

## STANDARD OPERATING PROCEDURE CLOZAPINE CLINIC

<b>Document Reference</b>	SOP19-011
<b>Version Number</b>	2.7
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<b>Instigated by: Date Instigated:</b>	
<b>Date Last Reviewed:</b>	5 June 2023
<b>Date of Next Review:</b>	June 2026
<b>Consultation:</b>	Drugs and Therapeutic Group
<b>Ratified and Quality Checked by: Date Ratified:</b>	Director Sign off – Weeliat Chong (5 June 2023) Drugs and Therapeutics Group – (27 July 2023)
<b>Name of Trust Strategy / Policy / Guidelines this SOP refers to:</b>	

**VALIDITY – Documents should be accessed via the Trust internet to ensure the current version is used.**

### CHANGE RECORD

Version	Date	Change details
1.1	Aug14	Format updated and changed to accommodate procedure at all clozapine clinics. Removal of name of RMO at Miranda House and references to use of patient notes on eCPMS by HFT and Lloyds staff
1.12	Apr15	Amendment to layout Appendix 3 monitoring form, days and staffing requirements of Miranda house Clinic
2.0	Apr18	Review . Wording amendments due to changing on to Lorenzo system. Staffing levels. HFT name change. Pharmacy phone number. Guideline for discontinuation of clozapine. Guideline for out of area patient and when other manufacturers of clozapine are used. Signing for checking prescription and receipt of medication by patient. Collection of blood samples at Humber Centre.
2.1	Dec 18	Inclusion of responsibilities when admitting/discharging from hospitals and in/out of area. Wording amendments for registering staff for use of POCBA.
2.2	Jan 19	Letter when going abroad. Wording to sections 15 and 25.
2.3	Jan 20	Addition to Introduction, wording changes to sections 17 and 21
2.4	Nov 20	Changes to the dispensing process, moved appendix 4 to section 26. Addition of appendix 5.
2.5	March 21	“where they can have a hot/cold drink” removed as not appropriate during pandemic. “Any score of ‘2’ or above should be considered for reporting” amended to “all scores of 2 will be reported”.
2.6	March 2023	Reviewed. Section 21.3 - Plasma levels are now analysed by ASI Laboratory and are £17.70 per sample. The link to access results has been added 20 21.3. The Milan group is now named Viatrix (SOP amended to reflect this). Section 16.3 Inpatient prescriptions are now dispensed with directions printed on the label in line with other departments. Approved at DTG (30 March 2023).
2.7	June 2023	Reviewed. Section 10.3 - Removal of disengagement flow chart and more specific guidelines added to specify actions in the event of a patient disengaging from the blood sample and physical monitoring appointment. Approved by Director sign-off (Weeliat Chong – 5 June 2023) and at DTG (27 July 2023).

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## Abbreviations used in this Standard Operating Procedure:

PoCHi -	Point of Care Haematology information
PoCBA -	Point of Care Blood Analyser
FBC -	Full Blood Count
WCC -	White Cell Count
CPMS -	Clozapine Patient Monitoring Service
RC -	Responsible Clinician
ECG -	Electro-Cardio-Graph
QC -	Quality Control
NEQAS -	National External Quality Assessment Scheme
STR-	Support Time Recovery
BDH-	Bridlington and District Hospital
HRI-	Hull Royal Infirmary
HTFT-	Humber Teaching NHS Foundation Trust

## 1. Introduction

Clozapine is a newer generation, atypical, anti-psychotic drug which has proved very effective in cases of drug resistant schizophrenia. (See NICE guidance for further information) However because the drug is known to cause neutropenia and/or agranulocytosis in some patients, it is a requirement that patients receive regular blood testing and a differential white cell count obtained. Patients may only receive continued treatment on receipt of a valid result (WCC, neutrophils and platelets within an acceptable range) from CPMS

This monitoring will be carried out in line with Humber Teaching NHS Foundation Trust (HTFT) policy and guidelines.

Evidence from pilot schemes at Miranda House, Hull and Becca House, Bridlington shows that it is most favourable for the patient (thereby increasing/facilitating compliance) if this monitoring can be carried out in a clinic specially designated for the performance of phlebotomy, the carrying out the differential white cell count on a Point of Care Haematology Analyser (PoCHi) and in the case of Miranda House the subsequent issuing of the patient's next supply of Clozapine (if appropriate).

Further detailed information re. all aspects of Clozapine is available locally on the HTF Trust website by typing 'clozapine' in to the search engine.

The SOP is to be used in conjunction with the clozapine guidelines.

**Patient Confidentiality** All staff in the clinic is aware of the trust's 'Safe Haven Policy' and will always adhere to the procedures within it to maintain patient confidentiality.

## 2. Environment & Equipment requirements

The designated clinic area is large enough to accommodate the equipment and meets infection control standards ie. Uncarpeted and wipeable surfaces. It has enough electrical sockets and internet connections.

There is a hand washing sink with all the necessary equipment.

The phlebotomy/testing area is private enough to maintain the patient's dignity

An office area is available with access to a computer, fax machine, printer, lockable filing cabinets and a telephone. There is a suitable waiting area and a toilet. There is provision for the disposal of 'bio-hazardous' waste.

## 3. Equipment

- PoCHi analyser-----Supplied and maintained by Sysmex
- Centrifuge-----Supplied and maintained by Sysmex
- Computer and monitor-----Supplied and maintained by Sysmex
- Desk-----Supplied by Sysmex
- Fridge (solely for the storage of blood samples)-Supplied and maintained by Sysmex
- Lockable medicine cabinet (for the storage of pre-dispensed, quarantined Clozapine and other dispensed medications for issue)
- Lockable filing cabinet for patients' clozapine clinic notes
- Digital scales, height measurer and tape measure

- Digital NIBP machine
- Manual sphygmomanometer and stethoscope.
- Examination couch
- Phlebotomies, or other suitable, chair.
- Phlebotomy equipment
- FBC haematology tubes (plus BCP and glucose tubes as per BNF testing regime) □
- Sharps disposal bins and clinical waste bins
- Toxicology kits
- 12 lead ECG machine (desirable)
- Lap-top or desk-top computer for the recording of monitoring results

#### 4. Staff requirements

To efficiently operate routine clozapine clinics the following is the minimum staffing requirements.

##### Miranda House

- 2 registered nurses trained in phlebotomy at advanced level.
- 2 healthcare assistants trained in phlebotomy one at advanced level and one to basic level.
- 1 of the registered nurses is a certified user of the PoCBA ie trained directly by Sysmex and can train other staff members to become registered to be able to use it.

##### Becca House

- 1 registered nurse trained in phlebotomy and 1 STR worker trained in advanced phlebotomy techniques.
- 4 other nurses who are recognised users of PoCHi.

These services have access to a non-medical prescriber and a consultant psychiatrist, on telephone number:

- Miranda House – 01482 216624
- Crystal Villas – 01262 401292

#### 5. Staff Training

The lead nurse(s) for the Clozapine Clinic must have received training to use PoCHi from Sysmex. These nurses are then able to train others in the use of PoCHi using the recognised training manual; these will then be certificated by Sysmex on receipt of the completed competencies.

Other training requirements for all registered nurses/phlebotomists in the Clozapine clinic:

- 1 advanced phlebotomy trained nurse/phlebotomist to be present at each clinic
- Training by the Trust's pharmacy technicians re. The procedure for issuing predispensd Clozapine, use of the CPMS website and access to their pharmacy work list. (Currently at Miranda House only)

- Training in the use of portable 12 lead ECG monitoring is an optional training requirement.

## 6. Referral to clinic

Referral to the clinic will normally be made by Lorenzo or telephone, this will be followed by the forwarding of the referral/transfer form (Appendix 1 pg 21) to the referrer for completion and who will return it to the clinic. This may be carried out by either post or email.

Referrals may be made by either the patient's care-co-ordinator or one of the medical team responsible for the patient.

Patients eligible for referral to the clinic must be:

- Prescribed Clozapine
- Registered with CPMS
- Undergoing titration following initiation
- Undergoing re-titration following a treatment break.
- Willing and able to attend the clinic

On receipt of the completed referral the clinic will:

- Inform CPMS to add the patient to the relevant clinical analysing area. □ Inform HTFT Pharmacy ([hnf-tr.clozapineclinic@nhs.net](mailto:hnf-tr.clozapineclinic@nhs.net)).
- Inform the patient's RC and Care-Co if appropriate □ Arrange the first appointment with the patient.
- Compile a clinic pack which will contain: the referral, monitoring/ communications sheets, CPMS labels and management care plan.
- Add the patient to the clinic's electronic recording system, Lorenzo (Currently Miranda House only)
- Send a letter to the patient's GP to inform them of the patient's referral to the clinic.

