have been lost should not necessarily be replaced if the clinician is not confident that it is safe to do so.

Requests for repeat prescriptions of drugs of dependence must be treated with caution. If a patient is on a weekly/daily script, the clinician can refuse to issue further medication if it is deemed unsafe or inappropriate. In such cases all resources must be checked/validated e.g., EMIS/summary care record/ connecting care/community pharmacy/NHS spine and further discussion with CC or pharmacist is strongly recommended. Consideration for a special patient note should be given.

Homeless Health Service

At the HHS, particular care should be taken if starting a Pregabalin or Diazepam script. Initiating pregabalin or diazepam is a major event and should almost never occur. The decision needs to be very clearly documented in the notes and where possible should be discussed at the weekly Multidisciplinary Team meeting with the Addictions consultant. Blue prescriptions should be used for diazepam.

Diazepam must not be stored at the HHS as stock or as patients own supply under any circumstances.

CD prescriptions are issued as blue paper scripts at HHS. This allows prescribers and pharmacists to monitor missed doses of OST more accurately for patients who are on daily supervised consumption. This is essential for managing risk of accidental overdose.

All Services - Process

Blue FP10 prescriptions will be ordered from PCSE by a senior member of staff. On receipt the serial numbers will be checked and recorded it in Blue Script Spreadsheet.

Blue FP10 prescriptions should be stored in a secure place at all time and access to them is only for HHS staff. This is currently the safe in the SMART team cupboard.

The spreadsheet record should include:

On Receipt

- date received
- name of person who received the order
- what FP10s have been received
- quantity and serial numbers received
- FP10SS (issued in batches of 50) first and last number of batches

On Issue

- date of issue
- what Blue FP10s have been issued
- quantity and serial numbers issued
- name of person who taken the Blue FP10s
- serial numbers of any unused Blue FP10s returned
- details of Blue FP10s that have been destroyed, including who destroyed them and how they were destroyed (these records should be retained for at least 18 months).
- All destruction of Blue FP10s must be conducted by two people.

Recording every blue script issued in the prescriber's page of the Excel Spreadsheet "Blue Scripts" (shortcut on prescriber's Windows desktop)

A clinician can take a small number of scripts to be held in a locked location in their consulting room. These scripts must be recorded on the "Blue Script Register" tab of the Blue Script spreadsheet (a shared file on the T drive, with shortcut on each clinician's desktop). It is necessary to record the clinician's name, number of the top script and number of the bottom script. The scripts should be returned at the end of the session to the safe in the SMART Team's cupboard. The relevant numbers of returned scripts should again be recorded in the spreadsheet. Each prescriber is responsible for the security of the prescriptions they have taken.

Whenever a blue script is issued the clinician must fill in the spreadsheet in their own page of the spreadsheet.

- Date of issue
- Patient's NHS number
- Unique Prescription number
- Click on the save button

The prescriber must make a note in the patients record that a prescription has been issued and whether it has been given to the patient, stored to give to the patient later, hand delivered and by whom, or posted to a pharmacy. If it is to be given later, instructions should be given as to who may do this.

Patients, temporary staff, and visitors should not be left alone with Blue FP10s or allowed into secure areas where forms are stored.

The forms must be removed from the printer at the end of a clinic as these forms are acceptable in handwritten form. Patients must never be left unaccompanied by staff in areas where printers contain FP10 SS forms.

If it is necessary to post a completed Blue FP10 to the patient or to a community pharmacy, then this must be recorded in the patient's electronic record including the serial number of the form.

Under no circumstances should prescription forms be pre-signed before use.

Emergency and Out of Hours Supplies of CDs

Under no circumstances may an emergency supply of a Schedule 2 or 3 CD be made to a patient without a valid prescription. An emergency supply of Schedule 4 or 5 CDs may be made if the other conditions for the supply of a POM to a patient in an emergency are satisfied, including the fact that the patient must request the emergency supply in person except in cases where the patient is end of life care. However, the abuse potential of these drugs when considering an emergency supply must be considered.

A basic stock of palliative care drugs that might be needed urgently in the IUC setting is available in the Treatment Centres. There are several pharmacies participating in a Palliative Care Local Enhanced Service open for extended hours, where a range of palliative care medicines is kept in stock in sufficient quantities. There is an up-to-date list of participating pharmacies available on Remedy, and via the clinical toolkit.

When supplying CDs to a patient representative or community healthcare professional, steps to confirm their identity must be taken before providing the CD.

Methadone Prescribing in IUC

BrisDoc does not issue prescriptions for methadone and Subutex unless by exception when the criteria set out in the position statement below are fully met.

Position Statement

Substitute prescribing for patients with substance misuse e.g., Methadone and Buprenorphine (Subutex) is offered by General Practice and the Drugs Services, often under shared care arrangements. This can lead to an expectation that the IUC Service will similarly offer this service. However, there are increased risks in issuing such prescriptions via IUC when the patient is not known to IUC, and such prescribing could be subject to potential abuse. As such the IUC Service will only prescribe if it can be confirmed with the patient's normal pharmacy (i.e., they are still open) that there has been a problem originating from the patient's own GP or the pharmacy which means that medications that have been prescribed by the patient's own GP cannot be safely dispensed. As such the request should preferably come directly from the pharmacy (via the Professional Line) rather than via NHS 111. Hence a situation in which a patient has, for whatever reason, missed their pick-up will not be managed by IUC.

If a prescription is requested for any other reason the IUC Service will not prescribe and has no responsibility to do so. Patients should be referred to dedicated substance misuse services that are provided to respond to such circumstances. Specifically, IUC will not initiate such medicines.

Any patients requesting a methadone/buprenorphine prescription who are transferred to IUC via NHS 111 should be forwarded to the Clinical Coordinator queue for advice and management, or the IUC pharmacist (if available).

If a prescription is issued, then this should be sent electronically to a pharmacy and ideally prescribed as a daily supervised dose. The pharmacy should be contacted directly before sending a prescription to ensure they have appropriate stock and are willing to issue the Methadone/Buprenorphine with a new prescription.

Destruction of Schedule 2 Controlled Drugs

It should be noted that IUC must not accept waste medicines, including CDs, from care homes providing nursing care or patients and their carer.

