Procedure for Monitoring Psychotropic Medication – a guide to essential tests and investigations (Med37)

Document authors	Assured by	Review cycle
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This procedure should be read in conjunction with the following Trust documents:

AWP Medicines Policy (P060)

AWP High-dose antipsychotic prescribing (MG01)

AWP Procedure for the prescribing, administration and monitoring of clozapine (Med20)

AWP Procedure for the prescribing and monitoring of lithium (Med07)

AWP Valproate prescribing for bipolar disorder including in women of child-bearing potential (Med28)

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1. Introduction

People with mental illness have a higher risk of physical illness such as cardiovascular disease and type 2 diabetes. This can result in a reduced life expectancy compared to the general population. This is not entirely due to lifestyle factors such as higher smoking rates, poor diet and substance misuse. These factors can be compounded by the medicines used to treat mental illness. Many of these can cause weight gain and adversely affect lipid profiles. Many have other serious side effects affecting the liver and kidneys.

This procedure contains the recommended physical health monitoring that is required for someone taking psychotropic medication. It does not cover the general health monitoring that is required for people with mental health problems, monitoring of other side effects not associated with physical health, or medication effectiveness.

The current prescriber, in conjunction with the care co-ordinator, should ensure that the regular physical health checks required are being carried out and recorded. This should form part of the care plan. The care plan should include who is carrying out the monitoring and who will follow up, to ensure the agreed monitoring has been carried out.

Most physical health monitoring is best performed in primary care. NICE Clinical Guideline 178: Psychosis and schizophrenia in adults: prevention and management, recommends monitoring of physical health by secondary care for the first year of treatment, or until medicines are stabilised. Local agreements and the treatment setting, in-patient or community, will determine the best arrangement for physical health monitoring.

If a test or examination is not undertaken, the reasons for this should be documented. This may include if a test has recently been undertaken in another setting, or the service user refuses.

If the service user declines any aspect of recommended monitoring, their understanding of why this is recommended should be explored. It may be appropriate to provide additional information regarding this, perhaps using accessible information. Barriers to effective monitoring should also be explored and, where possible, addressed to enable them to have appropriate monitoring. Reasonable adjustments should be considered for those declining blood tests due to needle phobia. If the service user lacks capacity to make informed decisions regarding monitoring, there should be processes to consider what steps may be in their best interests, in line with the Mental Capacity Act 2005.

2. Scope

This procedure applies to nursing, medical, pharmacy and other staff who are involved in providing care to service users taking psychotropic medication.

This procedure is also applicable to key stakeholders in organisations with whom AWP has a working relationship; particularly in situations where the care of the individual may be shared by the GP and an AWP consultant.

This medicines procedure represents the **minimum** recommended monitoring standards. It includes the physical health monitoring and investigations recommended by NICE, the summary of product characteristics (SPC) and other sources, for example the Maudsley Prescribing Guidelines, BNF and AWP medicines procedures.

Prescribers may use their clinical judgement to monitor more frequently if deemed appropriate. Those with pre-existing physical health conditions such as diabetes or dyslipidaemia may need monitoring undertaken as per other guidance, for example NICE.

The schedule relates to adults. Children and adolescents, or those over 65 years, may require increased monitoring or frequency of monitoring.

High dose antipsychotic prescribing will require additional monitoring.

The procedure does not cover the interpretation of the test results or the actions required following abnormal test results. Where abnormal results are obtained, at baseline or during treatment, these should be managed appropriately using NICE guidance where available, and seeking specialist support where appropriate.

Record all relevant clinical information in RiO.

Inform the service user of the results and share with the GP.

Medicines that do not have any specific monitoring requirements listed in the standard reference sources are not included in the tables, but some patients may still have monitoring requirements when taking these medicines, depending on their comorbidities.

3. Abbreviations

BMI	body mass index
BP	blood pressure
ECG	electrocardiogram
eGFR	estimated glomerular filtration rate
FBC	full blood count
LFTs	liver function tests
TFTs	thyroid function tests
U&Es	urea and electrolytes
CK	Creatine kinase
UNL	upper normal limit
HbA_{1c}	Glycosylated haemoglobin

4. Roles and Responsibilities

4.1 All staff working in AWP who are involved in the use of medicines must be aware of this procedure.

4.2 The **prescriber** who is signing the prescription for psychotropic medication is responsible for ensuring that the relevant tests and monitoring are undertaken, as described in this procedure. In emergency/exceptional situations, where the prescriber feels that treatment should be initiated or continued despite limited or no monitoring, then the clinical rationale for this, with a risk: benefit analysis cited, must be documented in RiO.