## 7. Setting up and running a routine clinic

### 7.1. Objective

To effectively prepare for and run a routine clinic.

### 7.2. Principles

Procedures to accomplish the above have been developed and adapted during pilot schemes at Miranda House and Becca House.

### 7.3. Guidelines

Reception of pre-dispensed Clozapine at Miranda House.

See Management and Supply of Pre-Dispensed Clozapine to the Clozapine Fast Track Clinic Miranda House. Appendix 4 (page 27)

## 7.4. Clinic Preparation

For each day the PoCHi will be used:

- All surfaces in the phlebotomy area must be wiped with a disinfectant wipe.
- Turn on PoCHi, computer, monitor and centrifuge. Deal with any PoCHi maintenance messages as required.
- Log in to eCPMS home page and subsequently the 'PoC result screen. User number and password required.
- QC sample removed from refrigerator and dated for the week. This is placed in the centrifuge, but not spun, to acclimatise to room temperature. Minimum 10 minutes
- Discard any remaining blood samples from the previous week in the sharps bin.
- Ensure adequate phlebotomy equipment is available.
- Turn on data scope and electronic (sit on) weighing scales.
- Ensure all the relevant patient files are available
- Print copies of the Clinic Log for the day and ensure reception receive a copy
- Run the QC test when the sample has reached room temperature. When 'QC successful' message received replace the sample in the refrigerator.
- Turn on the computer, monitor, weighing scales and dynamap.

## 7.5. Patient reception and journey through the clinic

- At Miranda House, the patient will be asked to sign in the visitors' book at reception and wait there while a member of clinic staff is notified of their arrival. A member of staff will go to the reception area or will meet them at the top of the stairs to accompany the patient to the clinic.
- If the patient arrives escorted by a member of staff, they will sign in the visitors' book at reception and then come to the clinic and go into the waiting room.
- If the patient is unknown/new to the clinic they will be asked to confirm their identity by giving their name and date of birth.
- The patient may be asked to wait in the sitting room until the staff and phlebotomy room become available.
- When the phlebotomy area is free, the patient will be asked to remove their outer garments and go through to the phlebotomy room.
- Phlebotomy is performed and the ensuing sample is tested as per guidelines on page 8.
- The patient will then have their weight, BMI, sitting and standing blood pressure, temperature and waist measurement taken and recorded.
- The patient will then be asked by a staff member about their experience of any side effects following a 13 point questionnaire adapted from the Maudsley Prescribing Guidelines 10<sup>th</sup> Edition (2009) (See Appendix 3 pg 25). Each being scored using the following scale: Paper format S/E questionnaire.

<b>Not reported</b>	<b>0</b>
<b>Mild/Occasional</b>	<b>1</b>
<b>Moderate/Regular effects</b>	<b>2</b>
<b>Severe/Constant effects</b>	<b>3</b>

- All score of '2' or above will be reported to the patient's RC
- Any concerns will be documented and dealt with, ie further BP check, bleeding, dispensing / supply problems.
- Medication will be supplied, if pre dispensed, by following guidelines in Appendix 4 pg26.
- The patient will be issued with an appointment card for their next monitoring session before leaving the department.
- All monitoring results will be recorded on Lorenzo and, if necessary, the patient's RC and GP will be informed directly.
- An important aspect of the patients' visit to the clinic is that they are encouraged to engage with the staff, providing an ideal forum for discussion of any issues important to the individual as well as discussion of any problems/progress.
- Any areas of concern resulting from this interaction will be discussed with the relevant agencies and the outcome documented. Similarly, the patient will have every opportunity to interact with his/her peer group and to gain mutual support.

## **8. Routine procedure for phlebotomy and sample testing**

### **8.1. Objective**

To carry out phlebotomy and blood testing on patients, receiving Clozapine, who are assigned to the Clozapine clinic.

### **8.2. Principles**

Patients receiving Clozapine risk developing neutropenia and must therefore have regular blood tests to ascertain their differential WCC.

### **8.3. Guidelines**

- Patients attend the clinic on their appointed day and hand in any excess clozapine medication they may have after a dose change, (staff to confirm they have enough tablets to last up to and including Thursday night dose). Staff records any discrepancies in their pack and inform HTFT pharmacy, CPMS, the patient's RC and/or Care-Co.
- The patient's physical monitoring is carried out and this is recorded on Lorenzo and in their clinic notes.
- A blood sample will be obtained by a trained phlebotomist (check if more than one required for additional testing e.g. BCP, HbA1c).
- If a sample cannot be obtained, for whatever reason, then an advanced practitioner may attempt to obtain a sample from the dorsal aspect of the patient's hand.
- If this should also prove unsuccessful then the following courses of action will be considered:
  - Seek medical assistance from a doctor.
  - Arrange for the patient to attend the phlebotomy department at BDH within 24 hours, or for the patient to attend the Clozapine clinic on the following day (Tuesday) for a sample to be obtained by the ECT anaesthetist.
- Blood sample tested in PoCHi by trained users.



- If the blood sample taken from Hull, Bridlington, Goole or Market Weighton patients is insufficient then this should be tested at HRI and the results obtained the following day by checking HEY Lorenzo. The results are then entered onto the CPMS system.
- Results should be entered electronically on to CPMS and pharmacy informed immediately.
- Deal appropriately with any error messages, e.g. T2, corrupt sample; change Pochi pack etc. until Green/Amber/Red result returned.
- Result checked by second practitioner.
- Refer to Trust Clozapine Guidelines for further information.
- Samples are kept until the following Monday in the fridge in case CPMS require further tests.

<b>Green result</b>	<b>Issue medication. Refer to 'dispensing policy'.</b>
<b>Amber result</b>	<b>Issue medication. Arrange for patient to be re-tested as per advice from CPMS. Record in documentation.</b>
<b>Red result</b>	<b>Discontinue Clozapine therapy IMMEDIATELY Refer to 'red result policy'.</b>

## 9. Monitoring of patient's physical health and Clozapine side-effects

### 9.1. Objective

To maintain a holistic view of the patient's general health and evidence of clozapine side-effects so as to be able to act on any findings.

### 9.2. Principles

There is evidence to show that patients undergoing Clozapine therapy are frequently those who neglect their general health and may concurrently suffer unpleasant side effects of the drug. Efficient annual monitoring enables clinicians to report findings/concern to the patient's RC and GP for BCP, glucose and HbA1c and taking an ECG will be undertaken.

### 9.3. Guidelines

At each attendance the physical health checks below will be carried out and recorded:

- Blood pressure (sitting and standing)
- Pulse
- Temperature
- Weight (kg)
- Waist size (cm)
- Height (cm) – only on initial visit
- BMI

At each attendance the patient will be asked about the presence of the following possible side effects. The results will be recorded according to severity ie: 0=None,

1=Mild/Occasional, 2=Moderate/Regular, 3=Severe/Constant. Initial scores of 2 or 3 will be reported to the RC or if it is an increase from the previous result or is reported as an issue/problem by the patient.

- Over sedation
- Hyper salivation
- Dizziness
- Constipation
- Nausea/Vomiting
- Sweating
- Dry mouth
- Urinary problems/incontinence
- Tremor
- Visual disturbances
- Sexual dysfunction
- Involuntary movements
- Palpitations

All recordings will be inputted on Lorenzo.

Annual ECG's will be carried out and scanned on to Lorenzo. The consultant will be informed when they have been taken and for them to review it and record when they have seen it. Any issues resulting from the ECG will be their responsibility.

## **10. Non-attendance**

### **10.1. Objective**

To re-engage with the patient and ensure Clozapine therapy continues.

### **10.2. Principles**

Continued involvement and monitoring of the patient is important to avoid the risk of relapse.

### **10.3. Guidelines**

On the day the patients does not attend their planned appointment, Clinic staff will contact the patient by telephone to prompt, leaving a message where appropriate.