In accordance with legal requirements, all obsolete Schedule 2 CDs must only be destroyed in the presence of an authorised witnesses. The NHS England CD Accountable Officer will allocate the status of authorised witnesses for each episode of destruction of schedule 2 drugs.

There are two pathways to destroy Schedule 2 controlled drugs.

The first pathway is for a named clinician on the Home Office Authorised Witness list to lead the destruction of drugs with a witness following process outlined.

The second pathway is for a lead clinician to arrange for the appropriate, safe destruction of any



CDs held at any of the Treatment Centres. The lead clinician will contact the controlled drugs team at NHS England and NHS improvement (Southwest) to arrange destruction of CD The application will be reviewed by the NHS England CD Southwest team and a designated person (the lead clinician) will be allocated for the purposes of witnessing the destruction of the controlled drugs. The second person stated on the authorisation form will destroy the controlled drugs in the presence of the witness specified.

The authorisation timeframe will be a short window and limited to the premises to which the application is related.

For further information or clarification, email: southwestcontrolleddrugs@nhs.net

The website <u>www.cdreporting.co.uk</u> has all the resources required on-line.

All the CDs held at any of the IUC Treatment Centres will be disposed of in accordance with NHS England CD guidelines – this includes expired drugs and accidental breakages and spillages.

Each Treatment Centre where control drugs are stored and therefore destroyed requires a T28. This is a Waste exemption certificate that allows bases to denature controlled drugs and complies with the Misuse of Drugs Regulations 2001.

T28 waste exemption: sort and denature controlled drugs for disposal - GOV.UK (www.gov.uk)

Details of the stock CD that is being destroyed must be documented and accounted for in the base CD register.

All CDs requiring destruction need to be destroyed so that the active ingredient is irretrievable. IUC will use commercially available CD denaturing kits to denature Controlled Drugs. There are 100mls kits available at base and larger kits available from Facilities if required to denature a larger batch.

Please see SOP - Destroying and Recording the Destruction of Controlled Drugs on the Treatment Centre/GP Practice Premises in Appendices. Once the CDs have been destroyed, the resultant mixture should be added to the general pharmaceutical waste in a DUMP bin, or equivalent. Good practice, to ensure the active ingredients are denatured would be to keep the container in the Drugs cupboard until fully deactivated in 24 hours. This is the responsibility of the Lead clinician and Facilities.

Expired stock of schedule 2 controlled drugs

Expired CD stock should be stored in the CD cupboard until destruction and placed in the 'Expired / broken CD ' plastic sealed box.to prevent it from being issued in error.

This will be registered in the CD Register as expired and form part of the daily CD Register count.

The lead clinician will report expired drugs on the NHS England CD website.

Home (cdreporting.co.uk)





Please follow process for Destruction of Schedule 2 Drugs above.

Accidental breakages of vials stock of schedule 2 controlled drugs

Complete a learning event for the accidental breakages. The Learning event should specify the medication details broken, details of the incident and details of all individuals witnessed the incident or affected by the incident as well as the date and time.

If the vial is intact and has active medication present inside the vial, carefully put the vial in the sealed plastic box in the safe marked 'Broken / expired CD'.

This will be registered in the CD Register as expired and form part of the daily CD Register count.

A Lead Clinician or Governance will complete a Controlled Drug Incident for the NHS England CD website

Home (cdreporting.co.uk)

The broken vials will be denatured following the process for Destruction of Schedule 2, 3 and 4 drugs above.

Accidental spillages and irretrievable breakages

Complete a learning event for the accidental breakage and the irretrievable nature. The Learning event should specify the medication details broken, details of the incident and details of all individuals witnessed the incident or affected by the incident as well as the date and time.

If the active ingredient and the vial is irretrievably broken, use absorbent material to mop up the active ingredient using PPE provided and dispose of in a sharps bin. Carefully, put the fragments of glass in a sharps bin and dispose of gloves in a sharps bin if necessary. There will be a box of cat litter in each base for denaturing and mopping up spills for this purpose.

A Lead Clinician or Governance will complete a Controlled Drug Incident for the NHS England CD website

Home (cdreporting.co.uk)

Disposal of Waste / unused schedule 2 controlled drugs scheduled 3 and 4

Any medicine left over in a vial after administration is considered waste. Medicine is also considered waste if it has been prepared for administration but not actually used.

Please follow Destruction of schedule 2,3 and 4 controlled drugs but it does not need to be formally witnessed or reported. The bases will have denaturing kits – these can be used, and the used kit disposed of in a sharps bin or left in the safe for disposal by Facilities. Please

ensure the Host is aware so that this can be actioned appropriately. Please leave the kit in the CD safe for 24 hours before moving as specified in Destruction of schedule 2 drugs.

Significant Incidents Involving CDs

Significant incidents include:

- any incident where a patient is harmed, or the potential for harm or a 'near miss' has occurred.
- Patient or carer complaints involving the prescribing of CDs, including complaints of a failure to prescribe appropriate doses and/or appropriate medicines
- Concerns expressed by colleagues, police, drugs misuse services or others about unusual, excessive, or inappropriate prescribing of CDs
- discrepancies at the time of stock checks and transfer of CDs

Any significant incident involving CDs must be reported and managed in accordance with BrisDoc's Learning Event Management Policy and reported to the through the NHS England CD website. All CD's that are unaccounted for thefts and losses must be reported to the Home Office, through on-line forms below, and the Police within 48 hours.

Controlled drugs and precursor chemicals: thefts or losses - GOV.UK (www.gov.uk)

The Commissioner will monitor incidents involving CDs in conjunction with the NHS England Accountable Officer.

The Head of Nursing or Lead Pharmacist will attend the CD Local Information Network (LIN) meeting to share information and intelligence about the misuse and safe use of controlled drugs.

Dealing with CD Discrepancies

If a discrepancy is found during a routine stock check and the source CAN be identified, the clinician checking the stock should record the outcome and make any corrections to the CD register with a signed and dated entry in the margin or, at the bottom of the relevant page.