4.3 On initiating a psychotropic medicine, or amending the dose, the prescriber must inform the patient's GP. The GP should be asked to communicate any physical health findings that might indicate serious side effects or potential side effects of the prescribed medicine. The mental health service must communicate to the GP any relevant physical health findings, in addition to the mental health findings, on a regular and ongoing basis.

4.4 Pharmacy staff working in the AWP pharmacies in Callington Road and Calne are responsible for taking reasonable steps to ensure it is safe to dispense medication to a person named on a prescription. They should ensure they follow the AWP Pharmacy procedure for Screening of Prescriptions in the Dispensary (D039) and Monitoring Blood Results for Service Users taking Clozapine (Z002).

4.5 Locality Lead clinical pharmacists must be assured that the recommended monitoring is being carried out for patients prescribed psychotropic medication on inpatient wards and/or within community teams, in order that ongoing supplies should be made by the AWP Pharmacy. If the pharmacist has concerns, these must be addressed with the prescriber.

5. Recommended monitoring

5.1 Antipsychotics

Class	Drugs	Baseline monitoring Starting/changing	Monitoring 0 - 12months	Monitoring at 12 months and thereafter	Ongoing monitoring	Further information
Antipsychotics	All antipsychotics (except clozapine)	• Weight/ BMI • Waist circumference • BP & pulse • Lipids • HbA1c (for those with diabetes continue as per NICE) • U&Es • LFTs • FBC • Prolactin * • ECG** • TFTs (quetiapine) • Creatine phosphokinase (CK)	Weekly: • Weight/BMI for first 6 weeks • Side-effect monitoring At 3 months: • Weight/BMI • BP & pulse • Lipids • HbA1c • Side-effect monitoring • TFTs (quetiapine) • Prolactin* in symptomatic individuals or sooner where indicated Lipids and HbA1c can be repeated again if there are concerns. For those with a higher baseline risk of developing diabetes, 3 monthly HbA1C should be undertaken.	• Weight/BMI • Waist circumference • BP & pulse • Lipids • HbA1c *(Continue monitoring every 3-6 months for patients with a higher baseline risk of developing diabetes)* • U&Es • LFTs • FBC • TFTs (quetiapine) • ECG • Side-effect monitoring	Annually **Except:** CK monitoring if clinically indicated (i.e. NMS suspected) **Side effect monitoring:** Weekly for the first month after starting a new treatment. Including (but not limited to): Assessment of movement disorders Enquiry about sexual side effects Enquiry about menstrual changes (if applicable)	Ref: NICE CG178 Weight & waist circumference to be plotted on a chart *Consult MG12 for further information. A baseline of >1000 mIU/L would require further investigation and possible referral to endocrinology. **ECG – if stated in SPC, personal history, or family history of cardiovascular disease, high BP, admitted as an inpatient, taking other medication known to cause ECG changes or on high-dose antipsychotic therapy (MG01). After initiation period, ongoing monitoring required at least every 6 months if high dose antipsychotic prescribing (MG01) Olanzapine Long-acting Injection – mandatory 3hr post-dose monitoring (MG09)

