Somerset Partnership NHS
NHS Foundation Trust

CLOZAPINE POLICY

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Relevant Staff Groups:	All clinical staff involved in the prescribing, supply, administration and monitoring of clozapine.

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DOCUMENT CONTROL

Reference Number	**Version**	**Status**	**Author**
AB/Jul13/CP	2	Final	Head of Medicines Management
Amendments	Amended to reflect the acquisition of Somerset Community Health and changes to the Trusts governance structure.		
Document objectives: This policy sets out the procedures for the safe and effective use of clozapine. It specifies the procedures which must be followed in ordering, supplying, prescribing, and administering clozapine including initiation and re-titration.			
Intended recipients: All clinical staff involved in the prescribing, supply, administration and monitoring of clozapine.			
Committee/Group Consulted: Circulated to members of Medicines in Clinical Practice Group and Medicines Management Group			
Monitoring arrangements and indicators: See relevant section.			
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Contact for review	Head of Medicines Management		
Lead Director	Medical Director		

CONTRIBUTION LIST Key individuals involved in developing the document

Name	**Designation or Group**
Anne Cole	Senior Clinical Pharmacist
Karen Hochmuth	Deputy Head of Medicines Management
Jill Leppard	Lead nurse for Medicines Management
Val Kidner	Senior Pharmacy Technician
Angela Griffiths	Senior Clinical Pharmacist
Michele Crumb	Risk Manager
Jamie Denham	Clinical Skills Facilitator
Peter Park	Consultant Psychiatrist
Carolyn Partridge	Specialty Doctor in Psychiatry
Chris Mortimore	Medical Director
Nina Vinall	Senior Nurse for Clinical Practice

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1. INTRODUCTION

1.1 Clozapine is an antipsychotic drug indicated for treatment-resistant schizophrenia and in schizophrenia patients experiencing severe, untreatable neurological adverse reactions to other antipsychotic agents, including atypical antipsychotics. Clozapine is also licensed for the treatment of psychotic disorders occurring during the course of Parkinson's disease, in cases where standard treatment has failed.

1.2 Due to the risk of reductions in white blood cell count (neutropenia and agranulocytosis) there is a mandatory requirement for monitoring of full blood counts for all patients prescribed clozapine. The frequency of monitoring, the analysis of the blood sample, the authorisation of results and the dispensing procedures have all been approved by the MHRA as part of the licensing process for each brand of clozapine.

2. PURPOSE & SCOPE

2.1 The purpose of the policy is to promote safe and effective use of clozapine.

2.2 The policy applies to all clinical staff involved in the prescribing, dispensing or supply, administration and monitoring of clozapine.

3. DUTIES AND RESPONSIBLITIES

3.1 The **Chief Executive** is ultimately responsible for ensuring the Trust complies with legal requirements and national recommendations for medicines management.

3.2 The **Trust Board** has a responsibility to ensure training is available to all relevant staff.

3.3 The **Medical Director** is the Executive Lead responsible for this policy but will delegate authority for the operational implementation and ongoing management of this policy to the Head of Medicines Management.

3.4 The **Head of Medicines Management** is the nominated ‘Accountable Officer’ for Controlled Drugs in the Trust.

3.5 **Each registered healthcare professional** is accountable for his/her own practice and will be aware of their legal and professional responsibilities relating to their competence in the ordering, prescribing, administering, monitoring, dispensing and supplying of clozapine whichever is within their scope of practice; and work within the Code of practice of their professional body. All healthcare professionals involved in the use of clozapine:

- must acquaint themselves with this policy and other related policies
- will be aware of the action that should be taken if their practice or their

patients safety is compromised

- will be aware of the safe dose range, frequency, side effects, contra-indications and interactions of clozapine

- will monitor the patients for side effects and adverse reactions and manage them appropriately

- will be aware of their limitations and seek advice or support from appropriate health professionals when in doubt

3.6 **All staff** should appreciate the importance of involving the patient and/or carer in their treatment as much as possible. This includes ensuring the patient or carer has been given information about the treatment in a language and format which they can easily understand, that they agree to the use of clozapine and appreciate as far as possible any risks of side effects. In order to fully understand, patients may need the support of a professional interpreter or translation service. Information on medication and its side effects should be made available in a range of formats and languages to meet patient need. Please contact the Medicines Management Team for advice on how to access.

3.7 **Line Managers** are responsible for ensuring all staff are conversant with this policy. Line managers are responsible for ensuring that staff attend mandatory training in line with the Staff Mandatory Training Matrix.

3.8 **Consultants** are responsible for ensuring that all medical staff in their team are competent to prescribe clozapine and are aware of this policy. The specific responsibilities of consultants during initiation and re-titration of clozapine are outlined in the relevant guidelines.

3.9 **Clozapine Clinic Staff** are responsible for operating the point of care haematology analyser in line with the procedures produced by Novartis.

3.10 **Sysmex UK Limited** is responsible for the maintenance and repair of the point of care haematology analyser. They are also responsible for training certified users and providing training material for certified users to train other operators.

3.11 **Novartis** is responsible for ensuring that the operating instructions for the use of the point of care haematology analyser comply with the licensing requirements for Clozaril. They are also responsible for monitoring the completion of the Sysmex Point of Care on-line training and will notify, within one working day, the Head of Medicines Management of anyone who is subsequently prohibited from using the machine as a result of non completion of the training.

3.12 **Yeovil Hospital Pharmacy** is responsible for ensuring that dispensing of clozapine complies with the license requirements. They are responsible for the production of all Standard Operating Procedures for the dispensing

process and for ensuring that their staff are competent to dispense clozapine. They will investigate any dispensing or supply incidents and report their findings back to the Head of Medicines Management.

3.13 The **Director of Nursing and Patient Safety** is responsible for ensuring that non-medical prescribers are authorised and competent to prescribe.

3.14 The **Medicines Incident Group** is responsible for reviewing incidents involving clozapine and disseminating lessons learned. The Medicines incident Group may delegate this authority to the Trust Clozapine Group.

3.15 **The Trust Clozapine Group** is a subgroup of the Medicines in Clinical Practice Group and is responsible for undertaking clinical audits as scheduled within this policy.

3.16 The **Medicines in Clinical Practice Group** will make recommendations based on Audit Reports.

3.17 **The Clinical and Social Care Effectiveness Group** is responsible for the approval and implementation of any clinical audit recommendations.

3.18 **The Clinical Governance Group** is responsible for approving this policy and will ensure it is reviewed at least every three years or sooner in line with local and/or national requirements. The Group is responsible for the overall monitoring of the Clinical Audit plan.

3.19 **Learning and Development Facilitators** are responsible for ensuring attendance records are signed by each participant and forwarded to the Learning and Development Department.

3.20 **The Learning and Development Department** is responsible for entering all data relating to Mandatory and Non-Mandatory training attendance onto the Electronic Staff Record (ESR) system and reporting non-attendance to Local Managers.

4. EXPLANATIONS OF TERMS USED

4.1 **CPMS - Clozaril Patient Monitoring Service**
The patient monitoring service operated by Novartis as part of the licensing requirements of the Clozaril brand of clozapine.