If the source of the discrepancy CANNOT be identified during the stock check, then the clinician checking the stock should immediately submit a learning event and inform the Shift Manager. The Shift Manager, in conjunction with the senior clinician on duty will then co-ordinate a formal internal investigation and advise the NHSE CD Accountable Officer and potentially the police subject to findings if there is a large discrepancy.

The clinician should record the discrepancy on a Learning Event Form. This will include:

- date and time of discovery of discrepancy
- drug, form, and strength
- the nature of discrepancy
- the names of the members of staff who discovered the discrepancy.
- any other relevant information

This discrepancy will then be investigated at the earliest opportunity by:

- examining current stock in CD cupboard
- examining current and previous entries in CD register
- checking the calculation of the running balance
- any other relevant investigation
- review of available CCTV
- all details of the discrepancy MUST be reported to the NHSE CD Accountable Officer within 24 hours of its discovery. An incident panel will be established to investigate if considered necessary.

Monitoring CD Use

This will be undertaken through monitoring ordering trends and from Prescription Prescribing Authority (PPA) information provided by the ICB Head of Pharmacy. The Head of Nursing and AHPs will maintain appropriate links with the NHSE CD Accountable Officer and Local Intelligence Networks.

It is also an annual requirement that the Home Office CD division is sent an annual drug return to confirm that we have not supplied to CD's to any other organisations. There is no requirement for detail of end-to-end use but a confirmation email stating of "Nil return". The email address for this is <u>annualdrugreturns@homeoffice.gov.uk</u>.

Date	Version	Author	Change Details
1 st January 2014	1.0	CLN	New Policy
14 th October 2016	2.0	CLN	Update CD schedules, inclusion of Pharmacists in BrisDoc skill mix, removal of reference to Senior Clinical Operations Lead, update role responsibilities, inclusion of practice prescription processes. Ensure CD standards comply with NG46. – routine policy review
6 th October 2016	2.1	CLN	General edits including rationalising section on managing cases of measles out of hours. Following review by Medical Director and ensure applicability to HHS.
1 st March 2019	2.2	FB	Reviewed prior to IUC Service commencement
26 th October 2020	2.3	CLN, FB	Update language and roles to IUC, change PGD development to IUC responsibility, remove prescription pad location at Charlton Form Hospice, removal of processes related to paracetamol and ibuprofen suspensions. Routine review.
1 st August 2022	2.4	RH, FB, TA, RC	Full policy review and update. Routine review.

Change Register

17 th October 2022	2.5	Sabrina Flew	Minor correction to Clevedon equipment.
16 th December 2022	2.6	NR, RS	Updates to CD transportation, Medication issued from stock, destruction of schedule 2 drugs
19 th January 2023	2.7	RS, SF, NB	Updates to CD's in terms of destroying, managing and collecting CDs to ensure within NHS England procedure, Oramorph monitoring
25 th January 2023	2.8	RS	Update to CD destruction and CD process following compliance visits from Home Office
13 th February 2023	2.9	RS	Theft or loss reporting, code changes on all locks and CD licence management updates
3 rd April 2023	3.0	RL	SOP for applying for CD Licence
16 th May 2023	3.1	RL	Update to CD responsibilities
29 th November 2023	3.2	RS	Update on transportation of CDs following a LE
3 rd January 2023	3.4	NB	Update of medication pack down (diazepam)
3 rd January 2023	3.4	NB	Dispensing medication from stock update
3 rd January 2023	3.4	NB	Update on facilities responsibilities
11 th March 2024	3.4	NB	Update on t28 denaturing for schedule 3 and 4
11 th March 2024	3.4	NB	Update SOP Operational Management of CDs and ensuring consistency
11 th March 2024	3.4	NB	Update on spoon and oral syringe sizes
11 th March 2024	3.4	NB	Update on daily reconciliation of CDs
11 th March 2024	3.4	NB	Update on accidental breakages of vial stock of schedule 2 CDs
11 th March 2024	3.4	NB	Update disposal of waste/schedule 2,3,4
11 th March 2024	3.4	NB	Update SOP ordering and receiving CDs
11 th March 2024	3.4	NB	Update on the process for daily check of CDs in the cars

Temperature Monitoring Record

Month / Year:

Ensure a MAX/MIN thermometer is used. Ensure the alarm is set to go off at the appropriate temperature boundaries (15°C and 25°C for ambient, 2°C and 8°C for fridge). Ensure the alarm is ON. Store the thermometer next to the medication. Record the temperatures shown then RESET the thermometer.

Date	Ambier	nt room	Fri	dge	Monitor reset	Signature
	Max	Min	Max	Min	(Tick)	C
1						
2 3 4						
3						
5						
6						
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To be completed daily, if possible, except when unit is unstaffed or when no drugs present.

END OF MONTH REVIEW: (Signature) Role.....

SOP - Supplying Medication from Stock

When supplying medicines from stock OOH only a complete box of medication should be issued for the patient to take away. It should be labelled with the patient's name, directions for use and date of issue. The medication should be in its original packaging with the PIL.

- 1. It is BrisDoc policy to provide medication, wherever possible, via the issuing of a prescription to be dispensed by a community pharmacy.
- 2. At each treatment centre there is a stock of commonly used urgent medication to enable the clinician to provide the patient with the required medication when pharmacy is unavailable.
- 3. When medication is issued from stock the clinician will record the drug, dosage, and method of administration in the Adastra case record.
- 4. When supplying medicines from stock in IUC, patient information leaflet (PIL).
- 5. Spoons and oral syringes For liquid medicines and especially medicines for children, BrisDoc provides a 5ml spoon, or an oral syringe. Both comply with BS3321: Part 7 1995. An oral syringe should be supplied when an oral liquid medicine is prescribed in a dose other than 5ml or multiples of 5 ml. The syringe is marked in 0.5-ml divisions from 1 to 5ml to measure doses of less than 5ml and is provided with an adaptor and an instruction leaflet for the patient or carer on its use.
- 6. **Shelf-life** Medicines for supply must have a sufficient shelf life to cover the intended period of treatment for the patient to whom it is supplied, so expiry dates must always be checked before supply. Some medicines needing reconstitution prior to supply (e.g., oral antibiotic suspensions) have a limited shelf life once reconstituted. Anyone supplying a medicine of this type must ensure that supplied quantities allow for this and must reconstitute the medicines for the patient prior to dispensing. Patients requiring treatment courses which exceed the shelf-life of the reconstituted medicine will need appropriate arrangements put in place for further supplies. Whichever arrangement is put in place, the procedure for the supply of completed courses should be discussed and agreed with the patient or their carer.
- 7. **Accuracy checking** No one is free from the potential to make errors. There may not always be another clinician available to assist with second-checking any medication issued form stock so careful checking and documentation is essential.
- 8. When a stock drug is given from Treatment Centre stock a prescription will be recorded in the usual way as an EPS. Any prescription must be signed by the clinician and placed in the metal prescription box in reception at each site or an entry made in the dispensing log.
- 9. The prescriptions will be collected by the Stock Control Officer who will then reconcile against existing stock. Stock Control Officer will ensure there are adequate supplies of stock medication kept at each Treatment Centre
- 10. The only exception to this policy is when a drug is given on a one-off basis, such as Entonox, Oxygen, or emergency drugs whereby the administration of this will be recorded in the patient record only