On the second day of non attendance, clinic staff will again contact the patient by phone and if this is unsuccessful the following actions will be taken

- Clinic Staff will contact both the care co-ordinator and the prescriber by email and or telephone (this will also include a copy to the duty email)
- Clinic Staff will provide relevant details of the patient's disengagement, blood sample due date and Clozapine medication regime.
- Clinic Staff will contact assisted living where the patient resides to encourage and prompt patient to attend for blood sample.

On the third day of disengagement, Clinic staff will again attempt telephone contact with the patient and if this is unsuccessful the following actions will be taken

- Verbal (where possible) handover of information to the care co-ordinator or Duty Person about the patient with regards to details of disengagement, blood sample due date, date of CPMS restriction, and Clozapine medication regime.
- Verbally hand over care and responsibility of the disengaging patient to their care co-ordinator or the Duty Person for follow up in accordance with their policy and procedure

Should verbal handover not be possible and Email is used, Clinic staff to ensure a reply has been received before a presumption is made that the Care coordinator has actioned a plan for the disengaging patient.

Should the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> day actions above fall on a Saturday or Sunday then the relevant action will resume on the Monday.

***Please note that if the patient misses Clozapine medication for a period of 48 hours or more, then they will require a medical review, change of care plan and re-titration of dose starting at 12.5mg daily. For increase titration liaise with CPMS.***

## **11. Red Result**

### **11.1. Objective**

To effectively deal with the required procedure, as set out in the guidelines on the CPMS website and Trust Guidelines when a patient returns a 'Red Result'.

### **11.2. Principles**

It is widely acknowledged and documented that one of the prime side effects of Clozapine is neutropenia, hence the regular FBC monitoring of all patients receiving the drug to monitor WCC, neutrophil and platelet results.

### **11.3. Guidelines**

REFER TO 'RED ALERT ADVICE' ON CPMS WEBSITE and act on any applicable advice including discontinuation of Clozapine if red result confirmed.

- On the initial RED result, CPMS advise to retest the sample immediately and then liaise with them. If the second result is also RED, then inform the patient they must stop taking clozapine IMMEDIATELY.
- 2 further blood tests are required on the next 2 consecutive days.
- Consult with HTFT Pharmacy (01482 301724), CPMS (08457 698269) and Haematology (01482 607777) if required, as soon as initial Red result received.
- Consult with the patient's RC re; alternative antipsychotic cover and ensure return of unused supply of Clozapine.
- Continue to monitor physical observations at each attendance.

## Special phlebotomy arrangements for outlying clinics

- All Beverley and Haltemprice patients to attend Miranda House for extra phlebotomy
- Pocklington: GP's for all phlebotomy.
- Goole: Goole and district hospital for all phlebotomy.
- Bridlington and Driffield: All patients attend Becca House for phlebotomy.
- Holderness patients attend Rosedale Community unit or the clozapine clinic at Hornsea Cottage Hospital

## Longer term Intervention

- If RED alert is confirmed follow the guidelines outlined in the 'Red Alert Card'
- Full Blood Counts should be performed DAILY whilst the blood counts remain in the RED range, results should be reported to the CPMS as soon as they are available.
- At weekends or bank holidays special arrangements may be made by contacting the crisis team at Miranda House (Hull) or College House (East Yorkshire)
- The patient must be observed closely for infection, i.e. sore throat, fever, by carrying out physical observations at each attendance
- If antipsychotic medication is considered essential, use agents with low potential to cause neutropenia e.g. haloperidol and avoid depot preparations. Other medication should be reviewed for potential to cause neutropenia
- If the patient becomes neutropenic i.e. Neutrophil count less than 1.0 or the WCC less than 2.0 or if the patient develops a fever then the guidelines as given in the Red Alert Card (eCPMS) should be acted upon. A care plan must be formulated for each individual patient.
- If this occurs at the weekend/bank holiday then this will be carried out by liaising with the on-call doctor and on-call consultant, as this will entail the patient being admitted into an acute facility where barrier nursing and the administration of the appropriate medication can be carried out.
- Re-referral to Haematology may have to be considered if protracted neutropenia results. Haematology Department based at Hull Royal Infirmary can be contacted on telephone number: 01482 607777
- Return any unused Clozapine to HTFT clozapine clinic at Miranda House.

## 12. Discontinuation of clozapine

### 12.1. Objective

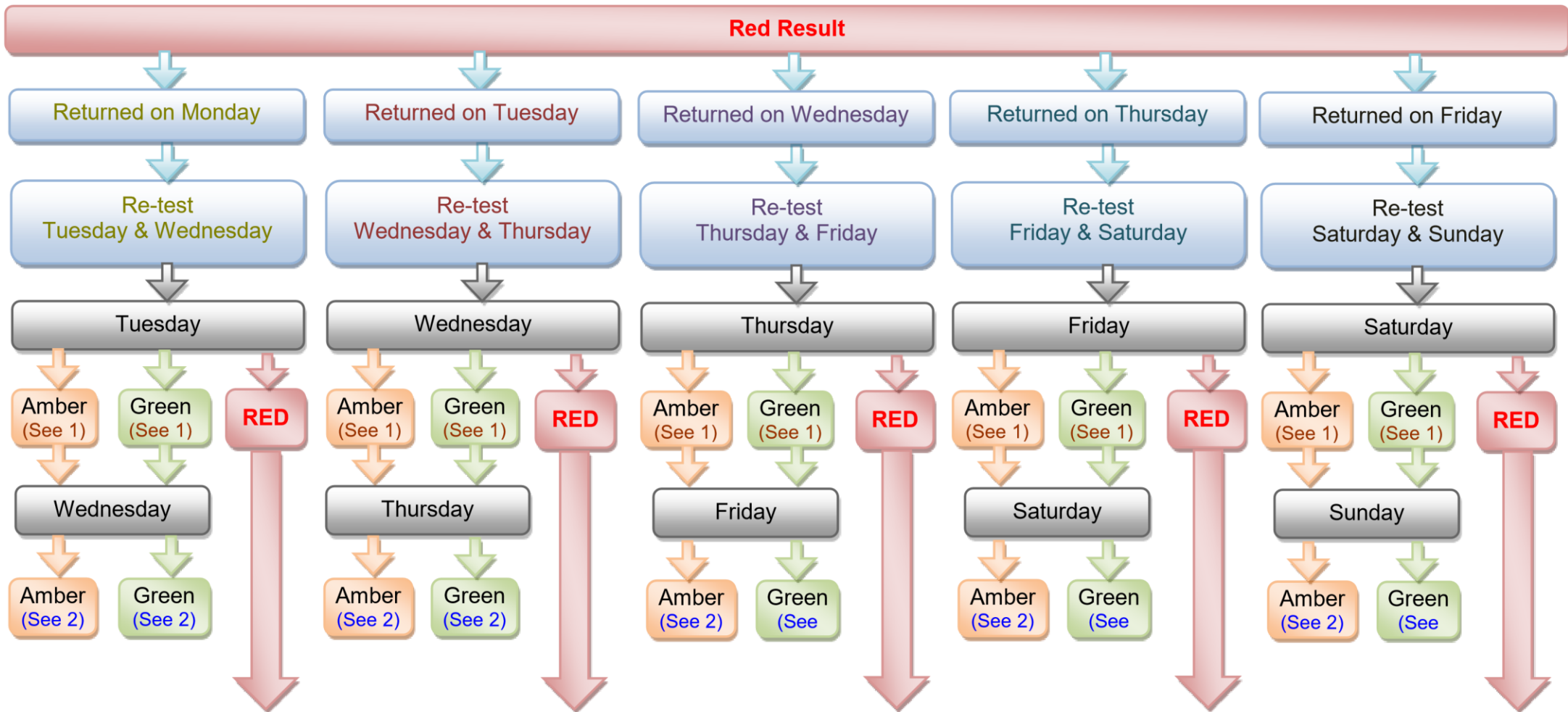
To effectively manage the discontinuation of clozapine.

### 12.2. Principles

There are different reasons for stopping clozapine e.g. Following a confirmed RED result (see above), neutropenia, after review by RC and side effects becoming too difficult to manage and patient stopping of own accord and against medical advice.

### 12.3. Guidelines

- If the discontinuation is planned i.e. following a review by RC, a gradual reduction in dose over a 1 to 2 week period is recommended (CPMS guidelines).
- If abrupt discontinuation occurs, the patient should be carefully observed for the occurrence of withdrawal reactions. E.g. flu-like symptoms or other symptoms suggestive of infection.
- Following discontinuation of Clozapine, haematological evaluation is required until haematological recovery has occurred.
- Monitoring must continue for at least 4 weeks after discontinuation at the frequency when the clozapine was stopped ie weekly for weekly patients, once a fortnight for 2-weekly patients and once after 4 weeks for 4-weekly patients.
- There are no requirements in the license to perform physical health checks though good practise and guidance from RC should be undertaken.



