Document Control

Title			
Lithium Monitoring Standard Operating Procedure			
Author			**Author's job title** Clinical Pharmacist **Clinical Pharmacy Manager**
Directorate Unplanned Care			**Department** Pharmacy **Team/Specialty** Pharmacy
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0.2		Draft	Comments from Clinical Pharmacy Service Manager Matt Kaye Northern Devon Healthcare NHS Trust and information regarding salts added. Remove reference to community hospitals.
1.0	Dec 2014	Final	Ratified at Drug and Therapeutics Committee on 20 November 2014 and Published on BOB.
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2.1	Sept 2018	Final	Small update to change registered nurses to Registered Practitioners in light of Nurse Associates.
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Main Contact Pharmacy Department North Devon District Hospital Raleigh Park Barnstaple, EX31 4JB			**Tel: Direct Dial** – **Tel: Internal** – **Email**:
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CONTENTS

1. Background

1.1. This document sets out the Northern Devon Healthcare NHS Trust's procedure for Lithium Monitoring Standard Operating Procedure.

1.2. Lithium is a salt licensed for the management of acute manic or hypomanic episodes, prophylaxis against relapse in bipolar affective disorders & in the management of episodes of depressive disorders where treatment with other antidepressants has been unsuccessful. Lithium reduces the risk of attempted & completed suicides by 80% in bipolar.

1.3. This document replaces all previous versions of this procedure.

2. Purpose

2.1. The Standard Operating Procedure (SOP) has been written to:

Provide a framework for staff who will undertake blood monitoring of patients who are receiving Lithium Therapy

This SOP has been developed following the National Patient Safety Agency Alert PSA/005 2009, Safer Lithium Therapy

3. Scope

3.1. This Standard Operating Procedure (SOP) relates to the following staff groups:

Registered Practitioners

Support workers

Medical staff

Registered Practitioners, medical staff should assess the patients need for lithium monitoring.

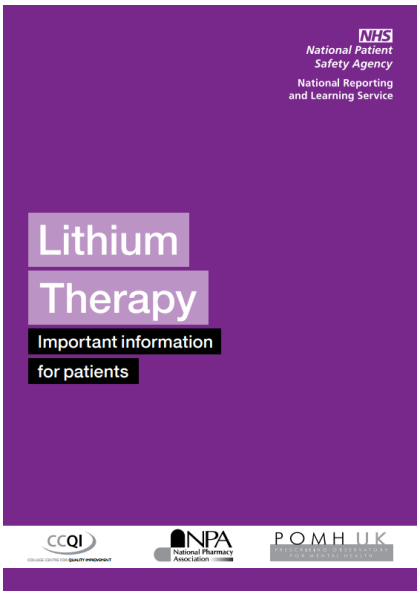
Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

4. Responsibility

Specialist psychiatric services	GP	Individual	Community Pharmacist
Perform relevant baseline checks (in collaboration with GP)	Continue prescription	Attend routine follow up appointments (including blood tests)	Ensure prescribers are informed of any interacting medicines
Ensure patient receives lithium 'Purple Book'	Monitor the patient for signs of toxicity, other side effects and signs of deterioration in mental state	Maintain an open and honest relationship with their practitioners	Ensure individuals present their 'Purple Book' for inspection prior to dispensing supplies
Initiate therapy and ensure dose is appropriate	Perform routine monitoring & ensure consultant receives copies of relevant results & complete individual's 'Purple Book' with results	Ensure they have their 'Purple Book' when seeing doctors or obtaining supplies from pharmacy	Ensure individual is using their lithium safely as far as possible
Ensure GP is informed of initiation and any subsequent dose changes and all copies of blood tests are sent to GP	Act on any abnormal results or observations	Report any side effects they are experiencing to the prescriber	
Request 'Shared Care' transfer when stabilised	Seek specialist advice when necessary		

5. Equipment

- Patient held lithium monitoring booklet – 'Purple Book'
- An National Patient Safety Agency (NPSA) alert on lithium - Safer Lithium Therapy requires all healthcare organisations where lithium therapy is initiated, prescribed, dispensed and monitored to ensure:



1. patients prescribed lithium are monitored in accordance with NICE guidance
2. there are reliable systems to ensure blood test results are communicated between laboratories and prescribers
3. at the start of lithium therapy and throughout their treatment patients receive appropriate ongoing verbal and written information and a record book to track lithium blood levels and relevant clinical tests
4. prescribers & pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed lithium
5. systems are in place to identify and deal with medicines that might adversely interact with lithium therapy.

6. Procedure

- Initiation

Contraindications to lithium therapy:

- Hypersensitivity to lithium or to any of the excipients.
- Cardiac disease or insufficiency.
- Severe renal impairment.
- Untreated hypothyroidism.
- Breast-feeding.
- Patients with low body sodium levels, including for example dehydrated patients or those on low sodium diets.
- Addison's disease.
- Brugada syndrome or family history of Brugada syndrome.