5.2 Clozapine

Class	Drugs	Baseline monitoring Starting/changing	Monitoring 0 -12 months	Monitoring at 12 months and thereafter	Ongoing monitoring	Further information
Clozapine	Clozapine	• Weight/BMI • Waist circumference • BP & pulse • Lipids • HbA1c • U&Es • LFTs • FBC • ECG • Temperature • Troponin & CRP • CK • Bowel function* • Smoking status** **Note:** pre-dose monitoring of temperature, pulse and blood pressure for all doses during titration phase.	Weekly: • FBC for first 18 weeks • Weight for first 6 weeks • Troponin and CRP for the first 4 weeks Fortnightly: • FBC for 18-52 weeks At 4 weeks • Weight/BMI/ waist circumference • HbA1c • Lipids At 3 months: • Weight/BMI /waist circumference • BP & pulse • ECG • HbA1c At 6 months: • Clozapine plasma level At 6 and 9 months: • Weight/BMI • Lipids • HbA1c • LFTs at 4-6 months • BP & pulse	• FBC (mandatory)	4 weekly	Ref: NICE CG 178 AWP Procedure for the prescribing, administration and monitoring of clozapine (Med20) *bowel function should be reviewed on a weekly basis for the first month and then reviewed as required, but at least on a 3-monthly basis. **smoking status should be reviewed on a weekly basis for the first month and then as required, but at least on a 3-monthly basis. *Recheck clozapine plasma level if smoking status has changed at least 5 days previously.* **Side-effect monitoring** – as per Antipsychotics section
				• Weight • Waist circumference • BP & pulse • Lipids • U&Es • LFTs • HbA1c *(Continue monitoring every 4-6 months).* • ECG • Clozapine plasma levels are recommended annually by ZTAS as change in metabolism can occur with age	Annually **Except:** CK monitoring if clinically indicated (i.e. NMS suspected) Clozapine plasma level can be done more frequently as indicated. Ensure dose stable for at least 5 days before sampling. Trough sample (at least 6hrs post-dose) is recommended.	

5.3 Mood stabilisers

Class	Drugs	Baseline monitoring Starting/changing	Monitoring 0 - 12 months	Monitoring at 12 months and thereafter	Ongoing monitoring	Further information
Mood Stabilisers	Lithium	• Weight or BMI • U&Es plus calcium • eGFR • TFTs • FBC • ECG if cardiovascular disease or risk factors	1 week after initiation and each dose change: • Lithium level Weekly: • Lithium level until levels stable Every 3 months: • Lithium level Every 6 months: • Weight or BMI • U&Es plus calcium • eGFR • TFTs	• Lithium level (with risk factors e.g. older adult, interacting drugs, raised calcium level, plasma level > 0.8, poor adherence, poor symptom control, impaired renal or thyroid function)	3 monthly	Ref: NICE CG185 Monitor lithium dose and level more frequently if urea and creatinine levels become elevated or eGFR falls over 2 or more tests. If evidence of impaired renal or thyroid function repeat U&Es and TFTs more often AWP Procedure for the prescribing and monitoring of lithium (Med07)
				• Lithium level (no risk factors)	6 monthly	
				• Weight or BMI • U&Es plus calcium • eGFR • TFTs	6 monthly	
	Valproate/ valproic acid	• Weight or BMI • FBC • LFTs	At 6 months: • Weight or BMI • FBC (stop valproate immediately if blood dyscrasia detected) • LFTs (increase monitoring frequency if abnormal; if persistently elevated to over 3 times the upper limit of normal (ULN), continuing to rise or accompanied by clinical symptoms, the drug should be withdrawn)	• Weight or BMI • FBC (stop valproate immediately if blood dyscrasia detected) • LFTs (increase monitoring frequency if abnormal; if persistently elevated to over 3 times the upper limit of normal (ULN), continuing to rise or accompanied by clinical symptoms, the drug should be withdrawn)	Annually	Ref: NICE CG185 Do not offer valproate to females of childbearing potential (aged 0-54), unless other options are unsuitable and pregnancy prevention programme is in place [MHRA]. Do not routinely measure plasma levels unless there is evidence of ineffectiveness, poor adherence or toxicity. See AWP Procedure for Prescribing Valproate for Mental Health Conditions in Women of Childbearing Potential (Med28).

Class	Drugs	Baseline monitoring Starting/changing	Monitoring 0 - 12 months	Monitoring at 12 months and thereafter	Ongoing monitoring	Further information
Mood Stabilisers	Carbamazepine	• U&Es • FBC • LFTs • Weight/BMI • ECG* if cardiovascular disease or risk factors	At 2-4 weeks: • Plasma levels (recommended in Maudsley) At 6 months: • U&Es • FBC • LFTs • TFTs • Weight/BMI	• U&Es • FBC • LFTs • Weight/BMI if patient gains weight rapidly • TFT	U&Es every 6 months, LFTs and FBC annually Plasma levels 2 weeks after dose changes	Ref: SPC and Maudsley (p264. NB: formulary and listed as an option in Maudsley but not recommended by NICE CG185. Plasma levels should be undertaken 2 weeks after initiation and dose changes, thereafter do not routinely measure unless evidence of lack of effectiveness, poor adherence or toxicity. *If abnormalities detected, repeat ECG after each dose increase as a minimum
	Lamotrigine	• FBC • U&Es • LFTs	At 6 months: • FBC • LFTs	• FBC • LFTs	Annually	Ref: NICE CG185 and SPC Do not routinely measure plasma levels. Monitoring should be undertaken if stopping or starting interacting drugs, such as hormonal contraceptives or some HIV medicines – see SPC.