4.2 **DMS - Denzapine Monitoring Service**
The patient monitoring service operated by Genus as part of the licensing requirements of the Denzapine brand of clozapine

4.3 **PocHi 100 machine**
Sysmex UK Limited Point of Care Haematological Analyser (POCHA). The Trust currently has four of these machines, one in each of the clozapine clinics. They are on loan from Novartis and must be operated in accordance with the procedures produced by Novartis and approved as part of the

licensing process by the Medicines and Healthcare products Regulatory Authority (MHRA).

4.4 **Green Blood Result**

A green result indicates white blood cell (WBC) count greater than 3.5x10^9/L and neutrophils more than 2.0 x10^9/L and no decreases of more than 10% or repeatedly decreasing values in the previous test(s). Clozapine may be prescribed and dispensed.

4.5 **Amber Blood Result**

An amber result indicates WBC count 3.0-3.5 x10^9/L and/or neutrophils1.5-2.0 x10^9/L. If the patient's medical condition is satisfactory, clozapine treatment may continue. The monitoring service will require twice-weekly samples until counts stabilise or increase.

4.6 **Red blood result**

WBC count less than 3.0 x10^9/L and/or neutrophils less than 1.5 x10^9/L and/or platelets less than 50 x10^9/L.

Clozapine treatment must be stopped immediately. The monitoring service will telephone the hospital and the pharmacist to inform them of this, and to request that a further blood sample is taken urgently and analysed locally. The patient must be monitored for signs of infection and further blood tests will need to be taken daily until a green blood result has been achieved. A red blood test is confirmed if either of the blood tests on the following two days after the initial red blood test produces a further red blood result. Once confirmed, the patient should not routinely be re-exposed to clozapine.

5. POLICY

Licensed Use of Clozapine

5.1 Due to the risk of reductions in white blood cell count (neutropenia and agranulocytosis) there is a mandatory requirement for monitoring of full blood counts. In the UK, a full blood cell count with a differential count must be monitored:

- at least weekly for the first 18 weeks of treatment.
- at least fortnightly between weeks 18 and 52
- after 1 year of treatment with stable neutrophil counts, patients may be monitored at 4 week intervals.
- monitoring must continue during treatment and for at least 4 weeks after stopping clozapine.

The frequency and processes involved in the monitoring are part of the license for each brand of clozapine and hence are approved by the MHRA.

5.2 The dispensing pharmacy, prescribing consultant and patient have to be registered with the relevant patient monitoring service. This service exists

to ensure that all the necessary regulatory requirements surrounding use of this medication are fulfilled and that patients are managed safely and monitored appropriately.

5.3 Currently the brand of clozapine in tablet formulation used by Somerset Partnership NHS Foundation Trust is Clozaril® and their monitoring service is called the Clozaril Patient Monitoring Service (CPMS). Each patient is allocated a unique CPMS registration number to be used in all correspondence with CPMS.

5.4 Currently the brand of clozapine in oral suspension (liquid) formulation used by Somerset Partnership NHS Foundation Trust is Denzapine® and their monitoring service is called the Denzapine Monitoring Service (DMS). Each patient is allocated a unique DMS registration number to be used in all correspondence with DMS.

Initiation of clozapine

5.5 Although it is no longer a requirement in the drug licence of clozapine in the U.K that patients are admitted to hospital for initiation of clozapine, it is the **recommended default** for patients **within Somerset,** because of potentially serious adverse reactions to the medication.

5.6 Guidelines for initiation of clozapine for the treatment of schizophrenia in adults under 65 years in an inpatient setting are available on the Staff Intranet under Prescribing>Clozapine.

5.7 Guidelines for initiation of clozapine for the treatment of schizophrenia in adults under 65 in a non inpatient setting are available on the Staff Intranet under Prescribing>Clozapine.

Prescribing

5.8 Clozapine is classified locally as a red drug with prescribing restricted to Somerset Partnership NHS Foundation Trust staff. Clozapine cannot be prescribed by the patient's GP.

5.9 For outpatients prescribers are responsible for ensuring that the repeat paper prescription or electronic prescription is amended following any alteration of dose that has been agreed with the patient.

Monitoring

5.10 Patients should attend one of the four Trust clozapine clinics (Bridgwater, Taunton, Wells and Yeovil) to have their full blood count monitored unless there are exceptional circumstances which prevent this (see section 5.12). The frequency of full blood count monitoring will be specified by the monitoring service the patient is registered with.

5.11 The clinic will also ensure that the required physical monitoring is conducted in line with the Trust Guidelines on the Monitoring of Adult Patients Taking Psychotropics and the patient is regularly assessed for side effects.

5.12 If the patient attends their General Practitioner (GP) surgery to have their full blood count monitored, the Somerset Partnership prescriber is responsible for ensuring that the required physical and side effect monitoring is carried out by the GP. If the GP declines to undertake the required monitoring the prescriber is responsible for ensuring that it occurs.

5.13 Procedures for monitoring are outlined in the Standard Operating Procedure for Clozapine Clinics (appendix C).

Ordering and supply of medication

5.14 The process for the ordering of medication for outpatients is outlined in the Standard Operating Procedure for Clozapine Clinics (appendix C).

5.15 For those patients who attend their GP surgery for full blood count monitoring the Somerset Partnership prescriber is responsible for ensuring that the required prescriptions are sent to the registered pharmacy.

5.16 The process for the ordering of medication for inpatients is outlined in the Standard Operating Procedure ordering clozapine for inpatients (appendix D)

5.17 Clozapine can only be dispensed for the patient by the pharmacy registered with the patient monitoring service. For most patients in the Trust the registered pharmacy is Yeovil Hospital and for these patients clozapine cannot be prescribed on FP10.

5.18 The dispensing pharmacy can only dispense for patients currently registered with the patient monitoring service. The dispensing pharmacy is not allowed to dispense a supply of clozapine which exceeds the validity period of the current blood test.

5.19 Clozapine will always be dispensed as individual named patient supplies which must be administered or supplied to the named patient only. Another patient's supply must never be administered or supplied to another patient.

5.20 The process for obtaining emergency supplies of clozapine out of hours is outlined in the Process for Ordering Clozapine Prescriptions (appendix E).

5.21 Receipt of dispensed clozapine, storage and issue / delivery to patients must be in line with the appropriate sections of the Trust Medicines Policy.

5.22 If the patient has a red blood result the care co-ordinator will be responsible for retrieving any remaining clozapine tablets from the patient.

Re-titration

5.23 The **recommended default** for patients **within Somerset** is that they are admitted to hospital for re-titration of clozapine because of potentially serious adverse reactions to the medication.

5.24 Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in an inpatient setting are available on the Staff Intranet under Prescribing>Clozapine.

5.25 Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in a non inpatient setting are available on the Staff Intranet under Prescribing>Clozapine.

6. TRAINING REQUIREMENTS

6.1 The Trust will work towards all staff being appropriately trained in line with the organisation's Staff Training Matrix (training needs analysis). All training documents referred to in this policy are accessible to staff within the Learning and Development Section of the Trust Intranet.