SOP – Dispensing Medication for IUC Treatment Centre Stock

Medication should only be dispensed from stock in exceptional circumstances, if a chemist is closed and is needed for immediate treatment

Prescribing Process:

1. **Prescription Entry:** The clinician responsible for prescribing should enter the medication details into Adastra as a prescription (not as free text). This should be saved for later retrieval instead of sending it through the Electronic Prescription Service (EPS).

2. **Administration:** Forward the case using the 'F2F' button for the operational team to schedule an appointment.

Appointment and Collection:

1. **Booking:** Arrange the appointment using the standard booking procedure.

2. **Arrival:** When the patient or their representative arrives, check them in following the standard process.

Dispensing Medication:

1. Access to Medication: The Host must accompany the clinician to unlock the medication cupboard. The Host is to keep the keys and remain present during the entire process.

2. **Documentation**: The clinician must fill out a 'Medication issued from stock' form and leave it with the Host to be placed in the prescription post box. Log all controlled drugs in the controlled drug register and record Codeine, Midazolam, Oramorph, Diazepam, and Lorazepam in the drug audit book.

3. **Medication Handling:** The clinician retrieves the necessary medication; The Host is responsible for relocking the drug cupboard.

4. Securing Medication: The Host is responsible for relocking the drug cupboard.

5. Labelling: The clinician dispensing the medication must label it prior to handing it over.

6. **Handover:** Provide the medication to the patient or their representative. Give any relevant medication advice.

Final Step:

• **Case Closure**: Conclude the case on Adastra after the medication has been dispensed. They should also mark 'issued from stock' in the Adastra prescription menu.

Please ensure all steps are followed diligently to maintain compliance and safety standards.

SOP - Repeat Prescribing in Practice Services

This can seem a daunting task, but there a few basic principles, which will ensure safe prescribing. Repeat prescriptions will come electronically through workflow.

Straight signing vs reauthorisation

All drugs on repeat prescription will have several authorisations, usually set at 3-6. This means that if a patient is receiving a medication every two months, the prescribing clerk can issue the prescription for signing six times, which will last a year. Once the authorisations have finished, the prescribing clerk will need a reauthorisation from the prescriber before any further prescriptions are issued.

Do I need to check every prescription for straight signing?

It is important to scan the prescription for obvious issues (e.g. – benzodiazepines on repeat prescription or incorrect drug dosages). Workflow of repeat prescriptions make this task much easier.

Shared Care Protocol and Traffic Light Status (TLS)

The traffic light status within the BNSSG formulary, tells us the circumstances in which we are allowed to prescribe a drug.

https://remedy.bnssgccg.nhs.uk/

- **Red** drugs can ONLY be initiated and maintained by specialists and there is no involvement with either GP prescribing or monitoring.
- **Amber** drugs are initiated by specialists who will ensure dose stability before handing over to the GP for ongoing maintenance of a drug. This handover must be accompanied by a **shared care protocol**.
- **Green** drugs can be initiated and maintained in general practice. Care should be taken to use formulary items over non-formulary items.
- Blue drugs can be used in primary or secondary care but are considered second-line drugs.

Although we should not be prescribing hospital only red drugs in primary care, it is important to document them in the medication screen to highlight potential drug interactions. This can be done as follows:

- Add the drug as a repeat medication with a re-authorisation of only 1/1
- In the dosage instructions, free text "Red drug, hospital only to dispense"
- Issue a quantity of only 0

MOUSE, Mick (Mr)			Born 24-Feb-1938 (8 NHS No. Unknown	1y) Gender Male	2
Name	Alert - Tacrolimus 1mg modified-release cap	sules	*	Pack Details Optional Prescript	ion Information	٥ ×
Dosage	HOSPITAL DRUG DO NOT DISPENSE		•	Pharmacy	Patient	^
Quantity	0 capsule	Duration	28 Day(s)	Info	Info	
Rx Types	Repeat 🔹	Authorised Issues	1		Ŧ	Ŧ
Authorising Clinician	NABI, Shaba (Dr) 🔹 🔎	 Private Pers Variable use 	ionally-administered	Review Date Days Before Next Issue		
Warnings Drug Jofo	rmation Current Medication Past Medicatio		-			

• Proceed as if to issue the medication but use the change all drop down box to convert to hospital print.

🕽 Authoriser 🛛 📷 Medication Regime Review 🛛 🗏	🖕 Change All 👻 🛝 Change Selec	tion 👻 📒 Pharma	cy Message 🛛 📃 Patient I	Message
TESTY, Testy (Mr)	Born 12-Dec-1969 (46y)	Gender Male	NHS No. Unknown	Usual G
Last regime review has expired				<u>Send</u>
NHS Printed Script (non-EPS)				
To Be Signed By: NABI, Shaba (Dr	1			
A Tacrolimus 1mg capsules RED DRUG	, HOSPITAL ONLY, DO NOT DISF	PENSE, 1 capsule		

Reauthorisation of amber drugs

Many of the amber drugs need ongoing monitoring as part of the shared care protocol. Examples would be methotrexate, sulfasalazine, and azathioprine. Although warfarin is green in the traffic light status, this is also treated as an amber drug because of its requirement for frequent monitoring. Any medication requiring ongoing monitoring will have an active problem code of "Near Patient Testing – enhanced services admin" and will have the frequency and type of monitoring free texted next to it.

