

Government of Western Australia South Metropolitan Health Service

Clozapine - General Practitioners Shared Care Program (C-GPSC)

Dr Mitul Bhatt

Head of Service, Consultant Psychiatrist, Fremantle Hospital Mental Health Service South Metropolitan Health Service respectfully acknowledges the past and present traditional owners of this land on which we are meeting, the Noongar people. It is a privilege to be standing on Noongar country.

We also acknowledge that the Aboriginal population in the South Metropolitan Health Service is diverse and includes Aboriginal people from many communities across Australia.

We also acknowledge the contributions of Aboriginal and non-Aboriginal Australians to the health and wellbeing of all people in this country we all live on and share together.

Clozapine

- Clozapine is an effective antipsychotic medication for the management of treatment resistant schizophrenia
- In cases where patients are non-responsive or experience side-effects to at least two neuroleptic agents, Clozapine improves outcomes in around 50-60% of these patients (Meltzer, 1997)
- However, because of the risk of neutropenia and agranulocytosis as well as other potentially life -threatening side-effects, all consumers are enrolled in a registry and monitored regularly



Clozapine

- Benefits
 - Improvement in positive, negative and cognitive symptoms
 - Reduction in suicidal ideation
 - Low extra-pyramidal symptoms compared with other antipsychotics
 - Reduced tendency for aggression leading to an improvement in quality of life
- Risks
 - Agranulocytosis
 - Myocarditis/Cardiomyopathy
 - Seizures
 - Metabolic syndrome

Clozapine

- Clozapine was introduced in 1960s but withdrawn in the 1970s because it caused agranulocytosis
- Clozapine was reintroduced with a strict scheme for neutrophil monitoring
- Since Clozapine was reintroduced in Australia 1993, its use has steadily increased



Clozapine Therapy Monitoring Requirements

- All patients and health care professionals involved in the prescription and supply of Clozapine must be registered with a Clozapine Patient Monitoring System before starting treatment
- Blood monitoring is MANDATORY for the prescription of Clozapine
- Ongoing regular physical health monitoring and side-effects checking



Clozapine General Practitioner Shared Care Model



 This model works with general practitioners to assist in the monitoring of the prescription of clozapine and of patients treated with clozapine

 Strict suitability criteria utilized to identify stable Clozapine consumers who will be discharged back to primary care with regular oversight of a Psychiatrist and Clozapine Coordinator from Fremantle Hospital

Clozapine General Practitioner Shared Care Model

From 1st July 2015 GPs became eligible managing clozapine without needing to be affiliated with a hospital At the same time, Community pharmacies became eligible to dispense clozapine under the Pharmaceutical Benefits Scheme

This meant GPs and community pharmacies could manage maintenance clozapine with regular oversight of a psychiatrist Eastern States, Rockingham, Bunbury, Park and Wanneroo/Butler MHS have a version of the Clozapine General Practitioner Shared Care model.



Clozapine - GP Shared Care Model – Fremantle Hospital

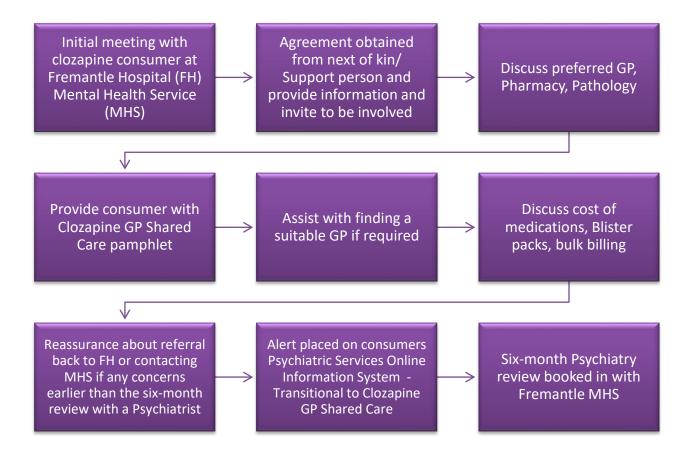
- In October 2023, Clozapine GPSC working group committee was established
- A dedicated Clozapine Care coordinator was appointed to work on the project
- Other Nationwide C-GPSC models were reviewed
- In April 2024, Fremantle C-GPSC Model of Care was finalized
- Suitable patients were identified meeting the criteria
- Out of 128 Clozapine patients, 60 suitable patients were identified
- GP engagement process was started, information sessions done
- Patients were asked to identify their GPs
- Currently there are 16 clozapine consumers in the program

Patient's suitability criteria for Clozapine GP Shared Care

- Active with the Community Treatment Team (CTT) for a minimum of six months with minimal or no case management needs, stable accommodation and readily contactable
- U Clinically stable with no mental health inpatient admissions and good adherence to taking clozapine for a minimum of 12 months
- Stable dose of clozapine for a minimum of three months or the treating psychiatrist considers clozapine dose to be stable
- Able to independently attend blood tests, appointments, and other investigations, or adhere to the requirements of the treatment plan with a personal support person (PSP) when required. The PSP must be readily contactable in case of emergency

The psychiatrist, pharmacist, consumer and GP agree to shared care in the community.