- Medicines Management Training – annual mandatory training for all medical and nursing staff.

- Trust Clozapine Training – mandatory training for all clinical staff involved in the Trust Clozapine Clinics and recommended training for all clinical staff involved in the prescribing, administration, supply of dispensed clozapine or who act as care co-ordinator for a patient prescribed clozapine. The training should be repeated every 3 years.

- PocHi operators – certified POCHA machine operators will have completed the two day training course, content of which is specified by Sysmex. Certified operators can train other operators locally using training materials provided by Sysmex.

- Sysmex Point of Care on-line training – all PocHi machine operators must complete the annual on line training to enable continued operation of the PocH-100i machine.

7. EQUALITY IMPACT ASSESSMENT

7.1 All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

8.1 Monitoring arrangements for compliance and effectiveness

Overall monitoring of compliance with and effectiveness of the policy will be the responsibility of the Medicines Management Group.

8.2 Responsibilities for conducting the monitoring

The Medicines Management Group will be responsible for monitoring compliance with the training requirements outlined in this policy.

The Trust Clozapine Group will be responsible for:-

- The audit of physical monitoring of patients prescribed clozapine
- Review of all reported incidents involving clozapine and identifying lessons learnt and changes in procedures to the Medicines Incident Group.
- The Group will report every 6 months to the Medicines in Clinical Practice Group.

The Medicines Incident Group will conduct an annual analysis of all reported incidents involving clozapine

8.3 Methodology to be used for monitoring

- Monthly training attendance reports to the Medicines Management Group
- Quarterly review of all incidents involving clozapine by the Trust Clozapine Group and Medicine Incident Group.
- Audit of physical monitoring of patients prescribed clozapine – to be included on the Trust Clinical Audit Plan and undertaken at least every 3 years. Standards are set out in Appendix H.

8.4 Process for reviewing results and ensuring improvements in performance occur.

Audit results will be presented to the Medicines in Clinical Practice Group and Medical Audit Group for consideration, identifying good practice, any shortfalls, action points and lessons learnt. The Medicines in Clinical Practice Group will be responsible for ensuring improvements, where necessary, are implemented. The Clinical and Social Care Effectiveness Group will ensure the audit is included in the Trust Clinical Audit Plan.

The report and lessons learnt will be accessible to all staff on the Trust Intranet and hyperlinked into SPICE newsletter to raise awareness.

9. COUNTER FRAUD

9.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by

fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

10. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

The standards and outcomes which inform this procedural document are as follows:

Section	Outcome	
Personalised care, treatment and support	4	Care and welfare of people who use services
Safeguarding and safety	9	Management of medicines
	11	Safety, availability and suitability of equipment
Suitability of staffing	12	Requirements relating to workers
Quality and management	16	Assessing and monitoring the quality of service provision
	20	Notification of other incidents
	21	Records

Relevant National Requirements

NICE Clinical Guideline CG82 – Schizophrenia - Core interventions in the treatment and management of schizophrenia in adults in primary and secondary care. March 2009

11. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

References

Summary of Product Characteristics for Clozaril Tablets – accessed via www.medicines.org.uk/emc

Summary of Product Characteristics for Denzapine oral solution - accessed via www.medicines.org.uk/emc

Sysmex PocHi 100i Training Manual

Trust Guidelines on the Monitoring of Adult Patients Taking Psychotropics

Cross reference to other procedural documents

Development & Management of Procedural Documents
Health and Safety Policy
Healthcare Clinical Waste Policy
Infection Prevention and Control Policy
Learning Development and Mandatory Training Policy
Mandatory Training Matrix (Training Needs Analysis)

Medical Devices Policy
Medicines Policy
Point of Care Testing Policy
Risk Management Policy and Procedure
Training Prospectus
Untoward Event Reporting Policy and procedure

All current policies and procedures are accessible to all staff on the Trust intranet (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet (within Policies and Procedures).

Relevant Objective within Trust Strategy

Five year Integrated Business Plan

12. APPENDICES

12.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such. This should include any relevant Clinical Audit Standards.

Appendix A	Guidelines for initiation of clozapine for the treatment of schizophrenia in adult under 65 years in an inpatient setting. This is available on the Staff Intranet under Prescribing>Clozapine.
Appendix B	Guidelines for initiation of clozapine for the treatment of schizophrenia in adults under 65 in a non inpatient setting. This is available on the Staff Intranet under Prescribing>Clozapine.
Appendix C	Standard Operating Procedure – Clozapine Clinics
Appendix D	Standard Operating Procedure – Ordering Clozapine on Inpatient Units
Appendix E	Process for ordering Clozapine Out of Hours
Appendix F	Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in an inpatient setting. This is available on the Staff Intranet under Prescribing>Clozapine.
Appendix G	Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in a non inpatient setting. This is available on the Staff Intranet under Prescribing>Clozapine.
Appendix H	Clozapine Clinical Audit Standards

FOR THE AVOIDANCE OF ANY DOUBT, PLEASE NOTE APPENDICES A, B, F AND G ARE AVAILABLE ON THE STAFF INTRANET UNDER PRESCRIBING>CLOZAPINE AND ARE NOT ATTACHED TO THIS DOCUMENT.

APPENDIX C

STANDARD OPERATING PROCEDURE

TITLE	**CLOZAPINE CLINICS**
Purpose	Standard Operating Procedure for Clozapine Clinics throughout the Trust
Scope	Applies to all staff involved in Clozapine Clinics
Responsibilities	Nominated Operational Manager

Document Control

Title:	**Standard Operating Procedure – Clozapine Clinics**	
Version	**Date Issued**	**Brief Summary of Change**
3.0	June 2012	Amended to include Use of Point of Care Haematological Analyser (POCHA) in Clozapine Clinics and amalgamation of document into overall Clozapine policy.
Author(s) name/ job title/ e-mail:		Val Kidner, Senior Pharmacy Technician Jill Leppard, Lead Nurse for Medicines Management Clozapine Clinic leads
SOP Number		**MM3**
Approving Group		**Medicines Management Group**
Date approved:		**June 2012**
Implementation date:		**June 2012**
Review date:		**June 2016**

Document History

Version	Start date	End date	Author	History
1.0	**June 2012**	**December 2012**	**Val Kidner/Jill Leppard**	**Original SOP**
2.0	**December 2012**	**June 2013**	**Val Kidner/Jill Leppard**	**Amended to include Clozapine Clinic procedures in Taunton, Yeovil, Bridgwater and Wells**

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CLOZAPINE CLINIC
STANDARD OPERATING PROCEDURE

Aims:

- To facilitate better control and supervision of patients taking Clozapine.
- To establish a routine, with which patients are familiar, giving them reassurance and a sense of security.
- To encourage regular contact between the patient and the care team.
- The overall aim is to promote safety and concordance while reducing the risks associated with poor/non compliance

Personnel:

