PROTOCOL FOR POINT of CARE BLOOD ANALYSIS (PoCBA) IN CLOZAPINE CLINICS

AND

THE SUPPLY of CLOZAPINE – (Appendix)

EXECUTIVE SUMMARY:

Protocol to support the use of PoCBA within clinical settings for those patients who require routine blood sampling for the purpose of maintenance on clozapine treatment. This policy outlines and supports the appropriate training needs of staff to enable safe practice using PoCBA equipment. The protocol appendix covers the Supply of Clozapine from Clozapine Clinics that use Point of Care Blood Analysis (PoCBA) testing.

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Appendix: The Supply of Clozapine from Clinics that use PoCBA testing
1.0 INTRODUCTION

1.1 Purpose of protocol

1.1.1 This protocol has been produced to assist clinicians in managing the use of Point of Care Haematological Analysis Equipment (PoCBA). It enables staff to carry out immediate blood tests used for clozapine, and is set against the following background:

- an identified need to change our current working practice to meet the needs of the service;
- an offer of provision of equipment within the current Novartis contract;
- a move towards more user-friendly practices such as same day blood test results and medication collection by patients.

1.1.2 It also enables clozapine to be issued from clinics that utilise PoCBA testing. (See appendix).

1.2 Definitions

1.2.1 PoCBA refers to point of care blood analysis.

1.2.2 PoCBA equipment refers to the Novartis supplied Sysmex ‘pocH-100i’ machine. This is a small, fully automated haematological analyser used by selected clozapine clinics across the Trust for analysing three areas of a traditional full blood count (FBC). These results are used in determining the continued suitability of patients to continue to receive clozapine medication.

1.3 Scope of protocol

1.3.1 This protocol extends to all clozapine clinic staff using PoCBA equipment

1.4 Principles

1.4.1 Patients on clozapine are required to attend for routine blood sampling on a weekly, fortnightly or monthly basis and are then asked to re-attend to collect their medication. The introduction of PoCBA means that the patient can attend for sampling and usually collect their medication in the same clinic visit

1.4.2 The underpinning principle of this protocol is that it improves patient care by reducing attendance at clinics.
2.0 PROTOCOL STATEMENT

2.1 All staff engaged in PoCBA activity are expected to adhere to all aspects of this protocol.

3.0 PROTOCOL AIMS

3.1 To introduce the use of PoCBA in a safe and effective manner, giving patients a more cohesive service and providing clinicians further tools to expand the service provided.

3.2 To ensure that recording of blood sampling, and the quarantining and supply of clozapine subsequent to PoCBA use, is managed within a safe and well governed framework.

3.3 To ensure that through adequate training, staff are competent to use the equipment.

3.4 To ensure that adequate error reporting methods are in place to deal with any future problems with use of the PoCBA equipment, utilising the Trust’s incident reporting process (IR1).

3.5 To ensure changes to use are implemented correctly and in a timely fashion after proper consultation.

3.6 To ensure use of PoCBA conforms to Health and Safety, Management of Medical Devices, and Infection Control Policy and Procedures.

3.7 To ensure that staff are aware of the processes of quarantining and issuing clozapine in a safe way

4.0 PROCEDURAL GUIDELINES FOR THE USE OF PoCBA

4.1 Training

4.1.1 All staff using PoCBA equipment must have adequate training in its use. This training can be external, (via Novartis/Sysmex), or internal (by staff trained by Novartis/Sysmex to a 'trained to train' level).

4.1.2 Certified trainees, (at least two per machine), will be trained at Sysmex UK Ltd by the Sysmex point of care team

4.1.3 A register of trained staff will be kept at the clinical base, at Sysmex and at Novartis and will be available for scrutiny by stakeholders, - e.g. the Medical Devices Committee. Annual updates to this register will be made, with clinical staff responsible for ensuring their professional practice is within the training guidelines. Clinic staff will undergo further training as required by Novartis/Sysmex.
4.1.4 Staff carrying out these procedures will have up to date BBV vaccinations such as hep-B and should attend periodic infection control update training.

4.1.5 Sysmex will initially give clinic staff two days of training. This will enable these staff to properly use the pocH-100i equipment and be proficient in undertaking any specific quality control procedures required.

4.1.6 These staff will be trained to a level where they can then train other staff in the use of the equipment. These additional staff will not be able to train further staff unless they undertake the Sysmex two day training course.

4.1.7 Review of training is described in section 4.12

4.2 Overview of equipment

4.2.1 The Sysmex PoCBA machine is a small, fully automated haematological analyser used within clozapine clinics for analysing 3 areas of a traditional full blood count (FBC).

4.2.2 It is approximately the size of a computer tower and is equipped with an LCD touch screen, a patient label bar code reader and a secure internet connection.

