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Clinical Guideline

Physical Health Monitoring for patients prescribed antipsychotics and mood stabilisers

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgment should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

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Contents

Introduction

Clinical guidelines for shared care facilitate the sharing of care and transfer of prescribing for medications that have previously been used in secondary care to primary care. The goal of this agreement is to provide consistency in the monitoring of these medications and to provide a framework to allow them to be safely prescribed in the community by primary care.

The risks of specialists prescribing medicines via HBP prescriptions in the community include:

- Potential for high risk interactions between the patient's other medicines and the suggested new psychotropic. These are often picked up when the new medicine is added to the GP prescribing system.
- Potential for new medicine not to be included in compliance aids increasing the risk of non adherence to treatment.
- Potential for suggested medication being prescribed without full knowledge/access to medical history. For example- history of QTc prolongation, epilepsy.

It is hoped that, in the context of this agreement/guideline GPs (and the ever expanding primary care team) will have the knowledge and confidence to prescribe psychotropic medicines and monitor patients appropriately.

Why is physical health monitoring required?

Therapies for mental health conditions range from talking therapies, art therapy and medication. Medication regimes can be relatively simple with one drug or complex with a high risk antipsychotic augmented by a second antipsychotic and a mood stabiliser. In the treatment of bipolar affective disorder (BPAD) and schizophrenia medication is a mainstay of therapy [2]. Patients living with BPAD or schizophrenia are likely to die 15-20 years younger than the general population [3]. This is due to a multitude of factors including:

- side effects of medication
- chaotic lifestyles, poor diet
- Increased risk of developing diabetes and heart disease
- An increased incidence of smoking in this population.

This clinical guideline includes guidance on the physical health monitoring that is recommended for patients prescribed:

- Antipsychotic medication
- Mood stabilizers

Appendix 1 contains a list of the included medicines.

Responsibilities

Consultant/ specialist service responsibilities:

- Perform mental health assessment prior to advising psychotropic medication
- Discuss the proposed medication, any alternatives, risks and potential benefits with the patient, offer written information and an opportunity to ask questions
- Request that the GP initiate psychotropic medication after baseline investigations have been completed
- Monitor for side effects of the medication, document these and inform all concerned if these occur, taking appropriate action
- Inform the GP of patients' response to medication and general progress
- Inform the GP of any change in the medication dose or if it is to be stopped
- Ensure a copy of this guideline is available to the GP
- To liaise with the GP on how to manage any abnormal results which may occur during psychotropic drug monitoring

GP/ Primary care responsibilities:

- Initially, to refer the patient for specialist advice, following appropriate physical investigation including blood tests, ECG and appropriate scans (where indicated)
- Review the patient and if need be seek specialist advice from the psychiatrist or CMHT
- Monitor for side effects of the medication, document these and inform all concerned if these occur, taking appropriate action (*see appendix 2 for common side effects*)
- Arrange via the treatment room the initial investigations within a reasonable timescale to establish a baseline and any ongoing required investigations
- Inform the psychiatry team should the patient decline the initial investigations
- Inform and discuss any abnormalities or concerns arising from the physical investigations
- Initiate and prescribe the medication in line with the recommendations from the CMHT

Note: A patient declining the initial investigations should not delay their commencement of treatment. The CMHT should be advised of this, but may recommend that the medicine is started and baseline investigations are completed once the clinical situation stabilizes.