Lithium should be initiated in secondary care by psychiatry (or by a suitably experienced GP with a specialist interest in psychiatry).

The prescriber should explain the relevant side effects of lithium including the signs of toxicity and complete the Initiation Checklist (Appendix 1). The National Patient Safety Agency have produced a Lithium Therapy Information Pack (Purple book) which includes all relevant information as well as a lithium therapy record book).

When treating someone with a diagnosis of bipolar disorder an assessment of likely future adherence with lithium therapy **for at least 3 years** should be made prior to initiation. Evidence suggests lithium may have a negative effect on the course of bipolar disorder if not taken for this period of time.

Refer to the latest BNF for dosage instructions on initiation. When restarting lithium for those who recently stopped, higher starting doses may be used based on previous maintenance dose.

There are a variety of preparations available. The dosage regimes associated with each is different and it is important these are followed. In order to minimise risk, **lithium must always be prescribed by brand** and not generically. **The common formulary choice in Devon is Priadel®.**

Brand name	Form	Salt	Strengths	Recommended frequency
Priadel®	**Tablet**	**Lithium carbonate**	**200mg** **400mg**	**Once daily**
Priadel®	**Liquid**	**Lithium citrate**	**520mg/5ml**	**In divided doses, ideally twice a day.** **When changing between preparations start at a daily dose as close as possible to the previous dose.**
Lithium carbonate	Tablet	Lithium carbonate	250mg 400mg	Once daily
Camcolit	Tablet	Lithium carbonate	400mg	Once daily
Liskonum®	Tablet	Lithium carbonate	450mg	Twice daily
Li-liquid®	Liquid	Lithium citrate	509mg/5ml	Initially twice daily then once daily
Li-liquid®	Liquid	Lithium citrate	1018mg/5ml	Initially twice daily then once daily

NB. Tablets are scored and may be halved to give smaller doses (eg 100mg).

When switching between liquid and tablets, every caution must be made to ensure the dose is correct – see BNF for full details.

Serum lithium levels should be checked between 4 to 7 days following initiation and the dose adjusted accordingly. **Serum levels should be repeated after every dose change and then every week until dosage has remained constant for 4 weeks.**

Blood samples should be taken 12 hours after the previous dose of lithium. Occasionally levels are taken just before the next dose is due, to measure the serum lithium level at its trough.

Target serum levels depending on dose frequency (mmol/L); specialists must always advise primary care of the individual's target lithium level.

Dosage frequency	12 hours post dose	24 hours post dose
Once daily	0.7-1.0	0.5-0.8
Twice daily	0.5-0.8	

Lower levels may be used for prophylaxis (between 0.4 and 0.75mmol/L). Optimal plasma levels in depression are not clear; levels up to 1mmol/L, as tolerated, have been used.

Monitoring:

On admission to hospital

● To ensure that a patient is screened for potential lithium toxicity, all patients on regular lithium should have a lithium level checked in admission. Advice should be sought from psychiatry if levels are above or below desired range.

The on-going requirements for monitoring lithium are:

- **renal, thyroid & calcium function every 6 months** during treatment (test repeated more often if there is evidence of impairment)
- **serum lithium levels every 3 months for the first year, then every 6 months** (except high risk groups such as elderly, taking interacting meds, renal or thyroid impairment, poor symptoms control or adherence, last lithium level over 0.8mmol/L)
- Calcium function every 12 months.
- **weight and BMI monitored annually**
- consider ECG monitoring if additional risk factors

When blood tests are being performed, a local system must be in place to flag these blood tests as being relevant for lithium therapy and a copy should be sent by the pathology lab to the individual's GP and/or consultant psychiatrist, depending on who is taking the test. Psychiatrists should endeavour to ensure GPs are fulfilling this requirement and equally make every effort to ensure results are copied to GPs when completed.

Care must be taken when prescribing concomitant medication to ensure any interaction between the new medicine and lithium is acknowledged and managed safely. See initiation checklist in appendix 1 or the BNF for a list of interacting medicines.

Results should be recorded in the person's electronic notes, 'Purple Book' and Wellbeing passport if being used.

Continuation of Treatment –

Shared Care Guidelines

As of 2017, Shared Care Guidelines exist for the prescribing of Lithium. These stipulate "Lithium should be initiated in secondary care or by a suitably experienced GP with a specialist interest in psychiatry. **Specialist services must initiate and stabilise therapy (in exceptional circumstances, GPs may initiate lithium treatment under specialist advice). Patients will have been stabilised on a suitable dose for at least one month before being referred to their GP for sharing of care.**"

GPs are invited to participate. If a GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

If transfer of care to local GP is appropriate then the Consultant should complete the Shared Care Agreement Letter in the guidelines and send these to the GP.

