## Clozapine Clinic Protocols

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1. **INTRODUCTION**

Within the Doncaster, Rotherham and North Lincolnshire localities there are Nurse led Clozapine clinics which provide a treatment and monitoring service to all patients who are prescribed Clozapine. In addition to this staff in the clinics also undertake physical health screening with the patients who attend and provide health and wellbeing advice.

2. **PURPOSE**

The purpose of this protocol is to set out the minimum standards in relation to how the service is provided within the clinics and are to be read in conjunction with the Trust Safe and Secure Handling of Medicines Policy.

3. **SCOPE**

Whilst these protocols are specific to the staff who work within these clinics there is an expectation that other clinical staff, who in the course of their work may be involved in the care of patients receiving Clozapine treatment or attending the clinic, will have an awareness of the protocols.

4. **RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES**

4.1 **Nurse Lead for the Clozapine Clinics**

It is the responsibility of the Nursing staff in charge of the clinics to:

- Follow this protocol.

- Advise on baseline measurements that need to be done.

- Provide information on Clozapine to the patients who attend the clinic, including side effects, and how to manage them, and when to seek medical attention.

- Check patient details at each attendance.

- Monitor physical health is the responsibility of the patients lead professional, and will only be carried out by the clinic where the patients has no other lead professional, and record in the patient’s record. Over and above monitoring for side effects, health monitoring will mainly entail using health screening tools, with referral to the appropriate service, e.g. patients GP. Good communication between the lead professional and clozapine clinic is essential.

- Advise and monitor in respect of side effects from the medication and inform relevant medical staff (either primary or secondary care) of any concerns. For patients who do not have a Care Coordinator the clinic
staff will inform, the Responsible Medical Officer (RMO) or duty care worker, depending on who is most appropriate.

- Monitor patient’s mental state and inform the Lead Professional of any concerns.
- Undertake/participate in any required audit work.
- Provide local induction to any new staff in the clinic.
- Report any adverse events through the Trust electronic incident reporting system.
- Identify any training needs.
- Attend any training which is provided to enable them to fulfill their duties within the clinic safely.

4.2 Care Coordinator

Care coordination remains the responsibility of the allocated Care Coordinator or Lead Professional.

The patients Care Coordinator will be responsible for:

- Supporting the patient in their attendance at the clinic.
- Physical Health Monitoring
- Following up any patients who do not attend their appointment.
- Highlight any concerns raised by the patient to the clinic

4.3 Consultant Psychiatrist / Lead Professional

It is the responsibility of the Consultant Psychiatrist / Lead Professional to refer the patient to the Clozapine clinic and register them with the relevant Clozapine Company.

If the clinic does not have a non-medical prescriber they are also responsible for:

- Prescribing the patients Clozapine.
- Informing clinic staff, pharmacy and GP of any dose changes.
- Refer to primary care any concerns over the patients physical health

4.4 Supplying Pharmacy

The supplying pharmacies are responsible for:

- Informing the clinic staff of any problems in respect of the dispensing of Clozapine.
- For patients currently under the clinic
- Will pre-dispense the clozapine, with the clinic releasing the
prescription on receipt of a green/amber result as per SOP
- For inpatients
- Will only dispense on receipt of green/amber result

5. PROCEDURE AND IMPLEMENTATION

Background information and pre-clinic process

5.1 When to consider Clozapine

Clozapine is an atypical antipsychotic which can be used to treat schizophrenia in patients where:

- There has been a poor response to two or more other antipsychotic medications, one of which should ideally have been atypical.
- The patient has experienced severe side effects, or intolerance to either typical or atypical antipsychotic medication, which clozapine is less likely to cause.

Clozapine is known to be effective in the treatment of both positive symptoms such as auditory hallucinations, and negative symptoms such as a lack of motivation and poor social interaction.

5.2 Contra Indications

The use of Clozapine is not recommended for a patient where any of the following are present:

- Severe Cardiac problems.
- Uncontrolled epilepsy.
- History of previous hypersensitivity to Clozapine.
- Severe renal impairment.
- Active liver disease.
- Paralytic ileus, abdominal/gastrointestinal examination or history is recommended
- Pregnancy.
- History of Neutropenia or Agranulocytosis.

5.3 Caution in prescribing

Caution is advised in the commencement of Clozapine in the following cases:

- Hepatic impairment.
- Glaucoma.
- Renal Impairment.
- Prostatic hypertrophy.
- History of constipation and the co-prescribing of anticholinergic medication
5.4 **Possible side effects**

The most commonly reported side effects are sedation, increase in salivation, fluctuation in blood pressure, increased heart rate and increased body temperature, but these usually settle within four weeks of doses being stabilized, however they may still need managing before this e.g. hypersalivation. Other reported side effects are constipation and weight gain both of which can be managed by a high fibre diet, and dietary advice.

For full details staff should refer to the most recent issue of the British National Formulary (BNF).

5.4.1 **Specific serious side effects**

Agranulocytosis, Acute Intestinal Obstruction and Constipation, Pyrexia, Seizures, Cardiovascular Events, Diabetes and Impaired Glucose Tolerance, for further information see the monitoring section.

5.5 **Patient information**

Please see Appendix 7 Chart for Initiation on Clozapine.

Prior to the initiation of Clozapine treatment patients and, if appropriate, their carers must have a full discussion with the prescribing clinician about the risks and benefits of the proposed treatment. This discussion should also cover:

- Common side effects.
- Requirement to attend for regular monitoring and the restrictions that this can impose on the patient.
- The need to avoid alcohol, driving, and machine operation during the first few weeks of treatment commencing.
- What to do if significant side effects occur.
- The importance of not missing more than 48 hours of clozapine

Patients will also be given the above information in writing.

For patients whose first language is not English arrangements will be made for the presence of an interpreter during any clinic appointments. Staff should refer to the Trust policy for the provision and access to interpreters.

5.6 **Patient Registration**

Patients must be registered by the Consultant team, using the Zaponex Treatment Access System (ZTAS) forms, available from the ZTAS website [www.ztas.co.uk](http://www.ztas.co.uk), the initial blood sample should be carried out by the treating team and the results sent to ZTAS.
The team will then contact the clozapine clinic to arrange the first appointment, once titration is completed

5.7 Consent

Due to the need for the patient to comply with the monitoring requirements through regular attendance at clinic, Clozapine is usually only prescribed once informed consent has been obtained. (staff should refer to the Trust Policy for Consent to Examination and Treatment.) However in the case of a patient who lacks the capacity to consent but does not object, Clozapine can be administered under the Mental Capacity Act 2005 if it is deemed:

- necessary to save life, prevent deterioration or ensure an improvement in the patients physical or mental health.
- in the best interest of the patient.
- to be done so in accordance with the practice accepted at the time by a reasonable body of medical opinion skilled in that form of treatment.

5.8 Patients detained under the Mental Health Act 1983 who refuse to have blood samples taken for Clozapine monitoring

In the event that a patient detained under the Mental Health Act 1983 for treatment refuses to have their bloods taken for Clozapine monitoring the sample can be obtained under section 63 and then if necessary a section 58 certificate. However the benefits of instigating treatment in this way must outweigh any possible adverse effects to the patient and minimal force is to be used to obtain the blood sample.

5.9 Patient Appointments for clinic

5.9.1 Inpatients

If the person is an inpatient, contact staff on the relevant ward and arrange a time to take a local sample. This can then either be taken to the local clozapine clinic who can analyse it using the Pocchi machine, or can be sent to the local laboratory for testing, the results can then be faxed directly to ZTAS on 02073655843, include patient name date of birth and full blood count (this can be printed off ICE or pathlinks

5.9.2 Outpatients

If the person is an outpatient:

- Contact them by telephone and arrange a time for them to attend the clinic for a blood sample to be taken if the appointment has not already been made at the previous one, which is the normal practice
- If clinic staff will not be available to take the blood sample a form for phlebotomy will be left for them to collect. (Convenient pick up
point to be arranged with the patient), and the patient told to attend the phlebotomy department at the local hospital at the earliest time possible.

- An entry to this effect is to be made in the patient’s clinical record.
- When the results are available the clinic staff will upload these to the ZTAS website

5.10 **Action to be taken if a patient fails to attend their appointment at the Clinic or is un-contactable**

5.10.1 **Inpatients**

In the event that an inpatient fails to keep their appointment the clinic staff are to contact ward staff and request that if possible the patient attend clinic. In the event that the patient is not able to attend the clinic ward staff are to be instructed to obtain a sample which is to be brought to the clinic either for testing, or dispatch to the local laboratory.

5.10.2 **Outpatients**

In the event that an outpatient fails to attend their appointment clinic staff will: Attempt to contact the patient by phone to make an alternative appointment for them to have their blood sampling done

- If the patient is not able to attend the clinic the Care Coordinator/Lead Professional must be contacted to facilitate a blood test as soon as possible.

- In the event that no contact is made with the patient clinic staff are to try and establish contact either through the patients relative/carer or Care Coordinator / Lead Professional.

- In the case of repeated non-attendance or difficulty in contacting the patient for a sample the following are to be informed:

  o Patients Consultant Psychiatrist.
  o The supplying pharmacy service.

- Depending upon the frequency of testing required for individual patients, an extra week, or 3 day supply of Clozapine may be authorised in order to facilitate continued Clozapine therapy. This is arranged with the local pharmacy supplier who will facilitate the delivery of medication to the patient’s home address, ward or relevant community team.

- If the patient’s medication has been delivered to clinic at the beginning of the week then this may to be returned to pharmacy for re-dispensing in the appropriate numbers. [e.g. patients/service users on 4 weekly monitoring will receive 3 weeks supply of Clozapine
at their appointment the next week and will therefore require a 3 week appointment when they next attend.

- If a blood result is not received within 7 days of the due date a courtesy reminder will be faxed to their Consultant Psychiatrist. Further reminders will be sent each week. If there is no result, after 28 days the Clozapine company will modify the patients status to “interrupted” and the person will need to be re-registered

5.11 Monitoring Requirements

For the first 18 weeks of treatment the patient will require weekly blood monitoring, this initially will be on the ward, and subsequently be at the clinic. At the appointment blood pressure, pulse, temperature and weight monitoring will take place.

However at 3 months the patient should be informed that some additional tests are carried out to monitor their physical health, if the patient is still an inpatient this will be done by the inpatient team, when discharged the team should inform the clinic when these are due. These will then be completed annually by their GP. These tests are:

- Calculation of Body Mass Index (BMI) using either the electronic scales (as outlined in the instruction manual) or by using a BMI calculator.
- Measuring of abdominal girth using a tape measure.
- Side effects questionnaire
- The following blood tests:
  - Urea and Electrolytes
  - Lipids
  - Liver function test
  - Glucose
  - Prolactin

To request these, tick the appropriate boxes in the biochemistry section, next to the glucose box write either random or fasting as appropriate. To order the prolactin serum test write ‘PRL’ under ‘other biochemistry requests’. The above tests will require a gold top bottle of blood be collected.

The Clozapine side effect questionnaire must be completed, along with a review of their mental health, and any issues addressed or referred to the appropriate professional.

ECGs’ are not routinely the responsibility of the clozapine clinic, for inpatients they should be carried out and reviewed by the treating team. For community patients then the patients lead professional should organize them as agreed locally, and again reviewed by the treating team.
Once the results from the above tests arrive back at the Clozapine clinic, staff should contact the Consultant Psychiatrist/junior trainee in Psychiatry for that patient and ask them to come and review the results, and record the outcome in the patient’s record. Once this has been done the results are to be sent for filing. The medical team is responsible for any follow up or actions required following the receipt of the results.

Clinic staff or Consultant secretary should then complete the GP Letter by adding the patients’ details and signing it to inform the GP that the 3 monthly interventions is complete and they should now review the patient annually. Patient details and GP addresses are available in the patient contact details file.

For the next **34 weeks** the patient will be required to attend clinic for blood tests every two weeks and once a month their blood pressure, pulse, temperature and weight monitoring will take place.

Thereafter attendance is four weekly and at each appointment the patient’s blood pressure, pulse, temperature and weight monitoring will take place.

Please see Appendix 2 for initial monitoring for patients initiating or being titrated on clozapine.

At all appointments there will be an assessment of the patients mental health both informally and through the use of available clinical assessment tools.

In addition to this patients will have the opportunity to discuss any issues they may have in relation to their general physical health, social needs, and or employment /educational needs.

The monitoring of side effects will take place at each appointment with clinic staff completing the agreed side effects rating scale. If side effects are evident the severity of them is to be assessed and the need to increase the frequency of future monitoring is to be agreed with the patient.

The clozapine side effect questionnaire should be completed on each visit, and where appropriate any issues addressed (Appendix 1).

During the monitoring of patients particular attention should be paid to flu like symptoms such as sore throat and raised temperature, as these could be indicative of neutropenia. In the event that this is suspected contact is to be made with ZTAS for guidance.

In the event that any unusual adverse effects are noted practitioners should report these either using the yellow card found in the back of the British National Formulary or on line at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)
5.11.1 Protocols for obtaining blood samples.

Wherever possible the blood samples will be obtained in the Clozapine clinic. Clinic staff will follow consent procedures, and make any adjustments that are deemed necessary for the patients comfort during the procedure.

<table>
<thead>
<tr>
<th>PURPOSE</th>
<th>FREQUENCY</th>
<th>WHERE TAKEN AND TESTED</th>
<th>SENT VIA</th>
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<tr>
<td>Routine Full Blood Count with Differential</td>
<td>Weekly for 18/52 Fortnightly till 52/52 Four weekly thereafter</td>
<td>Clinic PocHi/ZTAS Local Labs</td>
<td>Online/Courier/Local Labs</td>
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<tr>
<td>Urgent FBC</td>
<td>As required</td>
<td>PocHi/local lab</td>
<td>Online/Transport</td>
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<tr>
<td>Serum Level (trough)</td>
<td>See below</td>
<td>Clinic using Magna Laboratories</td>
<td>Royal Mail</td>
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<tr>
<td>Other Blood Tests for monitoring e.g. Lipids, prolactin</td>
<td>Baseline at 3 months then annually</td>
<td>Clinic Local Labs</td>
<td>Transport</td>
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Withhold morning dose prior to blood collection if carrying out a serum level (not routine blood tests)

5.11.2 Point of Care Haematology (PocHi) Analyser is available

Patient procedure

Patient attends Clozapine Clinic as per appointment and the clinic nurse will review the patient’s mental and physical state. A routine blood sample will be taken and patients will be asked to stay until their blood results are available to enable medication to be issued following a ‘green’ blood result.

Doncaster, Rotherham and North Lincolnshire

Follow the Standard Operating Procedure (SOP) for the PocHi machine in Appendices 3, 4 and 5.

For full details Staff are to refer to the internal quality control procedure for the point of care analyser contained in Appendices 3, 4 and 5.