- A nominated community consultant will act as the lead consultant for the clinic.
- The management of the clinic will be the responsibility of the recovery team manager in Taunton, Wells and Yeovil and the CMHT manager in Bridgwater.
- The Team manager is responsible for ensuring that appropriately trained staff are available to run the clinic on a weekly basis. For periods of planned absence clinic staff should liaise with the team manager to ensure cover is provided.
- The team manager is also responsible for ensuring that the appropriate staff are available to receive dispensed medication from the supply pharmacy and when the medication is subsequently issued to the patient.
- An appropriately trained registered nurse, supported by a pharmacy technician (Foundation House only) will run the clinic and carry out the blood tests and clinical monitoring.
- Registered nurses, trained to take blood
- Trust pharmacy staff and pharmacy staff at the supply pharmacy
- Medical staff
- Advice and support from the CLOZARIL Patient Monitoring Service (CPMS) (0845) 7698269
- Advice and support from Sysmex on pocHi machine (0870 902 9228)
- Advice and support from DENZAPINE Patient Monitoring Service (DMS) 0333 200 4143

Equipment:

- Sharp Bins
- Local FBC bottles
- Aprons and gloves
- Haematology forms
- Sysmex pocH-100i Haematology machine
- Weighing Scales
- Sphygmomanometer/stethoscope
- Thermometers
- Drug Cupboard

- Refrigerator
- Computer system
- Patient's Clozapine folders.
- Clozapine information File.
- Pharmacy Prescription Order Fax File/ access to electronic prescribing system
- Sysmex PocHi-100i Training Manual
- Clozapine Plasma level testing equipment and forms

Use of Point of Care Haematological Analyser (POCHA) in Clozapine Clinics

The POCHA machine within each clinic can only be operated and maintained by appropriately trained staff competent in its use. Each clinic will have 2 certified operators who have been trained by the Sysmex UK Ltd Point of Care team. Further operators of the machine can be trained in-house by existing certified operators to become registered operators. The content of this training and assessment of competence is specified by Sysmex.

The Medicines and Healthcare Products Regulatory Agency (MHRA) state the following –

- Only staff whose training and competence has been established and recorded should be permitted to carry out Point of Care Testing. They should also receive continued support and regular updates

Novartis provide an e-learning package for all staff to complete annually to fulfill the above. Failure to complete the e-learning will result in an operator being suspended from using the POCHA machine.

Staff operating the POCHA are responsible for the safe handling and storage of all internal and external quality control samples. It is their responsibility once samples have arrived on site, to ensure that they are processed in a timely manner as required. Failure to comply with the external quality control samples (supplied via National External Quality Assessment Scheme), may result in removal of the POCHA machine.

The handling of blood samples (all internal and external quality control samples must be stored in a separate fridge) and diluent waste must be in line with the Trust Health & Safety Policy, Infection Control Policy and Healthcare Waste (Clinical Waste) Policy.

A successful internal quality control sample must be processed each time the machine is used. Failure to process this sample in any way will render further testing of any samples invalid.

The POCHA machines will remain the sole property of Novartis and its contracted supplier, Sysmex. The Clozapine Patient Monitoring Service is responsible for the analysis of all samples and for categorising results as red, amber or green. The process forms part of the license for Clozaril and has been approved by the MHRA.

In the event of the POCHA machine being unavailable for sample analysis, local pathology systems must be used and results relayed to CPMS.

Contact numbers for Sysmex can be found at Appendix 4.

Timing:

- Blood will be taken and analysed on site using the pocH-100i machine. Blood test results are immediately available and the results transferred automatically online to CPMS. The supply Pharmacy is also able to see results.
- When a valid green blood result has been transferred to the computer screen, clozapine medication can be dispensed by the supply pharmacy or released from the quarantine cupboard (Foundation House only).
- Confirmation of the next appointment should be given at the clinic.
- When a Bank Holiday occurs on the nominated clinic day the clinic staff will liaise with the supply pharmacy and agree with the team manager the most appropriate alternative day for sampling to occur on that week
- When a patient has a holiday pending the registered nurse will need to make both CPMS and pharmacy aware of the change in sampling (if there is one), when next sample will be taken and how much medication is needed.

Interpretation of haematological results

Blood samples are analysed to measure the white blood cell count (WBC) and in particular the differential neutrophil count. For ease of interpretation, results are divided up into 3 colour bands: **GREEN, AMBER** and **RED**

GREEN	WBC > 3.5 X 10^9/L
AMBER	WBC > 3.0 – 3.5 10^9/L and/or neutrophils 1.5 – 2.0 x 10^9/L
RED	WBC < 3.0 X 10^9/L and/or neutrophils 1.5 x 10^9/L and/or platelets < 50 x 10^9/L

Action to be taken in respect of results is as follows:

GREEN – A further supply of drug may be prescribed and dispensed for 1, 2 or 4 weeks depending on the frequency of monitoring. Occasionally if the count falls within the range WBC 3.5 – 4.0 x 10^9/ and/or neutrophils 2.0 x 2.5 x 10^9/L or there is significant downward trend additional samples may be requested by the monitoring service.

AMBER - Providing the patient's medical condition is satisfactory treatment may continue. The CPMS will alert the prescriber and supply pharmacy to the result but the pocHi user will be responsible for requesting the patient attend for a repeat test as per CPMS amber blood result flow chart (available on eCPMS site).

FALSE RED BLOOD RESULTS (SAMPLE ERROR) – Occasionally a sample, which has either clotted or deteriorated in transit, will produce a false red blood result. To avoid confusion with true red status such a result is classified as **sample error**. In such circumstances, the CPMS will contact the sampling venue and arrange for a repeat sample to be done.

Unsatisfactory samples can occur and can be kept to a minimum by ensuring thorough mixing of the blood with the anticoagulant.

RED - The CPMS will telephone both the psychiatrist and supply pharmacist to inform them that treatment must be stopped **immediately**. An urgent blood sample must be taken and sent to local lab to confirm the result.

Medical staff associated with the CPMS will advise on appropriate local care of the patient. Advice from an independent haematologist is available if required. Any patient whose blood results have fallen into **RED** range will be de-registered from the CPMS database to ensure that Clozapine therapy will not be inadvertently restarted (even if the patient subsequently moves to another locality and an attempt is made inadvertently to restart Clozapine).

Red alert advice

NEUTROPENIA IS A SERIOUS MEDICAL CONDITION

If the patient's neutrophil count is less then 1.5 x 10^9/L, the following advice will help to ensure that the patient recovers quickly from this episode, minimising the time during which the patient's safety is at risk:

1. Follow the CPMS advice.
2. Stop the CLOZAPINE immediately.
3. **DO NOT** give other antipsychotic drugs (use Haloperidol if absolutely necessary).
4. Seek immediate advice from the Consultant Haematologist at General Hospital
5. Arrange **DAILY** neutrophil counts (i.e. full blood count and differential) until the count is above 1.5 x 10^9/L.
6. Observe for secondary infection (i.e. sore throat/fever) and ensure that the patient/carer is aware of the need to watch for signs of infection.
7. **DO NOT RESTART CLOZAPINE**.

SEVERE NEUTROPENIA

Where the neutrophil count of a CLOZAPINE patient is less then 1.0 x 10^9/L **OR** a patient with a neutrophil count between 1.5 and 1.0 develops a fever, it is **EXTREMELY IMPORTANT** to contact the hospital specialist haematologist, or failing this the general medical physician, with regard to the most appropriate

treatment for the patient. This will probably involve transferring the patient to a ward with the facilities for the care of neutropenic patients.