All these drugs will have a reauthorisation of only 1/1. This means that the prescribing clerk is unable to issue these prescriptions and they are passed to a prescriber each time.

How do I re-authorise an amber drug?

It is essential to check the <u>shared care protocol</u> for each drug within the BNSSG formulary. This will inform you of the frequency of monitoring and actions to take if there are any abnormalities.

What if there has been no recent monitoring as per guideline?

Then you must issue only TWO WEEKS of the medication and communicate with the patient/pharmacy (see below) Please check ICE when looking for results.

Checks for reauthorisation of medication for long term conditions

Most repeat prescriptions will be for long term conditions such as Hypertension, Depression and Asthma. The important checks for these groups of patients are as follows:

- When was their last **chronic disease review**? Is it due? Look in diary but also consider any backlogs associated with the Covid-19 pandemic
- Have they had relevant blood tests in the last year?

(More frequent if CKD 3 or more)

- Are they on the **correct doses** of medication? (e.g.: secondary prevention statin doses, reduced doses DOACS with reduced GFR)
- Do they **still need it?** (e.g.: ticagrelor normally for a year, nutriprem for 6 months adjusted age)
- Do they need additional investigations? (e.g.: long term steroids)
- Is there a potential for dependence? (Opiates, benzodiazepines)
- Is the patient on the Palliative Care Register? If not, should they be Can drugs be rationalised? See validated tools such as STOPP/START criteria and the <u>BNSSG</u> <u>Medication Review Tool for the elderly</u>
- Are medications synchronised?
- How is **compliance** with medication? It is important to check for both under and overuse.
- Is the choice of medication in line with local and national policies?
- Has the patient recently been discharged from hospital/OOH? If so, look through discharge summary for any medication changes

Prescription Refusal

Prescription refusal (as opposed to issuing smaller quantities and asking for review) should only happen if:

- You feel the medication is inappropriate
- You feel there may be safety issues if you prescribe
- (e.g. multiple diuretics with no renal function for over 18 months, over-use of prescription drugs of dependence)
- Prescription refusal if no other medication being issued

If you are refusing all the medication requested, then text the patient via SMS text template (if they have not opted out). If they have opted out, you must generate a "prescription refusal" letter within EMIS. This can be found as an EMIS template within letters. It is important to write the name of the pharmacy above the patient's name. This letter can be sent electronically to the patient's pharmacy, either by the practice pharmacist or the prescribing clerks.

• Prescription refusal if other medications being issued

It may be that you are happy for some medications to go through but not others. The best way to do this is via SMS text which leaves a consultation note in EMIS. If the patient has opted out of SMS text, you need to use the following method:

First, it is important to write a consultation note about why you are not prescribing a certain medication because there will need to be an audit trail of this. This consultation note can be copied and pasted as a message to the patient and pharmacy. An example of this could be:

"Sept 2016 - iron not issued, need repeat blood test to see if still needed"

If you are in EPS workflow, you need to "reject" the individual medication not being issued:



You then need to issue the medications which are allowed (either on paper or electronically) and copy and paste this message for the patient and pharmacy about the rejected medication. This is done at the point of issue when you can click on to the yellow message boxes as follows:

ssue						
🔱 Authoriser	📷 Medication Regime Review	५ Change	e All 👻 🖣 Change Selec	tion 🔹 📐 Pharma	cy Message 🥠 Patie	nt Message
TESTY, Tes	ty (Mr)	Born	12-Dec-1969 (46y)	Gender Male	NHS No. Unknow	n Usual GP
NHS Prin	nted Script (non-EPS)					
To Be	Signed By: NABI, Shaba (D	<u>er)</u>				
∧ Trin	nethoprim 200mg tablets One	To Be Ta	ken Twice A Day, 14 tab	olet		

It is important to realise that there is no permanent record of a patient/pharmacy message when written like this, so the consultation note is crucial for the reception team.

Prescription issued but review required

This will be a more common scenario when no harm will come to a patient if a prescription is issued, but they are due a review or blood tests.

The easiest way of communicating that a review is due, is to text a patient as this message is stored in the consultation screen. The quantity may also need to be reduced (if it is a patient safety issue) as well as re-authorising only one issue. Please do not reduce quantities of medication for long term medication without first communicating with the nurse team.

If you are unable to text the patient, it is important to highlight the medication and edit it (which can be done in the medication and workflow screen). The quantity should be reduced to whatever is clinically appropriate, but be mindful of the availability of the next routine GP appointment (can be up to 3 weeks)



As well as reducing the quantity, and reauthorizing only one issue, you need to put a message in the pharmacy and patient information as follows:

TESTY, Testy (Mr))	Born 12-D)ec-1969 (46y)	Gender Male	NHS No.	Unknown	Usual GP SIMMO	NS, Philip	(Dr)
Name	Amlodipine 5mg tablets				-	Pack De Optiona	tails Prescription Inf	formatio	n
Dosage	One To Be Taken Each Day				-	Pharmacy	Sept 2016 - due	Patient	Sept 2016 - due
Quantity	28 tablet		Duration	28	Day(s)	Info	blood pressure review with nurse	Info	blood pressure review with nurse
Rx Types	Repeat 👻		Authorised Issue	s 1					
Authorising Clinician	NICHOLLS, Kate (Dr)	-	🔲 Private 🔲 I	Personally-adminis	tered	Review Dat	ie 🗌 🔤	2-Dec-2016	5 🔳
						Days Before	e Next Issue Min		Max

You do not need to add the message to a consultation note because it will be visible in the medication screen, but it is important to delete the message once it has been actioned.

Repeat Dispensing

** Important Update for Chronic Disease Reviews during Covid-19 pandemic**

During the Covid-19 pandemic, the nurse team have been prioritising the highest risk patients for review. Nurse capacity will be significantly impacted at certain times such as lockdowns, the flu vaccination programme and the Covid vaccination programme.