5.11.3 Procedures if a PocHi is not available

(Note: Blood samples must be obtained by an accredited venepuncturist)

Doncaster, Rotherham and North Lincolnshire:

- If necessary 2-3 days medication can be given to the patient whilst
waiting for the blood result. Once a green result is obtained the rest of
the medication can be sent.

5.11.4 Protocol for obtaining a blood sample for local analysis

(Note: Blood samples must be obtained by an accredited venepuncturist)
This protocol should only be used if:

- For any reason a sample could not to be obtained at the Clozapine
  clinic.
- A sample has been contaminated or lost.
- A request has been made for a further sample.
- The patient did not attend clinic.

To obtain a blood sample for local analysis staff must complete
‘biochemistry, haematology and immunology form with the following:

- Tick Full Blood Count and underneath write ‘with differential’.
- In the clinical details box write ‘patient on Clozapine’.
- Ensure all the fields are completed, surname, forename, hospital
  number (use Silverlink or PAS/ICE to obtain information), date of
  birth (DOB), tick male/female, tick NHS, Consultant (RMO),
  relevant team, ward or Clozapine clinic, sample type – v blood and
  sign the form.

If clinic staff (or other phlebotomy trained staff) are not available the
patient is to be asked to take the completed form and attend their GP or
local walk in center, in an emergency they may also be able to go to the
phlebotomy at the department at the local general hospital.

If staff are available a sample should be obtained using a red top
monovette bottle or a Lavender top bottle, whichever is used for EDTA,
in yours area(check expiry date) following local phlebotomy protocols.

The sample should then be taken to the laboratory at the local
General Hospital either by a member of staff or hospital transport.

Swallownest Court only: Place the sample in the drug fridge. If the
sample is ready before 11am it will be taken by hospital transport. If after
11am the sample should be taken to the laboratory at Rotherham General
Hospital by a member of staff.

Please note if a sample is infected it should be labeled accordingly and
carried in additional packaging following Trust protocols.

If the sample has been done by the ward, then it is their responsibility to
fax the results to ZTAS, if however it is a community patient then the
Clozapine clinic staff will input the results. Alternatively the sample can be
sent to the clinic to be run through the Pocchi machine
Clinic staff to retrieve the blood results and enter onto ZTAS system manually in order for medication to be dispensed. If clinic staff is unavailable the results are to be obtained from PAS/ICE system and faxed to ZTAS as soon as possible, alternatively ZTAS can be telephoned with the result.

5.11.5 Procedure for obtaining serum clozapine levels

Frequency

- One week post dose stabilization
- Annually
- For checking compliance e.g. on admission to a ward or as clinically indicated
- Post change in smoking habits
- Change in caffeine consumption

Where

Either by prior arrangement with the clozapine clinic or for inpatients on the ward by ward staff if the clinic is off site. This will depend on the individual clinic. The request should normally be made by the consultant or key worker.

- The request should be clearly marked in the Clozapine clinic diary once received.
- The patient must be aware of the need for a serum sample and informed not to take their morning dose of Clozapine otherwise the serum level cannot be taken. Clinic staff to contact ward area (if appropriate) to ensure the morning dose of Clozapine is omitted.
- Prior to taking the sample check with the patient that they have not taken their morning dose of Clozapine.
- For patients where it is being taken on the ward, the paperwork and containers can be accessed via the clozapine clinic
- If they have taken their Clozapine the test must be re-scheduled for a later date.
- For a serum sample a separate sample is required (2 samples if routine monitoring is being done at the same time), and a separate Clozapine serum assay request should be sent, using the Magna Laboratory paperwork.
- Please ensure that labels are placed on the request form and blood bottle sent. For inpatients who may not have the stickers enter the ZTAS pin and patient details
- The sample should be posted using Royal Mail.
- The results may take 3-7 days and will be faxed directly to the Consultant Psychiatrist. Alternatively the blood results are uploaded to a web based service, and can be accessed through this mechanism. To do this the viewer must be registered with Magna laboratories:
- Tel 01989 763333 - Fax 01989 763533 - E-mail info@magnalabs.co.uk
Results

It is the responsibility of the consultant to follow up and act on the blood results, where abnormal results are found Magna will contact the consultant concerned.

Normal Range

Clozapine: 0.35-0.6mg/L

For advice on how to interpret the levels please contact either Trust Pharmacy or clozapine clinic if necessary.

5.11.6 Protocol for Red blood results

On receiving a RED result clinic staff must:

Doncaster, Rotherham and North Lincolnshire:

- Do not retest the result. ZTAS will not allow two results for one patient on the same day. Only obtain a new sample to send that day if the first one appears clotted, then still send it locally.

  **N.B. If staff unavailable to utilize PocHi, then an urgent ‘fast-track’ local sample should be sent to the local lab and results retrieved and faxed to ZTAS as soon as possible. STOP CLOZAPINE IMMEDIATELY.**

- The initial sample should be sent to the local laboratories for testing, to check of any issues with the PocHi machine. Once the local sample results are received by ZTAS then staff should contact ZTAS for guidance regarding any further action required.

- Upon receipt of a RED result ZTAS will generate an alert/warning to the patient’s psychiatrist and Clozapine pharmacist. Other appropriate healthcare providers are also contacted by phone.

- Contact the psychiatrist, Care Co-ordinator and/or ward staff as appropriate and inform them that the patient is to STOP CLOZAPINE IMMEDIATELY. Whilst there is a significant risk of relapse at this time, patients should not take other antipsychotics (however haloperidol can be used if necessary as discussed with RMO).

- Ask the patient to return to the Clozapine Clinic for a further blood test within 24 hours [*this may require liaison with Crisis Team in order that procedure may be followed; e.g. out of hours, weekends or Bank Holidays*]. They should bring all Clozapine with them if possible to be kept in secure storage until the blood results are satisfactory. This can be carried out on the ward if an inpatient, or being
admitted

- The Responsible Clinician or their nominated deputy should be informed immediately. They may wish to arrange for an assessment of the patients’ mental state and may request the patient to remain in hospital to be assessed.

- If there is a secondary infection, or when the neutrophil count decreases below $1.0 \times 10^9/L$, the Psychiatrist should contact a haematologist in the hospital or at ZTAS to discuss the appropriate treatment regime.

- Any local samples taken should be ‘fast-tracked’ and staff trained to enter results onto the ZTAS system should do so as soon as possible. If such staff are unavailable (evenings, weekends or bank holidays) the on-call SHO can telephone or fax the results through to ZTAS and feedback the result to the appropriate staff.

- If the patient has only one red result, they may be able to re-start Clozapine. However this cannot occur until there have been 2 separate GREEN results on 2 consecutive days. If AMBER results occur at any point daily testing is to be continued and the Clozapine withheld. This may mean that the patient needs to be re-titrated if the delay is more than 48 hours; the RMO will decide how quickly this can be done.

- If the patient has 2 RED results, they are ‘non-re-challengeable’ which means they will no longer be able to take any brand of Clozapine. At this point daily testing should occur until 1 green result is found. Once a green result has occurred the patient will have stopped Clozapine, however further weekly testing will be required for a period of 4 weeks to ensure blood results remain stable.

5.11.7 Protocol for Amber blood results

If an amber result is received the clinic staff must:

- Re-test blood sample locally to confirm it is not an error. If a second AMBER result is obtained, then advise them to return in 48hrs [or as soon after this as possible] for further testing. Advise pharmacy that the patient is AMBER and will therefore require only one week’s supply of medication.

- Where no PocHi machine is available contact the patient to arrange a second blood test within 48 hours.

- After follow-up test, if result is GREEN, then patient is supplied remaining 3 weeks medication following liaison with pharmacy and requested to attend for their regular routine appointment. If result remains AMBER then the patient is required to attend for twice weekly
testing, being supplied with weekly medication until a GREEN result is obtained.

- The patient should be informed to watch for further signs of infection and contact the clinic or their Consultant Psychiatrist / Lead Professional if they occur. They can go home once the blood has been taken. Twice weekly blood tests will continue until signs of infection have abated.

- Bloods should be monitored twice a week until blood results return to the GREEN classification, this may mean only one further test is required following an AMBER if the follow up blood result is GREEN. However, if there are signs of infection then testing should continue twice weekly until the symptoms have abated.

- The patient can continue to take Clozapine but must have a further blood test taken; this may mean arranging a taxi or contacting their Care Coordinator to bring the patient to clinic as soon as possible for a local sample to be taken.

- The patient should be informed to watch for signs of infection and contact the clinic or their Consultant Psychiatrist / Lead Professional should they occur. They can go home once the blood has been taken.

- It is also advised to increase monitoring to twice weekly if there are symptoms of infection, even if the samples are normal, until the symptoms have abated. This is also advised if there is a ‘single drop’ or ‘downward trend’ in the White Blood Count greater than 3.0 x 10/L this is indicated by a downwards arrow against the blood result on the ZTAS monitoring screen.

If unsure of any of the above contact ZTAS for advice.

5.11.8 Monitoring for Specific Serious Side effects

Agranulocytosis

- Routine blood monitoring will identify sub-clinical cases. Particular attention must be paid to flu like symptoms such as sore throat and raised temperature that may be indicative of neutropenia. The Zaponex Treatment Access System (ZTAS) currently provides guidance about procedures to be followed in the event of neutropenia or agranulocytosis developing.

Acute Intestinal Obstruction and Constipation

- Clozapine exerts anticholinergic activities, which may produce undesirable effects to patients on this treatment. Its anticholinergic properties may cause varying degrees of impairment or slowing of intestinal peristalsis ranging from constipation to intestinal obstruction, faecal impaction and paralytic ileus that may be fatal. Acute obstruction
is a medical emergency. Symptoms include abdominal distension, pain and vomiting.

- Particular care is necessary in clients who are receiving concomitant medications known to cause constipation: especially those with anticholinergic properties such as other antipsychotics, antidepressants, and antiparkinsonian treatment. Clients who have a history of colonic disease or a history of lower abdominal surgery should be carefully monitored as this may exacerbate the risk of constipation.

**Pyrexia**

- Mild hypothermia occurs in approximately 5% of patients, typically early in treatment and is usually not significant; however a medical examination and full blood count should be performed as soon as possible. If the body temperature exceeds 38.50 C, clozapine should be stopped until the temperature drops. The ZTAS (or equivalent) should be contacted and their advice followed.

**Seizures**

- Clozapine may lower the seizure threshold, this is a dose or dose increased related effect.

Should a seizure occur, withhold clozapine for one day, restart at a lower dose. Those needing doses of clozapine that cause seizures may be prescribed sodium valproate at doses between 1000-2000mg /day, use of modified release preparation (Epilim Chrono) may aid compliance as it can be given once daily and may be better tolerated. Plasma levels may be useful as a rough guide to dosing – aim for 0.35 – 0.6mg/L, although some may require higher levels.

**Cardiovascular Events**

- Clozapine may increase the risk of pulmonary embolism and sudden death.

- Clozapine has been associated with cardiomyopathy and myocarditis. The risk of myocarditis is highest during the first two months of treatment. Cardiac complications should be suspected if clients experience **persistent tachycardia** at rest, palpitations, chest pain or heart failure develops. In these cases clozapine should be promptly stopped and the client referred to a cardiologist by their psychiatrist. Such clients should never be re-exposed to clozapine.

- The risk of orthostatic hypotension can be minimised by slowly tapering the dose and spreading doses through the day.
Diabetes and Impaired Glucose Tolerance

- Clozapine has been strongly linked to hyperglycaemia, impaired glucose tolerance and diabetic ketoacidosis.
- As many as a third of patients may develop diabetes after 5 years of treatment.
- Most cases of diabetes are noted in the first 6 months of treatment and some occur within one month.
- Death from ketoacidosis has also been reported.
- Diabetes associated with clozapine is not necessarily linked to obesity or to a family history of diabetes.
- Patients should be referred to primary care to manage this.

5.11.9 Procedure for reporting and managing identified side effects

5.11.9.0 Managing Constipation

A gastrointestinal history and/or abdominal examination is recommended in all patients prior to starting clozapine. If there is a pre-existing problem this should be adequately treated prior to initiation. Other concomitant medication should be assessed and where possible discontinued, e.g. procyclidine, opiates etc. Suitable advice should be given to the patient around appropriate diet, exercise and mobility and not ignoring the urge to defecate.

Be aware of the warning signs indicative of severe constipation:
- Abdominal pain
- Abdominal dilation
- Vomiting

The use of a stool diary could be considered, especially in the first 4 months of treatment.

If constipation does occur a full assessment should be made to assess the role of clozapine in this and to rule out other causes. A three step approach should be taken:

1. Lifestyle changes: fluid intake, dietary fibre, exercise & toileting routine
2. Stimulant laxatives
3. Osmotic laxatives
4. Prokinetic drugs

Severe constipation needs to be managed but generally does not warrant discontinuation, however in cases of intestinal obstruction, faecal impaction or paralytic ileus it should be **stopped immediately and the patient referred urgently to a specialist for treatment.**
If blockage/paralytic ileus has occurred then patients should be reviewed with respect to restarting it, and where alternative options are available these would be preferred. In instances where this is not possible it is important that the constipation has fully resolved first, and the patient retitrated slowly and monitored carefully.

5.11.9.1 General considerations

- Enter information in the patient record (Silverlink or similar) along with details of who you have informed, and what advice has been given.
- Inform the treating team, including the consultant, by email, and where urgent by telephone as well, advise them to read the entry in the patients notes and act accordingly.
- If non urgent ask the team/consultant to inform the patients GP re any advice or follow up that might be necessary
- If urgent contact the GP directly, ideally faxing the Silverlink entry to them, or asking admin support to make it into a letter if less urgent.
- Follow up any issues during the next clinic visit to ensure action has been taken.

5.12 Clozapine Supply

Doncaster, Rotherham and North Lincolnshire:

- Follow the SOP for taking blood and setting up the PocHi machine (Appendices 3, 4 & 5)

- When access has been gained to patient detail screen minimise it and log onto SILVERLINK.

- NEQAS monthly QC results should be filed.

- Get out the patient files from the filing cabinets for the correct clinic week.

- The pharmacy order is in the light blue transport boxes. Break the seals to open, and inside each box is a single delivery receipt that has patient identifying labels on it for all of the medication in that box. Check that each patient’s medication is present and tick on the clinic log sheet to confirm arrival. Repeat with each box and then place the medication alphabetically into the drug cupboard. Keep the clinic log sheets next to the clinic computer so that the medication given and date boxes can be completed each time a green ZTAS patient result is seen in clinic in the following week.

- When the blood is tested on the pocchi machine normally the patient’s name will appear highlighted in green to indicate a ‘green’ result. It also states whether the patient has 2 or 4 weekly blood tests and the date of the last test (which should always be that days date)
NB. If there are several patients with the same surname check carefully to see you are looking at the correct patients result.

