Appendix 4

Clozapine Clinic Standard Work

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1 Introduction

1.1 This procedure documents the processes required to effectively run a clozapine clinic. It is not an exhaustive procedure as there are many clinical situations and issues with the Yumizen H500 Automated Haematology Analyser system that can occur during the course of the clinic. Therefore this standard work must be supported by the operating manual from the manufacturer of the machine (HORIBA Medical). Staff groups must have been trained to the required level previous to their work in clinic.

2 Scope

2.1 The purpose of this document is to define the standards to be attained in the operation of a Northumberland, Tyne and Wear NHS Foundation Trust (NTW/the Trust) clozapine clinic in relation to physical health monitoring, recording and medicines management.

2.2 The majority of NTW patients prescribed clozapine are managed within the Trust’s clozapine clinics. If anyone falls outside of this system, arrangements must be documented as part of the patient’s care plan.

3 Staff Training/Qualification Requirements

3.1 It is recommended that two members of staff are needed to run a clozapine clinic - a qualified member of staff accompanied by a non-qualified member of staff.

3.2 The activities described in this standard work must only be undertaken by staff who are trained and have demonstrated competence in each relevant aspect. Staff who are not competent or confident should seek advice before carrying out any of these activities.
### Terminology

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Staff Group/Requirements</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualified</td>
<td>Nurse or pharmacy technician registered with professional body</td>
<td>All activities</td>
</tr>
<tr>
<td>Non-qualified</td>
<td>Support workers and pharmacy assistants</td>
<td>All activities except:</td>
</tr>
<tr>
<td></td>
<td>- checking and issuing medication to patients</td>
<td>- mental state examination</td>
</tr>
<tr>
<td>Yumizen H500</td>
<td>Qualified or non-qualified staff must have completed the e-learning and either Level 1 or Level 2 training provided by HORIBA Medical. Online annual update required to maintain registration</td>
<td>Operation of Yumizen H500 system</td>
</tr>
<tr>
<td>Phlebotomy trained</td>
<td>Qualified or non-qualified staff must have completed the NTW Phlebotomy Training and have been deemed competent by a Phlebotomy Supervisor (see NTW(C)35 Phlebotomy Policy)</td>
<td>Take blood sample</td>
</tr>
</tbody>
</table>

### 4 Procedure

#### 4.1 Setting up the clinic

4.1.1 Power up Yumizen H500 machine.

4.1.2 Carry out any required maintenance and run daily low and normal ‘Quality Control’ samples. Access to information on the operation of the equipment can be sought from the Yumizen H500 User Guide supplied with each machine.

4.1.3 Collect and arrange required phlebotomy equipment as per the Trust's NTW(C)35 Phlebotomy Policy.

#### 4.2 Medication availability check

4.2.1 Check off pre-dispensed medication against pharmacy dispensing list.

4.2.2 Check off the dispensing list against RiO clinic diary to ensure appropriate medication has arrived for every patient due to receive it from the clinic (including compliance aids/correct quantity of medication).

4.2.3 Lock the clozapine in a designated medicines cupboard until it is needed.
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4.2.4 Sign and date the dispensing list and file in the clinic room.

4.2.5 Liaise with pharmacy technician attached to clinic/dispensing pharmacy to arrange supply of any required medication and resolve any discrepancies

4.3 Physical/Mental Health Interventions

4.3.1 Greet patient and seat in waiting area.

4.3.2 Check RiO for Progress Notes and Clozapine Clinic Record New for information since/from last clinic. The Clozapine Clinic Record New can be found on RiO at the following location: Service Specific Files > Physical Treatment > Clozapine Documentation.

4.3.3 Call patient into clinic/treatment room.

4.3.4 Measure patient’s BP, pulse, weight/BMI/waist circumference and height.

4.3.5 Check for changes in smoking status.

4.3.6 Perform Mental State Examination.

4.3.7 Any physical health monitoring parameters, side effects or changes to mental state that require further investigation should be reported to the care co-ordinator, consultant or GP as appropriate.

4.3.8 Take FBC (full blood count) sample as per the Trust’s NTW(C)35 – Phlebotomy Policy

4.3.9 Process in Yumizen H500 machine as per HORIBA Medical operating manual.

4.4 Medicines Management Interventions

4.4.1 At every clinic visit, question the patient on side-effects (bowel motility, respiration/breathing difficulties, hypersalivation, sedation and any other problems), adherence issues, efficacy of medication, difficulty accessing medication.

4.4.2 The RiO Side-Effect Monitoring Record for Clozapine should be completed with the patient at least annually. There is a link to this from the Clozapine Clinic Record New.