**CONFIRMED RED**

- a) Must not continue with Clozapine.
- b) Refer to RC asap
- c) Adhere to Red result Care plan

**1** Ring CPMS, who would normally advise a further test the next day

**2**

- a) Ring CPMS
- b) May re-commence Clozapine.
- c) Re-provide with quarantined supply if less than 48 hours since last dose.
- d) Contact the patient's RC or his junior to re-titrate if more than 48 hours.
- e) Identify pharmacy for dispensing of medication to patient

## **13. Amber result**

### **13.1. Objective**

To maintain the patient's physical health whilst continuing Clozapine therapy uninterrupted (if possible)

### **13.2. Principles**

To conform to the CPMS' guidelines.

### **13.3. Guidelines**

- If the patient has regular amber results - call CPMS as repeat samples may not be required as frequently
- If the amber result is unexpected and the patient is physically well then a repeat sample should be tested in 2-3 working days.
- If the patient is not physically well then a repeat sample should be tested in 1-2 working days and call CPMS for advice.
- For Pocklington or Goole patients the amber result will not be available until Wednesday or Thursday.
  - Consult with patient's RC/Pharmacy/CPMS and agree re-testing interval following the above guidelines.
  - Samples to be tested locally at HRI or can be tested at Miranda House.

## **14. Side-effects**

### **14.1. Objective**

To ensure all relevant agencies are made aware of a patient showing symptoms of side-effects, as well as any resulting action/treatment instigated.

### **14.2. Principles**

It is vital that robust communication between all relevant agencies is maintained.

### **14.3. Guidelines**

On suspecting a patient to be exhibiting any indication of excessive side-effects, clinic staff will:

- Inform the patient's RC. and Care-co.
- Inform CPMS (by phone).
- Make an entry in the patient's notes.
- Make HTFT pharmacy aware.

## **15. Patients going away on holiday**

### **15.1. Objective**

To maintain patients' blood monitoring and issuing of medication throughout any holiday away they may wish to take.

## 15.2. Principles

Once established on Clozapine, it is vital that the patient's monitoring regime carries on uninterrupted.

## 15.3. Guidelines

- Liaise with pharmacy and re-arrange scheduling if necessary.
- Patients may be able to take holidays away with no action being required if taken within their monitoring/prescribing period.
- If the patient wishes to be away for a period which includes their monitoring /prescribing dates, then arrangements may have to be made to lengthen the prescribing period.
- In England, Scotland and Wales arrangements can be made for the patient to attend the most appropriately located clinic for monitoring.
- Contact CPMS to find most suitable venue
- Contact identified clinic and make appropriate arrangements.
- Patients travelling abroad may wish to take a letter giving details of their Clozapine therapy to validate them being in possession of the drug and they are to take their clozapine information card. The letter can be found in Appendix 5 and in Lorenzo.

## 16. Patients admitted to mental health units (monitoring of samples)

### 16.1. Objective

To continue Clozapine therapy and monitoring in consultation with in-patient facility. To tailor a plan of care for the individual patient reflecting their specific needs.

### 16.2. Principles

Whilst admitted to mental health units, it is important for the patient's Clozapine therapy and monitoring schedule to remain as stable as possible, as well as maintaining their links with the Clozapine monitoring service.

### 16.3. Guidelines

- The relevant in-patient facility will liaise with HTFT pharmacy, CPMS and clozapine clinic of the reason for admission. The patient takes in their supply of clozapine tablets.  
The admitting area will contact HTFT pharmacy to check the present dose and arrange for a new script to be sent to them.
- The relevant in-patient facility will then: Draw up a care plan to identify who will;
  - a. Inform the clozapine clinic
  - b. Can the patient still attend the clinic
  - c. Who will perform the phlebotomy
  - d. Delivery of sample to the clinic \*
  - e. When will monitoring take place
  - f. How often the monitoring is required?
- Dispensed medication will be issued to the in-patient unit on receipt of a current valid result and copy of MAR chart. Prescriptions are dispensed with directions



printed on the label, checked and bagged then sealed with patient details in the pharmacy dispensary at Miranda House.

If the patient is admitted from a different trust and is prescribed clozapine by a different manufacturer e.g. Denzapine or Zaponex, the in-patient facility will:

- Liaise with the previous care coordinator re last blood sampling date
- Inform CPMS of transfer (having patient Denzapine or Zaponex number will be very helpful)
- CPMS will liaise with the other maker and transfer the blood results.
- Continue blood sample dates as usual.
- Inform pharmacy of admission and name of maker of clozapine.
- Register patient with clozapine clinic at Miranda House. (See section 6 page 6).

\*Consider using local path lab facilities if the clinic is closed

## **17. Recording - including untoward events**

### **17.1. Objective**

To keep accurate electronic records for all patients attending the Clozapine Clinic.

### **17.2. Principles**

Each patient will have a 'pack' of paper records (demographics and cpms labels) in the department as well as details of recordable events on their eCPMS records and on Lorenzo.

### **17.3. Guidelines**

- Each patient will have a record sheet within their Lorenzo notes where any untoward events are recorded.
- The following 'recordable events' must be recorded on the patient record sheet:
  - Consistent raised BP –back up with a phone call to CPMS and RC.
  - Discrepancies in the number of tablets remaining-back up with a phone call to HTFT pharmacy, care coordinator and consultant.
  - Signs of side effects.
  - Physical illness
  - Holiday details.
  - Admission to general hospital.

## **18. Bank Holiday arrangements**

### **18.1. Objective**

To maintain the patient's monitoring regime despite closure of the clinic on bank and public holidays.

## 18.2. Principles

There are usually 6-7 bank and public holidays, which fall on a Monday, throughout the year, when the clinic will be closed. The clinic will then usually be open on the Wednesday of the week in question.

## 18.3. Guidelines

- On the last appointment before the bank holiday week, the patient will be asked about his supply of Clozapine, ensuring that he has enough to last over the extended period.
- If they have an insufficient supply, then arrangements must be made for a prescription to be scanned and emailed to HTFT pharmacy for provision of the outstanding tablets.
- Ensure CMHT/carers are aware of the arrangements.
- At Christmas and New Year special arrangements may be made for samples to be taken to Miranda House or HRI for testing, rather than using the postal system

## 19. In Case of PoCHi Breakdown

### 19.1. Objective

To ensure continuation of service/monitoring despite the unavailability of the PoCHi machine.

### 19.2. Principles

Sysmex are contracted to maintain/repair Pochi throughout its life, however faults may occur at any time.

### 19.3. Guidelines

- Arrange for a replacement machine with Sysmex
- Patients to attend for phlebotomy as usual and samples obtained.
- Samples to be sent for FBC sampling locally at HRI and WCC, neutrophil and platelet results taken from HEY Lorenzo and input in eCPMS to get a green/amber/red.
- Arrange with patients who receive Clozapine from fast track to return for their medication on receipt of Green result

**OR**

- Liaise with pharmacy to arrange delivery of clozapine to the patient.
- Inform patient and relevant CMHT/Care – co of plans for delivery.

## 20. Non-Medical Prescribing

- Non-medical prescriber must have completed “independent non-medical prescriber” training.
- Designated medical prescriber to be identified for non-medical prescriber to refer to.
- Clozapine may only be prescribed under supervision of consultant psychiatrist □  
Non-medical prescriber to prescribe Clozapine on PPO3R.

- Non-medical prescriber to prescribe medication other than Clozapine on PPO3.
- Non-medical prescriber and medical prescriber to meet to discuss side effects, etc., initially on a monthly basis.

## 21. Toxicology/Plasma levels

### 21.1. Objective

To ensure optimum therapeutic levels of Clozapine

### 21.2. Principles

It is acknowledged that some patients may have varying plasma levels of Clozapine due to:

- Poor compliance.
- Mistakes in self-medication.
- Physical illness.
- Self-instigated 'treatment breaks'.

### 21.3. Guidelines

If it is suspected that the patient is either over or under medicated, some of the symptoms of this may be:

- Recurrence of pre-existing psychotic symptoms.
- Over sedation.
- Evidence of recognised Clozapine side effects.