- Give the patient their medication and complete the clinic log sheet.
- On the SILVERLINK system find the patient and enter a new case note stating
- “(Patients name) attended the Clozapine clinic at today. POC)Hl issued a green result and he/she was given 1, 2 or 4 weeks’ supply of his/her medication”. You will also enter a brief statement regarding their mental state and any problems which need addressing. Remember to save the entry. Remember to sign the Clozapine clinic log sheet to say you have supplied the medication to the patients.
- Put the ZTAS patient information folders back in the filing cabinet and lock it.
- Lock the fridge, the drug cupboard any clinical cupboards that are open and return the keys to allocated key cupboard.
- Lock the clinic door and switch off the light.
- Fax the drug receipt and issue forms to, once all service users have been seen, and medication been issued, include any DNA patients:

  **Rotherham clinic** – Lloyds pharmacy Fax: 01226 289695

  **Doncaster clinic** - Lloyds pharmacy Fax 01302 344166

  **Scunthorpe clinic** – Lloyds pharmacy Fax 01724 277830

**Rotherham**

The Rotherham clinic is held at Ferham Clinic which opens at 9:00am, with the clinic starting at 9:30am weekday mornings, and the medication is delivered at 3pm on a Friday Afternoon. The key for the drug cupboard is kept in the key cupboard in reception, and held by qualified nursing and pharmacy staff only. A spare key cupboard key is held by the Recovery Team Manager if needed. The key to the Treatment Room is kept in reception in the key cupboard.

**Doncaster**

The Doncaster Clinic is held at Bungalow 4 and the medication is delivered at 8.30am on a Thursday morning. The key for the drug cupboard is kept in the key cupboard in reception, and held by qualified nursing and pharmacy staff only. The main clinic door is accessed via a keypad lock. The code for which is available from the Opal Centre reception if required. A spare treatment room key is also available from
the Opal Centre reception.

**North Lincolnshire**

The clinic in North Lincolnshire is held at 344 Ashby Road, and the medication is delivered on Friday. The key for the drug cupboard is in a locked key cabinet in a locked room. The spare key is in the locked key board.

### 5.13 Ordering and Receipt of Clozapine

**Lloyds Pharmacy for Doncaster, Rotherham & North Lincolnshire Services (see SOP Appendix 3, 4 & 5)**

Prescriptions are requested by Lloyds Pharmacy to the relevant patients community team or inpatient ward. The frequency is dependent on how the patient is currently being managed or how long the last repeat prescription was requested for. The prescriptions are faxed to the relevant Lloyds Pharmacy on the numbers stated above and the originals are sent via the Lloyds drivers either in the Lloyds pouch or blue pharmacy boxes. Yellow copies of the prescription are to be filed in the patients notes.

On receipt of the medication staff are to check that the medication has been received for the patients who are on the list. Once this has been confirmed the received by section on the delivery sheet is to be signed. All medication is then to be locked away in the drug cupboard. The key for which is held in the key cupboard in reception.

#### 5.13.1 Ordering Clozapine out of hours (e.g. if admitted to a general hospital)

Patients admitted to an acute hospital should have a supply of their own clozapine with them. The ward should be advised to contact the local clozapine clinic to inform them of their admission. Where they exist the mental health liaison service should be contacted who will be able to facilitate further supplies, and will be able to access their electronic record and inform the ward when further blood tests are due. Where possible if the patient has not brought in their supply a carer should be asked to bring it in. If the patient has a valid blood test then the nominated Lloyds pharmacy may be able to supply, if they have a prescription. This is Barnsley for Rotherham patients, Thorne Road for Doncaster patients and Ashby High Street for Scunthorpe.

### 5.14 Protocol for patients who are going on holiday whilst on Clozapine

Patients are able to take a holiday for a maximum of two weeks if established on fortnightly monitoring or four weeks if established on four weekly monitoring. If the holiday period does not exceed the normal sampling time this protocol does not need to be instigated.
Holidays in the UK

- The patient should discuss the dates of the holiday with the clinic staff so that they can ensure a sample is not required during the holiday period and there is adequate time to collect medication prior to departure. This may require the routine appointment being adjusted to one or two weeks early (depending on frequency of monitoring and holiday dates). The Pharmacy supplier should also be informed and the prescription adjusted accordingly. E.g. if a patient attends one week early and is four weekly monitoring, they will have a week of medication left from the last prescription, so a three week prescription can be given and an appointment four weeks from the last appointment.

- In the event that a patient is planning to be away for more than four weeks clinic staff should liaise with the relevant company to arrange for sampling and medication delivery in the locality of the holiday destination.

Holidays outside the UK

- For any patients who are planning to take a holiday outside the UK the following should have occurred prior to the holiday:

  - The Responsible Clinician will have assessed the likely effect of the trip on the patient’s health.
  - Emergency contact between the Clozapine clinic and the patient is to be agreed.
  - Patient has a satisfactory blood result prior to leaving the country. If necessary a sample should be taken and analysed locally just prior to departure and placed on the ZTAS system by pharmacy/clinic staff.

No more than 14 days (or 28 days for 4 weekly monitoring) supply of Clozapine should be taken on holiday with the patient.

Patients are unable to take holidays exceeding their monitoring schedule as the clinic is unable to organise supplies beyond this

Patients and carers should be aware of the procedure to follow if the patient develops an infection. If an infection does develop an emergency white blood count with differential should be performed immediately and the results transmitted urgently to the patient’s consultant.

If an emergency occurs and you are unsure of any contact details in any destination, contact ZTAS for advice.

In an emergency, if a patient cannot return in time to have a sample or collect medication:
1. Inform pharmacy immediately.
2. Discuss with Responsible Clinician /Lead Professional.
3. This may involve liaising with a hospital at the holiday destination to obtain a blood sample; this should be faxed to the pharmacy.
4. Pharmacy may be able to liaise with the hospital at the destination to dispense a supply of Clozapine (depending on which company they obtain their supply from).
5. If this is not possible clinic staff should discuss with Responsible Clinician/Lead Professional, Care Coordinator, and family/carers to see if arrangements can be made to deliver a supply.

5.15 Minimum clinic checks

As a minimum the following checks should be carried out on the first Clozapine clinic of every month:

- That there are adequate supplies of paperwork, if supplies are low photocopy.
- That there are adequate supplies of consumables such as blood bottles, needles, needle holders, rigid transporters, absorbent material, plastic bags, envelopes and request forms. If there are not enough for a further 5 clinics order more using the consumables request form (which is faxed to Magna Laboratories). Blood bottles and needles for use in the PocHi machine should be ordered via the usual route.
- That there are supplies of other equipment e.g. gloves, streets, cotton wool, plasters and sharps bins. If supplies are low an order is to be put through.
- A review of the sampling frequency of all the patients by looking on the appropriate site, contact ZTAS by phone if confirmation is needed.
- The scale are calibrated annually professionally, and should be adjusted to ensure they are level by the clinic
- The record form for the health and safety checklist should be completed and signed and any comments placed in the appropriate box. Any further issues which cannot be dealt with immediately should be written in the communications book and a check made that staff have been able to resolve the issues.

5.16 Transfer of patients between Clozapine Clinics (To another Pharmacy supplier)

To transfer a patient:

- Ensure the transferring Consultant is aware of the need for planning and the time it may take.
- The transfer can only proceed if a Consultant Psychiatrist has accepted responsibility in the new area. It is the responsibility of the receiving consultant to register or complete change of consultant forms
- The details for the Clozapine Clinic in that area and which company the area uses to purchase and monitor Clozapine are to be
obtained and when the next blood test is due.

- If a different company is used to purchase and monitor Clozapine the patient will need registering by the new Consultant.
- Once the details of the new Clozapine Clinic have been received a photocopy of the patient’s record is to be forwarded to the new clinic along with a copy of the standard letter.
- If the new area also uses ZTAS do not send them the patient stickers as they are bar-coded to send the results to the current Consultant not the new one.
- Ensure there is time for the patient to find and attend the new Clozapine Clinic before they run out of medication, and that they and the new clinic are aware of their appointment date and time.
- Inform pharmacy of the transfer dates.

To receive a transfer:

- If a referral is received without a standard letter if time allows send a copy for completion, or telephone if referral has been made at short notice.
- Check which company the patient was registered with in their last area, if it isn’t the same company as the clinic referred ask the new Consultant to complete a patient information form and fax it to them as soon as possible (ASAP) (registration may take 24 hours).
- If it is the same company they will request a fax from the new Consultant stating the date they took over care and all the patients details, this should also include the new pharmacy and Clozapine Clinic addresses and contact details.
- Once registered on the local database, order new labels by faxing the request to the relevant company.
- Contact pharmacy and make sure they are aware of the new patient.
- Book the patient an appointment at Clozapine Clinic and commence the routine monitoring. (Please note if they have been monitored on a different day in the other area they must be seen on the clinic day BEFORE that date. For continuity of care it is important that samples are sent early rather than late.)

5.17 Re-initiation of Clozapine

5.17.1 Following non-compliance

In patients in whom the interval since the last dose of clozapine exceeds 48 hours, treatment should be re-initiated with 12.5mg given once or twice on the first day. If this dose is well tolerated, it may be feasible to titrate the dose to the therapeutic level more quickly than is recommended for initial treatment. However, in any patient who has previously experienced respiratory or cardiac arrest with initial dosing, but was then able to be successfully titrated to a therapeutic dose, re-titration should be carried out with extreme caution.
Monitoring Frequency | Time Off clozapine ≤ 48 hours | Time Off clozapine >48 hours BUT <7 days | Time Off clozapine >7 days
--- | --- | --- | ---
Weekly | No change to monitoring frequency | No change to monitoring frequency | Retitration dose as per initial titration, Restart at 18 weeks of monitoring.
Fortnightly & Monthly | No change to monitoring frequency | No change to monitoring frequency | Retitration dose as per initial titration, Treatment Break

ZTAS must be contacted in the event of treatment break and they will confirm the changes to monitoring requirements.

Please see Appendix 2 for the monitoring requirement when patients are being retitrated on clozapine and the suggested dose titration schedule.

Please see Appendix 8 Re-titration on clozapine guidance.

5.17.2 Following red blood result

Consideration of re-initiation of clozapine is only appropriate in specific circumstances. The risks and benefits of rechallenge of clozapine therapy need to be considered by the whole MDT. Neutropenia during clozapine therapy needs to be assessed for the likelihood of being directly attributable to clozapine and not from any other cause, such as concomitant myelosuppressive drugs such (eg. carbamazepine) and underlying physical conditions (e.g. benign ethnic neutropenia). Determination if neutropenia is due to clozapine or another cause cannot be made with certainty. Risk factors for true clozapine induced neutropenia are a low baseline WBC, Afro- Caribbean ethnicity and young age. True clozapine induced neutropenia usually develops early in treatment e.g. in the first 18 weeks decreasing rapidly over 1-2 weeks, with a slow return to normal levels.

The final decision for rechallenge of clozapine therapy must be made between the Chief Pharmacist and the named Consultant Psychiatrist in consultation with ZTAS and should be initiated on a named-patient basis with completion and filing in the patients notes of a new consent form as in such circumstances use will be ‘off-licence’. The patient and family/carers where appropriate must have a fully documented discussion with the clinician regarding the risks associated with a rechallenge of clozapine.
Please see Appendix 2 for the monitoring requirement when patients are being retitrated on clozapine and the suggested dose titration schedule.

Please see Appendix 8 Chart for Re-titration on clozapine.

### 5.18 Planned discontinuation of Clozapine

- As with all antipsychotic medication discontinuation from Clozapine should if possible occur gradually. This should take a period of 1 to 2 weeks.
- The patient should be carefully monitored for signs and symptoms of psychosis during this time.
- The Consultant should fax a letter to ZTAS explaining the dates and reason for discontinuation.
- Monitoring should continue for a further 4 weeks at the established frequency from the day the last dose was taken.
- Sudden withdrawal from Clozapine may give rise to physical symptoms such as confusion, sweating, restlessness, nausea, dyskinesia, headache, insomnia and vomiting. If necessary treatment with an anticholinergic agent may be helpful.

### 5.19 Smoking and Clozapine

Please see the Trust leaflet regarding smoking and clozapine. This leaflet should be gone through with the patients.

[http://www.choiceandmedication.org/rdash/](http://www.choiceandmedication.org/rdash/)

#### 5.19.1 Stopping smoking

If a patient wishes to stop smoking the procedure for obtaining serum clozapine levels from section 5.11.5 should be followed and the clozapine doses should be subsequently adjusted accordingly.

#### 5.19.2 Starting smoking

Serum clozapine levels should be monitored and clozapine doses subsequently adjusted to ensure the plasma level does not become sub-therapeutic.

Unless clinically indicated the levels should be checked 2-4 weeks post change in status

### 5.20 Record Keeping

All patients attending the Trust Clozapine clinics will have a care plan in place, and an entry will be made following each clinic attendance. The record should include

- Brief Mental State
- Record of any assessments carried out
• Results of side effects questionnaire, and where aberrant results are detected what has been done about them
• What has been supplied
• Date of next appointment

6. TRAINING IMPLICATIONS

The Clozapine clinic leads will be responsible for coordinating any Clozapine related training which is required by clinical staff working within either the community or inpatient services.

All staff working in the Clozapine clinical are responsible for keeping their own training up to-date, and informing their service manager of any identified training needs.

With regards to this protocol clinical staff will be made aware of it in the following ways:

• The reissue of the protocol will be included in the Trusts Monthly Team Talk
• Discussion at Team/Ward meetings.
• A copy of the protocol will be available on the Trust web site

7. MONITORING ARRANGEMENTS

<table>
<thead>
<tr>
<th>Area for Monitoring</th>
<th>How</th>
<th>Who by</th>
<th>Reported to</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance with the side effects monitoring requirements.</td>
<td>Clinical records audit</td>
<td>Clinic Leads</td>
<td>Service Manager and Care Group Directors</td>
<td>Annual</td>
</tr>
<tr>
<td>Patient satisfaction with the service delivered by the clinics.</td>
<td>Patient satisfaction survey. Instigation and outcome of any complaints received in respect of the clinics, and review of action plans.</td>
<td>Clinic Leads</td>
<td>Service Manager and Care Group Directors</td>
<td>Annual/ Ongoing</td>
</tr>
<tr>
<td>Any emerging themes from incidents reported through on the electronic IR1 system.</td>
<td>Review of any IR1s submitted in respect of the Clozapine clinics.</td>
<td>Service Manager</td>
<td>The Care Groups patient safety Groups</td>
<td>Ongoing as incidents are reported.</td>
</tr>
</tbody>
</table>

8. EQUALITY IMPACT ASSESSMENT

The completed Equality Impact Assessment for this Protocol has been
8.1 Privacy, Dignity and Respect

The NHS Constitution states that all patients should feel that their privacy and dignity are respected while they are in hospital. High Quality Care for All (2008), Lord Darzi’s review of the NHS, identifies the need to organise care around the individual, ‘not just clinically but in terms of dignity and respect’.

As a consequence the Trust is required to articulate its intent to deliver care with privacy and dignity that treats all service users with respect. Therefore, all procedural documents will be considered, if relevant, to reflect the requirement to treat everyone with privacy, dignity and respect, (when appropriate this should also include how same sex accommodation is provided).

