Directorate of Chief Medical Officer

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleagues,

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

Lithium is a drug used as a treatment for bipolar disorder, as an adjunct in the treatment of depression, and to treat self-injurious behaviour. It has a narrow therapeutic index and requires careful monitoring to support patient safety. Lithium is teratogenic and special consideration is needed with women of child bearing potential. In addition, it can be associated with long term physical health issues. This new standard aims to support NHS Scotland maintain the safe use of this important drug.

I attach a copy of a document which defines a minimum standard for health monitoring for all patients taking lithium in Scotland.

Actions for NHS Boards and HSCPs

NHS Boards and HSCPs should ensure current practice is reviewed against the standard, and encourage its 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 standard, including primary care and mental health services.

Yours sincerely

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From the Chief Medical Officer Dr Catherine Calderwood MA FRCOG FRCP (Edin)

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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
RoyalCollege of Psychiatrists in Scotland
Royal College of General Practice
Royal Pharmaceutical Society
Voices of Experience
Mental Welfare Commission for Scotland
Chief Officers HSCPs

Background Note

The care and treatment of people with mental illnesses such as bipolar disorder 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 physical health burden seen among some people with bipolar disorder is a concerning health inequality.

Lithium, a mood stabilising drug, is prescribed to some of our most ill and most vulnerable people with bipolar disorder. This is in line with good practice guidelines such as those of NICE (NICE; Bipolar disorder: assessment and management (CG185), last update February 2016). While the outcomes of this treatment are good, side effects are common, as is the risk of developing toxicity.

Lithium is a known teratogen. In severe mental illness up to 80% of pregnancies are unplanned. Risks and benefits in relation to childbearing must be discussed fully with all women of childbearing potential prior to prescription and consent appropriately recorded. This should be revisited at least annually. Discussion should include review of contraception status and advice/signposting on effective contraception for the duration of prescribing, with preference for long-acting reversible methods.

For women who become pregnant on lithium it is important to review the risks and benefits of continuing treatment or discontinuation. Specialist advice regarding on going prescribing should be sought.

Prior to the removal of the Quality Outcomes Framework in 2016, General Practitioners were encouraged to actively call lithium patients for monitoring at defined intervals. Though appropriate care that was associated with this framework is expected to continue, it is important that clinicians and organisations assure themselves that this is the case. This standard intends to support the good clinical care that primary and secondary care services provide.

By setting a national standard within Scotland to outline the monitoring requirements of people treated with lithium, 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 this standard and encourage its adoption as the basis for local audit and further research.

NHS Scotland Lithium Physical Health Monitoring Standard (June 17)

Lithium is an effective medicine, particularly in the maintenance treatment of bipolar affective disorder, recurrent depression and for some self-harm. It is widely used, and most patients prescribed lithium are in primary care. The narrow therapeutic index of lithium, and the potential for acute and chronic side effects, place an absolute requirement to establish clear systems of work that protect patient safety. This should include robust systems to ensure monitoring is carried out irrespective of setting. Special consideration is needed with women of child bearing potential as lithium is teratogenic. This document describes the monitoring required to support safe lithium use.

Individual Health Boards will determine how best to undertake this monitoring. This is likely to involve a combination of specialist services and primary care services, and good communication systems will be required to avoid duplication of effort and appropriate management of physical health problems.

Parameter/test	**Frequency**	**Action / suggested Action if outside reference range**
Lithium levels	**3 monthly** Trough samples for routine monitoring should be taken approximately 12 hours after the last dose. Additional levels should be taken 5 – 7 days after the initial dose, after any dose or formulation change or introduction/discontinuation of interacting medication, and if there is a suspicion of toxicity.	Confirm the timing of the blood test and compliance with lithium Review treatment and adjust dose if clinically indicated. Lithium toxicity is defined as any lithium level greater than 1.2mmol/L. However it should be noted that some patients may exhibit toxicity at lower levels e.g. over 65 year olds.
Urea & Electrolytes	**Baseline** (Include Sodium, Potassium, Urea, Creatinine & eGFR. Patients must have adequate renal function (eGFR>60ml/min) before commencing lithium. Note in some populations the eGFR may overestimate renal function and therefore calculation of creatinine clearance would be more appropriate), **6 monthly.** Monitor more frequently if evidence of deterioration, or if the patient is prescribed or takes medicines known to affect renal function e.g. ACE inhibitors, NSAIDs or diuretics.	If eGFR falls rapidly to <45ml/min review lithium treatment and refer to renal medicine. Investigate and correct for hyponatraemia /hypernatraemia.
Thyroid function	**Baseline & 6 monthly** Monitor more often if evidence of impaired thyroid function or an increase in mood symptoms that might be related to impaired thyroid function	Treat as necessary
ECG	**Baseline &6 monthly**	Review lithium treatment and consider cardiology advice.