The plasma level should be routinely carried out annually with additional tests if the consultant RC is reviewing the patients' mental health and side effects. When the prescribing RC request that serum plasma levels be monitored. They must be aware of the cost implication of this test which is currently £17.50 per sample. This request will be forwarded to the Clozapine clinic staff where arrangements will be made for the sample to be obtained. This may be at the next routine sampling date or an extraordinary sampling appointment may be requested between the normal routine sampling regimes. Samples must be taken at 'trough level' i.e. the morning dose of Clozapine must be omitted.

The following information must be available to complete the request form:

- Date and time of last Clozapine dose.
- Total DAILY Clozapine dose
- Is the patient a smoker
- Consultant making the request
- Weight
  - The sample will be correctly labelled and packaged by the clinic staff and sent to ASI laboratory.
  - The result is usually available on their secure website 1 to 2 weeks later.
  - The results are available to access at [HOME \(asilab.co.uk\)](http://HOME.asilab.co.uk)

## 22. Bridlington Trough Level Pathway

### Criteria for trough level to be considered.

- Apparent lack of response to treatment.
- Clozapine dose has been changed.
- Change in smoking habit.
- Change in caffeine intake.
- Increased side effects.
- Change in other prescribed medication.
- Change in patient's physical health.
- Doubts over compliance.



### If one or more of the criteria above is met then the following process will be implemented at patient's next attendance:

- Ensure morning dose of Clozapine has been omitted (If not do NOT send)
- Collect sample in a purple topped bottle, the sample used for FBC can be used.
- Complete the Assay form, pack and send sample to Kings Path.
- Email, confirming sample has been sent, to be sent to: RC, clinical lead, care-co and budget holder.
- Print copy of this email and place in RAST folder for discussion at next RAST MDT meeting.



### Kings Path emails the result to Clozapine lead whilst version is posted to the patient's RC.

- Result emailed to RC and care-co by Clozapine lead. a paper
- RC reviews result and forwards management plans to Clozapine lead and care-co.
- Care-co discusses results and proposed plans with the patient.
- All results discussed at RAST MDT and management decisions confirmed.
- New prescriptions written (if necessary) at MDT by RC or his junior.
- Postal results filed in patient's notes by RC's secretary.

## **23. Change or Monitoring frequency**

### **23.1. Objective**

To maintain regular monitoring of all patients assigned to the Clozapine clinic.

### **23.2. Principles**

There exist several reasons why a patient's monitoring frequency may change. These are:

- Normal progression of the Clozapine treatment programme.
- Following a treatment break.
- During adverse result episodes.

### **23.3. Guidelines**

In the case of normal progression from weekly to fortnightly to 4 weekly monitoring it is the responsibility of the clinic staff to obtain details of the date this change is to take place by checking the patient's profile on eCPMS. They will inform the patient and his/her carer if appropriate of the change and make arrangements for monitoring to take place on the new regime.

Pharmacy and the CMHT will normally be notified by email from CPMS.

Paper records and spread-sheet in the clinic must be amended to reflect this change.

## **24. Monitoring at the Humber Centre**

### **24.1. Objective**

To ensure that patients prescribed Clozapine within the forensic service at the Humber Centre receive monitoring and basic physical health monitoring in accordance with their required regimes.

### **24.2. Principles**

The management of Clozapine monitoring within the forensic service needs to be efficient and systematic.

### **24.3. Guidelines**

- One member of the Humber Centre health hub team will obtain blood samples from the patients at the Humber Centre each Tuesday. Clinics will be held in the health garage at the Humber Centre.
- Each patient's Clozapine file will be retained in the Health Hub office at the Humber Centre as appropriate.
- At the end of the clinic all the resulting blood samples will be taken to Miranda House for processing in the PoCHi machine and all the results relayed by phone to the nurse at the Humber Centre who will record the result in the patient's Clozapine file and contact the patients' ward to inform them of the result.
- In the event of adverse results being returned i.e. amber or red, then the relevant protocol will be implemented.
- In the event of failed phlebotomy, the phlebotomist will access –via main reception, one of the doctors at the Humber Centre, to attend the 'Health Garage' and assist in obtaining a blood sample.

## **25. Discharge from Mental Health units and HRI wards to/from the community (medication issues)**

### **25.1. Objective**

To ensure the continued supply of clozapine medication when a patient either is admitted or discharged to a mental health unit or a ward at HRI or from there back to the community.

### **25.2. Principles**

When patients are discharged they should have enough clozapine medication to ensure they do not run out. Information should be relayed between teams to ensure this occurs and each service (community team, pharmacy, cpms, clozapine clinic and GP) is aware where the patient is.

Following CPA transfer and NG53 recommendations these guidelines should be followed.

### **25.3. Guidelines**

#### **Discharge from mental health unit to community**

During the discharge meeting, a care plan will identify:

- a) Which staff and the pharmacy technician from the unit will inform the community team (if not at the meeting), HTFT pharmacy, clozapine clinic (either Miranda House, Bridlington, Goole or Hedon/Hornsea) and GP of the discharge date, when the patients next blood sample is due and who will perform the phlebotomy after discharge.
- b) Dependent on the sampling frequency and when the last sample was taken - if the patient is on weekly monitoring then up to one weeks' amount of clozapine will be prescribed (TTO), if on fortnightly or four weekly monitoring then HTFT pharmacy are to be contacted to ensure the correct amount is prescribed (for two or four weekly monitoring up to the respective amount of tablets will be dispensed).
- c) The discharge summary should be on Lorenzo within 24 hours, communicated to the community RC, care co-ordinator, HTFT dispensing pharmacy and clozapine clinic where indicated.
- d) The discharge letter from the unit should be completed and be on Lorenzo within maximum 7 days.

#### **Discharge from HRI to community**

Hospital HRI pharmacy will liaise with HTFT pharmacy to ensure adequate and continuous supply of clozapine tablets.

Patient (and ward staff) to inform care coordinator of admission (and discharge) to HRI as soon as possible to ensure continuity of treatment.

#### **Transfer from HTFT to out of area**

Care co-ordinator, or unit key worker, will liaise with accepting care co-ordinator, informing them of the last blood sampling date, the frequency of sampling, the present consultant, the dose, CPMS number and if any results were amber or red.

## 26. Management and Supply of Pre-Dispensed Clozapine to the Clozapine Fast Track Clinic Miranda House

### 26.1. Responsibilities of the Clinic and the HTFT dispensing Pharmacy for provision of the HTFT Fast Track service

#### Joint Responsibilities

- The Clinic and the dispensing pharmacy must operate in accordance with the Trust guidelines for the Management of Clozapine
- Effective communication must be maintained by and between the Clinic and the dispensing pharmacy

#### Responsibilities of the Clinic:

- The Clinic must operate in accordance with all Trust Policies and Procedures.
- The Clinic is responsible for updating the e-CPMS "Patient Profile"
- Clinic to inform the dispensing pharmacy of new referrals by telephone. Refer to Contact List accessed via the Trust Intranet; Directorate: Medical: Medicines Management for relevant emails.
- Storing medication alongside photocopied prescriptions as per trust policy and procedure in a locked cupboard.
- Additional sampling, patients going on holiday, bank holidays and nonattendance should not affect the sample group of the patient.
- **Patient's going on holiday and Bank Holiday arrangements:** to accommodate holidays and Bank Holidays it may be necessary to arrange sampling for a supply of Clozapine supply to be made earlier or later than the regular sample date. Consult the dispensing pharmacy for advice.
- **Non-Attendance at scheduled sampling session:** If a sample is taken later than due as a result of non-attendance, the next sample should be taken on the date indicated in the original Patient Group. This is provided the patient has not had any interruption to their Clozapine medication which may result in a change to frequency of sampling and supply. Please refer to "On/Off Treatment Guidelines" on the e-CPMS site. Consult the dispensing pharmacy for advice.