<table>
<thead>
<tr>
<th>Indicate how this will be met</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no additional requirements in relation to privacy, dignity and respect</td>
</tr>
</tbody>
</table>

8.2 Mental Capacity Act

Central to any aspect of care delivered to adults and young people aged 16 years or over will be the consideration of the individuals capacity to participate in the decision making process. Consequently, no intervention should be carried out without either the individuals informed consent, or the powers included in a legal framework, or by order of the Court.

Therefore, the Trust is required to make sure that all staff working with individuals who use our service are familiar with the provisions within the Mental Capacity Act. For this reason all procedural documents will be considered, if relevant to reflect the provisions of the Mental Capacity Act 2005 to ensure that the interests of an individual whose capacity is in question can continue to make as many decisions for themselves as possible.

<table>
<thead>
<tr>
<th>Indicate How This Will Be Achieved.</th>
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<tbody>
<tr>
<td>All individuals involved in the implementation of this policy should do so in accordance with the Guiding Principles of the Mental Capacity Act 2005. (Section 1)</td>
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</table>

9. LINKS TO ANY ASSOCIATED DOCUMENTS

Policy for Consent to Care and treatment - Clinical Policies/ Clinical General, Care Treatment and Assessment, Trust website

Policy for the Provision of, Access to and Use of Interpreters for Patient/Service Users and Carers – Clinical Policies/ Clinical General, Care Treatment and Assessment, Trust website

Policy for the Safe and Secure Handling of Medicines – Clinical policies/ Prescribing and Medicines Management, Trust website

Mental Capacity Act 2005 Policy – Clinical Policies/ Mental Health Legislation, Trust website
Incident Reporting Policy – Corporate/ Health Safety and Security, Trust website.

10. REFERENCES

Zaponex Treatment Access System http://www.ztas.co.uk/

11. APPENDICES

Appendix 1 – Clozapine Clinics - Side effects questionnaire
Appendix 2 – Initiation and Retitration of Clozapine for inpatients (see separate pack for use on ward)
Appendix 2 - Doncaster PocHi Standard Operating Procedure
Appendix 4 – Rotherham PocHi Standard Operating Procedure
Appendix 5 – North Lincolnshire PocHi Standard Operating Procedure
Appendix 6 - Common Clozapine Drug Interactions
Appendix 7 - Initiating or Retitrating Inpatients on Clozapine Ward pack
<table>
<thead>
<tr>
<th>ZTAS ID No.</th>
<th>Date: Time: Sign:</th>
<th>Date: Time: Sign:</th>
<th>Date: Time: Sign:</th>
<th>Date: Time: Sign:</th>
<th>Date: Time: Sign:</th>
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<tbody>
<tr>
<td>Have you taken all medication as prescribed since your last appointment?</td>
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<td>Has your smoking status changed since your last appointment? If yes consider likely impact on clozapine levels</td>
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<td>Have you visited your GP, if so why, and what have they prescribed? If yes inform the psychiatrist, and update the notes</td>
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<tr>
<td>How are you feeling generally? Any temperatures sore throat or minor infections recently? If yes inform psychiatrist, or recommend GP appointment</td>
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<td>Have you felt over tired or been falling asleep / napping? If yes offer advice on structuring day, and sleep routines.</td>
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<td>Have you noticed excess saliva in your mouth, or a wet pillow? If causing distress consider treatment.</td>
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<td>Have you been persistently constipated (e.g. passing stools less than three times per week)? If yes refer to GP and inform psychiatrist.</td>
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<tr>
<td>If yes to above have you suffered from: Abdominal discomfort, or bloating and or vomiting. If yes refer to psychiatrist/GP urgently</td>
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<td>Is your pulse persistently elevated (&gt;120bpm) or do you get palpitations (see chart on back of sheet). If yes refer to psychiatrist/GP (check to see if recent ECG done)</td>
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<tr>
<td>Have you had any chest pain, breathlessness? If yes refer to psychiatrist/GP</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Have you noticed any dizziness on standing or getting up? If yes check sitting standing BP and refer to psychiatrist if a postural drop is noted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been aware of any twitching movements of your limbs or face? If yes refer to psychiatrist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has your weight increased without any change in diet. If yes offer dietary advice and refer appropriately</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you noticed increase in thirst, or passing more urine? If yes refer to psychiatrist and inform GP</td>
<td></td>
<td></td>
<td></td>
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</table>

Please grade side effects as below:
1 – Rarely 2 – Occasionally 3 – Often 4 - Persistently
<table>
<thead>
<tr>
<th>Name:</th>
<th>DOB:</th>
</tr>
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<tbody>
<tr>
<td>Year</td>
<td>Date</td>
</tr>
<tr>
<td>Time</td>
<td></td>
</tr>
<tr>
<td>Key R TUM</td>
<td>Baseline</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
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<td>S 10</td>
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</tr>
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<td>S 5</td>
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<tr>
<td>CNS AVPU</td>
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</tr>
<tr>
<td>O2 Sats</td>
<td></td>
</tr>
<tr>
<td>O2 DELIVERED</td>
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</tr>
<tr>
<td>EWS SCORE</td>
<td></td>
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<tr>
<td>WEIGHT (Kg)</td>
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The Adult Early Warning Score

<table>
<thead>
<tr>
<th>Key R rei</th>
<th>T rapid</th>
<th>tranquillisation</th>
<th>U unwell</th>
<th>M Monitoring</th>
<th>B baseline</th>
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</thead>
<tbody>
<tr>
<td>Pulse</td>
<td>51-100</td>
<td>41-50 or 101-110</td>
<td>111-130</td>
<td>≤40 or ≥130</td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>101-200</td>
<td>81-100</td>
<td>71-80 OR 201-220</td>
<td>≤70 or ≥220</td>
<td></td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>8-20</td>
<td>21-30</td>
<td>31-35</td>
<td>≤8 or ≥35</td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>36.1-37.9</td>
<td>35.1-36 OR 38-38.5</td>
<td>34-35 OR 38.5-39.9</td>
<td>≤34 or ≥400</td>
<td></td>
</tr>
<tr>
<td>CNS AVPU</td>
<td>ALERT</td>
<td>VOICE</td>
<td>PAIN</td>
<td>UNCONSCIOUS</td>
<td></td>
</tr>
<tr>
<td>O2 Sats</td>
<td>100%-95%</td>
<td>90%-94%</td>
<td>≤90%</td>
<td>≤85%</td>
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</tr>
<tr>
<td>Score</td>
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<td>1</td>
<td>2</td>
<td>3</td>
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</table>

The Adult Early Warning Score

<table>
<thead>
<tr>
<th>SCORE</th>
<th>0</th>
<th>1</th>
<th>2</th>
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</tr>
</thead>
<tbody>
<tr>
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<tr>
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<td>90%-94%</td>
<td>≤90%</td>
<td>≤85%</td>
</tr>
<tr>
<td>Score</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
**Appendix 2**

**Clozapine Inpatient Initiation**

|   |   |   |   
|---|---|---|---
| 1. | Patient information (clozapine clinic booklet) or similar discussed with the patient and or carers | Done |   
| 2. | Record consent, or authority to prescribe under mental capacity act or mental health act |   |   
| 3. | Register patient with ZTAS, check consultant is already registered (www.ztas.co.uk) |   |   
| 4. | Baseline monitoring (see attached) |   |   
| 5. | Inform appropriate clozapine clinic of decision to start treatment |   |   
| 6. | Baseline bloods fax to ZTAS, (0207 3655843) |   |   
| 7. | If results are within acceptable parameters and a green result from ZTAS is received, within 10 days clozapine can be initiated, for practical reasons best done on a monday |   |   
| 8. | Prescribe clozapine on the variable dosage section of the drug card (see suggested dose titration schedule - appendix 2) |   |   
| 9. | Physical health monitoring see appendix 2- these should be recorded on the clozapine side effect chart (appendix 1) (NOT GASS) |   |   
| 10. | Repeat full blood count 3 days after starting clozapine, and inform ZTAS of results |   |   
| 11. | Weekly bloods, this may be done in clozapine clinic following discussion with staff. |   |   
| 12. | Complete side effect monitoring in line with routine blood monitoring |   |   
| 13. | Inform clozapine clinic of when patient is ready for unescorted leaves and the dose is stable |   |   
| 14. | Organize follow up appointments with clozapine clinic |   |   

**Clozapine Clinic Numbers:**

Doncaster: 01302 798401  
Rotherham: 01709 302525  
rotherhamclozapinelithium@rdash.nhs.uk *  
Scunthorpe: 01274 275959  
*preferred
<table>
<thead>
<tr>
<th></th>
<th>Retitration of Clozapine Guideline (inpatients only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Inform ZTAS by fax of treatment break (must be done by doctor)</td>
</tr>
<tr>
<td>2.</td>
<td>Contact ZTAS and inform them of decision to restart, they will inform you of any changes to the patients routine monitoring schedule (see 5.17 for general guidance)</td>
</tr>
<tr>
<td>3.</td>
<td>If break is &lt;72 hours re-initiation of clozapine, no additional monitoring is required, however Retitration is required</td>
</tr>
<tr>
<td>4.</td>
<td>Record consent, or authority to prescribe under mental capacity act or mental health act</td>
</tr>
<tr>
<td>5.</td>
<td>If break is &gt;72 hours, re-titrate clozapine (see suggested dose titration schedule – appendix 2, if well tolerated after 2 doses consider faster dose escalation)</td>
</tr>
<tr>
<td>6.</td>
<td>Baseline monitoring (see appendix 2) if no recent results available</td>
</tr>
<tr>
<td>7.</td>
<td>Baseline Bloods faxed to ZTAS (0207 3655843)</td>
</tr>
<tr>
<td>8.</td>
<td>Inform appropriate Clozapine Clinic of decision to re start</td>
</tr>
<tr>
<td>9.</td>
<td>If results are within acceptable parameters and a green result from ZTAS is received, within 10 days clozapine can be initiated, for practical reasons best done on a Monday</td>
</tr>
<tr>
<td>10.</td>
<td>Prescribe clozapine on the variable dosage section of the drug card(see suggested dose titration schedule - appendix 2)</td>
</tr>
<tr>
<td>11.</td>
<td>Physical health monitoring see appendix 2 these should be recorded on the clozapine side effect chart (appendix 1) (NOT GASS) This should be done at the same time as the blood tests</td>
</tr>
<tr>
<td>12.</td>
<td>Repeat full blood count 3 days after starting clozapine, and inform ZTAS of results</td>
</tr>
<tr>
<td>13.</td>
<td>Weekly bloods, this may be done in clozapine clinic following discussion with staff, once unescorted leave is in place.</td>
</tr>
<tr>
<td>14.</td>
<td>Complete side effect monitoring (appendix 1) at the same time as the blood monitoring.</td>
</tr>
<tr>
<td>15.</td>
<td>Inform Clozapine Clinic of when patient is ready to be discharged to the community or if patient is starting to go on leave. This must be done in enough time to allow the clinic to organise appointments</td>
</tr>
<tr>
<td>16.</td>
<td>Organize follow up appointments</td>
</tr>
</tbody>
</table>

**Clozapine Clinic Numbers:**
Doncaster: 01302 798401  
Rotherham: 01709 302525  
rotherhamclozapinelithium@rdash.nhs.uk *  
Scunthorpe: 01274 275959  
*preferred
# Clozapine Initiation Monitoring

<table>
<thead>
<tr>
<th>Personal/Family History of heart disease</th>
<th>Done/date</th>
<th>Daily with titration**</th>
<th>With blood tests</th>
<th>Steady state (after one week)</th>
<th>6 Week</th>
<th>Comment</th>
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<td></td>
<td></td>
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<tr>
<td>Alcohol/Drug history</td>
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</tr>
<tr>
<td>Temperature</td>
<td>x</td>
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<td></td>
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<tr>
<td>Pulse</td>
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<td>X*</td>
<td>x</td>
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<tr>
<td>Clozapine levels</td>
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<tr>
<td>Side effect questionnaire</td>
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<td>Weight (BMI)</td>
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<tr>
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<tr>
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<td>x*</td>
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<tr>
<td>Fasting Lipids</td>
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<tr>
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</table>

* See below for frequency of monitoring  ** may be more frequently if clinically indicated, ideally carried out by ward staff on initiation, and the clinic annually

---

**Clozapine Initiation Monitoring**

<table>
<thead>
<tr>
<th>Day</th>
<th>Monitoring (to be recorded on the side effect chart – appendix 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Blood pressure and pulse every hour for the first 6 hours after the first dose</td>
</tr>
<tr>
<td>2 - 14</td>
<td>Blood pressure and Pulse twice daily, before and six hours after morning dose</td>
</tr>
<tr>
<td>15 -28</td>
<td>Blood Pressure and Pulse daily</td>
</tr>
</tbody>
</table>

---

* See below for frequency of monitoring  ** may be more frequently if clinically indicated, ideally carried out by ward staff on initiation, and the clinic annually
### Suggested dosing Schedule

<table>
<thead>
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<th>Day</th>
<th>1</th>
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<th>3</th>
<th>4</th>
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<th>6</th>
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<th>11</th>
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<th>15</th>
<th>16-20</th>
<th>21-24</th>
<th>25-29</th>
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<td>12.5</td>
<td>12.5</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>75</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>Fur</td>
<td>400</td>
</tr>
<tr>
<td>Evening Dose (mg)</td>
<td>-</td>
<td>12.5</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td>75</td>
<td>75</td>
<td>75</td>
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<td>100</td>
<td>125</td>
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<td>125</td>
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<td>175</td>
<td>200</td>
<td>250</td>
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<td>500</td>
</tr>
<tr>
<td>Total Daily Dose (mg)</td>
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<td>25</td>
<td>37.5</td>
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<td>275</td>
<td>300</td>
<td>350</td>
<td>400</td>
<td>900</td>
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</table>

(accessed from ZTAS Aug 2016)

Patients with treatment-resistant schizophrenia

**Initial dosing schedule**

In patients with treatment-resistant schizophrenia, the recommended starting dose of Zaponex is 12.5mg (half of one 25mg tablet) taken once or twice on the first day, followed by one or two 25mg tablets on the second day. Some patient groups (e.g. elderly patients) should be started more slowly, with only 12.5mg per day.

**Increasing the dose**

If well tolerated, the daily dose can be increased slowly, usually by 25 - 50mg increments, up to a dose of 300mg/day within 2 - 3 weeks. If necessary, the daily dose may be slowly increased in further 50 - 100mg increments at half-weekly or preferably weekly intervals. To obtain full therapeutic benefit, a few patients may require higher doses, up to a maximum of 900mg/day.

**Decreasing the dose**

Once maximum therapeutic benefit has been established, many patients can be maintained effectively on lower doses. Careful downward titration is recommended. If the total daily dose required does not exceed 200mg/day, it may be more convenient and appropriate for the patient to be given a single dose in the evenings. Treatment should be maintained for at least 6 months.