PLEASE DO NOT TEXT THE PATIENT ASKING THEM TO BOOK IN WITH THE PRACTICE NURSE.

Re-authorise the prescription, and if you feel they need to be prioritised for review, please task your nurse buddy.

Repeat Medications for Nurse Chronic Disease Reviews

The nurse team will have a system for recall, and it is important to adopt the following principles for medications requiring nurse review:

- 1. No reduction of medications
- 2. Text patients to say review/bloods due and re-authorise 1/1
- 3. If still not seen, re-authorise 1/1 and task nurse team
- 4. If still not seen, decline meds only if considered a patient safety issue

SABA inhaler over-use

• Task practice nurse team to phone patient for review

Combined contraceptive pill review overdue

- Check if high or low risk patient (BP, BMI, age, risk factors)
- Offer 1-3 months treatment depending on risk status and task PN to invite for review
- Decline further treatment if not attended for review

Repeat Dispensing

If a patient is stable on medication, a batch of prescriptions can be printed out for the pharmacy to dispense at regular intervals. Examples would be a patient on a stable dose of thyroxine or those stable hypertensive patients. You can default to repeat dispensing in the Rx types:

TESTY, Testy (Mr)		Born	12-Dec-1969 (46y)	Gender Male	NHS No. U
Name	Levothyroxine sodium 50microgr	ram tab	blets		•
Dosage	take one each morning				•
Quantity	56 tablet		Duration	56	Day(s)
Rx Types	Repeat Dispensing 🔹		Authorised Issues	б	
Authorising Clinician	NABI, Shaba (Dr)	-	🗋 Private 🔲 Pe	ersonally-admini	stered

Blister packs

Weekly blister packs can be made up by pharmacies for those patients who are fulfilling the criteria for eligibility. These include patients with sensory impairments, dexterity issues or cognitive impairment. If you think a patient may be eligible, it is important to liaise with their nominated pharmacy so they can complete an assessment form.

You do not need to issue weekly prescriptions for this to happen.

You can simply add a message that a drug is to be put in a blister pack using the patient information box.

Weekly prescribing

The only indications to be prescribing weekly are as follows:

- Dangers of intentional overdose
- Overuse of medication such as opiates
- Drug dependency

You do not need to be prescribing weekly for patients to receive a blister pack

Postdating prescriptions

You may wish to issue a delayed prescription for several reasons:

- Antibiotics in reserve
- Weekly prescribing of controlled drugs

You can postdate the prescription in this way:

		<u>S</u>	end Reminder	<u>Review</u>
Postdate	×			
23-Sep-2016	1211			Issue 1 of 4
dd-MMM-yyyy				
dd-MMM-yyyy				
dd-MMM-yyyy				
ОК	Cancel			
			Total Approxim	ate NHS Cost: £0.81
🕞 🔿 Store	Postdate 4 🔻	23-Sep-2016		Separate Non-GP
			Approve and Co	omplete Cancel
	23-Sep-2016 dd-MMM-yyyy dd-MMM-yyyy dd-MMM-yyyy OK	23-Sep-2016	Postdate × 23-Sep-2016 III dd-MMM-yyyy III dd-MMM-yyyy III OK Cancel	23-Sep-2016 dd-MMM-yyyy dd-MMM-yyyy dd-MMM-yyyy OK Cancel Total Approxim

SOP - Ordering and Receiving a Delivery of schedule 2 Controlled Drugs for Stock

TASK	COMMENTS
A stock check is to be undertaken daily to identify drug items that are running low and confirm accuracy of totals. Average weekly usage will show whether the Centre is likely to run out in the next 2-3 days	It is best practice to keep stock levels of CDs to a minimum, whilst ensuring that they are adequate to meet normal patient demand.
Drug items needed should be discussed with the relevant medicines lead for re-ordering	N.B. Only "whole packs" of Controlled drugs can be ordered. Shift leader who will notify the Head of IUC Nursing and AHPs via the shift report.
The Requisition / Order Form must be signed by a registered nurse or doctor in ink.	
This with the organisation code, name, occupation / professional qualification, and the address of Head Office.	
These forms are held by the Facilities Manager / Head of IUC Nursing and AHPs / Practice Lead	
A copy of the Requisition / Order Form should be placed in a folder which is in BrisDoc HQ or Practices and must be kept for at least 2 years.	Facilities Manager to maintain the folder.
The Requisition / Order Form should be taken, posted, or sent electronically to the supplier.	
The Designated Staff Member goes to collect the CDs from the Supplier, they must take their ID Badge.	To minimise the risk if a staff member is collecting then they must carry the items in a locked receptacle and ensure they reduce their risk of vulnerability (e.g., not collecting after dark).
The Designated Staff Member checks the delivery against the order.	
If the delivery is correct, sign the Delivery Note and return the relevant copy to the Pharmacist.	

SOP - Recording Prescriptions of Controlled Drugs

TASK	COMMENTS
Prescription pads must not be left in patient accessible locations in the IUC Treatment Centre or patient's home.	
Any loss of prescriptions should be reported immediately to the Head of IUC Nursing and AHPs or Medical Director. This may be via the Shift Manager out of hours. The BrisDoc learning event portal will be used.	
Prescriptions for Schedule 2 and 3 CDs may be computer generated but the signature must be in the prescriber's own handwriting in indelible ink	
The prescription must contain the following details:	
The patient's full name, address, NHS Number and, where appropriate, age.	'No fixed abode' is acceptable as an address for homeless people.
 The name and form of the drug, even if only one form exists 	
 The strength of the preparation, where appropriate (if more than one strength exists) 	Dosages and frequencies must be specific - not 'as directed'.
 The frequency and dosages to be taken 	Any remaining analog on the form
 The total quantity of the preparation, or the number of dose units to be supplied, in both words and figures (e.g., '60 sixty tablets') 	Any remaining space on the form must be crossed through to reduce the opportunity for fraud.
• Signed by the prescriber with their usual signature (this must be handwritten) and dated by them (the date does not have to be handwritten and can be either the date of signing OR the date the prescriber wishes the prescription to start).	It is inappropriate for a prescriber to prescribe a CD for themselves a family member, or a friend unless in a clinical emergency.
The address of the prescriber which must be within the UK.	
 The professional registration number and the profession of the person who signs the prescription 	
When a prescription containing a Schedule 2 or 3 CD, which directs that specified instalments of the total amount may be supplied at stated intervals, the first instalment must be supplied no later than 28 days after the 'appropriate date'.	If the prescription specifies a start date, the prescription can only be dispensed in accordance with the prescriber's directions.