#### Prescribing / Dispensing of Clozapine for the Fast Track Clinic

- Prescribing of Clozapine for patients using the Fast Track Clinic remains with the named consultant who is managing the treatment for that particular patient.
- Clozapine should be prescribed using the Clozapine prescription in Lorenzo.
- Prescription should be produced no later than the Wednesday morning of the delivery week.
- The pharmacy must liaise with the CMHTs to ensure this is achieved
- The dispensing pharmacy will inform the CMHT on the last dispensing of prescriptions written to organise a new prescription for the following month.
- The Pharmacy dispensary keep a prescription file for each Clozapine patient clinic group, week 1,2,3,4 for the fast track clinic, weekly, fortnightly, deliveries and nomad trays. These files are kept in a locked cupboard in the locked Pharmacy dispensary

- Clozapine stock is ordered via Viatrix Hospital Orders where it is delivered to the Clozapine Clinic at Miranda House and left in reception for collection from the pharmacy staff.
- The clozapine prescription must be authorised by a pharmacist prior to dispensing. This process is completed in Lorenzo.
- The prescriptions are dispensed, labelled, checked, bagged and sealed with the patients' details in the pharmacy dispensary at Miranda House.
- The completed prescriptions are placed in the clinic groups along with any MAR sheets that are needed. These are taken to the Clozapine Fast track clinic ready for collection once the patient has completed bloods and health checks.
- The deliveries are completed as above and kept in a locked cupboard in the locked pharmacy dispensary waiting for collection from the delivery drivers.

### Fast Track clinic Photocopied Prescription

- On receipt of the photo copied prescription it must be stamped twice with the following supply stamp:

<i>Clozapine Fast Track Clinic</i>			
<i>Miranda House HFT Hull, HU3 2RT</i>			
<i>Supplied against current, valid sample result</i>			
<i>Yes / No</i>	<i>Sign/date</i>	<i>Yes / No</i>	<i>Sign/date</i>
<i>1 .....Y/N...../.....</i>	<i>...../.....</i>	<i>4 ....Y/N...../.....</i>	<i>...../.....</i>
<i>2 .....Y/N...../.....</i>	<i>...../.....</i>	<i>5 ...Y/N...../.....</i>	<i>...../.....</i>
<i>3 .....Y/N...../.....</i>	<i>...../.....</i>	<i>6 ...Y/N...../.....</i>	<i>...../.....</i>

One stamp is to be labelled for the qualified staff to complete and the other is to be labelled for the patient to complete after checking the prescription and the amount of medication supplied is correct.


The stamp can only be amended by the Trust pharmacy dept.

- For copies of prescriptions which are used for a single supply of clozapine, spaces 2 to 6 for recording supply must be scored out.
- The stamped, photocopied prescriptions must be kept in the patient groups file
- Section 9 outlines how replacement prescriptions supplied part way through a patient's dispensing schedule should be handled

### 26.2. Sampling Process (routine sampling)

- The practitioner is responsible for processing the sample on the PoChi Machine
- Following a Current, **Valid** sample result the first practitioner should identify the patients supply of pre-dispensed clozapine which should be checked against the current prescription then handed to a second practitioner
- The second practitioner should continue the process outlined in Section 7



Results	Status	Action
GREEN	VALID	<ul style="list-style-type: none"> <li>▪ Routine sampling and supply</li> </ul>
AMBER	VALID	<ul style="list-style-type: none"> <li>▪</li> <li>▪ Supply medication as usual. Follow CPMS additional sampling instructions</li> </ul>
RED	 <b>Prohibited</b>	<ul style="list-style-type: none"> <li>▪ Follow instructions by CPMS this will include <ul style="list-style-type: none"> <li>○ Immediate cessation of therapy</li> <li>○ Retrieval of all Clozapine</li> <li>○ Return to dispensing pharmacy on confirmed RED result</li> </ul> </li> </ul>

**CARE: always check the STATUS of the result**

### 26.3. Quarantining system for pre-dispensed meds

Supplies of pre-dispensed clozapine should be quarantined in the following circumstances clearly indicating that they should not be used unless clarification has been provided by the dispensing Trust Pharmacy.

- On receipt of a supply of clozapine against an amended prescription after a routine supply of clozapine has been made
- On unconfirmed RED result
- On confirmed RED- arrangements for return to the dispensing Pharmacy must be made immediately
- In the event of a confirmed treatment break

### 26.4. Supply and Logging of Pre-dispensed Clozapine to Patients following a Current, Valid (Green/Amber) Sample Result

- A second practitioner must check that dose, quantity and patient name are correct against the current photocopied prescription.
- Log onto the e-CPMS site using allocated User ID and chosen Password
- Record details of supply on the e-CPMS system as follows .(single left “click” to select field):
  - Select “worklist” then “pharmacist worklist”
  - Check the patient details to ensure the correct patient is to be selected.
- The STATUS of the patient must display as ACTIVE in order to allow a supply of Clozapine on the worklist table.
- If status is PROHIBITED, do not supply and contact CPMS and the Trust pharmacy immediately
- Select “Dispensing”

- Check the patient details to ensure the correct patient has been selected.
  - For Trust Clozapine prescriptions enter the details of the clozapine supplied
- Under “Outpatient” replace the Zero with the actual quantity of tablets being supplied against the appropriate strength of tablets.
- At the “Dispensed” prompt select NO. The screen usually defaults to Dispensed No. Check all entries are correct.
- Click SUBMIT
- Click “OK”.
- The system returns to the Dispensing screen however the details of the patient and quantity supplied do not clear from the screen following the “OK” command
- Log out by choosing the “log out” option on the menu bar to the left of the screen which will return you to the “log in “screen.
- As a security feature the system will automatically “time out” after a period of inactivity.

Endorse the photocopied prescription confirming supply as follows:

- For the relevant supply space (i.e. 1,2,3,4,5 or 6) circle “Y” and sign and date
- If all six supply issue spaces have a record of issue against then, contact the dispensing pharmacy immediately, they will advise action to be taken. Do not issue a supply to the patient until appropriate direction has been agreed with the dispensing pharmacy.
- The second box is used for confirmation that the patient has checked the prescription and is in receipt of the correct number of tablets. They are to initial and date the corresponding spaces (i.e. 1,2,3 etc) as the nurse had.

## 26.5. Process for the End of the Clinic Session

The Clinic and the dispensing pharmacy must ensure the following process is completed on the same day as the Clinic session.

### The Clinic

The prescriptions must all be endorsed indicating one of the following:

- Circled “Y” Signed and Dated; confirming that the supply of pre- dispensed Clozapine has been made to the named patient.
- Circled “N” Signed and Dated; to alert the dispensing pharmacy that the pre-dispensed Clozapine has not been supplied at that session.

### The Dispensing Pharmacy

- Photo copies received from the Clinic must be matched with the original prescriptions.
- The dispensing pharmacy will access the e-CPMS system and, where appropriate, will COMPLETE the dispensing details for each Fast Track patient for whom they have pre-dispensed for that particular session.
- Any discrepancies with the logging of supply will be investigated and any action taken will be documented following consultation with the clinic.

## 26.6. Change of prescription

Change of prescription part way through the patient's dispensing schedule

- If the prescriber requires a change of dose part way through the patient's dispensing schedule, a new prescription must be supplied to the dispensing pharmacy.
- The dispensing pharmacy will deliver the new supply of Clozapine to the relevant CMHT or as otherwise directed.
- The dispensing pharmacy must update their Patient Notes accordingly
- Any excess Clozapine that results from a dose change must be removed from the patient by a member of the CMHT and forwarded to HTFT dispensing pharmacy for destruction
- The CMHT must inform the Clinic of all action taken
- The HTFT dispensing pharmacy will forward a photocopy of the new prescription to the Clinic
- On receipt of the photocopy of the new prescription the Clinic must retrieve the previous photocopied prescription and proceed as follows:
  - Strike through any remaining unused supply "sign/date" spaces from the stamp endorsement.
  - Sign and date, stating new prescription supplied due to dose change.
  - Record new dose and frequency.
  - Archive the old prescription in the patient's Clozapine information file

### **Change of prescription whilst patient is attending the clinic for scheduled sample**

If the change of dose is URGENT and needs to take effect immediately the consultant should:

- Contact the dispensing pharmacy informing them of the situation.
- Liaise with the dispensing pharmacy to confirm the exact quantity of clozapine that needs to be prescribed.
- Remember the supply of medication issued to patient attending the clinic is due to start on the Friday morning following clinic attendance.
- Assemble all the pre-dispensed Clozapine for that particular patient together with the new prescription and organise for this to be taken directly to the dispensing pharmacy for additional dispensing and / or relabelling
- Ensure that the dispensing pharmacy has provided a photocopy of the new prescription
- On return to the Clinic continue the supply issue process (Section 8) ➤ Cancel any previous photocopied prescriptions

