

Dear Colleagues

NATIONAL STANDARD FOR MONITORING THE PHYSICAL HEALTH OF PEOPLE BEING TREATED WITH CLOZAPINE

The Mental Health Strategy 2012-15 committed the Scottish Government to develop a national standard for monitoring the physical health of people being treated with Clozapine. Clozapine is a drug used for treating schizophrenia. This was communicated to Health Boards 12 July 2013 in [SGHD/CMO \(2013\) 12](#). Revision was needed following cardiology and pharmacy advice. Good physical health monitoring in people with severe and enduring mental illness is important.

I am pleased to attach a copy of the updated document which defines a minimum standard for health monitoring for all patients taking Clozapine in Scotland. It is in addition to the manufacturer's protocol for monitoring for agranulocytosis.

Actions for NHS Boards and HSCPs

NHS Boards and HSCPs should ensure current practice is reviewed against the standards and encourage their adoption as a basis for local audit and further research.

NHS Boards and HSCPs should also ensure that all clinicians and others with an interest are made aware of the revised standards, including primary care and mental health services.

Yours sincerely

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SGHD/CMO(2017) 4

For action

Medical Directors, NHS Boards

For information

Chief Executives, NHS Boards
Chairs, NHS Boards
Directors of Public Health, NHS Boards
Directors of Pharmacy, NHS Boards
Royal College of Psychiatrists in Scotland
Royal Pharmaceutical Society
Voices of Experience
Mental Welfare Commission for Scotland
Chief Operating Officers HSCPs

Background Note

The care and treatment of people with mental illnesses such as schizophrenia is a priority for health services within Scotland.

We are concerned not only with their mental health and wellbeing but their physical health too. The premature mortality seen among people with schizophrenia is a concerning health inequality.

Evidence exists, including from within Scotland, of low rates of recognition of cardiovascular risk factors among adults with a diagnosis of schizophrenia compared to the general population, even although this is the most common cause of death for this group.

Clozapine, an atypical antipsychotic, is prescribed to our most ill, most vulnerable people with schizophrenia in line with good practice guidelines such as those of SIGN (Guideline 131 on the Management of Schizophrenia). While outcomes of this treatment are good, side effects are common.

The licensing arrangements ensure that people who take Clozapine have their full blood count monitored at least monthly, however, it appears that opportunities to focus on healthy behaviours and co-morbid physical problems are being missed.

By setting a national standard within Scotland to monitor for significant physical problems in people with schizophrenia treated with Clozapine, we set a clear benchmark. Using this benchmark we can improve the quality of care and treatment we provide, improve patient safety and reduce this established health inequality.

I am pleased to have the opportunity to promote these standards and encourage their adoption as a basis for local audit and further research.

NHS Scotland Clozapine Physical Health Monitoring Standards (February 17)

Clozapine is the ‘gold standard’ antipsychotic for the patients with treatment resistant schizophrenia. Unfortunately it is associated with a range of troublesome side-effects some of which can have a profound effect on a patient’s on-going physical health. This document updates the original standards produced in 2013. The main changes include additional cardiac monitoring during the first four weeks of treatment which have been included following a review of recent literature and consultation with cardiology. Enhanced advice is also given regarding the monitoring required to identify, prevent and manage clozapine induced constipation.

Patients and carers should be included by ensuring that side effects, treatment and monitoring is talked through and explained with them.

Parameter/test	Frequency	Action if outside reference range
Full Blood Count	Follow manufacturer’s mandatory protocol	
BMI	Baseline, weight during initiation, 3 monthly for 1 year, then annually.	Offer lifestyle advice.
Plasma glucose (fasting)	Baseline, at 1 month, then from 3 months, 3 monthly up to 1 year, then 6 monthly.	Offer lifestyle advice. Obtain HbA _{1c} . Consult with GP and/or specialist as appropriate.
Blood lipids	Baseline, 3 monthly for 1 year, then 6 monthly.	Offer lifestyle advice and consult with GP and/or specialist for consideration of treatment e.g. statin therapy as appropriate.
Constipation	Assess bowel habits at baseline, any point of blood sampling and ideally at every point of contact. Ensure patients and carers are aware of the risks associated with clozapine induced constipation.	Treat symptomatically and seek help from physicians if Complete obstruction or poor response to conservative laxative treatment.
Blood pressure	Baseline, as per initiation protocol, 3 monthly for 1 year, then annually. Also following dose changes.	If hypotensive: Consider slower titration or dose reduction If Hypertensive: Offer lifestyle advice and consult with GP and/or specialist for consideration of treatment.
Pulse	Baseline and as per initiation protocol, at 3 months, then annually	Consider slower titration or dose reduction. If tachycardia persistent, observe for other indicators of myocarditis or cardiomyopathy.

ECG	Baseline, 3 weeks, at 3 months and then annually. Additional ECGs should be performed as clinically indicated (see actions)	<p>Act on abnormality according to significance and clinical indication. Refer to cardiologist if in doubt.</p> <p>Continue clozapine with daily CRP and troponin monitoring and request echocardiography if:</p> <ul style="list-style-type: none"> • Signs or symptoms of unidentified illness <p>OR</p> <ul style="list-style-type: none"> • $HR \geq 120$bpm or increased by >30bpm over 24 hours <p>OR</p> <ul style="list-style-type: none"> • CRP 50 – 100 mg/l <p>OR</p> <ul style="list-style-type: none"> • Mild elevation of troponin I $\leq 2 \times$ Upper limit of normal <p><u>Stop clozapine</u>, consult a cardiologist and request echocardiogram if:</p> <ul style="list-style-type: none"> • Troponin $> 2 \times$ upper limit of normal <p>OR</p> <ul style="list-style-type: none"> • CRP >100mg/l
Troponin I	Baseline, day 7, 14, 21 & 28	
CRP	Baseline, day 7, 14, 21 & 28	
Urea & electrolytes	Baseline then as clinically indicated.	Investigate as clinically appropriate.
Liver function tests	Baseline then annually or more frequently if clinically indicated.	Investigate as clinically appropriate.
Side-effects	“GASS for Clozapine” or other recognised side-effect questionnaire for antipsychotic medication during initiation and regularly thereafter, with general side-effect enquiry at least at any point of blood sampling.	As clinically appropriate.
Smoking status	On initiation and at regular intervals thereafter, at least annually. Warn patient regarding effect of changes in smoking status on clozapine levels and side-effects	Check Clozapine level and GASS for Clozapine if change of status.

Women of reproductive age	Pregnancy/contraceptive status on initiation and at regular intervals thereafter, at least annually	In all cases: Pre-pregnancy discussion of pregnancy intentions. Offer advice/signposting on contraception. Early discussion of options if unplanned pregnancy.
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Individual Health Boards and HSCPs will determine how best to undertake this monitoring. This is likely to involve a combination of specialist services and primary care services and therefore good communication systems will be required to avoid duplication of effort and appropriate management of physical health problems.

References used in the production of these standards

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Endorsements

1. Voices of Experience
2. Royal College of Psychiatrists in Scotland

Contributors

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