Antipsychotic Medicines: Physical Health Monitoring Requirements

Parameter	Suggested frequency	Action to be taken if results outside reference range	Drugs with special precautions
Urea and electrolytes (including creatinine or eGFR)	Baseline and then annually	Investigate all abnormalities detected	Amisulpiride and sulpiride renally excreted – consider reducing dose if GRF reduced
Full blood count	Baseline and annually	Stop suspect drug if neutrophils fall below $1.5x10^9$/L – refer to psychiatrist for review Refer to haematology if neutrophils below $0.5x10^9$/L	Clozapine- weekly for 18 weeks, then fortnightly up to 1 year, then monthly
Blood lipids (fasting cholesterol and triglycerides)	Baseline, at 3 months, annually	Offer lifestyle advice Consider changing antipsychotic and/or initiating statin therapy – refer to psychiatrist for review	Clozapine, olanzapine – 3 monthly for the first year
Plasma Glucose (fasting)	Baseline, at 6 months, annually	Offer lifestyle advice. Obtain fasting sample and HbA_{1c} Refer to diabetes if required	Clozapine, olanzapine, chlorpromazine – baseline, 1 month, then 6 monthly
Liver function tests	Baseline, annually	Stop suspect drug if LFTs indicate hepatitis (transaminases x 3 normal) or functional damage (PT/ albumin change) – refer to psychiatrist	Clozapine and chlorpromazine associated with hepatic failure (rarely)
Prolactin	Baseline, at 6 months, annually taken at least 1 hour after waking	Recheck if raised (>557mIU/L) and refer to psychiatrist for review Arrange MRI pituitary fossa if >2500mIU/L Refer endocrinology if prolactinoma identified; if symptomatic hyperprolactinaemia and stopping/swapping antipsychotic not possible or if hyperprolactinaemia persists despite medication changes – Consider DEXA scan to	High risk of high prolactin: amisulpiride, sulpiride, risperidone and paliperidone. Aim to avoid in patients under 25y (before peak bone mass); young women (possible increased risk of breast cancer) and those with osteoporosis or hormone dependent breast cancer.

		assess bone mineral density if chronically raised Switch medication if amenorrhoic and wishing to achieve pregnancy.	
Creatinine phosphokinase (CPK)	Baseline, then if NMS suspected		More likely with first generation antipsychotics
Weight (include waist size and BMI)	Baseline, monthly for 3 months, then annually	Offer lifestyle advice Consider changing antipsychotic and/or dietary / pharmacological intervention	Clozapine and olanzapine - + 3 monthly for first year
Blood Pressure	Baseline, frequently during dose titration/ annually	Severe hypotension or hypertension observed – slow rate of titration Consider switching antipsychotic if symptomatic postural drop Treat hypertension in line with local guidance	Clozapine, chlorpromazine and quetiapine most likely to cause postural hypotension
ECG	Baseline and when target dose reached, annually, on admission to hospital and before discharge if medicines changed	Discuss with/refer to cardiologist if abnormality detected If QTc prolonged- contact psychiatrist for review of antipsychotic	Haloperidol- ECG mandatory

Antipsychotic Monitoring Form

Patient Name:	CHI:
Address:	Consultant/CMHT:
	Antipsychotic prescribed: Date started:

Parameter	U&E	FBC	LFTs	Lipids	Glucose	Prolactin	CPK
Baseline							
Month 3							
Month 6							
Year 1							
Year 2							
Year 3							
Year 4							
Year 5							

Parameter	ECG	Blood pressure	Pulse	Weight	BMI	Patient education	Smoking status
Baseline							
Month 1							
Month 2							
Month 3							
Month 6							
Year 1							
Year 2							
Year 3							
Year 4							
Year 5							

Date	Abnormality noted	Action taken

Clozapine

The physical monitoring required for patients prescribed clozapine is the same as all other antipsychotics with the following additions:

Parameter	Suggested frequency	What to do if abnormal	Note
Troponin I	At baseline, week 1, week 2, week 3 and week 4 (this will likely be done in secondary care)	If raised – stop clozapine	This is done due to the risk of myocarditis and cardiomyopathy
CRP	At baseline, week 1, week 2, week 3 and week 4 (this will likely be done in secondary care)	If raised – stop clozapine	This is done due to the risk of myocarditis and cardiomyopathy
Full blood count	Weekly for first 18 weeks Then fortnightly up to 1 year Then monthly	As per Green, Amber, Red results guidance/ contact psychiatry urgently if Red If amber- increase FBC to twice weekly If red- stop	This is monitoring for the agranulocytosis/ neutropenia
Smoking Status	At every appropriate consultation	If smoking status changes contact mental health team as dose may need to be changed	If a patient stops smoking clozapine levels can increase significantly increasing the risks of side effects and toxicity. Similarly if a patient starts smoking levels will drop and the patient is at risk of relapse.
Constipation	At every appropriate consultation	If constipation is reported by a patient treat aggressively with laxatives, advise fibrous diet and inform mental health team as clozapine dose may need to be reviewed	Clozapine has been implicated in faecal impaction, gastric immobility including deaths. Constipation must be taken very seriously and treated with a combination of an osmotic and stimulant laxative.

High Dose Antipsychotic Monitoring

For full information on high dose antipsychotic monitoring refer to the clinical guideline on the intranet.