Preparation of patient



Preparation of GP

- Clozapine Coordinator emails GP giving information about the program
 - ClopineCENTRAL Protocol
 - FH Clozapine: General Practitioner Shared Care Policy
- Education session to Practice Manager via phone or face to face
- Phone call to GP if interested to give verbal info or meet prior to consumers appointment
- If GP and client agreeable book initial GP appointment, willing to bulk bill
- Emphasized to GP "Shared Care" and encouraged to contact clinic if there is any concerns before the six-monthly review with a Psychiatrist
- Identify back up GP at each practice willing to also prescribe Clozapine
- Register with ClopineCENTRAL



First GP appointment

Clozapine Coordinator guides GP through Clozapine process:

- Review mental Health and side-effects, highlighting constipation, smoking tobacco and caffeine habits
- Review observations, weight, pulse, blood pressure to screen for Metabolic Syndrome
- Strict monitoring Neutropenia/ Agranulocytosis/ Cardiac implications
- Ensure 4 weekly appointment and script for Clozapine for 28 days only
- Assist with streamline prescribing code
- Review bloods Blood Count record form must accompany Clozapine script for pharmacist to enter ClopineCENTRAL
- Book next month appointment with GP and continue to attend if consumer and or GP request



Community Pharmacies

Clozapine Coordinator will

- Establishes they are registered and already dispensing Clozapine
- Registers them with ClopineCENTRAL
- Offers information sessions to guide pharmacists through the process and ensure they are aware of the responsibilities and are informed of consumer transition to GPSC
- Follow up if there are alerts from ClopineCENTRAL about late blood tests (usually an error at Pharmacy level)

Clozapine side-effects

• Contact FH and consult with a Psychiatrist

 Tachycardia

 check pulse at relaxed state, may commence beta blocker if comfortable

- For chest pain

 send to emergency department
- Consider Cardiology referral

Туре	Very common	Common	Rare
Cardiac	Tachycardia	Electrocardiogram changes	Circulatory collapse, arrythmias, myocarditis, pericarditis
Central Nervous System	Fatigue/drowsiness/ sedation	Extrapyramidal symptoms, seizures, tremor	Confusion, delirium
Haematological/ Lymphatic	N/A	Leukopenia, neutropenia, eosinophilia, leucocytosis	
Metabolic	N/A	Weight gain	Impaired glucose tolerance, aggravated or new onset diabetes mellitus, ketoacidosis
Gastrointestinal	Constipation, hypersalivation	Nausea, vomiting, dry mouth	Dysphagia
Vascular	N/A	Hypertension, postural hypotension, syncope	Thromboembolism (including pulmonary embolism)
Renal		Urinary incontinence or retention	



Agranulocytosis/Neutropenia

- consumer complete bloods test the day before appointment
- GP checks blood results every 4 weeks at GP appointment
- Contact FH if Amber or Red result
- Check for signs and symptoms of infection if results in Amber or Red

Status	WBC and neutrophil count result	Action
'Green' range	WBC ≥3.5 x 10º/L AND Neutrophils ≥2.0 x 10º/L	Following successful registration, commencement of Clopine® therapy is at the discretion of the treating Medical Practitioner.
'Amber' range	WBC ≥3.0 x 10°/L and <3.50 x 10°/L AND/OR Neutrophils ≥1.5 x 10°/L and <2.0 x 10°/L	Wait one week and repeat blood count. If haematological results are still in this range, Clopine® therapy may be commenced under the supervision of the treating Medical Practitioner once registration has been completed.
'Red' range	WBC <3.0 x 10º/L AND/OR Neutrophils <1.5 x 10º/L	Patient is permanently ineligible for treatment with Clopine®. Consult haematologist.