4.4.3 Check medication against current prescription:

- Quantity to last until next appointment
- Directions on label
- Dose matches copy of prescription
- Check the dose of clozapine with the patient and carer
- Record dose in Clozapine Clinic Record New
4.4.4 The supply of clozapine is dependant on the result obtained from the Yumizen H500 machine:

- **Green result** - record result, dose and next appointment on Clozapine Clinic Record New, issue medication to patient
- **Amber result** - re-spin then re-analyse blood sample in Yumizen H500 machine to confirm amber result. If result is still amber, issue appointment for follow-up blood sample as per DMS Amber Protocol. Issue medication and document arrangements on Clozapine Clinic Record New and Progress Notes
- **Red result** - re-spin then re-analyse sample in Yumizen H500 machine to confirm second red result. Question patient on how they feel physically. Liaise with DMS, record result onto RiO Progress Notes and Clozapine Clinic Record New. Inform consultant/care co-ordinator/carer and give appointment for follow-up blood sampling.

**WITHOLD CLOZAPINE SUPPLY**

Counsel patient on symptoms to look out for (sore throat, temperature, flu like symptoms) and what to do if they experience any of them (access medical attention). Express importance of not taking any further clozapine until instructed to do so by clinic staff (there may be a supply of clozapine at home). Enquire if patient has knowledge of out of hours access to NTW services should they need them.

4.5 Changes to medication

4.5.1 When doses have been changed after the medication has been dispensed/arrived in clinic the following steps must be followed:

- Contact prescriber/secretary and inform them that a new prescription is required which must be faxed to pharmacy SNH (0191 2232203) or SGP (01670 501889) with follow up phone call to ensure receipt and understanding of issue
- Arrange delivery as appropriate (if patient has a remaining supply at home, could it be posted/collected from clinic at a later time etc.). If urgent delivery is needed, care co-ordinator/support worker may be able to facilitate or arrange a taxi
- Supplies of medication must not be amended in clinic
- Pharmacy staff will continue to obtain repeat prescriptions from consultant psychiatrists and automatically supply medications to clinics using pharmacy dispensing lists which are updated by pharmacy staff in liaison with clinic staff

4.5 Short term non-attendance

<table>
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<tr>
<th>Monitoring Frequency</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly</td>
<td>Arrange for attendance ASAP</td>
<td>Query sufficient quantity of clozapine in possession. Can have up to <strong>3 days extra</strong> from current valid</td>
<td>Arrange extra supply if needed.</td>
<td>Document arrangement on RiO and book</td>
</tr>
</tbody>
</table>
### 4.6 Further non-attendance and follow up

4.6.1 Follow local DNA protocol. Usually attempt to contact via telephone/letter.

4.6.2 Arrange with patient/care coordinator to have patient attend at alternative time/venue whilst ensuring current valid blood result remains active until new appointment.

4.6.3 If a patient does not have a current valid blood sample analysed within the relevant timescale (as per DMS procedure) they will become ‘de-registered’ and require re-titration.

4.6.4 Contact DMS for guidance and inform consultant and nurse contact for that patient.

4.6.5 If patient does go outside of current blood validity, do not issue any medication. Record all information on Progress Notes/Clozapine Clinic Record New.

### 4.7 End of clinic

4.7.1 Switch off the Yumizen H500 system and tidy away all equipment.

4.7.2 Any medication not given out should be stored in the locked cupboard and returned to the dispensing pharmacy at the next available opportunity, after agreeing this with pharmacy staff.

### 5 Recording Clozapine Clinic Activity

5.1 All routine findings and results should be recorded in the Clozapine Clinic Record New.

5.2 It is good practice to make an entry in the Progress Notes of the patient’s attendance at the clinic with reference to the completion of the Clozapine Clinic Record New.
5.3 Any abnormal or unusual occurrences should be recorded in the Progress Notes in addition to the Clozapine Clinic Record New.

5.4 Additional physical health monitoring should be recorded in the Core Physical Health Monitoring Form.

5.5 The GP should be kept up to date on the patient’s clozapine monitoring. It is recommended that a copy of the Clozapine Clinic Record New is sent to the patient’s GP every six months. A printable version of this record is available from RiO in Service Specific Files > Physical Treatment > Printable Forms.

5.6 The Clozapine Maintenance Care Plan should be kept up to date in RiO Service Specific Files > Physical Treatment > Clozapine Documentation.

### 6 Summary of Physical Health Monitoring Requirements

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Monitoring</th>
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<tr>
<td>Every clinic visit</td>
<td>Weight/BMI&lt;br&gt;BP and pulse&lt;br&gt;FBC (for clozapine)&lt;br&gt;Changes to respiration&lt;br&gt;Changes to bowel habits&lt;br&gt;Smoking status</td>
</tr>
<tr>
<td>3 months following initiation</td>
<td>Lipid profile&lt;br&gt;LFTs&lt;br&gt;Blood glucose (preferably fasting) and HbA1c&lt;br&gt;Lifestyle review</td>
</tr>
<tr>
<td>Annually</td>
<td>Waist circumference&lt;br&gt;Lipid profile&lt;br&gt;LFTs&lt;br&gt;U&amp;Es and eGFR&lt;br&gt;Blood glucose (preferably fasting) and HbA1c&lt;br&gt;CV risk assessment&lt;br&gt;Clozapine plasma level&lt;br&gt;ECG&lt;br&gt;Side effect rating scale&lt;br&gt;Lifestyle review</td>
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