Patients with psychotic disorders occurring during the course of Parkinson's disease

**Initial dosing schedule**

In patients with psychotic disorders occurring during the course of Parkinson's disease the Zaponex starting dose must not exceed 12.5mg/day (half of one 25mg tablet), taken in the evening.

**Increasing the dose**

The dose can be increased in 12.5mg increments, with a maximum of two increments per week, up to a maximum dose of 50mg. This maximum dose must not be reached until the end of the second week of dosing. The mean effective dose is usually between 25mg/day and 37.5mg/day. In some patients, this dose may not provide a satisfactory therapeutic response - in these instances the dose may be cautiously increased by increments of 12.5mg/week. A dose of 50mg/day should only be exceeded in exceptional cases, and a dose of 100mg/day must never be exceeded. The total daily amount of Zaponex should preferably be given as a single dose in the evening.

**Missed Doses**

If one dose of Zaponex is omitted or forgotten, the next dose should be taken at the normal time. Do not attempt to make up for the missed dose by giving more. If Zaponex is omitted or forgotten for more than 2 days ZTAS must be informed about the treatment break. The patient must be restarted on therapy, increasing gradually from 12.5mg (half of one 25mg tablet) once or twice per day on the first day. If the first dose is well tolerated, it may be possible to titrate the dose more quickly than is recommended for initial treatment in order to re-establish the therapeutic dose, and thus reduce the risk of having a recurrence of psychotic episodes. However, in those patients that have previously experienced respiratory or cardiac arrest with initial dosing, but were then able to be successfully titrated to a therapeutic dose, re-titration should be carried out with extreme caution.
Doncaster PocHi Standard Operating Procedure

1.0 Introduction:

The Trust has welcomed the introduction of a Point of Care Haematology (PocHi) Analyser into Clozapine Clinic which is located in Bungalow 4, Catherine’s Close, St Catherine’s, Doncaster.

Clozapine is an atypical antipsychotic that requires validated full blood counts (FBCs) to be available prior to dispensing of medication to service users. The introduction of the Point of Care (PocHi) blood testing systems will be beneficial to service users in that the opportunity exists for the collection of Clozapine medication on the same day as venepuncture because blood sample results are available within 5 minutes.

The procedural information detailed in this document is one of a suite of documents to provide guidance on the Governance of Point of Care Analysers to Rotherham, Doncaster & South Humber NHS Foundation Trust.

2.0 Clozapine Clinics:

Clozapine Clinics have developed to monitor patients who are prescribed Clozapine. They monitor patients who require weekly, fortnightly or monthly blood tests, review their mental state and monitoring of their vital signs, including ECG (yearly).

The clinic monitors patients who require weekly, fortnightly or monthly blood tests, review their mental state and monitoring of their vital signs, including ECG (yearly). The clinic is led by Clozapine Clinic Nurse who provides and co-ordinates care in collaboration with the patient’s RMO, Care Co-ordinator and ward staff, as appropriate.

With the introduction of the Point of Care Analyser, the Clozapine Clinic Nurse and the Nursing Assistant have been trained to operate the analysers in accordance with stringent operating procedures. Each clinic has a named operator who is accountable for safe operation of the analyser and to ensure that standards are maintained.

3.0 Patient Procedure:

3.1 Patient attends Clozapine Clinic as per appointment.

3.2 The clinic nurse will review the patient’s mental and physical state and a routine blood sample will be taken.

3.3 Patients may be asked to stay until their blood results are available to enable
medication to be dispensed following a ‘green’ blood result.

4.0 Activating Procedure for Point of Care Analysers (PocHi):

4.1 The operator of the PocHi analyser must have undertaken PocHi training and be a certified (trained by Sysmex) or registered (trained by a Trust Trainer) operator.

4.2 The operator must follow the Trust’s Infection Control procedures.

4.3 At the beginning of the day, immediately upon switching on the PocHi machine, a background check runs automatically. After this the quality control sample must be run (see section 5). A satisfactory [or valid] quality control test is required prior to the testing of patient blood samples with the PocHi. The entire start-up procedure should take a total of thirteen minutes.

5. Internal Quality Control (QC) procedure:

1. Take the correct week’s QC sample from the fridge (Eightcheck 3 WPL Low Level)

2. Bring the sample to room temperature (15 minutes out of the fridge)

3. Mix the control sample for 2 minutes at 10 rpm in the rotary mixer just prior to analysis

4. Perform the QC check and check computer if result transferred to ZTAS

If QC result rejected by ZTAS, or if result has any incorrect values, repeat process

No incorrect values (Valid QC result)

PocHi is ready for use; Return QC sample to the fridge

5.1 If the QC result is within the limits of the QC target result, the computer subsequently displays the following messages: “Quality Check successfully completed”. “PocHi 100i ready for use”.

5.2 If the QC result is outside the limits of the QC target result:

- The PocHi indicates the incorrect values on the PocHi display and the printout
- The computer subsequently displays the following messages: “QC failed: result does not match reference values” “Please perform Quality Check”

Repeat steps 1 to 4 above.
5.3 If on a 2\textsuperscript{nd} attempt the result from the QC tests fails:

- The computer subsequently displays the following messages: "\textit{QC failed (2): result does not match reference values}" "\textit{PocHi has been disabled, please contact ZTAS}"

- Call the \textbf{ZTAS} helpdesk on \textbf{0207 365 58 42}

5.4 In case you have failed 2 consecutive QC tests, ZTAS and Sysmex will automatically be informed. You will however need to contact ZTAS to initiate the process of problem solving with your PocHi. The cause of your repeated QC failure must be investigated. If necessary, ZTAS will consult Sysmex for advice to solve the problem. Once the problem is solved, ZTAS will re-set the PocHi software for a repeat QC analysis, if applicable.

5.5 \textbf{Possible reasons for QC failure}:

Commonly – the sample has not been warmed or mixed sufficiently
Less commonly

- PocHi fails \rightarrow PocHi needs repair or replacement
- Sample corrupted \rightarrow repeat the QC with another sample
- QC lot expired
- QC lot not recognised
- Internet communication failure

5.6 All QC check results should be recorded in the "\textbf{Sysmex PocHi Analyser}" daily log sheet (Appendix 2).
6 Analysing Blood Samples:

Blood samples must be labelled with a Ztas sticker and analysed as soon as possible after they are taken, always within 8 hours. (Samples must be kept in the refrigerator if it is expected that analysis will be more than 4 hours from sampling – note: bring to room temperature before testing!)

- Insert a valid ZTAS user ID card in the card reader and log on (if applicable). The computer should display the message: "PocHi-100i ready for use".

- On the PocHi: Select “WB” (whole blood) analysis mode.

- Scan the Patient’s ZTAS number using barcode scanner.

- Ensure that the computer with PocHi software is connected to the internet and the PocHi PC software is running.

- Mix blood sample for two (2) minutes on the rotary mixer at 10 rpm and put into the PocHi.

- Visually confirm the PIN numbers match on the screen and the sample.

- Press “Run” on the screen. Analysis takes approximately 2 minutes.

- The result is automatically transferred to ZTAS and is visible on the PocHi display.

If the patient result has been accepted by ZTAS, the computer displays the message: "Result transferred to ZTAS database". The result is automatically submitted to the ZTAS database and the ZTAS website interprets and classifies the result instantly.

- Amber Result: ZTAS will start the alert procedure.

- Green Result: Refer to Clozapine Dispensing Protocol.

- Red Result: Contact ZTAS. Commence Red Result Procedure: Refer sample to local laboratory for re-test. ENSURE MEDICATION IS REMOVED FROM PATIENT.
If the patient’s result is not accepted by ZTAS:

The following are possible reasons:

7.1 ZTAS PIN of the patient is not recognised:
- Invalid patient identifier used
- Patient not registered with ZTAS

7.2 A 2\textsuperscript{nd} result for the same patient is submitted on the same day.

7.3 The sample has an invalid particle distribution:
- The sample is not sufficiently mixed
- The sample has clotted.

7.5 There is no sample tube in the PocHi during analysis, or the sample tube is empty or filled with watery fluid: values outside acceptable ranges.

7.6 Internet communication failure.

Other reasons may arise which will be discussed with ZTAS.

Patients’ Blood Samples:

Following analysis of the sample, it is stored in a specimen fridge. All samples from the weeks clinics are kept until the following Monday.

Samples tested on two occasions that have failed due to an invalid result “invalid particle distribution” should be sent to the local lab for analysis, or second sample can be taken and run on PocHi

Used/analysed blood samples/tubes are disposed of in plastic orange-lidded burn bins as advised.

Quality Assurance

9.1 Internal Quality Control Samples:

9.1.1 The type of Quality Control (QC) blood samples used for the internal Quality Control (see sections 4.0 and 5.0) of PocHi is Eightcheck 3 WPL (low level).

9.1.2 ZTAS has a standing order with Sysmex for Rotherham, Doncaster & South Humber NHS Foundation Trust for delivery of new QC samples every 3 months.

9.1.3 Every 3 months, a new pack of QC samples are delivered to PocHi Clinic sites. These will be delivered to the Opal Centre and the clinic coordinator informed of arrival.

The pack of QC samples must immediately be stored in the sample fridge. Upon receipt the delivery must be checked to ensure the correct type of QC samples ‘Eightcheck 3 WPL (low level)’ red tops and within date have been received.

9.1.4 If no new QC samples have been received a week before the expiry date of the batch in use, the
ZTAS Helpdesk must be contacted.

9.1.5 The QC samples are stored in a locked fridge at a temperature of between 2 - 8 degrees centigrade.

9.1.6 The new pack of QC samples must only be used once the previous pack has expired.

9.1.7 Prior to the use of the new QC pack, the batch number, expiry date and reference values should be entered into the PocHi (using barcode scanner).

9.1.8 A QC sample that is (to be) used should have two dates inserted on the tube label, one date when the sample is first used and the second date being the discard date one week later.

9.2 PocHi External Quality Assurance (NEQAS)

9.2.1 ZTAS have registered your PocHi with the National External Quality Assurance Scheme.

You are required to participate in the External Quality Control on a monthly basis in order to keep your PocHi service operational.

9.2.2 At the beginning of each month, a set of NEQAS samples is delivered to PocHi Clinic sites. These will be delivered to the Opal Centre and the clinic coordinator informed of arrival.

The NEQAS samples must tested - as if they were patient samples - and the result returned to NEQAS within the indicated timeframe on the enclosed instruction sheet.

9.2.3 The NEQAS samples must be kept in the sample fridge until they are being tested.

Instructions for testing are available with each set of NEQAS samples.

9.2.4 If no new NEQAS samples have been received by the 2nd half of the month, the ZTAS Helpdesk must be contacted.

9.3 Record keeping/ file maintenance

9.3.1 Keep temperature log: Every day your PocHi is in operation, check the temperature of the fridge that stores QC samples (see section 9.1) to confirm that the samples are appropriately kept. Record/ Make a note on your temperature log (date and signature)

9.3.2 Maintain daily log sheet (appendix 2): with relevant information on each day that the PocHi is in operation.

9.3.3 Training records: keep training records for trained operators.

10 PocHi Problems

10.1 PocHi Failure:

10.1.1 In the event of PocHi failure, ZTAS must be informed.

10.1.2 If the problem cannot be solved by ZTAS, the patients’ blood samples will be tested by Doncaster & Bassetlaw NHS Foundation Trust

10.1.3 ZTAS will ensure that the PocHi is repaired or replaced within 3 working days, usually the next
working day.

10.2 **PocHi Software Internet Communication Failure:**

10.2.1 When the PocHi software, or the internet communication fails, the PocHi results will not be transferred to ZTAS. ZTAS must be contacted.

10.2.2 If the QC check has already been performed that day, and the result is valid (accepted by ZTAS), the PocHi can still be used for analysis of patients’ samples.

10.2.3 If the QC has not been performed for that day, ZTAS must be informed for resolution of the problem. If the problem cannot be resolved the patients’ blood samples will be tested in the local lab.

10.2.4 ZTAS will attempt to ensure that the problems with the PocHi software are solved within 3 working days, usually by the next working day in liaison with Trust’s I.T department where necessary.

10.2.5 In the event of temporary internet communication failure, the PocHi software will continue to transfer the last result to ZTAS within the next 3 hours. This result will be transferred to ZTAS upon restoring the internet communication. The 100 last results are stored in the PocHi. If necessary/applicable the stored results can be submitted to ZTAS through the ZTAS PocHi software.

10.2.6 In the event that ZTAS is not available, the PocHi result should be compared with reference values as stated in the ZTAS manual and discussed with the dispensing pharmacy before Zaponex is dispensed. Results must be submitted to ZTAS later on. (Keep paper copy of ZTAS manual on hand for emergency)

11 **Regular Maintenance and stock:**

11.1 **PocHi Reagents and Fluids:**

11.1.1 A stock of PocHi pack 65 and Cell clean, the cleaning agent, are kept in a locked cupboard at all times in the Clozapine Clinic at ambient temperature.

11.1.2 To re-order Cell Clean, PocHi pack 65, contact the ZTAS Helpdesk via e-mail: info@ztas.co.uk.

Re-Ordering is performed as the stock level decreases to a [recommended: one weeks’ supply] of PocHi pack 65 and Cell Clean:1 bottle.

11.1.3 Protective goggles, gloves and plastic aprons should be worn when changing and handling reagents. All spillages will be cleaned according to safety sheet (see attached document)

11.1.4 The PocHi pack 65 reagents will be disposed of by adding the vernacare granules to solidify the liquid then taping up the box. The box can then be double bagged in an orange waste bag. After rinsing out, the cell clean bottle can be either put in to the plastic recycling or general household waste.
11.2 Changing Reagents:

The PocHi prompts that reagents need changing or change is deemed necessary by the operator

- PocHi prompt: press “Execute”
- Operator decision: press “Menu” and select “Chg.Reag”

Scan in or manually enter the Lot #, expiry date and serial number of the new pack

Replace the pack to be changed
11.3 Transducer Cleaning – prompted automatically
Performed every 2 weeks or after 150 blood samples

Add 1ml of Cell Clean to an empty sample tube

Put the tube, **without cap**, in position in the machine

If not cleaning in response to PocHi machine prompt, then press “Maint.”

If PocHi prompts to clean then press “Execute”. The process will take approximately 9 minutes

Press “Execute”. The process will take approximately 9 minutes

11.4 Waste chamber cleaning – prompted automatically
Performed every 3 months or after 1500 samples

Add 1ml of Cell Clean to an empty sample tube

Put the tube, **without cap**, in position in the PocHi

Select “Clean W. Chamber”

If PocHi prompts to clean then press “Execute”. The process will take approximately 13 minutes

Press “Execute”. The process will take approximately 13 minutes
Medications

12.1 Medication will be delivered from Lloyds pharmacy every Monday morning at 8:30am

12.2 Medication is to be checked against the delivery sheet and checked that each patient’s medication is present and the delivery note signed accordingly.