INPATIENTS – Follow the above CPMS advice, contacting the Consultant Haematologist at the General Hospital for patient specific advice and request transfer to appropriate ward at the General Hospital.

OUT-PATIENTS – Contact patient, NOK/Carer/Programme Worker to arrange immediate sample to be done locally by the duty Psychiatrist and conveyed urgently to haematology laboratory for WBC and differential. The patient should bring all medication in with them. Phone the result to CPMS as soon as possible.

Patient should remain at Somerset Partnership site until the result is known. The Consultant Psychiatrist (or deputy) should then contact the Consultant Haematologist (or deputy) at the General Hospital with the result and CPMS advice with a view to admission to an appropriate ward at General Hospital. The pharmacy must also be informed.

Procedure for dealing with request by CPMS for repeat blood following abnormal result:

- Contact patient as soon as possible
- Arrange and obtain further blood sample
- Sample to be tested in pocH-100i machine by trained staff or taken/sent to Local Haematological lab for local analysis
- If local lab is used the results must be obtained from Haematology and phoned/faxed through to CPMS or added to the CPMS website (eCPMS).

Ongoing Physical monitoring and Nursing assessment:

Each patient must have their weight, blood pressure and pulse monitored at each visit. The patient's Consultant Psychiatrist or deputy should be notified:-

- if blood pressure is persistently above 140/90 or
- a single blood pressure reading is above 160/110 or
- if pulse is above 115 beats per minute

Each patient should be assessed for the following at each visit:-

- signs of infection, sore throat etc. Take the patient's temperature if present.
- possible side effects of medication including sedation, constipation, salivation, fits and weight gain.
- evidence of hallucinations, thought disorder, odd ideas and behaviour etc. performing a brief mental state examination and refer psychiatric assessment if required.
- Check smoking status. Notify doctor of any change, as metabolism of Clozapine is affected by tobacco smoking.

Any changes to the patient's physical or mental health should be notified to the patient's Consultant Psychiatrist or deputy and care coordinator.

GP Liaison:

- Any change in the patient's condition or patient's medication should be notified to the GP by the Clozapine Clinic or the Prescriber.

Consultant Review:

- All patients attending the clinic should be reviewed by their Consultant or deputy at least every 12 months.

Record Keeping:

The following information should be available on RiO and in the patient's Care Plan and checked and updated as necessary:

- CPMS or DMS patient number
- Consultant Psychiatrist
- Care coordinator
- Address
- Name/s of carers in the community
- Contact telephone numbers and address of patient/carer.
- GP
- Name but not dose or frequency of concomitant medication

The result of the nursing assessment should be recorded in progress notes in RiO whilst physical monitoring results should be updated in core assessments in RiO.

Medication:

- Medication will be ordered from the supply pharmacy using the appropriate prescription for the clinic (see individual clinic procedure)
- Please refer to Medicines Policy for advice on Storage, Key Holding and documenting individual patient items.

Handing out Medication:

Please refer to Section 19 – Community Teams in the Medicines Policy.

Procedure for clozapine clinic non-attendees

The clinic staff or in their absence the team manager with responsibility for the clinic will action the following:

- Contact the patient at his/her own address and request their attendance
- If no reply, will contact carer or key worker (see referral form) to establish the patient's whereabouts and arrange an appointment

- The patient's blood sample should be taken as soon as possible following a non-attendance either by clinic attendance or home visit.
- Sample to be sent / taken to usual Hospital Haematology Lab for local analysis or tested in the pocH-100i machine by registered nurse/ pharmacy technician.
- The results must be obtained from Haematology and phoned/faxed through to the appropriate monitoring service or entered onto the appropriate website.
- Medication will be released from the supply pharmacy if there is a valid Green blood result.
- When the clozapine arrives the client can return to collect their medication

If no CLOZAPINE is taken for over 48 hours re-titration will have to take place again and the patient will require weekly blood tests according to monitoring service's protocol.

The following Trust Guidelines for re-titration must be followed and are available on the Staff Intranet under Prescribing>Clozapine.

Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in an inpatient setting

Guidelines for the re-titration of clozapine for the treatment of schizophrenia following a treatment break in adults under 65 years in a non inpatient setting

Inpatient Attendees to clozapine clinic

- Whist the client is an inpatient they can attend their local clozapine clinic to have bloods taken and tested through the pocH-100i machine, or bloods can be taken on the ward, labelled with the usual information **plus** the CPMS number, and delivered to the clinic to be tested.
- Clozapine medication will be ordered from the inpatient ward
- On discharge a plan must be put in place for the client to attend their local clozapine clinic for a blood test, physical monitoring and arrangements made for collection of clozapine tablets. Clozapine clinic staff and the care co-ordinators need to be involved in this process.

Clients who have bloods taken at the GP surgery

Some clients who are unable to attend the clozapine clinic have their bloods taken at their GP surgery. The prescription will be sent to the supply pharmacy from the clozapine clinic and is the responsibility of the named nurse running the clinic to ensure client has a blood test.

If the surgery sends the blood to CPMS / DMS these results will be automatically updated on the monitoring system and the supply pharmacy will be able to dispense the clozapine as long as the result is valid.

If the blood is sent to the Local Haematological lab then it is the responsibility of the named nurse who runs the clozapine clinic to enter the blood results on to the monitoring system or fax / contact them with the results. The supply pharmacy will then dispense the clozapine.

If the client has not had a blood test then it is important to follow the procedure for non-attendees but organise for the blood test to happen at the GP surgery.

Plasma clozapine assay

Clozapine dosage is normally adjusted according to clinical response and adverse effect profile. Therapeutic drug monitoring (TDM) of clozapine, i.e., the measurement of clozapine and norclozapine concentrations in an appropriate plasma sample, is not required for routine patient management, but may be helpful in certain situations.

- Dose adjustment: 'trough' plasma concentrations ≥ 0.35 mg/L are suggested to ensure a fair trial of the drug
- Assessment of the impact of changes in smoking habit on clozapine dose requirement
- Investigation of possible dose-related adverse effects
- Poor / non compliance

Further information and a Plasma Clozapine Assay Request Form are available on the Staff Intranet under Prescribing>Clozapine.

A target range for plasma clozapine of 0.35-0.50 mg/L is suggested in treatment resistant schizophrenia, but some patients respond at lower concentrations. The upper limit is likewise not well defined, but there is an increased risk of convulsions at higher doses/plasma concentrations. The measurement of norclozapine can be useful in monitoring adherence, and concentrations average 70 % those of clozapine during normal therapy.

Denzapine plasma level kits are available from the pharmacy team at Cheddon Lodge.

Clozapine suspension – Denzapine®

The licensed clozapine oral suspension available is Denzapine. The oral suspension should only be prescribed if the client is having swallowing difficulties. The client, prescriber and supply pharmacy must all be registered with the Denzapine Monitoring Service. If the patient is currently taking Clozaril tablets their registration will have to be transferred from CPMS to DMS.