High dose antipsychotic prescribing is defined as:

- A total daily dose of a single antipsychotic which exceeds the upper limit stated in the summary of product characteristics or BNF;
- A total daily dose of two or more antipsychotics which exceeds the summary of product characteristics or BNF maximum using the percentage method.

It is the responsibility of the consultant psychiatrist:

- Alert the GP to the prescribing of a high dose antipsychotic regime;
- To request high dose antipsychotic monitoring at appropriate intervals;
- To communicate any risk factors which may put the patient at additional risks of side effects;
- To update the high dose monitoring form on the psychiatric EMIS record.

It is the responsibility of primary care:

- To undertake requested monitoring and report any abnormalities to the mental health team
- The monitoring required includes ECG, Blood pressure, heart rate, weight, U&E (including lipid profile, prolactin and thyroid function, glucose), LFTs, and FBC every 3- 6 months when requested by consultant psychiatrist.

High Dose Antipsychotic Monitoring Form

This form must be completed for all high dose therapy patients – preferably prior to commencing treatment.

Name:	**DOB:**
CHI:	**Consultant:**
Date of initiation of high dose:	

PMH – contraindications/Cautions				**Possible drug interactions**
History of cardiac disorders?	**Y**	**N**		Identified interaction Y N *(please detail drugs below)*
Hepatic impairment?	**Y**	**N**		1. Drugs known to prolong QTc interval
Renal impairment	**Y**	**N**		
Obesity	**Y**	**N**		2. Pharmacokinetic interaction
Heavy smoker	**Y**	**N**		
Heavy alcohol intake	**Y**	**N**		3. Diuretics
Old age	**Y**	**N**		
Details:				

If there are any relative contraindications highlighted please state reasons why high dose therapy is to continue:

Rationale for High-Dose Antipsychotic Therapy

Failure to respond to Clozapine		During the switch of one antipsychotic to another	
Failure to tolerate Clozapine		As a temporary measure during an exacerbation of illness	
Partial response to Clozapine: as augmentation		Other:	

Consent Obtained Patient Consent ☐ Section 47 ☐ T2 ☐ T3 ☐

Prescription details

Start Date	Drug(s)	Dosage/frequency:	% BNF max	
				Total daily % BNF max

Signature: ---------- Print Name: ----------

Record of clinical monitoring (tick box when occurs) on 3 month basis. If results are abnormal, record in nursing/medical notes & inform the patients consultant. It is not anticipated that every patient will have CGI, HoNoS, GASS & LUNSERS performed but formal assessment of progress & side-effects is good practice,

Test	Pre-HDAT	After dose changes	On going	On going	On going	On going	On going	On going	On going
Date→									
ECG									
U&Es									
LFTs									
FBC									
CGI									
HoNos									
GASS									
LUNSERs									

Mood Stabilisers

Drug	Therapeutic Range	Time to steady state	Frequency	Ideal Sampling time	Monitoring Recommendations	
					Pre treatment baseline	Other regular checks
Carbamazepine	4.0-12.0 mg/l Take a trough level before first dose of the day	1-2 weeks	Check 2-4 weeks after a dose increase	Initiation of therapy: after 2 to 4 weeks Change in dose: after 2 weeks Sample immediately before next dose due	• FBC • U &Es • LFTs • Weight /BMI • Thyroid function • ECG if risk factors for or existing CVS disease.	At 6 months :FBC, U &Es, LFTs, weight Recheck ECG if abnormalities detected after each dose increase
Lithium	0.4- 1.0 mmol/L For elderly patients 0.4-0.8 mmol/L	5- 7 days	One week after starting Li, one week after each dose change and weekly until levels stable. Then 3 monthly	Initiation of therapy or change in dose: 5-7 days 12 hours post dose If BD liquid prescribed, sample immediately before next dose due	• eGFR, • U&Es, • T4/TSH, • BP, • Pulse, • Weight, BMI • ECG, • Ca • FBC if clinically indicated	All of baseline every 6 months *Frequency of ECG: new guidance 6 monthly but under review* *See Lithium clinical guideline*
Sodium Valproate	40-100mg/L Optimum at least 50mg/L	2- 3 days	Not routinely- only if control poor, toxicity suspected or compliance questioned. Short half life and diurnal variation make interpretation of single value difficult. Serial levels more accurate.	Sample immediately before next dose due	• LFTs • FBC • U&Es • Weight/BMI • Highly teratogenic: not to be prescribed in women of childbearing potential*(refer to the SMSC guidelines below?	First 6 months, then yearly: LFTs, FBC , weight
Lamotrigine	Not established but suggest 2.5 – 15mg/L	5 days	Not routinely – as for Na Valproate	Sample immediately before next dose due	• FBC • LFTs • U&Es	