12.3 Medication is then to be stored in the drug cupboard (key is locked in the key cupboard located in the clinic room – access by qualified nurse or nominated pharmacy staff)

12.4 Following a ‘green’ result medication is to be handed to the patient and recorded so on the delivery sheet.

12.5 When clinic has finished the delivery sheet is to be faxed to Lloyds pharmacy (01302 344166) for their records.

12.6 Original delivery sheet to be filed in correct folder.

End of Clinic

13.1 – Ensure at the end of the clinic that:

13.1.1 – Computer is shut down correctly.

13.1.2 – POCH-100i machine is shut down correctly

13.1.3 – Medication cupboard is locked and key stored back in the key cabinet

13.1.4 – Treatment room door is locked to restrict access.

Other information

14.1 This operating procedure is to be used in conjunction with the protocols on red and amber blood results and local blood testing.
<table>
<thead>
<tr>
<th>PocHi operators</th>
<th>PocHi Clinic</th>
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<tbody>
<tr>
<td>CERTIFIED (trained by ZTAS/Sysmex)</td>
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</tbody>
</table>
REGISTERED WITH ZTAS
(trained by <Trust Name>; Trainer name)
## Daily Log:

- QC Check must be performed every day the PocHi is used.
- The shutdown procedure must be done at the end of each working day the PocHi is used.
- Change reagents must be done each time the machine prompts.
- Number of tests must be recorded each working day.
- NEQAS Check must be recorded each month.
- Problems must be recorded as and when they happen in the “problems” section below.

| Day: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Change Poch Pack 65 |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Shutdown          |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Waste Chamber Clean |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Transducer Cleaning |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| NEQAS (monthly)   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| No. of Tests      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Initials:         |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

### Date

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<tr>
<th>Date</th>
<th>Problems:</th>
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# CLOZAPINE CLINIC LOG SHEET

<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>DOB</th>
<th>SILVERLINK</th>
<th>CLOZAPINE PRESCRIPTION</th>
<th>ARRIVED</th>
<th>TEST DATE/RESULT</th>
<th>DISPENSED</th>
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Prescriptions completed by……………………………… (print name) ………………………………………(signature)

Medication checked in by …………………………… (print name) ………………………………………(signature)

Result checked/medication dispensed by …………………………… (print name) ……………………………………… (signature)
## CLOZAPINE CLINIC LOG SHEET

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Medication checked in by……………………………..(print name) ……………………………………..(signature)

Result checked/medication dispensed by …………………………..(print name) ………………………………..(signature)
Rotherham PocHi Standard Operating Procedure

1.0 Introduction:

The Trust has welcomed the introduction of a Point of Care Haematology (PocHi) Analyser into Clozapine Clinic which is located at Ferham clinic, Rotherham.

Clozapine is an atypical antipsychotic that requires validated full blood counts (FBCs) to be available prior to dispensing of medication to service users. The introduction of the Point of Care (PocHi) blood testing systems will be beneficial to service users in that the opportunity exists for the collection of Clozapine medication on the same day as venepuncture as blood sample results are available within 5 minutes.

The procedural information detailed in this document is one of a suite of documents to provide guidance on the Governance of Point of Care Analysers to Rotherham, Doncaster & South Humber NHS Foundation Trust.

2.0 Clozapine Clinics:

Clozapine Clinics have developed to monitor patients who are prescribed Clozapine. They monitor patients who require weekly, fortnightly or monthly blood tests, review their mental state and monitoring of their vital signs, including ECG (yearly).

The clinic is led by the Lithium/Clozapine Clinic Nurse Coordinator who provides and coordinates care in collaboration with the patient’s RMO, Care Coordinator/Lead Professional and ward staff, as appropriate.

With the introduction of the Point of Care Analyser, the Clozapine/Lithium Clinic Nurse Coordinator, the Nurse Led Clinics Nurse (providing cover) and the Support Worker have been trained to operate the analysers in accordance with stringent operating procedures. Each clinic has a named operator who is accountable for safe operation of the analyser and to ensure that standards are maintained.

3.0 Patient Procedure:

3.1 Patient attends Clozapine Clinic as per appointment.

3.2 The clinic nurse will review the patient’s mental and physical state and a routine blood sample will be taken.

3.3 Patients may be asked to stay until their blood results are available to enable medication to be dispensed following a ‘green’ blood result.
4.0 **Activating Procedure for Point of Care Analysers (PocHi):**

4.1 The operator of the PocHi analyser must have undertaken PocHi training and be a certified (trained by Sysmex) or registered (trained by a Trust Trainer) operator.

4.2 The operator must follow the Trust’s Infection Control procedures.

4.3 At the beginning each day, immediately upon switching on the PocHi machine, a background check runs automatically, followed by a quality control sample (see section 5). A satisfactory [or valid] quality control test is required prior to the testing of patient blood samples with the PocHi. The entire start-up procedure should take a total of thirteen minutes.
5. **Internal Quality Control (QC) procedure:**

1. Take the correct week’s QC sample from the fridge (Eightcheck 3 WPL Low Level)

2. Bring the sample to room temperature (15 minutes out of the fridge)

3. Mix the control sample for 2 minutes at 10 rpm in the rotary mixer just prior to analysis

4. Perform the QC check and check computer if result transferred to ZTAS

---

5.1 If the QC result is within the limits of the QC target result, the computer subsequently displays the following messages: *Quality Check successfully completed*. *PocHi 100i ready for use*.

5.2 If the QC result is outside the limits of the QC target result:

- The PocHi indicates the incorrect values on the PocHi display and the printout
- The computer subsequently displays the following messages: “**QC failed: result does not match reference values**” “**Please perform Quality Check**”

Repeat steps 1 to 4 above.

5.3 If on a 2nd attempt the result from the QC tests fails:

- The computer subsequently displays the following messages: “**QC failed (2): result does not match reference values**” “**PocHi has been disabled, please contact ZTAS**”
- Call the ZTAS helpdesk on **0207 365 58 42**
5.4 If the system fails 2 consecutive QC tests, ZTAS and Sysmex will automatically be informed. The operator will need to contact ZTAS to initiate the process of problem solving with the PocHi analyser. The cause of the repeated QC failure must be investigated. If necessary, ZTAS will consult Sysmex for advice to resolve the problem. Once resolved, ZTAS will re-set the PocHi software for a repeat QC analysis, if applicable.

5.5 **Possible reasons for QC failure:**

Commonly – the sample has not been warmed or mixed sufficiently

Less commonly
- PocHi fails → PocHi needs repair or replacement
- Sample corrupted → repeat the QC with another sample
- QC lot expired
- QC lot not recognised
- Internet communication failure

5.6 All QC check results should be recorded in the “**Sysmex PocHi Analyser**” daily log sheet (Appendix 2).
6 Analysing Blood Samples:

**Blood samples must be labelled with a Ztas sticker and analysed as soon as possible after they are taken: Always within 8 hours.** (Samples must be kept in the refrigerator if it is expected that analysis will be more than 4 hours from sampling – note: bring to room temperature before testing!)

- Insert a valid ZTAS user ID card in the card reader and log on (if applicable). The computer should display the message: "PocHi-100i ready for use"

- **On the PocHi: Select “WB” (whole blood) analysis mode**

- Scan the Patient’s ZTAS number using barcode scanner

- Ensure that the computer with PocHi software is connected to the internet and the PocHi PC software is running.

- Mix blood sample for two (2) minutes on the rotary mixer at 10 rpm and put into the PocHi

- Visually confirm the PIN numbers match on the screen and the sample

- **Press “Run” on the screen. Analysis takes approximately 2 minutes**

- The result is automatically transferred to ZTAS and is visible on the PocHi display

- **If the patient result has been accepted by ZTAS, the computer displays the message: “Result transferred to ZTAS database”. The result is automatically submitted to the ZTAS database and the ZTAS website interprets and classifies the result instantly**

- **Amber Result**
  - Refer to Clozapine Dispensing Protocol

- **Green Result**
  - Contact ZTAS, Commence Red Result Procedure: Refer sample to local laboratory for re-test

- **Red Result**
  - ENSURE MEDICATION IS REMOVED FROM PATIENT

- ZTAS will start the alert procedure
7 If the patient’s result is not accepted by ZTAS:

The following are possible reasons:

7.1 ZTAS PIN of the patient is not recognised:
   - Invalid patient identifier used
   - Patient not registered with ZTAS

7.2 A 2\textsuperscript{nd} result for the same patient is submitted on the same day.

7.3 The sample has an invalid particle distribution:
   - The sample is not sufficiently mixed
   - The sample has clotted.

7.4 There is no sample tube in the PocHi during analysis, or the sample tube is empty or filled with watery fluid: values outside acceptable ranges.

7.5 Internet communication failure.

Other reasons may arise which will be discussed with ZTAS.

8 Patients’ Blood Samples:

Following analysis of the sample, it is stored in a specimen fridge. All samples from the weeks clinics are kept until the following Monday.

Samples tested on two occasions that have failed due to an invalid result “invalid particle distribution” should be sent to the local lab for analysis, or second sample can be taken and run on PocHi

Used/analysed blood samples/tubes are disposed of in plastic orange-lidded sharps bins as advised.
9 Quality Assurance

9.1 Internal Quality Control Samples:

9.1.1 The type of Quality Control (QC) blood samples used for the internal Quality Control (see sections 4.0 and 5.0) of PocHi is Eightcheck 3 WPL (low level).

9.1.2 ZTAS has a standing order with Sysmex for Rotherham, Doncaster & South Humber NHS Foundation Trust for delivery of new QC samples every 3 months.

9.1.3 Every 3 months, a new pack of QC samples are delivered to PocHi Clinic sites. These will be delivered to Ferham Clinic and the clinic coordinator informed of arrival.

The pack of QC samples must immediately be stored in the sample fridge. Upon receipt the delivery must be checked to ensure the correct type of QC samples ‘Eightcheck 3 WPL (low level)’ red tops and within date have been received.

9.1.4 If no new QC samples have been received a week before the expiry date of the batch in use, the ZTAS Helpdesk must be contacted.

9.1.5 The QC samples are stored in a locked fridge at a temperature of between 2 - 8 degrees centigrade.

9.1.6 The new pack of QC samples must only be used once the previous pack has expired.

9.1.7 Prior to the use of the new QC pack, the batch number, expiry date and reference values should be entered into the PocHi (using barcode scanner).

9.1.8 A QC sample that is (to be) used should have two dates inserted on the tube label, one date when the sample is first used and the second date being the discard date one week later.

9.2 PocHi External Quality Assurance (NEQAS)

9.2.1 ZTAS have registered the PocHi analyser with the National External Quality Assurance Scheme. The Trust is required to participate in the External Quality Control on a monthly basis in order to keep the PocHi service operational.

9.2.2 At the beginning of each month, a set of NEQAS samples is delivered to PocHi Clinic sites. These will be delivered to Ferham Clinic and the clinic coordinator informed of arrival.

The NEQAS samples must tested - as if they were patient samples - and the result returned to NEQAS within the indicated timeframe on the enclosed instruction sheet.

9.2.3 The NEQAS samples must be kept in the sample fridge until they are being tested. Instructions for testing are available with each set of NEQAS samples.

9.2.4 If no new NEQAS samples have been received by the 2nd half of the month, the ZTAS Helpdesk must be contacted.
9.3 Record keeping/ file maintenance

9.3.1 Keep **temperature log**: Every day the PocHi analyser is in operation, check the temperature of the fridge that stores QC samples (see section 9.1) to confirm that the samples are appropriately kept. Record/ Make a note on your temperature log (date and signature)

9.3.2 Maintain **daily log sheet** (appendix 2): with relevant information on each day that the PocHi is in operation.

9.3.3 **Training records**: keep training records for trained operators.

10 PocHi Problems

10.1 **PocHi Failure:**

10.1.1 In the event of PocHi failure, ZTAS must be informed.

10.1.2 If the problem cannot be solved by ZTAS, the patients’ blood samples will be tested by Rotherham NHS Foundation Trust.

10.1.3 ZTAS will ensure that the PocHi is repaired or replaced within 3 working days, usually the next working day.

10.2 **PocHi Software Internet Communication Failure:**

10.2.1 When the PocHi software, or the internet communication fails, the PocHi results will not be transferred to ZTAS. ZTAS must be contacted.

10.2.2 If the QC check has already been performed that day, and the result is valid (accepted by ZTAS), the PocHi can still be used for analysis of patients’ samples.

10.2.3 If the QC has not been performed for that day, ZTAS must be informed for resolution of the problem. If the problem cannot be resolved the patients’ blood samples will be tested in the local lab.

10.2.4 ZTAS will attempt to ensure that the problems with the PocHi software are solved within 3 working days, usually by the next working day in liaison with Trust’s I.T department where necessary.

10.2.5 In the event of temporary internet communication failure, the PocHi software will continue to transfer the last result to ZTAS within the next 3 hours. This result will be transferred to ZTAS upon restoring the internet communication. The 100 last results are stored in the PocHi. If necessary/applicable the stored results can be submitted to ZTAS through the ZTAS PocHi software.

10.2.6 In the event that ZTAS is not available, the PocHi result should be compared with reference values as stated in the ZTAS manual and discussed with the dispensing pharmacy before Zaponex is dispensed. Results must be submitted to ZTAS later on. (Keep paper copy of ZTAS manual on hand for emergency)
11 Regular Maintenance and stock:

11.1 PocHi Reagents and Fluids:

11.1.1 A stock of PocHi pack 65 and Cell clean, the cleaning agent, are kept in at all times at an ambient temperature in a locked cupboard in the Clozapine Clinic.

11.1.2 To re-order Cell Clean, PocHi pack 65, contact the ZTAS Helpdesk via e-mail: info@ztas.co.uk. Re-Ordering is performed as the stock level decreases to a [recommended: one weeks’ supply] of PocHi pack 65 and Cell Clean:1 bottle.

11.1.3 Protective goggles, gloves and plastic aprons should be worn when changing and handling reagents. All spillages will be cleaned according to safety sheet (see attached document).

11.1.4 The PocHi pack 65 reagents will be disposed of by adding the vernacare granules to solidify the liquid then taping up the box. The box can then be double bagged in an orange waste bag. After rinsing out, the cell clean bottle can be either put in to the plastic recycling or general household waste.

11.2 Changing Reagents:

The PocHi prompts that reagents need changing or change is deemed necessary by the operator

---

PocHi prompt: press “Execute”

Operator decision: press “Menu” and select “Chg.Reag”

---

Scan in or manually enter the Lot #, expiry date and serial number of the new pack

---

Replace the pack to be changed
11.3 Transducer Cleaning – prompted automatically
Performed every 2 weeks or after 150 blood samples

Add 1ml of Cell Clean to an empty sample tube

Put the tube, **without cap**, in position in the machine

- If not cleaning in response to PocHi machine prompt, then press “Maint.”
- If PocHi prompts to clean then press “Execute”. The process will take approximately 9 minutes

Press “Execute”. The process will take approximately 9 minutes

11.4 Waste chamber cleaning – prompted automatically
Performed every 3 months or after 1500 samples

Add 1ml of Cell Clean to an empty sample tube

Put the tube, **without cap**, in position in the PocHi

- Select “Clean W. Chamber”
- If PocHi prompts to clean then press “Execute”. The process will take approximately 13 minutes

Press “Execute”. The process will take approximately 13 minutes
12 Medications

12.1 Medication will be delivered from Lloyds pharmacy every Friday afternoon at 3pm.

12.2 Medication is to be checked against the clozapine clinic log sheet and checked that each patient’s medication is present and the log sheet signed accordingly.

