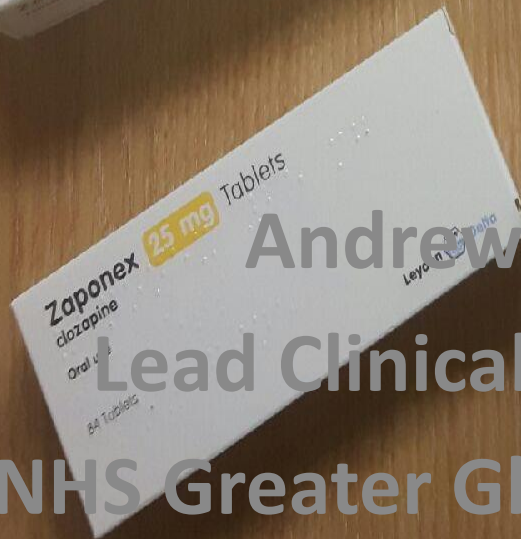
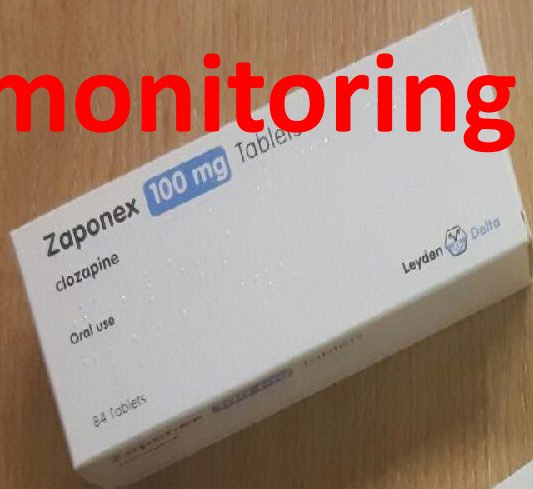


Lithium bundles and Clozapine monitoring in Older People



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Purpose

- To describe the development of the National Lithium Monitoring Standards
- To describe the NHS GG&C Lithium Ward Bundle
- To describe the National Clozapine Physical Health Monitoring Standards

National Lithium Physical Health Monitoring Standards

- Developed by Mental Health Pharmacy Strategy group in consultation with RCPsych, RCGPs and Bipolar Scotland.
- Requested by John Mitchell at SG in part to improve patient safety and encourage NHS Boards to improve.
- Introduced in June 2017.

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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

Catherine Calderwood

**Chief Medical Officer
Officer**

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

Parameter/test	Frequency	Action / suggested Action if outside reference range
Lithium levels	<p>3 monthly</p> <p>Trough samples for routine monitoring should be taken approximately 12 hours after the last dose.</p> <p>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.</p>	<p>Confirm the timing of the blood test and compliance with lithium</p> <p>Review treatment and adjust dose if clinically indicated.</p> <p>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.</p>
Urea & Electrolytes	<p>Baseline</p> <p>(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),</p> <p>6 monthly.</p> <p>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.</p>	<p>If eGFR falls rapidly to <45ml/min review lithium treatment and refer to renal medicine.</p> <p>Investigate and correct for hyponatraemia /hypematraemia.</p>
Thyroid function	<p>Baseline & 6 monthly</p> <p>Monitor more often if evidence of impaired thyroid function or an increase in mood symptoms that might be related to impaired thyroid function</p>	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

NHS GG&C Lithium Ward bundle – why?

- In response to actions from an SCI following the death of a patient.
- The SCI raised concerns about
 1. Staff knowledge
 2. Poor systems
 3. Lack of communication
- To support the implementation of the new lithium standards.

Bundle elements

- Key Lithium Facts
- Principles of safe lithium treatment
- MDT check list
- Clinical factors to consider before administering lithium
- Common lithium drug interactions
- Information sources
- Sample care plan
- Educational package available from Pharmacy.

Lithium Side Effect Checklist (LiSEC) Appendix 2

Patient name		CHI number				
Date of Assessment			Name of assessor			
Over the past week, have you experienced any of the following possible side effects and if so, to what extent?		None	Mild	Medium	Severe	Tick if this is distressing
1.	I have been very thirsty and/or passing urine more frequently					
2.	I have woken during the night because I needed to pass urine					
3.	I have felt more hungry than usual or have gained weight					
4.	I have a metallic taste in my mouth					
5.	My mouth has been dry					
6.	I have felt like I am going to be sick					
7.	My ankles have been swollen					
8.	I have had difficulty remembering things and/or concentrating					
9.	I have developed a rash/ skin problem or an existing skin problem has got worse					
10.	I am tired *					
11.	My skin/ hair is drier than usual *					
12.	I have had problems opening my bowels (constipation) *					
13.	My hands or arms have been shaky **					
14.	My vision has been blurry					
15.	My speech is slurred					
16.	I have felt very sleepy during the day					
17.	I have vomited and/or had diarrhoea					
18.	My muscles have felt weak and/or my muscles have been twitching					
19.	I have been unsteady on my feet					
20.	I feel confused					

Factors to consider before administering lithium

In the last 24 hours the patient has experienced:

- Increasing gastrointestinal disturbances (vomiting, diarrhoea etc.)
- Inadequate fluid intake (infection, hot weather, alcohol use)
- Muscle weakness/lack of co-ordination
- Muscle twitches
- Slurring of words
- Severe tremor
- Blurred vision
- Confusion
- Unusual drowsiness

If there are concerns contact the duty doctor for further advice.

What next?

- Introduced in April 2017
- Series of awareness sessions
- Process of continuous audit started in September 2017

National Clozapine Physical Health Monitoring Standards

- First introduced in 2013
- Revised in 2017
- Designed to promote a standard approach to the monitoring of the physical health of people prescribed clozapine.

Parameter/test	Frequency	Action if outside reference range
Full Blood Count	Follow manufacturer's mandatory protocol	
Constipation	Assess bowel habits at baseline, any point of blood sampling and ideally at every point of contact.	Treat symptomatically and seek help from physicians if Complete obstruction or poor response to conservative laxative treatment.
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.
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)	Act on abnormality according to significance, clinical indication. Refer to cardiologist if in doubt.
Troponin 1	Baseline, day 7, 14, 21 & 28	Continue clozapine with daily CRP and Troponin I monitoring and request echocardiography if: <ul style="list-style-type: none"> • Signs or symptoms of unidentified illness OR • HR \geq 120bpm or increased by $>$30bpm over 24 hours OR • CRP 50 – 100 mg/l OR • Mild elevation of troponin I \leq 2 x Upper limit of normal
CRP	Baseline, day 7, 14, 21 & 28	Stop clozapine, consult cardiologist and request echocardiogram if: <ul style="list-style-type: none"> • Troponin $>$ 2 x upper limit of normal OR • CRP $>$ 100mg/l
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.

What does this mean for Older People?

- Standards apply regardless of age
- Engagement with clozapine clinics
- Systems for physical health monitoring