References:
The Maudsley Prescribing Guidelines 12th Edition: Physical monitoring for people with BPAD.
NICE Clinical Guideline CG185: Bipolar Disorder: the assessment and management of bipolar disorder in adults, children and young people in primary and secondary care.
www.medicines.co.uk Electronic Medicines Compendium (accessed 27th July 2017)
CMO letter June 2017 Physical monitoring of patients on Lithium

Lithium

For full details on lithium initiation, side effects, toxicity and how to manage this refer to the NHS Borders Lithium protocol available on the intranet.

Parameter	Suggested frequency	What to do if abnormal	Note
Lithium levels	Weekly during dose titration, 5-7 days after increase of dose or addition of interacting medicine Once dose stable: 3 monthly	See NHS Borders policy on dose adjustments in response to lithium levels. If greater than 1mg/ml – stop lithium as risk of toxicity	Sample should be taken approximately 12 hours post dose
Urea and electrolytes (incl creatinine and eGFR)	Baseline ,then 6 monthly. Monitor more frequently (every 3 months) if renal impairment, patient takes medicines which affect renal function such as ACE inhibitors or NSAIDs or diuretics.	If eGFR/ creatinine clearance falls rapidly <45ml/min review lithium, refer to psychiatrist and consider renal referral Investigate and correct hyponatraemia/ hypernatraemia	
Thyroid function	Baseline and then 6 monthly	Treat hypothyroidism as necessary	Monitor more often if impaired thyroid function or an increased in mood symptoms
Calcium	Baseline and 6 monthly	Treat as necessary	
ECG	Baseline and then if clinically indicated	Discuss with cardiology if abnormal. If QTC is prolonged discuss with psychiatry as a review is indicated	Note: many other medicines which may also be prescribed also cause QTc prolongation. Be cautious and if possible get a baseline ECG before starting other psychotropic medicines
BMI	Baseline and 6 monthly	Offer lifestyle advice	
Side effects	At every clinical contact	If problematic refer to psychiatry for review	
Signs and symptoms of toxicity	At every clinical contact	As per lithium protocol, urgent lithium level, stop lithium	Check that the patient is aware of signs/symptoms and when to get help
Interacting medicines	At every clinical contact	Be aware of over the counter meds eg ibuprofen	Review all interacting medicines
Pregnancy planning	Baseline and annually	Refer to psychiatrist if planning a pregnancy/ discuss contraception regularly	Lithium has been associated with cardiac malformation after in utero exposure. 80% pregnancies in patients with severe mental illness are unplanned.

Appendix 1: List of applicable medicines

Antipsychotics (includes oral and injection formulations)	**Mood Stabilisers**
Chlorpromazine	Lithium
Flupentixol	Valproate (all formulations)
Haloperidol	Carbamazepine
Pericyazine	Lamotrigine
Sulpiride	
Trifluoperazine	
Zuclopenthixol	
Amisulpiride	
Aripiprazole	
Clozapine	
Lurasidone	
Olanzapine	
Paliperidone	
Quetiapine	
Risperidone	

Appendix 2: Common side effects of antipsychotics:

Drug	Sedation	Weight gain	Akathisia	Parkinsonism	Anti cholinergic	Hypot ension	Prolactin increase
Amisulpiride	-	+	+	+	-	-	+++
Aripiprazole	-	-	+	-	-	-	-
Chlorpromazine	+++	++	+	++	++	+++	+++
Clozapine	+++	+++	-	-	+++	+++	-
Flupentixol	+	++	++	++	++	+	+++
Haloperidol	+	+	+++	+++	+	+	++
Lurasidone	+	-	+	+	-	-	-
Olanzapine	++	+++	-	-	+	+	+
Paliperidone	+	++	+	+	+	++	+++
Quetiapine	++	++	-	-	+	++	-
Risperidone	+	++	+	+	+	++	+++
Sulpiride	-	+	+	+	-	-	+++
Trifluoperazine	+	+	+	+++	+	+	+++
Zuclopenthixol	++	++	++	++	++	+	+++

References:

The Maudsley Prescribing Guidelines in Psychiatry

Lithium letter CMO march 2019

NICE bipolar guidelines