## 26.7. Patient Non-attendance for Routine Scheduled Sampling and Supply

### **Clinic Session**

- Store the pre-dispensed Clozapine and the prescription in the weekly patient group file (Group 1,2,3,4.) in the locked Clozapine clinic medicines cupboard
- If the patient is contacted and a sample between Monday and Thursday of the Scheduled Sample week proceed as follows:

- Valid result (Green/Amber) supply the pre-dispensed Clozapine ➤  
Record as follows on the photocopied prescription:  
Full (1<sup>st</sup>, 2nd, 3rd, 4th, 5th, 6th) supply issued. Sign and date

**If the patient is contacted but no Sample is taken (e.g. unable to attend) by end of clinic Thursday of the Scheduled Sample week proceed as follows:**

- Confirm with the patient/ CARE-CO how much Clozapine the patient has in their possession.
- Do not supply the pre-dispensed Clozapine.
- Contact the dispensing pharmacy to:
  - Inform them of the current situation and how much Clozapine the patient may or may not have.
  - Make arrangements for a sample to be taken at the earliest opportunity and when the result is likely to input on CPMS website.
  - If a break in treatment occurs, arrange the return of the pre-dispensed Clozapine to the dispensing pharmacy. Return the supply in the original prescription bag and mark the bag “break in treatment”
  - Establish with the dispensing pharmacy exactly how many days the previous sample covers the patient to continue taking their Clozapine.
- If the patient is covered by his previous sample and has sufficient Clozapine in their possession, arrange to have a sample taken before either the patient’s supply or cover runs out.
- If the patient does not have sufficient Clozapine in their possession, arrange to have a sample taken as soon as possible. The dispensing pharmacy will dispense Clozapine as follows:
  - An appropriate supply of no more than 7 days. This supply is dependent upon the sampling frequency of the patient i.e. weekly, fortnightly, and monthly. This will be issued to the Clinic for prompt supply to the patient.
  - Weekly patient must have a sample taken no later than Thursday if their usual sample day is Monday.
  - The remaining prescription will be retained by the dispensing pharmacy. Further instalments may be issued if the previous sample allows again this is dependent upon the sampling frequency of the patient.
- Record the supply instalment(s) on the photocopied prescription
  - If a part issue, record the strength and number of tablets being supplied e.g. **X** x 100mg, **X** x 25mg of (1st, 2nd, 3rd, 4th, 5th, 6th) supply, Sign and date.
  - When the remainder of the Clozapine is supplied record as follows:  
**X** x 100mg, **X** x 25mg of (1st, 2nd, 3rd, 4th, 5th, 6th) supply, Sign and date.

## **Patient Unable to be Contacted and No Sample**

- Do not supply the pre-dispensed Clozapine.
- Contact the dispensing pharmacy to:
  - Inform them of the current situation and liaise regarding action to be taken.
  - Confirm exactly how many more days the previous sample covers the patient for taking their Clozapine.

### **26.8. Clozapine dispensed into a Multi-compartment aid**

See appendix 5.

### **26.9. Contact details**

Refer to the Contact List on the Trust Medicines Management page for details of address, opening hours, and telephone/fax numbers. (Trust Intranet: Directorates: Medical: Medicines Management).

## **27. Maintenance of PoCHi**

### **27.1. Objective**

To ensure that the Point of Care Haematology Analysis machine is correctly maintained by registered users, to optimise performance and to be serviced regularly.

### **27.2. Principles**

The analyser is a state of the art FBC analysis machine provided and serviced by 'Sysmex' and must be maintained by registered/trained users to optimise performance. This training is updated annually by means of an online test which must be completed by all registered users.

### **27.3. Guidelines**

Twelve blood samples for the QC checks will be sent to the clinic every 12 weeks (called 'Eight check') they are bar coded and their data range must be 'entered' into PoCHi on arrival by registered users of PoCHi. If the clinic is closed when the samples are delivered then the receptionist will ensure the samples are stored in the refrigerator on either Avondale or PICU.

- The machine requires a QC test to be carried out on the day prior to samples being processed.  
This will be performed by a registered PoCHi user
- The machine warns when:
  - A routine transducer clean is necessary.
  - The PoCH pack needs replacing.
  - Clog removal is necessary.
  - No LAN connection etc.

These must be all be dealt with before samples may be processed.

## **28. NEQAS (National External Quality Assessment Scheme)**

### **28.1. Objective**

To ensure that the PoCHi machine is performing optimally and in line with national standards for haematology.

### **28.2. Principles**

The PoCHi machine must be tested every month and the results analysed by NEQAS who compare these results with national standards. Penalties can be incurred for non-participation in the scheme.

### **28.3. Guidelines**

- 2 whole blood samples will be sent to the clinic at the beginning of every month and these must be refrigerated on arrival and processed before the deadline. If the clinic is closed on arrival of the samples, then the receptionist will ensure the samples are stored in the refrigerator on Avondale or PICU.
- In Bridlington the samples are sent to Becca House and collected as soon as possible.
- 2 extra samples will be sent to the clinic every 3 months and processed as above.
- The samples will be processed as normal samples and the result printed from PoCHi.
- These results will be relayed via the internet automatically to NEQAS.
- Reports are then received via the internet 1-2 weeks later.

# Appendix 1 – Clozapine Clinic Referral/Transfer form

Clozapine Clinic Referral / Transfer Form								
Surname		First Name(s)		Date of Birth				
Hospital No / NHS No		M/F		Care-Co/CPN				
Address		GP		CPMS Number				
		Tel No(s).		Ethnic Origin				
Ward / Unit / Nursing Home		Tel No.		Fax no.				
MHA Status		Expiry Date		T2	T3	C T O	Other	

Current Dose of Clozapine	mg day	Once daily dosing	Time:	Split doses	mg am	Time:
					mg pm	Time:
Dispensing Pharmacy						
Additional Dispensing Information						

Date of Commencement		Undergoing Titration	Yes	No	
Prescribed by		Monitoring frequency	Weekly	Fortnightly	Monthly
Monitoring last performed		Next Monitoring Due (confirm with dispensing pharmacy)			

Medical / Psychiatric History				
Risk Factors				
Other Medication	Dose	Frequency	Known Interaction	Prescriber

--	--	--	--	--

<b>Name of Referrer</b>		<b>Signature</b>		<b>Date</b>	
-------------------------	--	------------------	--	-------------	--

<b>For Office use only (please circle Yes or No):</b>					
CPMS informed and details amended	Yes	No	Pack compiled	Yes	No
Pharmacy informed with level of pre-dispensing status	Yes	No	Patient list amended	Yes	No
RC informed	Yes	No	Added to iPM caseload	Yes	No
Care-Co & patient informed. Red pack to be sent to clinic	Yes	No	Letter sent to GP	Yes	No
1st appointment arranged	Yes	No	Info. supplied to carer/home	Yes	No



## Appendix 2 - Clozapine Therapy Management Plan

Name	Date of Birth	Consultant
NHS Number		CPMS Number

.....has been prescribed Clozapine, the risks, benefits and possible side effects of which have been explained to him/her by the prescribing doctor.

As part of this therapy ..... undertakes to attend the Clozapine Clinic for monitoring at intervals in accordance with the Clozapine Patient Management Service (CPMS).

At each attendance the following will be carried out and recorded:

- A blood sample will be taken by a trained phlebotomist.
- The sample will be tested for a White Cell Count either in the department on the Point of Care Haematology (PoCHi) machine or taken to the path lab at HRI.
- When using PoCHi, the result will be passed electronically to CPMS who analyse the result (ie white cell count in relation to the neutrophil count) and give an immediate determination of either 'green' (treatment may continue), 'amber' (treatment may continue with special precautions) or 'red' (treatment must be stopped). See over.
- If the sample is sent to the local pathology laboratory, staff will check on HEY Lorenzo or telephone for the result the following day and then enter the WCC, neutrophil and platelets onto eCPMS. Adverse results will be reported by telephone to the patient and their care coordinator for immediate action.  Sitting and standing Blood pressure(BP)  Temperature.
- Weight and waist measurement  Pulse.
- Side effects monitoring.
- Some patients will be able to receive their next supply of Clozapine from the clinic.
- Appointment card will be provided with the next due date Every year, he/she will be offered a full blood screen and an ECG test.