4.2.3 Sundry equipment comprises a diluent bottle, which contains a carrier fluid used to enable the PoCBA machine to analyse blood, and a waste bottle where the small amounts of analysed blood and diluent are stored after use for disposal. Other sundries are the weekly quality control chemicals, (kept on site), and external quality control chemicals occasionally supplied by Sysmex.

4.2.4 PoCBA uses standard Vacutainer blood sampling tubes. This is instead of the analysis tubes used for courier or postal samples sent to Novartis for analysis from non-PoCBA clinics.

4.2.5 The internet connection is encrypted and runs through current Trust IT systems.

4.2.6 It is the responsibility of the manager of the clinic to ensure that the procedure concerning the documentation of loan equipment indemnity has been completed. (See Management of Medical Devices Policy, p47 onwards).

4.3 Support services in place

4.3.1 The PoCBA machine will remains the property of Novartis and its contracted supplier, Sysmex.
4.3.2 Novartis/Sysmex will be responsible for all repairs, alterations and replacement of the equipment as needed to ensure full functioning for its intended use.

4.3.3 Novartis/Sysmex monitors the equipment remotely via the secure internet connection and will contact clinic staff if any errors of use or equipment failure occur.

4.3.4 Novartis/Sysmex technical staff are available during normal office hours to advise on correct use of the machine.

4.3.5 Novartis/Sysmex staff provide initial training of staff to a ‘trained to teach’ level. Regular review of training will occur.

4.3.6 Any incorrect use, or failure of the equipment, will be reported following the Trust’s incident reporting procedures. Clinics have the following support services/lead resources available for advice and assistance:
   o Clinical pharmacy team
   o Infection control team
   o Clinical risk manager
   o Medical devices liaison officer (MDLO)

4.4 Use of the equipment – day to day clinic use

4.4.1 The use of the equipment is set out fully in the Sysmex pocH-100i Haematology Analyser Customer Training Course Manual. This document must remain available at all times to staff operating the PoCBA equipment.

4.4.2 The equipment may only be used by specifically trained staff, for the analysis of blood of patients registered with the Novartis Clozaril Patient Monitoring Service (CPMS). Any deviation from approved use must be agreed in advance with Novartis/Sysmex.

4.5 Equipment failure

4.5.1 In the first instance the equipment will need to be quarantined and clearly labelled and dated as ‘Faulty Device - Do Not Use’ in accordance with the Trust Management of Medical Devices Policy. Any blood-contaminated spillage should be dealt with as documented in the Trust Prevention and Control of Infection Policy. Biological spill kits must be available in the event that a spillage does occur.

4.5.2 Spillage within the PoCBA equipment will be dealt with by Sysmex. Clinic staff must contact them to arrange decontamination – the preferred method being machine removal from the site by Sysmex staff and later return or replacement of equipment.
4.5.3 Staff using the equipment will follow the procedure set out in section 4.11. They will assist Novartis/Sysmex in determining the cause of the failure and liaise with Trust staff around any outcome. The possible outcomes are:

a. Fault rectified over telephone.

b. Fault rectified by service engineer from Sysmex.

c. Fault will take time to rectify. Replacement equipment available.

d. Fault will take time to rectify. Replacement equipment not available.

e. Use of equipment is terminated in response to a Medical Device Alert from the MHRA. **MHRA notification is then a Trust responsibility carried out by the MDLO via the incident reporting process.** The Risk and Safety Team should be contacted by phone at the earliest opportunity.

f. Unforeseen circumstances put equipment out of use, (e.g. fire in clinic area, power cut).

4.5.4 For a) & b) staff should be able to continue use of the equipment after following event reporting guidelines set out in section 4.11

4.6 Back up systems for blood analysis

4.6.1 Should the PoCBA system become non-operational, staff will continue with CPMS procedures that are in use in clinics without PoCBA. This will involve posting/couriering collection of samples to the CPMS laboratory for analysis.

4.7 Data protection

4.7.1 The clinic will maintain clinical patient records in line with current Trust Policies.

4.7.2 The CPMS and eCPMS system allows registered users to access an online database of patient records. The registration procedure provides secure access. The PoCBA access for staff will be in addition to current secure eCPMS access.

4.7.3 Data protection responsibility for the CPMS and eCPMS systems lies with Novartis.

4.8 Quality control and quality assurance

4.8.1 **The procedure for internal & external quality control is documented in the Sysmex pocH-100i Haematology Analyser Customer Training Course Manual.**

4.8.2 All quality control procedures will be in line with the National External Quality Assurance Scheme (NEQAS).
4.8.3 Trained clinic staff under direction of Novartis/Sysmex will undertake internal quality control testing. Results from these tests will be available to Novartis/Sysmex and to PoCBA-trained clinic staff.