Clopine Haematological Monitoring Guide (Jan17).pdf (wnswphn.org.au)

Constipation

- Can be a serious adverse effect of Clozapine actively evaluate and monitor bowel health at every 4 weekly GP appointment.
- Ask about bowel frequency and intervene if frequency less than 4-5 times weekly e.g. osmotic laxatives
- Advise and encourage patients to modify behaviors improve fiber rich diet, exercise and hydration
- Consult Psychiatrist about dose reduction if deemed necessary



Smoking and Caffeine

Document baseline smoking and caffeine intake habits and update at each clinical review

Smoking

- Cessation of smoking increases clozapine levels which may result in toxicity
- Cigarette smoke decreases clozapine levels
- Nicotine replacement therapy (NRT) does not affect clozapine level

Caffeine

- Caffeine increases clozapine levels which may results in toxicity
- Be mindful of increased/decreased consumption of energy drinks e.g. Coke



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Clozapine-Monitoring-Form-B.PDF (health.wa.gov.au)



Glasgow Antipsychotic Side-Effect Scale

- May go through checklist with consumer to screen for side-effects of Clozapine
- Significant reduction in tobacco smoking may increase Clozapine levels
- Increased Caffeine use may reduce clozapine levels Assess mental state and check clozapine levels
- Long term clozapine consumers tend to have no significant changes in their Glasgow Antipsychotic Side-Effect Scale (GASS) form

GASS for Clozapine

Name:		Current Medications:
Date:		
Caffeine intake:	cups/day	
Smoker: Y / N	cigarettes/day	

This questionnaire is being used to determine if you are suffering from excessive side effects from your medication. Please put a tick in the column which best indicates how often or how severely you have experienced the following side effects.

Ove	er the <u>past week</u> :	Never	Once	A few times	Everyday	Tick if severe or distressing
1	I felt sleepy during the day					
2	I felt drugged or like a zombie					
3	I felt dizzy when I stood up or have fainted					
4	I have felt my heart beating irregularly or unusually fast					
5	I have experienced jerking limbs or muscles					
6	I have been drooling					
7	My vision has been blurry					
8	My mouth has been dry					
9	I have felt sick (nauseous) or have vomited					
10	I have felt gastric reflux or heartburn					
11	I have had problems opening my bowels (constipation)					
12	I have wet the bed					
13	I have been passing urine more often					
14	I have been thirsty					
15	I have felt more hungry than usual or have gained weight					
16	I have been having sexual problems					

Adapted from the Glasgow Antipsychotic Side-effect Scale@ 2007 by St. John of God Hospital and South London and Maudsley Trus

Waddell, Taylor and Hynes 2012 DT,FG,AA, PH, RD comments

Clozapine Side-effect Scale (scot.nhs.uk)

19 20



Clozapine Drug Interactions

Important drug interactions with clozapine CO

Potential to increase clozapine levels	Potential to depress bone marrow	Potential to decrease clozapine levels	Potential to depress respiration	Potential for hypotension	Potential for anticholinergic side effects
 Selective serotonin reuptake inhibitors (SSRI's) Fluvoxamine (very large effect) Fluoxetine Paroxetine Sertraline (large doses) Ciprofloxacin Cimetidine Some macrolide antibiotics including: Erythromycin Clarithromycin Azithromycin Caffeine (large doses) 	 Carbamazepine Trimethoprim / Sulfamethoxazole Nitrofurantoin Cytotoxic medication Immunosuppressant medication Phenothiazines 	 Carbamazepine Rifampicin St Johns Wort Omeprazole Phenytoin Phenobarbitone 	 Benzodiazepines (especially large parenteral doses or at start of therapy) 	 Antihypertensives TCA's (Tricyclic antidepressants) Some antipsychotics e.g. Chlorpromazine Pericyazine Trifluoperazine Risperidone (initially) Quetiapine (initially) 	Anticholinergic TCA's e.g. Amitriptyline Dosulepin Anticolinergic antipsychotics e.g. Chlorpromazine Pericyazine Quetiapine EPSE medication e.g. Trihexyphenidyl Benzaptropine Biperiden Sedating antihistamines e.g. Diphenhydramine Cyproheptadine Promethazine Trimeprazine Gastrointestinal antispasmodics e.g. Atropine hyoscine

Interactions between clozapine and other drugs: SA Health



Green Blood Result

Give to consumer after assessment

CLOPINE® (clozapine) Blood COUNT Record FORM

Blood count results can also be submitted online (www.clopine.com.au) by either the Medical Practitioner, pharmacist or Centre Coordinator.

This form is for recording the patient's WBC and neutrophil count at commencement of Clopine® therapy, during treatment and after discontinuation of therapy.

Each prescription for Clopine[®] must be accompanied by a WBC and neutrophil count no more than 48 hours old. Unless a current WBC and neutrophil count has been performed and assessed as satisfactory, the next prescription for Clopine[®] annucle dispensed.