12.3 Medication is then to be stored in the drug cupboard (key is locked in the key cupboard located in the reception office – access by qualified nurse or nominated pharmacy staff)

12.4 Following a ‘green’ result medication is to be handed to the patient and recorded accordingly on the clinic log sheet.

12.5 When clinics are finished the clinic log sheet is to be faxed to Lloyds Pharmacy (01226 289695) for their records.

12.6 Original clinic log sheet to be filed in correct folder.

13 End of Clinic

13.1 – Ensure at the end of the clinic that:

  13.1.1 – Computer is shut down correctly.

  13.1.2 – POCH-1001 machine is shut down correctly

  13.1.3 – Medication cupboard is locked and key stored back in the key cabinet

  13.1.4 – Treatment room door is locked to restrict access.

14 Other information

12.7 This operating procedure is to be used in conjunction with the protocols on red and amber blood results and local blood testing.
## Appendix 1

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REGISTERED WITH ZTAS
(trained by <Trust Name>; Trainer name)
**DAILY LOG SHEET**

**SYSMEX POCHI ANALYSER**

Month/Year: ................................ / .............

**Daily Log:**

- QC Check must be performed every day the PocHi is used.
- The shutdown procedure must be done at the end of each working day the PocHi is used.
- Change reagents must be done each time the machine prompts.
- Number of tests must be recorded each working day
- NEQAS Check must be recorded each month.
- Problems must be recorded as and when they happen in the “problems” section below.

| Day: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Change Poch Pack 65 |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Shutdown |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Waste Chamber Clean |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Transducer Cleaning |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| NEQAS (monthly) |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| No. of Tests |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

**Initials:**

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## CLOZAPINE CLINIC LOG SHEET

**Clinic date**

**Sheet**

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<tr>
<th>PATIENT NAME</th>
<th>DOB</th>
<th>SILVERLINK</th>
<th>CLOZAPINE PRESCRIPTION</th>
<th>ARRIVED</th>
<th>TEST DATE/RESULT</th>
<th>DISPENSED</th>
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Prescriptions completed by: (print name) (signature)

Medication checked in by: (print name) (signature)

Result checked/medication dispensed by: (print name) (signature)
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Result checked/medication dispensed by ............................. (print name) .................................................. (signature)
North Lincolnshire - Scunthorpe PocHi Standard Operating Procedure

1.0 Introduction:

The Trust has welcomed the introduction of a Point of Care Haematology (PocHi) Analyser into Clozapine Clinic which is located at 344 Ashby Road, Scunthorpe.

Clozapine is an atypical antipsychotic that requires validated full blood counts (FBCs) to be available prior to dispensing of medication to service users. The introduction of the Point of Care (PocHi) blood testing systems will be beneficial to service users in that the opportunity exists for the collection of Clozapine medication on the same day as venepuncture as blood sample results are available within 5 minutes.

The procedural information detailed in this document is one of a suite of documents to provide guidance on the Governance of Point of Care Analysers to Rotherham, Doncaster & South Humber Mental Health NHS Foundation Trust.

2.0 Clozapine Clinics:

Clozapine Clinics have developed to monitor patients who are prescribed Clozapine. They monitor patients who require weekly, fortnightly or monthly blood tests, review their mental state and monitoring of their vital signs, including ECG (yearly).

The clinic is led by the Clozapine Clinic Nurse who provides and co-ordinates care in collaboration with the patient’s RMO, Care Coordinator/Lead Professional and ward staff, as appropriate.

With the introduction of the Point of Care Analyser, the Clozapine Clinic Nurse and the Nursing Assistant have been trained to operate the analysers in accordance with stringent operating procedures. Each clinic has a named operator who is accountable for safe operation of the analyser and to ensure that standards are maintained.

3.0 Patient Procedure:

3.1 Patient attends Clozapine Clinic as per appointment.

3.2 The clinic nurse will review the patient’s mental and physical state and a routine blood sample will be taken.

3.3 Patients may be asked to stay until their blood results are available to enable medication to be dispensed following a ‘green’ blood result.

4.0 Activating Procedure for Point of Care Analysers (PocHi):

4.1 The operator of the PocHi analyser must have undertaken PocHi training and be a certified (trained by Sysmex) or registered (trained by a Trust Trainer) operator.

4.2 The operator must follow the Trust’s Infection Control procedures.
4.3 At the beginning each day, immediately upon switching on the PocHi machine, a background check runs automatically, followed by a quality control sample (see section 5). A satisfactory [or valid] quality control test is required prior to the testing of patient blood samples with the PocHi. The entire start-up procedure should take a total of thirteen minutes.

5.0 Internal Quality Control (QC) procedure:

1. Take the correct week’s QC sample from the fridge (Eightcheck 3 WPL Low Level)

2. Bring the sample to room temperature (15 minutes out of the fridge)

3. Mix the control sample for 2 minutes at 10 rpm in the rotary mixer just prior to analysis

4. Perform the QC check and check computer if result transferred to ZTAS

   - No incorrect values (Valid QC result)

   - PocHi is ready for use; Return QC sample to the fridge

If QC result rejected by ZTAS, or if result has any incorrect values, repeat process

5.1 If the QC result is within the limits of the QC target result, the computer subsequently displays the following messages: “Quality Check successfully completed”, “PocHi 100i ready for use”.

5.2 If the QC result is outside the limits of the QC target result:

   - The PocHi indicates the incorrect values on the PocHi display and the printout
   - The computer subsequently displays the following messages:
     “QC failed: result does not match reference values”
     “Please perform Quality Check”

   Repeat steps 1 to 4 above.

5.3 If on a 2nd attempt the result from the QC tests fails:

   - The computer subsequently displays the following messages:
     “QC failed (2): result does not match reference values”
     “PocHi has been disabled, please contact ZTAS”

   - Call the ZTAS helpdesk on 0207 365 58 42
5.4 If the system fails 2 consecutive QC tests, ZTAS and Sysmex will automatically be informed. The operator will need to contact ZTAS to initiate the process of problem solving with the PocHi analyser. The cause of the repeated QC failure must be investigated. If necessary, ZTAS will consult Sysmex for advice to resolve the problem. Once resolved, ZTAS will re-set the PocHi software for a repeat QC analysis, if applicable.

5.5 **Possible reasons for QC failure:**

Commonly – the sample has not been warmed or mixed sufficiently

Less commonly
- PocHi fails → PocHi needs repair or replacement
- Sample corrupted → repeat the QC with another sample
- QC lot expired
- QC lot not recognised
- Internet communication failure

5.6 All QC check results should be recorded in the “Sysmex PocHi Analyser” daily log sheet (Appendix 2).
Analysing Blood Samples:

Blood samples must be labelled with a Ztas sticker and analysed as soon as possible after they are taken: Always within 8 hours. (samples must be kept in the refrigerator if it is expected that analysis will be more than 4 hours from sampling – note: bring to room temperature before testing!)

1. Insert a valid ZTAS user ID card in the card reader and log on (if applicable). The computer should display the message: “PocHi-100i ready for use”

2. On the PocHi: Select “WB” (whole blood) analysis mode

3. Scan the Patient’s ZTAS number using barcode scanner

4. Ensure that the computer with PocHi software is connected to the internet and the PocHi PC software is running.

5. Mix blood sample for two (2) minutes on the rotary mixer at 10 rpm and put into the PocHi

6. Visually confirm the PIN numbers match on the screen and the sample

7. Press “Run” on the screen. Analysis takes approximately 2 minutes

8. The result is automatically transferred to ZTAS and is visible on the PocHi display

- If the patient result has been accepted by ZTAS, the computer displays the message: “Result transferred to ZTAS database”. The result is automatically submitted to the ZTAS database and the ZTAS website interprets and classifies the result instantly

- Red Result: Contact ZTAS. Commence Red Result Procedure: Refer sample to local laboratory for re-test. ENSURE MEDICATION IS REMOVED FROM PATIENT

- Amber Result: Refer to Clozapine Dispensing Protocol

- Green Result: ZTAS will start the alert procedure
If the patient’s result is not accepted by ZTAS:

The following are possible reasons:

7.1 ZTAS PIN of the patient is not recognised:
   - Invalid patient identifier used
   - Patient not registered with ZTAS

7.2 A 2nd result for the same patient is submitted on the same day.

7.3 The sample has an invalid particle distribution:
   - The sample is not sufficiently mixed
   - The sample has clotted.

7.4 There is no sample tube in the PocHi during analysis, or the sample tube is empty or filled with watery fluid: values outside acceptable ranges.

7.5 Internet communication failure.

Other reasons may arise which will be discussed with ZTAS.

Patients’ Blood Samples:

Following analysis of the sample, it is stored in a specimen fridge. All samples from the weeks clinics are kept until the following Monday.

Samples tested on two occasions that have failed due to an invalid result “invalid particle distribution” should be sent to the local lab for analysis, or second sample can be taken and run on PocH

Used/analysed blood samples/tubes are disposed of in plastic orange-lidded sharps bins as advised.
9 Quality Assurance

9.1 Internal Quality Control Samples:

9.1.1 The type of Quality Control (QC) blood samples used for the internal Quality Control (see sections 4.0 and 5.0) of PocHi is Eightcheck 3 WPL (low level).

9.1.2 ZTAS has a standing order with Sysmex for Rotherham, Doncaster & South Humber Mental Health NHS Foundation Trust for delivery of new QC samples every 3 months.

9.1.3 Every 3 months, a new pack of QC samples are delivered to PocHi Clinic sites. These will be delivered to 344 Ashby Rd and the clinic coordinator informed of arrival.

   The pack of QC samples must immediately be stored in the sample fridge. Upon receipt the delivery must be checked to ensure the correct type of QC samples ‘Eightcheck 3 WPL (low level)’ red tops and within date have been received.

9.1.4 If no new QC samples have been received a week before the expiry date of the batch in use, the ZTAS Helpdesk must be contacted.

9.1.5 The QC samples are stored in a locked fridge at a temperature of between 2 - 8 degrees centigrade.

9.1.6 The new pack of QC samples must only be used once the previous pack has expired.

9.1.7 Prior to the use of the new QC pack, the batch number, expiry date and reference values should be entered into the PocHi (using barcode scanner).

9.1.8 A QC sample that is (to be) used should have two dates inserted on the tube label, one date when the sample is first used and the second date being the discard date one week later.

9.2 PocHi External Quality Assurance (NEQAS)

9.2.1 ZTAS have registered the PocHi analyser with the National External Quality Assurance Scheme. The Trust are required to participate in the External Quality Control on a monthly basis in order to keep the PocHi service operational.

9.2.2 At the beginning of each month, a set of NEQAS samples is delivered to PocHi Clinic sites. These will be delivered to 344 Ashby Rd and the clinic coordinator informed of arrival.

   The NEQAS samples must tested - as if they were patient samples - and the result returned to NEQAS within the indicated timeframe on the enclosed instruction sheet.

9.2.3 The NEQAS samples must be kept in the sample fridge until they are being tested. Instructions for testing are available with each set of NEQAS samples.

9.2.4 If no new NEQAS samples have been received by the 2nd half of the month, the ZTAS Helpdesk must be contacted.
9.3 **Record keeping/file maintenance**

9.3.1 **Keep temperature log:** Every day the PocHi analyser is in operation, check the temperature of the fridge that stores QC samples (see section 9.1) to confirm that the samples are appropriately kept. Record/ Make a note on your temperature log (date and signature)

9.3.2 **Maintain daily log sheet** (appendix 2): with relevant information on each day that the PocHi is in operation.

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10 **PocHi Problems**

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The PocHi prompts that reagents need changing or change is deemed necessary by the operator

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Operator decision: press “Menu” and select “Chg.Reag”

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Replace the pack to be changed
11.3 Transducer Cleaning – prompted automatically
Performed every 2 weeks or after 150 blood samples

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Performed every 3 months or after 1500 samples
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    13.1.2 – POCH-100i machine is shut down correctly
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12.7 This operating procedure is to be used in conjunction with the protocols on red and amber blood results and local blood testing.
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- The shutdown procedure must be done at the end of each working day the PocHi is used.
- Change reagents must be done each time the machine prompts.
- Number of tests must be recorded each working day.
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|     |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Change Poch Pack 65 |
| Shutdown |
| Waste Chamber Clean |
| Transducer Cleaning |
| NEQAS (monthly) |
| No. of Tests |

Initials: 

Date | Problems:  
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<td>PATIENT NAME</td>
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Prescriptions completed by.................................(print name) ............................................(signature)

Medication checked in by .................................(print name) ............................................(signature)

Result checked/medication dispensed by ...................(print name) .............................................(signature)
<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>DOB</th>
<th>SILVERLINK</th>
<th>CLOZAPINE PRESCRIPTION</th>
<th>ARRIVED</th>
<th>TEST DATE/RESULT</th>
<th>DISPENSED</th>
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Prescriptions completed by……………………………(print name) ………………………………..(signature)

Medication checked in by ……………………..(print name) ………………………………..(signature)

Result checked/medication dispensed by …………………….. (print name) ……………………………….. (signature)
## Appendix 6