**It is an expectation that .....will:**

- Attend the clinic on the due date, or call to re-arrange if unable.
- Take Clozapine as prescribed.
- Liaise with their assigned mental health team worker or the clinic staff directly regarding any concerns.
- Tell the clinic staff of any holiday plans.
- Tell the clinic staff if they stop (or start) smoking.
- Inform staff if they have not taken their Clozapine for any reason.

- Inform staff if they do not have enough Clozapine. □ Carry an information card in case of medical emergencies □ If they have a planned admission to hospital.

**The clinic staff undertake to:**

- Input the monitoring on to Lorenzo and forward the results to your prescriber if any severe or constant side effects are noted.
- Send copies of same to the GP if requested.
- Attend your CPA review where possible.
- Make you aware of any changes to clinic times because of bank holidays etc.
- Give you the opportunity to discuss your physical health and mental health as required.
- Inform pharmacy and care coordinator if you are admitted to hospital.

Signed patient.....Date.....

Signed clinician.....Date.....

<b>Green result</b>	Treatment regime may continue uninterrupted
<b>Amber result</b>	Telephone contact will be made between clinic and CPMS who will determine the necessary procedure. This usually involves a retest within a few days, and the uninterrupted continuation of Clozapine.
<b>Red result</b>	The sample will be tested twice to verify the result and CPMS contacted, who will usually advise that Clozapine treatment must be stopped IMMEDIATELY. (Your doctor may wish to prescribe you an alternative) You will be asked to return for another blood sample to be taken and tested for the next 2 days.

Useful Telephone Numbers

Name	Telephone Number	Hours
<b>Miranda House Clozapine Clinic</b>	<b>01482 617553</b>	<b>08.00-16.00 every day except weekends and bank holidays.</b>
<i>Insert local contacts</i>		
<i>Insert local contacts</i>		

# CLOZAPINE CLINIC MONITORING FORM: SIDE-EFFECTS AND PHYSICAL OBSERVATIONS



Humber Teaching  
NHS Foundation Trust

Surname		First Name(s)		Date of Birth		Gender	
						M	F

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Care Coordinator and Team	Consultant	Height (cm)	GP Details

CPMS Number	NHS No	Patient Phone Number
Date		

<b>PHYSICAL OBSERVATIONS</b>	Clozapine Dose (mg)																									
	BP	Sitting/Lying																								
		Standing																								
	Pulse (bpm)																									
	Temp (C)																									
	Weight (Kg)																									
	BMI																									
	Waist Size (cm)																									

<b>SIDE EFFECTS</b>	Tired / Drowsy	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Hypersalivation	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Dizziness	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Constipation	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Nausea/Vomiting	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Sweating	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Dry Mouth	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Sore Throat	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Urinary Problems	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Tremor	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Visual Disturbances	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Sexual Dysfunction	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	Involuntary Movements	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
	<b>Key Side Effects:</b>	<b>0 = Non Reported    1 = Mild/Occasional    2 = Moderate/Regular    3 = Severe/Constant</b>																							
<b>Any score higher than 1 should be considered for reporting to Care-Co and / or Responsible Clinician</b>																									

<b>Key Recent Changes</b>	↑ = Increase	↓ = Decrease	U/C = Unchanged	Y = Yes	N = No
	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C
Tobacco use	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C	↑ □ ↓ U/C

<b>RECENT CHANGES</b>	Smokin g	Smoker														
	Caffeine consumption	↑ <input type="checkbox"/>	↓	U/C	↑ <input type="checkbox"/>	↓	U/C	↑ <input type="checkbox"/>	↓	U/C	↑ <input type="checkbox"/>	↓	U/C	↑ <input type="checkbox"/>	↓	U/C
	Loss of consciousness / Passing Out	Y	N		Y	N		Y	N		Y	N		Y	N	
	Change in MH Symptoms	Y <input type="checkbox"/>	N		Y <input type="checkbox"/>	N		Y <input type="checkbox"/>	N		Y <input type="checkbox"/>	N		Y <input type="checkbox"/>	N	
	Changes in Medication (especially SSRIs)	Y	N		Y	N		Y	N		Y	N		Y	N	
<b>COMMENTS</b>	If Yes see back/following page for details															
	Y	N		Y	N		Y	N		Y	N		Y	N		
<b>ASSESSOR'S INITIALS</b>	Humber Teaching on Trust Foundati															

## Appendix 3 – Monitoring forms

<b>Other Monitoring</b>										
<b>Blood test results</b>										
To be completed annually unless instructed otherwise										
Date	BCP	TFT	Lipids	Fasting Glucose	Random Glucose	FBC	HbA1c	Lithium	INR	Other

<b>ECG</b>			
To be completed annually unless instructed otherwise			
Date	Test performed by	Where Performed	Date Uploaded

<b>Clozapine Plasma Levels</b>			
As requested by Responsible Clinician			
Date Taken/Sent	Test performed by	Results	Date Results Uploaded

<b>Annual Wellbeing Status</b>		
Patient to be asked if this has been carried out		
Date	Comments	Initials

<b>Comments or Observations</b>		
Date	Comments	Initials

## Appendix 4 – letter if patient going abroad



**ECT and Clozapine Clinic**  
Miranda House  
Gladstone Street  
Kingston upon Hull  
HU3 2RT

To whom it may concern

RE:

Name:	D.O.B:	CPMS No:
Dose:	No of Tablets:	
Destination:	Date leaving UK:	Date Returning:

The above named Client has decided to travel abroad on holiday. The client is carrying their own personal dose of Clozapine medication. Clozapine is classed as a Red Drug, a drug only to be prescribed by a specialist psychiatric consultant. Supplies of the medication are restricted and the amount that can be supplied depends on the script from the consultant and requires a valid blood result monitored from an NHS site.

The brand of clozapine used by Humber Teaching NHS Foundation Trust (HTFT) is Clozaril® manufactured by Viartis. All patients receiving clozapine must be enrolled with the Clozaril® Patient Monitoring service (CPMS) and must be under the supervision of an appropriate specialist physician (usually a psychiatrist). Up to date records on any patient can be obtained from eCPMS which is a secure, validated web-based database of patients registered for treatment with Clozaril®.

Should you require any further information please visit [www.clozaril.co.uk](http://www.clozaril.co.uk) or alternatively contact the departments listed below:

HFT pharmacy department at Trust HQ, Willerby Hill, Telephone: (44)1482 301724  
Miranda clozaril Clinic: (44)1482 617553 during office hours, (44)1482 216624 out of hours. Clozapine Patient Monitoring Service: 0845 769 8269

Yours Sincerely

# Appendix 5 – Repackaging of Clozapine into a Multi compartment aid (MCA) protocol



## Repackaging of Clozapine into Multi-Compartment Compliance Aids (MCA) Protocol

### Overview

A number of Humber Teaching NHS Foundation Trust (HTFT) patients require their medication to be packaged into a Multi-Compartment Compliance Aid (MCA), which also includes clozapine.

This protocol is to provide agreement between HTFT and Morrill Pharmacy for clozapine to be repackaged into an MCA along with any other medication prescribed by the patient's GP as per local SOP's.

### Service

Clozapine will be pre-dispensed in line with a prescription generated by the associated community mental health team. Prescriptions for clozapine will be managed by HTFT staff and pre-dispensing will be done at the Miranda House site.

Once dispensed, clozapine will be provided to designated staff at Morrill Pharmacy, accompanied with a copy of the prescription, for repackaging into an MCA.

Filled MCAs will then be collected by HTFT staff in accordance with the patient's monitoring frequency, as set by the Clozaril Patient Monitoring Service (CPMS) and as per agreed delivery schedule.

Prior to collection, blood sample results will be checked and confirmed as valid by both HTFT and Morrill Pharmacy staff, to ensure delivery of medication can be made to the pre-agreed address for each patient.

Details of dispensing will be entered onto eCPMS by both parties, firstly to enter the amount that has been repackaged into an MCA by Morrill Pharmacy staff (but not cleared from the 'worklist') and the HTFT staff to confirm amounts and remove from the 'worklist'. This will help ensure full audit trail of the amount of clozapine supplied to each patient. This is in addition to PMR systems.

Patients are allocated specific 'groups' for routine dispensing of clozapine, which will be managed by HTFT. This information will be shared, securely, with staff at Morrill Pharmacy to ensure continuity of workload. Any changes will be communicated accordingly.

Dose changes will be confirmed via email with the supervising consultant prior to dispensing.