CD prescriptions must be recorded on Adastra against the patient.	
Repeat prescribing of Schedule 2 and 3 CDs is not allowed.	Schedule 4 and 5 CDs may be ordered on prescriptions issued under the repeat dispensing scheme. For Schedule 4 CDs, the first prescription must be dispensed within 28 days.
Although not a legal requirement, Prescribers (both NHS and private) are strongly advised to limit the quantity of Schedule 2, 3 and 4 CDs prescribed to amounts that meet the patient's clinical need for up to 30 days' supply.	In exceptional circumstances, where the prescriber considers more than 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, a record of the reasons for deviating from the guidance should be made in the patient's notes and the prescriber should be able to justify the decision, if challenged.
Use the form FP10(MDA) or FP10MDA-SS to prescribe in instalments for Schedule 2 CDs, buprenorphine (Schedule 3), buprenorphine with naloxone (Schedule 3) or diazepam (Schedule 4) for drug addiction.	 This form must not be used for any other purpose, e.g., when the total quantity needs to be dispensed at one time - the normal FP10 form must be used. FP10MDA instalment prescriptions are intended for no more than 14 days' supply.
To be legally valid, an instalment prescription for a	<u>The dose</u>
Schedule 2 or 3 CD (except Temazepam) must include the following:	('as directed' is not acceptable, but 'one as directed' is acceptable)
The date, address and signature of the appropriate practitioner issuing the prescription	
 The dose to be taken & the strength and form of the preparation (e.g., mixture / tablets / capsules / ampoules) 	<u>The strength of the preparation.</u>
 The total quantity of the preparation in words and figures. 	In the case of methadone, there is more than one strength available, therefore this must be specified on
 The name and address of the patient 	the prescription
 The instalment amount and the intervals to be observed: 	The total quantity of the
1. The number of instalments	preparation in words and figures.

 2. The intervals to be observed between instalments; if necessary, instructions for supplies at weekends or bank holidays should be included 3. The total quantity of CD that will provide treatment for a period not exceeding 14 days 	This must be in dosage units (that is ml for a liquid, or number of tablets, capsules, ampoules and not the total mg of the drug)
4. The quantity to be supplied in each instalment	

SOP - Supplying Controlled Drugs to Patients

TASK	COMMENTS
Only authorised staff may dispense Controlled Drugs.	The term 'dispense' means to assemble and to supply a medicine
Prescriptions that have been issued to one patient must not be reissued to other patients.	
Preparation and administration of injections is subject to the PCC's guidelines.	
A second person should check the quantity and strength of dispensed CDs. Special care is needed in ensuring quantities and strengths of dispensed Controlled Drugs are correct.	
Controlled Drugs should be supplied in child-resistant containers.	
To dispense the item, take the script to the CD Storage Cabinet, take out the item you require, check how much stock of that item is left in the Cabinet and lock it.	The security procedures to be implemented are the same as detailed in the SOP - Storing, & Recording Storage of PCC Stocks of Controlled Drugs
A record should be kept of who collected the patient's prescription.	When the CD is given out ensure the back of the script is signed in the top right-hand box where indicated and at the usual place at the bottom, confirming the identity of the person collecting the medication.
Supplied Schedule 2 CDs must be entered into the Controlled Drug Register immediately.	
The date in the Controlled Drug Register must be the date of supply to the patient (not the date of assembling the drug).	Prescriptions are valid for 28 days.
Ensure we dispense the most minimum amount appropriate for the patient.	In exceptional circumstances, where the prescriber considers more than 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, a record of the reasons for deviating from the guidance should be made in the patient's notes on Adastra and the prescriber should be able to justify the decision, if challenged.

If the dispenser is unable to supply the total quantity prescribed, then the entry into the Controlled Drug Register must only be for the quantity supplied.	

SOP - Destroying and Recording the Destruction of Controlled Drugs on the Treatment Centre/GP Practice Premises

TASK	COMMENTS
The nominated person(s) responsible for Stock Control will maintain a running balance of drug stock.	
Stock checks will be held daily and will involve both a stock count and checking of expiry dates of CDs in the CD Storage Cabinet with a registered clinician.	
The designated clinician will contact the CCG Medicines Management Team to arrange a mutually suitable time and date for an Authorised Witness to be in attendance for destruction to take place.	
At the agreed time of Destruction, the following procedure will be implemented:	
 The HoN will verify the identification of the CCG Authorised Witness and ensure every stage of the destruction process will take place in their presence. Schedule 2 CDs must be destroyed in the presence of and as directed by a person legally authorised to witness the destruction of CD such as a Police CD Liaison Officer (CDLO). 	
 Each CD will be 'written out' of the CDR as it is added to the kit, destroyed, and totals re- calculated. 	
Each entry will specify:	
 The name, strength, and form of the product, The date, quantity destroyed, The printed name & professional registration number of authorised witness followed by their signature, The printed name and signature of the second witness. 	
 The CD Destruction Record Sheet will also be completed by the authorised witness and the second witness. 	
4. For CD stock, the balance remaining will be reconciled with the CDR.	
 The used kit will then be put in the CD Storage Cabinet whilst the inactivation process is taking place (this usually takes around 24 hours). 	

The CDs are now considered 'irretrievable', and the responsibility of the authorised witness is complete.	
 The PCC will ensure that the kit will be stored in the CD Storage Cabinet for at least 24 hours and arrange appropriate disposal of the solidified gel into a clinical waste bin. 	

This is a checklist from the NHS England:



3. NHS England SSW CD Destruction

SOP – Applying for a Controlled Drugs Licence

Controlled Drug Licences are obtained through the Home Office and are site-specific so any new/relocated sites will need a new licence. This responsibility sits with the Facilities team.