4.8.4 External quality control will only be carried out by clinic staff that are specifically trained in how to do this on their certified training course. No other staff may carry out NEQAS testing.

4.8.5 A nominated clinician will be responsible for taking overall responsibility for quality control and for ensuring that this role is delegated to an appropriately trained and competent member of staff, in their planned absence. In instances of unplanned absence, responsibility for this will reside with the clinic manager.

4.8.6 Novartis/Sysmex retains management of all quality control requirements. Clinic staff will adhere to Novartis/Sysmex procedures for all quality control issues.

4.8.7 Novartis/Sysmex will lead on any changes to quality control procedures.

4.8.8 A record of quality control undertaken will be held within the clinic, (either within an electronic database or in written form), and this information will be used within internal audit or any review of use of the PoCBA equipment.

4.9 Disposal of blood by-products and storage of samples

4.9.1 Blood & diluent waste will be stored in the PoCBA equipment only so long as the collection bottle has capacity. On reaching ‘full’ level the equipment operator will remove the bottle, secure its top, seal the top with ‘hazmat tape’ and replace with a new, empty collection bottle.

4.9.2 The bottle of waste blood/diluent will be labelled with the clinic details, (as per current Sharps Policy), and sealed into a ‘fluid-tight’ clinical waste bin. At present NHS Supplies provides a suitable container – the FSL079 Clinisafe, fluid-tight bin. This will also be labelled and arrangements made with Trust support staff to remove from the clinic area, as is currently done with sharps boxes. A sharps transport box, (as used in community settings), will be provided to assist support staff and maintain good infection control.

4.9.3 Blood samples stored for up to 24hours will be kept in a locked fridge within the clinic premises. This fridge will solely be for the storage of blood samples that have been processed on the pocH-100i equipment, or are waiting to be analysed by this equipment. This fridge will be maintained in good working order, with temperature control checks carried out daily and recorded. Blood samples will be double-sealed in a disposable plastic bag within a sealed plastic container.
4.9.4 **Blood Samples – after 24hour storage** will be sealed into a ‘fluid-tight’ clinical waste bin and the same procedure followed as for blood & diluent waste.

4.9.5 **Sharps** will be disposed of in accordance with the current Trust Policy.

4.9.6 **Any other associated equipment, products or sundries** will be disposed of in accordance with the Trust Prevention and Control of Infection Policy.

4.10 **Health, safety, waste management and infection control issues**

4.10.1 The overall management of the Health & Safety aspects of use of PoCBA will rest with the Head of Risk and Safety and the Integrated Governance Teams.

4.10.2 **All staff carrying out blood-testing procedures must wear personal protection equipment (PPE) and should be vaccinated against blood borne infection such as hepatitis-B.**

4.11 **Event reporting**

4.11.1 The methods and procedures of incident reporting are to be understood and carried out by all clinic staff. All incidents or near misses must be recorded as per Trust policy using the IR1 form.

4.11.2 In the event of equipment failure, as set out in section 4.5, clinic staff will carry out the following actions:

- Fully complete an Incident Report Form [IR1].
- Monday to Friday between 9am and 5pm, phone or email the Risk and Safety team and the identified manager with operational management responsibility for the clinic and give a verbal or email report of the event. Supply any supporting information requested.
- Out of hours report the event at the next available time. This should also be reported to the person responsible for the management of medical devices
- Inform Novartis/ Sysmex in the following way:
  

  Further information can be found in the Sysmex pocH-100i Haematology Analyser Customer Training Course Manual.

- Any incident considered to be related to equipment failure must also be reported to the Trust’s MDLO.
4.11.3 All directions from Novartis/ Sysmex or from the MDLO to cease use of the machine must be followed immediately and recommencement of use must not occur without direct instructions from same.

4.12 Ongoing review of Use

4.12.1 Regular review of the use of PoCBA will occur. Reviews will involve Novartis/ Sysmex, clinic staff and appropriate staff involved in Health and Safety, Medical Devices and Infection Control. Any changes proposed to the use of the PoCBA will need to be agreed by all parties and policy amended.

4.12.2 Use of PoCBA within clinics will be reviewed at 3-month intervals for the first year. Subsequently, reviews should occur on a 6-monthly basis.

4.12.3 Reviews may involve the following:

- Clozapine clinic staff and managers
- Clinical Risk Manager
- Medical Devices Liaison Officer

4.12.4 Reviews may take the form of a formal reporting meeting, a circulated written report, or audit of the use of the equipment. Novartis may be asked to contribute information they may hold. At least one audit should occur within the first two years and the scope of this will be developed over the first 3 months of use.

4.12.5 The Novartis Contract of Use for PoCBA sets out the procedure for the Trust to withdraw from the Contracted Terms of Use for the PoCBA analysis equipment.