Calcium	**Baseline & 6 monthly**	Treat as necessary
Body Mass Index	**Baseline & 6 monthly**	Offer lifestyle advice
Side effects	**At every clinical contact** Check if recent diarrhoea and vomiting or dehydration / over-hydration due to other causes	Review lithium treatment if problematic
Signs & symptoms of toxicity	**At every clinical contact** Reinforce education on signs and symptoms of toxicity and avoiding dehydration. Lithium toxicity is defined as any lithium level greater than 1.2mmol/L. However it should be noted that some patients may exhibit toxicity at lower levels e.g. over 65 year olds.	Check an urgent lithium level and suspend lithium treatment. Lithium treatment can only be re-introduced once toxicity has resolved and if restoration of treatment is then deemed clinically appropriate. All episodes of toxicity must be clearly noted in the patient's clinical records and discussed with patients.
Interacting drugs	**At every clinical contact** Be aware that 'Over the counter' medications such as ibuprofen can interact with lithium	Review all drugs known to affect renal function.
Women of reproductive age	**Baseline and yearly** Lithium is a known teratogen. In severe mental illness up to 80% of pregnancies are unplanned. Risks and benefits in relation to childbearing must be discussed fully with all women of childbearing potential prior to prescription and consent appropriately recorded. This should be revisited at least annually. Discussion should include review of contraception status and advice/signposting on effective contraception for the duration of prescribing, with preference for long-acting reversible methods.	For all women of childbearing potential: Discussion of childbearing intentions and contraception status. Advice on risks and benefits in relation to childbearing. Advice/signposting on contraception (incl. LARC). Informed consent provided in writing. The 'BUMPS' website should be used to reinforce verbal information. www.medicinesinpregnancy.org For women who become pregnant on lithium: Review risks and benefits of continuing treatment or discontinuation. Seek specialist advice regarding ongoing prescribing.
Patient & care education	**Baseline and as necessary**	Provide patients with the education necessary to support informed choice and suited to their individual needs. The Choice and Medication and ' BUMPS' websites are recommended as below http://www.choiceandmedication.org/nhs24/ www.medicinesinpregnancy.org

References used in the production of these standards

NICE; Bipolar in Adults (QS95), July 2015
NICE; Bipolar disorder: assessment and management (CG185), last update February 2016
BNF 72; page325
Maudsley Prescribing Guidelines, 12th Edition 2015
Psychotropic Drug Directory 2016

Endorsements

Royal Pharmaceutical Society
Royal College of Psychiatrists in Scotland
Royal College of General Practitioners in Scotland
VOX
Bipolar Scotland

Contributors

Guideline development group
These standards were developed on behalf of the Scottish Government by the Mental Health Pharmacy Strategy Group.

Other Contributors
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Physical Health Monitoring for Patients on Lithium – Annual Audit Criteria

Name		CHI Number	
Lithium Started	mm/yy		
Audit year started	mm/yy		

Criteria	Standard	Exceptions
Urea & Electrolytes are monitored at baseline and 6 monthly	100%	None
Thyroid function are monitored at baseline and 6 monthly	100%	None
ECG is performed at baseline and 6 monthly	100%	None
Calcium levels are monitored at baseline and 6 monthly	100%	None
Body Mass Index is measured at baseline and 6 monthly	100%	None
Side effects are assessed at every clinical contact	100%	None
Signs & symptoms of toxicity are assessed at every clinical contact	100%	None
All episodes of toxicity are clearly recorded in the patients clinical records	100%	None
Lithium levels are measured every 3 months and additionally as necessary	100%	None
Interacting drugs are assessed at every clinical contact	100%	None
Pregnancy status is assessed prior to initiation and at every clinical contact.	100%	Applies to women of reproductive age only
Informed consent is obtained and recorded for all women of child bearing age prior to prescription.	100%	Applies to women of reproductive age only
Patient & carers are provided with appropriate education prior to initiation and as necessary thereafter	100%	None