Clients will attend the clozapine clinic and bloods will be taken by the registered nurse and sent to usual Hospital Haematology Lab. The results will then be entered onto DMS (https://www.denzapine.co.uk) the following day. The supply pharmacy can dispense medication with a valid blood result and clients can return to collect medication later in the week.

Information on the DMS amber and red result protocols and treatment break processes can be accessed on the Staff Intranet under Prescribing>Clozapine.

Continuing Professional Development:

- Nurses running the Clozapine Clinic should have access to further training/development and supervision applicable to venepuncture and facilitation of the clinic as required.
- Pharmacy and nursing staff trained in the use of the pocH-100i machine must ensure they keep their knowledge of the relevant policies up to date and complete the online Sysmex training yearly.
- All clinic staff must complete the Trust clozapine training every 3 years.

SOMERSET PARTNERSHIP NHS FOUNDATION TRUST **APPENDIX 1**
CLOZAPINE PRESCRIPTION FORM

Name……DOB……..
CONSULTANT……

BLOOD COLLECTION POINT…….

SCRIPT COLLECTION POINT…….

CPMS NO……..MPH NO……..

BLOODS TAKEN: WEEKLY FORTNIGHTLY MONTHY (please circle)

CLOZAPINE MEDICATION							Pharmacy use only
Date	Morning	Midday	Teatime	Night	Doctors signature	Print name	Quantity dispensed

Other medications

Date	Medication	Route / Form	Morning	Midday	Teatime	Night	Doctors signature	Print name	Qty disp

Special instructions…….

Clinic use only

Date ordered						
No of days required						
Date received						

Pharmacy use only

Week 1		Week 2		Week 3		Week 4	
Green blood result YES NO		Green blood result YES NO		Green blood result YES NO		Green blood result YES NO	
Disp by	Checked by	Disp by	Checked by	Disp by	Checked by	Disp by	Checked by

Appendix 2

CONTACTS

CPMS:		
Advice/information (and other services)		**0845 7698269**
Fax		**0845 7698379**
Out of Hours EMERGENCY Service		**01276 692504**
SYSMEX PocH100i Support Line		
pocH-100i Product Support		**0870 902 9228**
Technical Support Hotline		**0870 902 9229**
DENZAPINE	**Tel:**	**01635 568400**
	Fax:	**01635 568401**
SUPPLY PHARMACY:	**Tel:**	**01935 384940**
	Fax:	**01935 432642**
TRUST PHARMACISTS:		**(01823) 368265**
MUSGROVE PARK HOSPITAL HAEMATOLOGY:		**(01823) 342281**
YEOVIL DISTRICT HOSPITAL HAEMATOLOGY		**(01935) 384326**
WESTON SUPER MARE HOSPITAL HAEMATOLOGY:		**(01934) 647050**

CLINIC TIMES AND CONTACT NUMBERS

FOUNDATION HOUSE TAUNTON **Wednesday 9.00 – 12.30**	**Tel: 01823 368350**
GLANVILLE HOUSE BRIDGWATER **Mondays 09.00 – 16.00**	**Tel: 01278 720220**
HOLLYCOURT YEOVIL **Tuesdays 9.00 – 14.00**	**Tel: 01935 428420**
THE BRIDGE WELLS **Wednesdays 9.00 – 12.00**	**Tel: 01749 836600**

Appendix 3

CLOZAPINE CLINIC PROCEDURE
FOUNDATION HOUSE, TAUNTON

Timing:

- Clinic day: **Wednesday** between **0900 – 12.30**

Ordering Medication:

- A clozapine prescription form has been developed for outpatient use (see Appendix 1)
- The senior pharmacy technician (or deputy) is responsible for routinely faxing the prescriptions to the supply pharmacy.
- The supply pharmacy will accept a faxed copy of a patient's original prescription for the repeat dispensing of medication.
- All items on the original prescription must be individually signed by the patient's consultant or a member of the team.
- All original prescriptions will be kept in a file marked Clozaril Clinic Medication Lists (Purple File)
- The 'clinic use only' section must be completed each time the chart is faxed to the pharmacy.
- Electronic copies of the prescription may be maintained within Citrix. Electronic copies must not be saved out of Citrix.
- Gill Chilcott is the nominated person to maintain a file in her Citrix account.
- Any amendments made by Gill to the electronic copy must have first been hand written and signed by the prescriber on the patient's current prescription.
- When a new chart is printed, each item must be signed by a doctor. The old chart must have a line drawn across the page and must be dated.
- The hand written amended prescription should be sent to the pharmacy when a supply is needed, if it is not possible for the electronic copy to be amended.
- All printed copies of the prescription no longer in use must be stored safely for 2 years in a separate place. It is essential that there is a record of all the signed changes to a patient's medication.
- The prescription is designed for dispensing on a maximum of 6 occasions.
- 'Other medications' must only be prescribed after careful consideration of the needs of the individual patients, and this should be reviewed regularly. If possible prescribing of all medication other than Clozapine should be transferred to primary care.
- The need for continued dispensing into monitored dosage systems should be reviewed regularly.
- The faxed prescriptions will be kept by the pharmacy for their records.
- Responsibility on the accuracy of the prescription lies with the prescriber who signs the prescription.

Role of Trust pharmacy staff

A senior pharmacy technician will visit Foundation House twice a week to carry out the following duties:

- Wednesday morning

- to run the clinic with a registered nurse. This will include testing the blood on the PocH-100i machine and if results are normal releasing the medication from quarantine and handing to patients.
- Some clients have a blood 4 weekly but their medication is collected weekly or 2 weekly because of compliance issues or client choice. If the client does not collect medication during the clinic hours this medication is put in the adult team drug cupboard for collection later in the week. The duty nurse will be asked to give medication to the client when they come to collect and the client will sign the documentation.

- Thursday morning

- to release medication from quarantine for clients who did not attend the clinic on a Wednesday morning but have since had a blood test and a valid result.
- To check the pre-dispensed Clozapine for the next clinic received from the supply pharmacy and place in the quarantine cupboard.

	RECEIPT OF MEDICATION FOR CLOZAPINE CLINIC									
	Name of patient		**CPMS No.**	**Date received**	**Checked by**	**Result Ok √**	**Weeks given**	**Given out by**	**Date collected**	**Clients Signature**
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										

Appendix 4

CLOZAPINE CLINIC PROCEDURE
HOLLY COURT, YEOVIL

Timing:

- Clinic day: **Tuesday** between **0900 – 14.00**

Ordering Medication:

- Prescriptions will be generated, stored and amended via the electronic patient record and prescribing system. Only registered prescribers will be able to adjust and sign these. In the event of the electronic prescribing system not being available for a significant amount of time then a paper form has been developed for the Clozapine clinic to use (see Appendix 1).
- The Clozapine clinic nurse (or deputy) is responsible for routinely faxing the prescriptions to the supply pharmacy.
- The supply pharmacy will accept a faxed copy of a patient's original hospital prescription order (HPO) for the dispensing of medication.
- All original prescriptions will be kept in a file marked past Clozapine Clinic prescriptions.(box file in clinic)
- If the paper chart is used, in exceptional circumstances, then the 'clinic use only' section of the chart must be completed each time the chart is faxed to the pharmacy. Each item must be signed by a prescriber.
- All copies of prescriptions/charts no longer in use must be stored safely for 2 years in a separate place. It is essential that there is a record of all the signed changes to a patient's medication.
- 'Other medications' must only be prescribed after careful consideration of the needs of the individual patients, and this should be reviewed regularly. If possible prescribing of all medication other than Clozapine should be transferred to primary care.
- The need for continued dispensing into monitored dosage systems should be reviewed regularly.
- The faxed prescriptions will be kept by the pharmacy for their records.
- Responsibility on the accuracy of the prescription lies with the prescriber who signs the prescription.