5.4 Antidepressants

Class	Drugs	Baseline monitoring Starting/changing	Monitoring 0 - 12months	Monitoring at 12 months and thereafter	Ongoing monitoring	Further information
Antidepressants	All antidepressants	• Sodium, in patients at high risk of hyponatraemia*	After 2-4 weeks, then 3 monthly: • Sodium, in patients at high risk of hyponatraemia*	3 monthly: • Sodium, in patients at high risk of hyponatraemia*	Every 3 months	Ref: NICE CKS and Maudsley *Risk factors include: older age, female gender, major surgery, history of hyponatraemia or a low baseline Na concentration, co-therapy with other drugs known to be associated with hyponatraemia, reduced renal function, medical co-morbidity, low body weight.
	Citalopram Escitalopram	• ECG in those with cardiac disease, additional risk factors** and those over 65 years old • U&Es including potassium & magnesium	3 monthly: • U&Es including potassium and magnesium in elderly or those taking diuretics or proton pump inhibitors • ECG if cardiovascular symptoms develop	• U&Es including potassium and magnesium in elderly or those taking diuretics or proton pump inhibitors • ECG if cardiovascular symptoms	Annually if in high risk group, including those over 65 years old	**Ref: MHRA for extra risk factors for QT prolongation
	Mirtazapine	• Consider FBC if history of bone marrow suppression and blood dyscrasias			If clinically indicated	Risk of blood dyscrasias. Ref: BNF FBC if clinically unwell and signs of bone marrow suppression present.
	Duloxetine	• BP	After 1 month: • BP			Ref: SPC, NICE CKS
	Venlafaxine	• BP	After initiation and after each dose change:	• BP Cholesterol if on long-term	6 - 12monthly	Ref: SPC, NICE CKS

			• BP	therapy		May be associated with mydriasis therefore it is recommended that patients with raised intraocular pressure or patients at risk for acute narrow-angle glaucoma be closely monitored.
	Agomelatine	• LFTs (On initiation and if dose increased) Do not start if ALT or AST exceed 3x upper normal limit (UNL)	At 3, 6, 12 & 24 weeks: • LFTs If dose increased repeat LFTs at 0, 3, 6, 12, 24 weeks	If clinically indicated: • LFTs If ALT/AST increase repeat LFTs after 48 hours, and repeat until return to normal		Ref: SPC Non-formulary Discontinue if ALT or AST exceed 3xUNL

6. Therapeutic Drug Monitoring (TDM) of antipsychotics

In order to optimise antipsychotic treatment, therapeutic drug monitoring (TDM) can be considered, particularly if high-dose monotherapy or combined antipsychotic treatment is being considered. It should be noted that TDM monitoring is not mandatory and is only helpful for select individuals. Not all antipsychotics have a well-defined therapeutic plasma range for efficacy, however TDM may also be employed as a strategy to monitor adherence to treatment over time.

Magna Laboratories are able to process requests for antipsychotic plasma assays and this requires a sample to be posted to the lab. Results would normally be communicated via email +/- post to the locality lead pharmacist and Responsible Clinician/ Consultant, within three working days of the sample being received. Consultant and pharmacist details must be entered on the assay request form. TDM requests for antipsychotics other than clozapine should be discussed with a clinical pharmacist prior to ordering.

Magna Laboratories are able to offer an antipsychotic plasma assay service for the following medications; some medicines have a metabolite that can also be measured:

Drug	**Metabolite**
Clozapine	*Norclozapine*
Olanzapine	
Aripiprazole	*Dehydro-aripiprazole*
Risperidone	*Paliperidone (9-hydroxyrisperidone)*
Haloperidol	
Quetiapine	*Norquetiapine*

Plasma assay kits, request forms and pre-printed postal bags are available from the Magna labs website, www.magnalabs.co.uk, or speak to your local pharmacy team to obtain.