5.0 MONITORING COMPLIANCE

See section 4.12

6.0 DISSEMINATION AND IMPLEMENTATION OF POLICY

This document will be available to all staff via the Trust intranet. Managers who feel this is relevant to their teams will ensure that all staff have been briefed on its contents and on what it means for them.
7.0 REFERENCE DOCUMENTS

This protocol has been developed with reference to the following supporting documents:

Policy for use of point of care haematological analysis - Kent and Medway NHS Social care Partnership Trust

Sysmex pocH-100i Haematology Analyser Customer Training Course Manual

Novartis Contract of Use – POCBA

Blood count form for multiple patients (and other associated documentation) – Clozaril Patient Monitoring Service, Novartis

The Medicines Code – Sussex Partnership NHS Foundation Trust (SPT)

Venepuncture Guidance for Good Practice (SPT)

Prevention and Control of Infection Control Policy (SPT)

Management of Medical Devices Policy (RHS-04 2011) (SPT)

Reporting, Recording and Investigation of Incidents (SPT)

8.0 ADHERENCE TO OTHER POLICIES AND GUIDANCE

Clinic staff trained in the use of PoCBA must ensure that all relevant Health and Safety, Medical Devices and Infection Control Policies are adhered to.

9.0 BIBLIOGRAPHY / CROSS-REFERENCE

Reference is also made to the Clozaril Patient Monitoring Service – CPMS & eCPMS – online website at: https://www.clozaril.co.uk/scrMain.htm

Reference is also made to the Medicines & Healthcare Products Regulatory Agency (MHRA) via their online website at: www.devices.mhra.gov.uk
Appendix: The Supply of Clozapine from Clinics that use PoCBA testing

Purpose
To enable clozapine to be issued from clozapine clinics that utilize PoCBA testing.

Scope
Trust clozapine clinic staff: dispensing pharmacies

Location
Clozapine clinics within the Trust.

Procedure
There are four main aspects to the procedure: ordering the clozapine via faxing; placing the received clozapine into quarantine; releasing the clozapine on receipt of a valid blood result, opportunity for patient review.

A. Fax order
1. All the clozapine required for the clinic in any one week should be ordered by completing the faxing section of the PoCBA clozapine issue form (see form 1).

2. The form should be faxed to the dispensing pharmacy to allow sufficient time for the clozapine to be delivered and placed into quarantine in preparation for the clozapine clinic.

3. The person faxing the form should confirm that the information has been received by the dispensing pharmacy.

B. Placing Clozapine into quarantine
1. The clozapine supplied will be checked against the current prescription by a pharmacist or accredited checking pharmacy technician, at the point of dispensing. The “check against current script by pharmacy staff” box on the PoCBA clozapine issue form will be initialled and dated.

2. On arrival at the clinic, the medication will be placed in a separate locked cupboard used only for quarantined clozapine and the “date into quarantine” box on the PoCBA clozapine issue form will be initialled and dated.

C. Medication Issued
1. Medication can only be issued by a suitably qualified member of staff – the Trust pharmacy locality lead will agree the exact criteria with the clinic/team manager.
2. Once a valid blood result is received the date of the blood test and status of the result (RED, AMBER or GREEN) sections within the medication issued section of the PoCBA form should be completed.

3. If a GREEN result is obtained -
   a. Confirm that there have been no changes to the prescription for the clozapine to be supplied. Any discrepancies will be queried with dispensing pharmacy before medication is issued to patient.
   b. If there are no changes issue the clozapine currently in quarantine and complete the relevant columns of the medication issued section of form 1.

4. If an AMBER or RED result is obtained the relevant clozapine patient monitoring service should be contacted or dispensing pharmacy.

D. Patient Review

When patients attend for blood testing and collection of medication, this should be used as an opportunity to discuss their general health and also any concerns they may have about their treatment. Consideration should also be given to using the opportunity to complete 6-monthly GASS assessments.

NB: *If the machine is not operational, clozapine clinic staff should agree the appropriate procedure to follow with Trust pharmacy locality staff.*
Form 1: Clozapine issued from clinic with PoCBA

<table>
<thead>
<tr>
<th>Clozapine clinic name and address</th>
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<tbody>
<tr>
<td>Ordered by (print name)</td>
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<tr>
<td>Date required by</td>
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Fax order

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Date of Birth</th>
<th>List all medication required – including clozapine</th>
<th>Amount required (days)</th>
<th>✔ For compliance aid</th>
<th>Check against current script by pharmacy staff (initials)</th>
<th>Date into quarantine</th>
<th>Blood result (R, A, G)</th>
<th>Date of blood test</th>
<th>Issued to patient by (initials)</th>
</tr>
</thead>
</table>