Role of Trust pharmacy staff

A senior pharmacy technician may be available for advice and assistance around administrative processes e.g. entering bloods onto CPMS system from local pathology systems.

For general enquires about Clozapine trust pharmacy staff are available.

Pharmacy technicians are also trained in the use of POCHI and may be able to help in the use of these machines or advice re operating them if needed.

Appendix 5

CLOZAPINE CLINIC PROCEDURE
GLANVILLE HOUSE, BRIDGWATER

Timing:

- Clinic day: **Monday** between **0900 -1600**

Clozapine receipt and collection of medication

The medication for the Bridgwater clinic is ordered from the supply pharmacy and delivered to Glanville house. Patients will collect there Clozapine the following Tuesday.

All medication is to be locked away in the drug cupboard and the key is held in the key cupboard in reception.

The Clozapine receipt is on the wall of the clinic room to ensure accessibility for all nursing staff. Clozaril nurses will check the dose and details on the Clozapine receipt at the end of every clinic. A Registered nurse giving out the medication should contact the clinic leads or consult the medical notes from Rio in the first instance if there appears to be a discrepancy. Further to this the information can be checked with the pharmacy if there appear to be any discrepancies when cross checking (01275) 398723. The number for pharmacy is also available on the medication receipt.

The medication will have been checked by a registered Nurse upon delivery to Glanville House. This will be confirmed by a signature and date on the relevant part of the chart. **The medication should not be handed out unless it has been checked against the receipt.**

It's recommended that upon handing out medication the registered nurse will encourage the client/carer to confirm that they are being given the expected medication and that it is in their name. Once it has been handed to the client/carer the Clozapine Receipt should be signed and dated in the relevant section.

An electronic copy of the Clozapine receipt is available from the Medical Secretary or CMHT secretary.

The historic Clozapine receipts will be kept for two years in the clinic filing cabinet for reference if required.

Clinic Procedure

When patients arrive at Glanville House they should report to the reception and the clinic staff will come out to meet them. Patients will normally have pre-arranged appointment times those that come outside these arranged appointments will be seen on a 'first come, first served' basis.

Treatment on the day will comprise of the following:

i) Primary treatment
- Blood test

ii) Secondary treatment
- Assessment of mental state, side effect monitoring, informal emotional support and relationship building
- If any concerns arise the clinic will liaise with medical team, the care Co-ordinator and the CMHT.
- Counselling on medications.
- Wellbeing checks are also carried out regularly as the NICE guidelines for monitoring physical health for patients on anti psychotic medication.

Once the relevant treatment has been carried out, the clinic staff will record the next appointment date in the patient's appointment card and Clozapine diary.

Appendix 6

CLOZAPINE CLINIC PROCEDURE
THE BRIDGE, WELLS

Timing:

- Clinic day: **Wednesday** between **0900 – 12.00**
- This will be managed on each occasion by at least one Nurse who has been appropriately trained and maintained competences in Venepuncture and the use and operation of the Point of Care Haematological Analysis Equipment (POCHA).

Ordering Medication:

- Medication is ordered using the Hospital Prescription Order. This is printed from RIO, individually for Clients.
- It is the responsibility of the Nurse running the Clinic on any given occasions to fax the prescriptions to the supply pharmacy.
- The supply pharmacy will accept a faxed copy of a patient's original prescription chart for the repeat dispensing of medication.
- All items on the original prescription chart must be individually signed by the patient's consultant or a member of the team. This can include a Non Medical Prescriber.
- All original prescription charts will be kept in a file marked Clozaril Clinic and attached to each Client's individual clinic record.
- Any amendments to the RIO electronic prescription must have first been changed by the prescribing doctor or Non Medical Prescriber.
- In the event of the electronic prescribing system not being available for a significant amount of time then a paper form has been developed for the Clozapine clinic to use. (see Appendix 1)
- If the paper chart is used, in exceptional circumstances, then the 'clinic use only' section of the chart must be completed each time the chart is faxed to the pharmacy. Each item must be signed by a prescriber.
- All printed copies of the prescription charts no longer in use must be stored safely for 2 years in a separate place. It is essential that there is a record of all the signed changes to a patient's medication.
- 'Other medications' must only be prescribed via electronic prescribing after careful consideration of the needs of the individual patients, and this should be reviewed regularly. If possible prescribing of all medication other than Clozapine should be transferred to primary care.
- The need for continued dispensing into monitored dosage systems should be reviewed regularly.
- The faxed prescriptions will be kept by the pharmacy for their records.
- Responsibility on the accuracy of the prescription lies with the prescriber who signs the prescription.

Receiving and Storing Medication:

- Medication will be delivered to the Bridge by the Pharmacy delivery system.
- It will be received in reception. A qualified nurse will record acceptance of the medication in the received and given out documentation kept in the Clinic Room (see Medicines Policy)
- The receiving nurse is responsible for storing the medication in the drug cupboard in the Clinic Room.
- Medication is given to individual Clients when they present at the Bridge for a repeat supply of prescribed Clozapine and any other medication included on the current prescription.
- Medication given out should be recorded on the documentation for this purpose.

APPENDIX D

STANDARD OPERATING PROCEDURE

TITLE	**ORDERING CLOZAPINE ON INPATIENT UNITS**
Purpose	To outline the process for ordering clozapine on inpatient units
Scope	Applies to all inpatient nursing and medical staff in mental health services.
Responsibilities	Medical and nursing staff involved in the care of clozapine patients must follow the process outlined to order clozapine supplies for use on the in patient unit.

Document Control

Title:	**Standard Operating Procedure – Ordering Clozapine On Inpatient Units**	
Version	**Date Issued**	**Brief Summary of Change**
1.0	4.6.13	New Standard Operating Procedure for Ordering Clozapine on Inpatient Units
Author(s) name/ job title/ e-mail:		Val Kidner – Senior Pharmacy Technician and Jill Leppard – Lead Nurse for Medicines Management
SOP Number		**MM4**
Approving Group:		**Medicines Management Group**
Date approved:		**4 June 2013**
Implementation date:		**4 June 2013**
Review date:		**June 2016**

Document History

Version	Start date	End date	Author	History

Introduction

This procedure applies to inpatient supplies only. The process for ordering supplies for outpatients is outlined in the Clozapine Clinic Standard Operating Procedure. The process for obtaining clozapine outside of normal pharmacy hours is outlined in the Standard Operating Procedure – obtaining clozapine out of hours.