You can obtain a new licence through <u>Controlled drugs licence application form</u> (<u>eforms.homeoffice.gov.uk</u>). Governance Team have records of previous applications which can be used as an example.

The process of applying goes as follows:

- Submit application form
- Await to be assigned a Compliance Officer
- Compliance Officer will reach out and propose a date for a Compliance Visit. They will also ask for some further information, of which can be found below.
- Carry out the visit
- Action any improvements to process suggested in the visit.
- Await invoice for the CD Licence
- Pay invoice
- Receive CD Licence

This process can take between 2-3 months, including arranging and conducting the Compliance Visit. It's important that Controlled Drugs are not stored at a site until the CD Licence has been obtained.

Given that BrisDoc transport CDs between bases, we require a 'supply' and 'possess' licence – it's important to check that this is correct once the Licence has been received.

Authorised witnesses

When applying a CD Licence, you will need to appoint Authorised Witnesses for the destruction of drugs, enabling the destruction of CDs in the licenced persons' presence. These colleagues need to not handle medication for clinical use day-to-day, and have a DBS by security watchdog. If colleagues experience a change in address, name etc, they will need to apply for a new licence <u>through this link</u>. Please note that this can take up to 3 months to process.

Compliance Visit

Information requested ahead of the visit:

The visit:

The Compliance Officer will conduct a discussion around BrisDoc's process of storing, auditing, transportation, prescription and destruction of CDs. Examples of questions they may ask are:

- Who is usually present at the base where CDs are stored? e.g. hosts etc
- How often are the key codes changed?
- How often are CD Register records kept for?

All relevant information is in the Medicines Management Policy but it is worth meeting with relevant staff ahead of the visit to ensure that everybody is clear on process.

Renewing a Licence

Licences will need to be renewed yearly – it's worth beginning this application 2-3 months ahead of the previous licence's expiry date. This allows time for any necessary processing and Compliance Visits. You can renew CD Licences through this link - <u>Controlled drugs licence</u> application form (eforms.homeoffice.gov.uk).

Frequency of Compliance Visits will depend on decisions made by the home office. This could be only three-yearly or as often as yearly. It's important to look out for emails from the Home Office regarding CDs, and to forward these to the Director of Governance and other relevant colleagues.

Changing a Licence

You can make any changes to existing Licences, including:

- Change in authorised witness
- Requesting additional CD schedules
- Requesting a change of activity
- Change of name
- Change of registration details.

This would also be via this link <u>Controlled drugs licence application form</u> (eforms.homeoffice.gov.uk).

SOP – Operations management of CDs in Bases & Cars

The controlled drugs (CDs) we hold in Severnside, their class and schedule are all listed in the table below:

Medication	Class	Schedule
Codeine	B	5
Diazepam	С	4
Lorazepam	С	4
Midazolam	С	3
Oral morphine	С	5
Morphine	A	2
Oxycodone	A	2

It is a legal requirement for all organisations with controlled drugs to safely store, record, transport, and account for drugs in their possession. For best practice BrisDoc adopts the same schedule 2 principles for managing schedule 3, 4 and 5 CDs.

The role of operational co-owners is to ensure safe keeping of the keys and keycodes. All controlled drug checks, dispensing controlled drugs or transporting controlled drugs must be done together with a clinician. It is the clinician that **handles** controls drugs and are ultimately responsible for all CDs under all circumstances. Operational co-owners are witnesses, and counter-signatories in daily stock checks and dispensing all CDs.

The Process for Daily Checks of the CDs at bases

The schedule 2 drugs are stored in the CD safe inside the drug cupboard and the schedule 3,4 and 5 drugs are stored in the drug cupboard at 168 Locking Road, Cossham and Marksbury Road

There are two separate CD registers, one for Schedule 2 drugs and one for Schedule 3,4 and 5 drugs. These are stored inside the drug cupboard.

- The host will accompany the clinician to the carry out the checks at the beginning of the evening shift on weekdays, and at the start of the day on weekends to carry out the CD audit.
- The audit will be led by the clinician. The Host may open the safe and drug cupboard. The drugs will be handled by the clinician who will lead the count.
- The host will sign the register as a witness to the audit

- The clinician will place the drugs back in to the safe. The Host will lock the safe and store keys
- This process must be done together with the clinician.

Any discrepancies or breakages of any schedule CD must be reported as a Learning Event and flagged to the Shift Manager. BrisDoc has a requirement to report discrepancies within 24 hours, therefore it is important to log the learning event immediately.

Transportation of Schedule 2 drugs in the Car

Schedule 2 CDs are not stored in the cars, however on occasions they may need to be taken on a home visit or transported between bases. The following process must be followed:

- The Schedule 2 CD is signed out of the CD safe at base handled only by a clinician and witnessed by the operational team member.
- The CD register in the base is updated by the clinician and witnessed by the member of the operational team
- The clinician accompanied by the driver will take the CDs to the car and place them in the car CD safe and lock the safe
- The clinician will sign the CDs into the CD register in the car and be witnessed by the driver
- The clinician will take the CDs out of the CD safe and record this in the CD register witnessed by the driver
- If the CD is not used on a visit, it will be put back in the car CD safe and signed back into the CD register by the clinician witnessed by the driver
- Once back at base the clinician will signed the CDs out of the CD register in the car and remove the CDs from the car safe. This will be witnessed by the driver.
- The driver will accompany the clinician with the CDs and put back in the base CD safe and sign it into the base CD register witnessed by the driver / Host (this will be the same for signing a CD into a different base)

The Process for Daily Checks of the CDs in the cars

These drugs, schedule 3,4 and 5 CDs are stored in the car medication boxes. The CD log for the car is on the audit book 'In car drug list and stock level'.

• The driver will accompany the clinician to carry out the checks at the beginning of every shift, if there is no visiting clinician the driver will need to ask one of the base clinicians.

- The audit will be led by the clinician who will remove the drugs, carry out the count, record on the 'in car drug list and stock level' sheet, witnessed by the driver
- The clinician will place the drugs back in to the box

Discrepancies or breakages of any schedule CD must be reported as a Learning Event and flagged to the Shift Manager. BrisDoc has a requirement to report discrepancies within 24 hours, therefore it is important to log the learning event immediately.