PATIENT Status (Tick appropriate box)		
ON TREATMENT		
DISCONTINUED	DATE DISCONTINUED: /	/
• TERMINATION OF TREATMENT FORM COMPLETED?	YES/NO (please circle)	
COMMENCEMENT DATE: / /		
(PLEASE Print ALL DETAILS)		
* Clopine® PATIENT NUMBER:		
* DATE BLOOD TAKEN:	/ / WEIGHT:	kg
* WBC COUNT:	x 10%/L	
* NEUTROPHIL COUNT:	× 10%/L	
* PRESCRIBED CLOPINE* DOSAGE:	mg/DAY	
CENTRE: * MEDICAL PRACTITIONER NAME:		
* MEDICAL PRACTITIONER SIGNATURE:		
* PHARMACIST NAME:		
* PHARMACIST SIGNATURE:		
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Authority prescript

Only use Clopine Brand for scripts

- Give Pathology Form for the next 4 x week appointment/blood test – to check full blood count (white blood cells and normal count)
- Six monthly pathology background check including Clozapine Level, electrocardiogram yearly and echocardiogram at 2 years, 5 years and 10 years – continue if clinically indicated.

PHARMACY NAME

Escalation of Care

- GP practice to contact client and next of kin if client does not attend appointment or blood result
- It may be the client will attend the next day as long as treatment has not been missed >2 days
- In urgent situations GP will contact emergency services and inform Fremantle Hospital
- If client has not attended appointment or rescheduled and is not contactable or missed >2 days of treatment <u>complete the referral form (PDF 43KB)</u> fax to 9431 3479. If needed contact 9431 3333 and request Triage officer for urgent referral/ support



Escalation of Care

Contact the Clozapine Coordinator and/or Psychiatrist Fremantle Hospital for any concerns including;

- Significant deterioration in mental state or concerns about mental state.
- Evidence of non-adherence with medication, blood testing or not attending appointments.
- Blood tests are in the red range (white blood cells (WBC)<3.0 x 10⁹/L or absolute neutrophil count (ANC)<1.5 x 10⁹/L)
- Clozapine therapy interruption of greater than 2 days
- Unable to cover a clozapine appointment with a replacement GP in an acceptable time frame to meet clozapine protocol.
- Clozapine dose changes
- Blood test is in the Amber range (WBC 3 3.5 x 10⁹/L or ANC 1.5-2.0 x 10⁹/L) Consumer/personal support person (PSP) requests review
- Consumer/PSP requests review
- Changes to smoking and caffeine habits. Check clozapine level and consult with psychiatrist if adverse effects develop and dose needs to be reduced.
- Planning to conceive, pregnancy or breast feeding
- Navigating procedure for management of clozapine consumers

Recommencing Clozapine after an interruption

Period of interruption (time since the last dose taken)	Dosage	Monitoring requirements
Less than or equal to 48 hours	No change to dosage	No change to monitoring
Greater than 48 hours and less than or equal to 72 hours	Start on 12.5mg once a twice a day. If this dose is tolerated, it may be feasible to titrate the dose to the therapeutic level more quickly than recommended for initial treatment	No additional monitoring requirements
Greater than 72 hours and less than or equal to 28 days	Start on 12.5mg once daily and rapidly titrate up as per new consumer	 The six weeks rule applies Weekly monitored patients Weekly monitoring for six weeks or for as long as needed to ensure a total of 18 weeks; whichever is the greatest Four-weekly monitored patients Weekly monitored for six weeks if no abnormality, resume four weekly monitoring
Greater than 28 days	Restart patient with a new consumer registration form Start at 12.5mg once daily and titrate up as per new consumer	Commence as a new consumer New pre-treatment result and baseline monitoring Weekly monitoring for 18 weeks

Contacts and Resources

ClopineCENTRAL™ Ph: 1800 656 403 Email: <u>ClopineCentral@pfizer.com</u> Fax: 1800 657 454 CNS Clozapine Coordinator 0478 853 990 Email: FH.ClozapineGPSC@health.wa.gov.au Fremantle Hospital Switch 9431 3333 Ask for EGPL 08:30-1630 (Mon-Fri) or Triage 08:00-20:00 (Mon-Sun)

Clopine® Hub <u>| Clopine® Hub Australia</u> (clopinehub.com.au) Clopine[®] Central Login (clopine.com.au)

DoH Multi-page Template (health.wa.gov.au)

WA Health Mental Health Charts and Clozapine Resources)

Thank You



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