It is important that clozapine supplies are checked in advance on the ward and nursing staff must ensure that the patient has enough clozapine to cover weekends or bank holidays. This is especially important following dose increases.

Clozapine medication supplied to the ward will always be labelled with the individual patient's name on it. Administration of clozapine must always be from the named supply. It is a serious medication error to supply or administer from another patient's supply.

Procedure

Each time a request for clozapine is made the following forms must be faxed to the supply pharmacy.

- Patient Prescription Form
- Clozapine Escalation chart (if patient is being titrated)
- Patients Drug Prescription and Administration chart or screen shot of electronic patient record client medication screen.
- Fax header

Clozapine will only be released from the supply pharmacy when there is a valid blood test result confirmed by CPMS or DMS.

During initiation the clozapine tablets supplied will be labelled "To be taken as directed by the dose escalation chart". The supply pharmacy will continue to label in this way until there is a stable dose written on the drug chart or electronic patient prescription.

If an inpatient is prescribed a dose which is half a tablet of clozapine, the quantity supplied will be enough for the other unused half tablet to be disposed of following the procedure for the Disposal of Medicines in Section 8 of the Medicines policy. When the patient is discharged, if the patient is still having a half tablet dose then the supply pharmacy will supply the correct quantity of tablets to use both halves of the tablet.

Under no circumstances can a patient go on leave or be discharged with medication labelled to be taken as directed. A patient can only go on leave or be discharged with clozapine that has been clearly labelled with dose and frequency.

Short leave

Weekly blood tests

If the patient is likely to go out on short leave then the weeks supply of clozapine can be ordered in aliquots of the number of days leave the patient is taking e.g. if the patient is going on 2 days leave order a 2 day supply and a 5 days supply.

If leave is unplanned the patient can be given a clearly labelled 7 days supply of clozapine for short leave but it is important that they bring the supply back with them when they return to the ward, as the pharmacy are unable to send a further supply.

Fortnightly and Monthly blood tests

Clozapine should be ordered in aliquots to include leave and ward supply as above.

In exceptional circumstances, dependant on the frequency of the blood test, the supply pharmacy can supply a small additional supply of clozapine past the current due blood test. However, this needs to be agreed with the supply pharmacy or the medicines management team.

Discharge

The patient's existing named supply can be used for discharge as long as it is clearly labelled with directions for the patient including the correct dose and frequency.

Clozapine must be listed on the discharge summary but the prescriber must clearly indicate to the GP that they are not expected to prescribe and to the pharmacy whether or not a discharge supply is needed.

Prior to the patient's discharge the ward must contact the community prescriber to ensure that community prescribing and supply of clozapine is re-established. The ward must also contact the appropriate clozapine clinic to confirm arrangements for the patient's next blood test.

Yeovil District Hospital NHS
NHS Foundation Trust

OUT OF HOURS
Process for Ordering Clozapine Prescriptions

Urgent Clozapine required after cut off times, please ring YDH Pharmacy.

When YDH is not open call the On-Call Pharmacist at YDH

If the on call pharmacist at YDH is called there will be an additional cost of £200.
This must be approved by the on call manager
Delivery will also need to be arranged.

YDH opening hours

Monday to Friday	**09:00 to 17:30**
Saturday	**09:00 to 12:30**
Sunday	**10:00 to 12:00**

Out of hours services

http://ycloud/teams/Pharmacy/Pharmacyoncall

Appendix H

CLOZAPINE CLINICAL AUDIT STANDARDS

26/07/2013

Service area(s) to which standards apply:

✓	**MH Inpatient (CAMHS)**	✓	**Community CAMHS**		**CH Specialist Services**
✓	**MH Inpatient (Adult)**		**C & YP Integrated Therapy**	✓	**MH Specialist Services**
✓	**MH Inpatient (Older)**		**School Nursing**	✓	**MH Community Adult**
✓	**MH Rehab & Recovery**		**Health Visitors**	✓	**MH Community Older**
	Community Hospital		**CH Rehab**		**Learning Disabilities**
	MIU		**Musculo-Skeletal**		**District Nurses**

Ref:
Clozapine Policy 2013 version 1.8 ratified July 2013
Recommended Monitoring for Adult Patients Taking Psychotropics 2013

CLOZAPINE CLINICAL AUDIT STANDARDS				
Standard		**Compliance**	**Exceptions**	**Definitions** *(e.g. any interpretations, directions, or instructions on where/how to find information, **plus** relevant service where applicable)*
1	Monitoring must be carried out by one of the four Trust clozapine clinics, including: • Blood count • Physical monitoring • Side effects	100%	Patient attending GP for monitoring	Clinics: Bridgwater, Taunton, Wells and Yeovil. *(Clozapine policy ref 5.10 and 5.11)*
2	**Patients being monitored by their GP:** Somerset Partnership prescriber is responsible for ensuring that the required physical and side effect monitoring is carried out by the GP. If the GP declines to undertake the required monitoring the prescriber is responsible for ensuring it happens.	100%	None	*(Clozapine policy ref 5.12)*
3	**Blood count monitoring:** All patients prescribed Clozapine must have their full blood count monitored at the appropriate intervals	100%	Patient refusal after stopping clozapine	Full blood cell count with a differential account: • At least weekly for the first 18 weeks of treatment • At least fortnightly between weeks 18 and 52 • 4 week intervals after 1 year of treatment with stable neutrophil counts • Monitoring must continue during treatment and for at least 4 weeks after stopping clozapine *(Clozapine policy ref 5.1)*
4	**Baseline physical monitoring:** Baseline physical checks should be made prior to starting clozapine	100%	None	**Baseline checks:** ECG – if cardiac history or risk factors Weight Blood glucose

CLOZAPINE CLINICAL AUDIT STANDARDS				
Standard		**Compliance**	**Exceptions**	**Definitions** *(e.g. any interpretations, directions, or instructions on where/how to find information, **plus** relevant service where applicable)*
				Lipids FBC LFTs U+Es CPK *(Monitoring for adult patients taking psychotropics guidance)*
5	**Ongoing physical monitoring:** Continuation checks should be made on a regular basis for patients being prescribed clozapine	100%	None	**ECG** – if cardiac risk factors: at maintenance dose, upon admission, after subsequent dose change, offer annually. **Weight** – monthly **BP** – after each dose during titration and at each blood test **Blood Glucose** – After 1 month, then repeat 6 monthly **Lipid**s – after 3 months, then repeat 6 monthly **FBC** – (see standard 3) **LFTs** – 6 monthly **U+Es** – 6 monthly **CPK** – if NMS suspected **Prolactin** – only if symptomatic **Plasma level** – Target concentration for trough level 0.35 – 0.5mg/L *(Monitoring for adult patients taking psychotropics guidance)*

CLOZAPINE CLINICAL AUDIT STANDARDS				
Standard		**Compliance**	**Exceptions**	**Definitions** *(e.g. any interpretations, directions, or instructions on where/how to find information, **plus** relevant service where applicable)*
6	Patients prescribed clozapine should be closely monitored for side effects	100%	None	Side effects discussed with each patient each time blood is tested. *(Clozapine policy ref 5.11)*