Contact details for the lab:

Magna Laboratories Limited, Unit 5 Chase Industrial Estate, Alton Road, Ross-on-Wye, Herefordshire, HR9 5WA

Tel: 01989 763 333 - Fax: 01989 763 533 - www.magnalabs.co.uk - Email: info@magnalabs.co.uk

7. Related Procedures

Med23 Rapid Tranquillisation: Procedure for the use of medication to manage disturbed behaviour on inpatient mental health units for Adults, Older Adults and Adolescents

Med07 Procedure for the Prescribing and Monitoring of Lithium

MG03 Guidelines for the use of Zuclopenthixol Acetate 50mg/ml Injection (Clopixol Acuphase®)

MG06 : Citalopram and escitalopram dose and QTc prolongation risk flow chart based on advice from the MHRA.

MG09 Olanzapine Long Acting Injection (Zypadhera®)

MG18 Prescribing Guidance for Mental Health Prescribers and GPs in Perinatal Mental Health

8. References

NICE CG178: Psychosis and schizophrenia. February 2014

NICE CG185: Bipolar disorder, assessment and management. Feb 2020

NICE Psychosis and schizophrenia in adults Quality standard [QS80] Published date: February 2015

The Maudsley Prescribing Guidelines, 14th Edition. 2021

Summary of Product Characteristics medicines.org

BNF BNF online

MHRA: Clozapine and other antipsychotics: monitoring blood concentrations for toxicity. August 2020

Version History

Version	Date	Revision description	Editor	Status
0.4	17.11.17	Reformatted as Medicines Guideline	SB	Draft
1.0	28.11.17	Approved at MOG	SJ	Approved
1.1	04.12.19	Agreed document validity extension outside of MOG by Chief Pharmacist and Deputy Medical Director	JS	Approved
1.2	06.12.19	Reviewed as per 2 year cycle. Check and update of references. Review of monitoring required for various medication groups. Feedback from medical staff received 11.11.19. Feedback from Nursing and Quality 2-12-19. Recommendations from Regulation 28 report preventing future deaths added 6-12-19	BB	Draft
1.3	13.12.19	Reformatted as Medicines Procedure	BB	Draft
2.0	17.12.19	Approved by Medicines Optimisation Group		Approved
2.1	20.01.20	Addition of paragraph 4.3: advice about the need to communicate with the GP and to request that the GP communicate to the mental health team, about physical health findings. Approved by Associate Medical Director, Dr Peter Wood and Chief Pharmacist, Valerie McElhinney	V McElhinney	Approved
3.0	20.01.20	To be ratified by noting at MOG meeting in January 2020		Approved
3.1	29.01.20	Monitoring frequency for HbA1c amended following feedback during MOG Jan meeting.	B Browning	Draft
3.2	05.02.20	Amended wording to section 4.2 as per MOG meeting recommendation. Approved secondary to amendments	J Scott	Draft

4.0	05.02.20	Approved by MOG Chair following amendments		Approved
4.1	28/4/20	Review of content	E Brennan-Rist	Draft
4.2	12/6/20	Update following MOG meeting	E Brennan-Rist	Draft
5.0	26/05/20	Approved by the Medicines Optimisation Group		Approved
5.1	24/11/2020	Changes to clozapine plasma level monitoring recommendations following recent safety alert and POMH webinar. Addition of antipsychotic TDM monitoring	S Belcher B.Browning	Draft
5.2	13/07/2021	Review meeting with C.Broughton Eendo consultant), A.Day (Biochemist), E.Ewins, N.Leyland (Consultant Psychiatrists) and S.Belcher (Pharmacist) following comments from MOG	S.Belcher	Draft
5.3	23/11/2021	Approved by MOG		Approved
5.4	10/05/2022	Review of content. Removal of mandatory FBC for mirtazapine. Resources and references updated	H Chau	Draft
6.0	24/05/2022	Approved by Medicines Optimisation Group		Approved
6.1	26/07/22	Troponin made mandatory following SBAR discussed at MOG	S.Belcher	Draft
6.2	26/07/2022	Change approved by Medicines Optimisation Group	MOG	Final