### Common Clozapine Drug Interactions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interactions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone marrow suppressants (e.g. carbamazepine, chloramphenicol), sulphonamides (e.g. co-trimoxazole), pyrazolone analgesics (e.g. phenylbutazone), penicillamine, cytotoxic agents and long-acting depot injections of antipsychotics</td>
<td>Interact to increase the risk and/or severity of bone marrow suppression.</td>
<td>Clozapine <strong>must not be used</strong> concomitantly with other agents having a well known potential to suppress bone marrow function</td>
</tr>
<tr>
<td><strong>Benzodiazepines</strong></td>
<td>Concomitant use may increase risk of circulatory collapse, which may lead to cardiac and/or respiratory arrest.</td>
<td>Whilst the occurrence is rare, caution is advised when using these agents together. Reports suggest that respiratory depression and collapse are more likely to occur at the start of this combination or when Clozapine is added to an established benzodiazepine regimen.</td>
</tr>
<tr>
<td><strong>Anticholinergics</strong></td>
<td>Clozapine potentiates the action of these agents through additive anticholinergic activity.</td>
<td>Observe patients for anticholinergic side-effects, e.g. <strong>constipation</strong>, especially when using to help control hypersalivation.</td>
</tr>
<tr>
<td>e.g. Oxybutnin, procyclidine</td>
<td></td>
<td><strong>Antihypertensives</strong></td>
</tr>
<tr>
<td><strong>Antihypertensives</strong></td>
<td>Clozapine can potentiate the hypotensive effects of these agents due to its sympathomimetic antagonistic effects.</td>
<td>Caution is advised if Clozapine is used concomitantly with antihypertensive agents. Patients should be advised of the risk of hypotension, especially during the period of initial dose titration.</td>
</tr>
<tr>
<td><strong>Alcohol, MAOIs, CNS depressants, including narcotics and benzodiazepines</strong></td>
<td>Enhanced central effects. Additive CNS depression and cognitive and motor performance interference when used in combination with these substances.</td>
<td>Caution is advised if Clozapine is used concomitantly with other CNS active agents. Advise patients of the possible additive sedative effects and caution them not to drive or operate machinery.</td>
</tr>
<tr>
<td><strong>Highly protein bound substances (e.g. warfarin and digoxin)</strong></td>
<td>Clozapine may cause an increase in plasma concentration of these substances due to displacement from plasma proteins.</td>
<td>Patients should be monitored for the occurrence of side effects associated with these substances, and doses of the protein bound substance adjusted, if necessary.</td>
</tr>
<tr>
<td><strong>Phenytoin</strong></td>
<td>Addition of phenytoin to Clozapine regimen may cause a decrease in the clozapine plasma concentrations.</td>
<td>If phenytoin must be used, the patient should be monitored closely for a worsening or recurrence of psychotic symptoms.</td>
</tr>
<tr>
<td><strong>Lithium</strong></td>
<td>Concomitant use can increase the risk of development of neuroleptic malignant syndrome (NMS).</td>
<td>Observe for signs and symptoms of NMS.</td>
</tr>
<tr>
<td><strong>CYP inducing substances (e.g. omeprazole, smoking)</strong></td>
<td>Concomitant use may decrease clozapine levels</td>
<td>Potential for reduced efficacy of clozapine should be considered.</td>
</tr>
<tr>
<td><strong>CYP inhibiting substances (e.g. fluvoxamine, caffeine, ciprofloxacin, erythromycin and paroxetine)</strong></td>
<td>Concomitant use may increase clozapine levels</td>
<td>Potential for increase in adverse effects. Care is also required upon cessation of concomitant CYP inhibiting medications as there will be a decrease in clozapine levels.</td>
</tr>
</tbody>
</table>

Ref: Adapted from Clozapine SPC, accessed online July 2016
## Appendix 7

### Initiating or Retitrating Inpatients on Clozapine Ward pack

(More detail can be found in the clinic protocol)

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Clozapine Clinic Numbers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.o.b.</td>
<td>Doncaster: 01302 798401</td>
</tr>
<tr>
<td>Silver Link/NHS Number:</td>
<td>Rotherham: 01709 302525</td>
</tr>
<tr>
<td>Ward:</td>
<td><a href="mailto:rotherhamclozapinelithium@rdash.nhs">rotherhamclozapinelithium@rdash.nhs</a> * preferred</td>
</tr>
<tr>
<td>Allergy/Sensitivity Status:</td>
<td>Scunthorpe: 01274 275959</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INPATIENT INITIATION GUIDANCE</th>
<th>Done</th>
<th>Date</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient information (clozapine clinic booklet) or similar discussed with the patient and or carers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Record consent, or authority to prescribe under mental capacity act or mental health act</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Register patient with ZTAS, check consultant is already registered (<a href="http://www.ztas.co.uk">www.ztas.co.uk</a>)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Baseline monitoring (see attached)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Inform appropriate clozapine clinic of decision to start treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Baseline bloods faxed to ZTAS, 0207 3655843</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. If results are within acceptable parameters and a green result from ZTAS is received, within 10 days clozapine can be initiated, for practical reasons best done on a monday</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Prescribe clozapine on the variable dosage section of the drug card (see suggested dose titration schedule)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Physical health monitoring see attached- these should be recorded on the clozapine side effect chart</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Repeat full blood count 3 days after starting clozapine, and inform ZTAS of results</td>
<td></td>
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</tr>
<tr>
<td>11. Weekly bloods, this may be done in clozapine clinic following discussion with staff, if the patient is stable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Complete side effect monitoring in line with routine blood monitoring, this should be done at the same time as the blood sampling and recorded on the clozapine side effect chart (see attached)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Inform clozapine clinic of when patient is ready for unescorted leave, and the dose is stable to the community, sufficient time must be allowed for this to be organised</td>
<td></td>
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<tr>
<td>14. Provide an ongoing prescription for clozapine to the clinic</td>
<td></td>
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</tr>
<tr>
<td>15. Organize follow up appointments with clozapine clinic</td>
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</table>
### INPATIENT RETITRATION GUIDANCE

<table>
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<th>Done</th>
<th>Date</th>
<th>Initials</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Inform ZTAS by fax of treatment break (must be done by doctor)</td>
<td></td>
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<tr>
<td>2.</td>
<td>Contact ZTAS and inform them of decision to restart, they will inform you of any changes to the patient’s routine monitoring schedule (see 5.17 for general guidance)</td>
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<tr>
<td>3.</td>
<td>If break is &lt;72 hours re-initiation of clozapine, no additional monitoring is required</td>
<td></td>
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</tr>
<tr>
<td>4.</td>
<td>Record consent, or authority to prescribe under mental capacity act or mental health act</td>
<td></td>
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</tr>
<tr>
<td>5.</td>
<td>If break is &gt;72 hours, re-titrate clozapine (see suggested dose titration schedule – appendix 2, if well tolerated after 2 doses consider faster dose escalation)</td>
<td></td>
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</tr>
<tr>
<td>6.</td>
<td>Baseline monitoring (see appendix 2) if no recent results available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Baseline Bloods faxed to ZTAS 02073655843</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Inform appropriate Clozapine Clinic of decision to re start</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>If results are within acceptable parameters and a green result from ZTAS is received, within 10 days clozapine can be initiated, for practical reasons best done on a Monday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Prescribe clozapine on the variable dosage section of the drug card (see suggested dose titration schedule - appendix 2)</td>
<td></td>
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</tr>
<tr>
<td>11.</td>
<td>Physical health monitoring see attached these should be recorded on the clozapine side effect chart</td>
<td></td>
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<tr>
<td>12.</td>
<td>Repeat full blood count 3 days after starting clozapine, and inform ZTAS of results</td>
<td></td>
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</tr>
<tr>
<td>13.</td>
<td>Weekly bloods, this may be done in clozapine clinic following discussion with staff, when the patient is stable, and unescorted leave is granted</td>
<td></td>
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</tr>
<tr>
<td>14.</td>
<td>Complete side effect monitoring in line with routine blood monitoring</td>
<td></td>
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<tr>
<td>15.</td>
<td>Inform Clozapine Clinic of when patient is ready to be discharged to the community, sufficient time must be allowed for the clinic to organise everything</td>
<td></td>
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<tr>
<td>16.</td>
<td>Provide a prescription for the clozapine clinic to cover ongoing supplies</td>
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<tr>
<td>17.</td>
<td>Organize follow up appointments</td>
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# BASELINE AND INITIAL MONITORING

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</table>

* See below for frequency of monitoring ** may be more frequently if clinically indicated, carried out by ward staff on initiation, and the clinic annually *** for first four weeks

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<thead>
<tr>
<th>Day</th>
<th>Monitoring (to be recorded on the monitoring chart)</th>
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<tr>
<td>1</td>
<td>Blood pressure and pulse every hour for the first 6 hours after the first dose</td>
</tr>
<tr>
<td>2 - 14</td>
<td>Blood pressure and Pulse twice daily, before and six hours after the dose</td>
</tr>
<tr>
<td>15 - 28</td>
<td>Blood Pressure and Pulse daily</td>
</tr>
</tbody>
</table>

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Page 77 of 88
**Suggested Dosing Schedule.**

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<tr>
<td>Evening</td>
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<td>200</td>
<td>250</td>
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</tr>
<tr>
<td>Total</td>
<td>12.5</td>
<td>25</td>
<td>37.5</td>
<td>50</td>
<td>75</td>
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<td>225</td>
<td>250</td>
<td>275</td>
<td>300</td>
<td>350</td>
<td>400</td>
<td></td>
</tr>
</tbody>
</table>

(accessed from ZTAS Aug 2016)

**Patients with treatment-resistant schizophrenia**

**Initial dosing schedule**

In patients with treatment-resistant schizophrenia, the recommended starting dose of Zaponex is 12.5mg (half of one 25mg tablet) taken once or twice on the first day, followed by one or two 25mg tablets on the second day. Some patient groups (e.g. elderly patients) should be started more slowly, with only 12.5mg per day.

**Increasing the dose**

If well tolerated, the daily dose can be increased slowly, usually by 25 - 50mg increments, up to a dose of 300mg/day within 2 - 3 weeks. If necessary, the daily dose may be slowly increased in further 50 - 100mg increments at half-weekly or preferably weekly intervals. To obtain full therapeutic benefit, a few patients may require higher doses, up to a maximum of 900mg/day.

**Decreasing the dose**

Once maximum therapeutic benefit has been established, many patients can be maintained effectively on lower doses. Careful downward titration is recommended. If the total daily dose required does not exceed 200mg/day, it may be more convenient and appropriate for the patient to be given a single dose in the evenings. Treatment should be maintained for at least 6 months.

**Patients with psychotic disorders occurring during the course of Parkinson’s disease**

**Initial dosing schedule**

In patients with psychotic disorders occurring during the course of Parkinson’s disease the Zaponex starting dose must not exceed 12.5mg/day (half of one 25mg tablet), taken in the evening.

**Increasing the dose**

The dose can be increased in 12.5mg increments, with a maximum of two increments per week, up to a maximum dose of 50mg. This maximum dose must not be reached until the end of the second week of dosing.

The mean effective dose is usually between 25mg/day and 37.5mg/day. In some patients, this dose may not provide a satisfactory therapeutic response - in these instances the dose may be cautiously increased by increments of 12.5mg/week. A dose of 50mg/day should only be exceeded in exceptional cases, and a dose of 100mg/day must never be exceeded. The total daily amount of Zaponex should preferably be given as a single dose in the evening.

**Missed Doses**

If one dose of Zaponex is omitted or forgotten, the next dose should be taken at the normal time. Do not attempt to make up for the missed dose by giving more. If Zaponex is omitted or forgotten for more than 2 days ZTAS must be informed about the treatment break. The patient must be restarted on therapy, increasing gradually from 12.5mg (half of one 25mg tablet) once or twice per day on the first day. If the first dose is well tolerated, it may be possible to titrate the dose more quickly than is recommended for initial treatment in order to re-establish the therapeutic dose, and thus reduce the risk of having a recurrence of psychotic episodes. However, in those patients that have previously experienced respiratory or cardiac arrest with initial dosing, but were then able to be successfully titrated to a therapeutic dose, re-titration should be carried out with extreme caution.
# Clozapine Clinic Side Effects Questionnaire and Monitoring

(Please ensure full documentation is included in the patient record)

<table>
<thead>
<tr>
<th>ZTAS ID No.</th>
<th>Have you taken all medication as prescribed since your last appointment?</th>
<th>Date:</th>
<th>Time:</th>
<th>Sign:</th>
<th>Date:</th>
<th>Time:</th>
<th>Sign:</th>
<th>Date:</th>
<th>Time:</th>
<th>Sign:</th>
<th>Date:</th>
<th>Time:</th>
<th>Sign:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Has your smoking status changed since your last appointment? If yes consider likely impact on clozapine levels</td>
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<td>Have you visited your GP, if so why, and what have they prescribed? If yes inform the psychiatrist, and update the notes</td>
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<td>How are you feeling generally? Any temperatures sore throat or minor infections recently? If yes inform psychiatrist, or recommend GP appointment</td>
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<td>Have you felt over tired or been falling asleep / napping? If yes offer advice on structuring day, and sleep routines.</td>
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<td>Have you noticed excess saliva in your mouth, or a wet pillow? If causing distress consider treatment.</td>
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<td>Have you been persistently constipated (e.g. passing stools less than three times per week)? If yes refer to GP and inform psychiatrist.</td>
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<td>If yes to above have you suffered from: Abdominal discomfort, or bloating and or vomiting. If yes refer to psychiatrist/GP urgently</td>
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<td>Is your pulse persistently elevated (&gt;120bpm) or do you get palpitations (see chart on back of sheet). If yes refer to psychiatrist/GP (check to see if recent ECG done)</td>
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<td>Have you had any chest pain, breathlessness? If yes refer to psychiatrist/GP</td>
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<td>Have you noticed any dizziness on standing or getting up? If yes check sitting standing BP and refer to psychiatrist if a postural drop is noted.</td>
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<td>Have you been aware of any twitching movements of your limbs or face? If yes refer to psychiatrist</td>
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<td>Has your weight increased without any change in diet. If yes offer dietary advice and refer appropriately</td>
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<td>Have you noticed increase in thirst, or passing more urine? If yes refer to psychiatrist and inform GP</td>
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Please grade side effects as below:
1 – Rarely  2 – Occasionally  3 – Often  4 – Persistently
### Recording Chart for Initiation of Clozapine

<table>
<thead>
<tr>
<th>Year</th>
<th>Date</th>
<th>Date</th>
<th>Year</th>
<th>Time</th>
<th>Time</th>
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<tbody>
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</tbody>
</table>

#### Key R TUM
- R: Reint
- T: Rapid tranquillisation
- U: Unwell
- M: Monitoring
- B: Baseline

#### THE ADULT EARLY WARNING SCORE

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse</td>
<td></td>
<td>51-100</td>
<td>41-50 or 101-110</td>
<td>111-130</td>
<td>≤ 40 or ≥ 130</td>
</tr>
<tr>
<td>Systolic BP</td>
<td></td>
<td>101-200</td>
<td>81-100</td>
<td>71-80 OR 201-220</td>
<td>≤ 70 or ≥ 220</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td></td>
<td>8-20</td>
<td>21-30</td>
<td>31-35</td>
<td>≤ 8 or ≥ 35</td>
</tr>
<tr>
<td>Temperature</td>
<td></td>
<td>36.1-37.9</td>
<td>35.1-36 OR 38-38.5</td>
<td>34-35 OR 38.5-39.9</td>
<td>≤ 34 or ≥ 40</td>
</tr>
<tr>
<td>CNS AVPU</td>
<td></td>
<td>ALERT</td>
<td>VOICE</td>
<td>PAIN</td>
<td>UNCONSCIOUS</td>
</tr>
<tr>
<td>O2 Sats</td>
<td></td>
<td>100%-95%</td>
<td>90%-94%</td>
<td>≤ 90%</td>
<td>≤ 85%</td>
</tr>
</tbody>
</table>

#### CNS AVPU
- ALERT: Alert
- VOICE: Voice
- PAIN: Pain
- UNCONSCIOUS: Unconscious

#### O2 SATS
- 100% - 95%
- 90% - 94%
- ≤ 90%
- ≤ 85%