Shared Care Guidelines:

NEW Devon CCG: https://www.newdevonccg.nhs.uk/file?download=true&rid=113830

Torbay & South Devon: http://www.southdevonandtorbayccg.nhs.uk/about-us/commissioning/policies/Documents/joint-formulary-shared-care-guidelines.pdf

Toxicity and interaction:

Lithium toxicity can also occur in chronic accumulation for the following reasons: Acute or chronic overdose; dehydration, deteriorating renal function and drug interactions.

Symptoms of lithium intoxication include:

Mild: Nausea, diarrhoea, blurred vision, polyuria, light headedness, fine resting tremor, muscular weakness and drowsiness.

Moderate: Increasing confusion, blackouts, fasciculation and increased deep tendon reflexes, myoclonic twitches and jerks, choreoathetoid movements, urinary or faecal incontinence, increasing restlessness followed by stupor. Hypernatraemia.

Severe: Coma, convulsions, cerebellar signs, cardiac dysrythmias including sinoatrial block, sinus and junctional bradycardia and first degree heart block. Hypotension or rarely hypertension, circulatory collapse and renal failure.

At blood levels above 2-3 mmol/l, there may be a large output of dilute urine and renal insufficiency, with increasing confusion, convulsions, coma and death.

Management:

There is no specific antidote to lithium. In the event of lithium overdose, lithium should be discontinued and lithium serum levels monitored closely. Supportive treatment should be initiated, which includes correction of fluid and electrolyte balance, if necessary.

All patients should be observed for a minimum of 24 hours. ECG should be monitored in symptomatic patients. Steps should be taken to correct hypotension.

Slow-release tablets do not disintegrate in the stomach and most are too large to pass up a lavage tube. Gastric lavage is not useful for chronic accumulation. Activated charcoal does not adsorb lithium.

Haemodialysis is the treatment of choice for severe lithium intoxication (especially in patients manifesting with severe nervous system disorders), or in cases of overdose accompanied by renal impairment. **Haemodialysis should be continued until there is no lithium in the serum or dialysis fluid.** Serum lithium levels should be monitored for at least another week to take account of any possible rebound in serum lithium levels as a result of delayed diffusion from the body tissues.

In cases of acute on chronic overdose or in cases of chronic lithium toxicity if the lithium concentration is >4.0 mmol/l, discuss with your local poisons service.

Clinical improvement generally takes longer than reduction of serum lithium concentrations regardless of the method used.

Major interactions (see BNF for full list)**:**

Drug group	Magnitude of effect	Timescale of effect	Additional info
ACE inhibitors	Unpredictable. Up to 4x increase in levels.	Develops over several weeks.	7x increased risk of hospitalisation for Li toxicity in elderly. Angiotensin II blockers may have similar risks.
Thiazide diuretics	Unpredictable. Up to 4x increase in levels.	Usually apparent in first 10 days.	Loop diuretics safer. Any effects apparent in first month.
NSAIDs	Unpredictable. From 10% up to 4x increase in levels.	Variable; few days to several months	NSAIDs widely used PRN. Can be bought without prescription.

Stopping treatment:

- **Lithium must never be stopped suddenly** unless the individual is suffering from signs of toxicity or has a serum lithium level greater than 1.5mmol/L.
- In order to minimise the risk of relapse when stopping lithium it is recommended to reduce the dose gradually over a period at least 4 weeks and preferably over at least 3 months.

Pregnancy and breastfeeding:

- Please contact Perinatal Mental Health for specific information on prescribing in this group and up-to-date contact information for the local perinatal teams.

7. Hot weather advice for patients on lithium

- In prolonged and very high temperatures, it is doubly important that if you are taking lithium medication you make sure you drink a lot of fluid. The reasons for this are: becoming dehydrated or very thirsty may lead to excessively high lithium levels in your blood, which can be dangerous.

- Having too much lithium in your blood is called lithium toxicity (or lithium poisoning). This can make you very ill. If you experience any of the problems listed below, stop taking your lithium and contact your doctor or another healthcare professional straight away. If this is not possible ring the NHS helpline for advice.
- Severe hand shake (tremor)
- Blurred vision
- Stomach ache along with feeling sick and having diarrhoea
- Being unsteady on your feet
- Difficulty in speaking or slurring of words
- Muscle twitches
- Clumsiness
- Feeling unusually sleepy
- Confusion
- Muscle weakness
- You are sweating a lot for any reason
- The weather is hot
- You are travelling in a hot country
- You are exercising
- You have a high temperature
- You have diarrhoea.

If you have sickness and/or diarrhoea for more than a day or two, see your doctor to have your lithium level checked.

8. References

- National Patient Safety Agency Alert PSA.005 2009, Safer Lithium Therapy.
- National Institute for Clinical Excellence Bipolar Disorder. The management of Bipolar disorder in adults, children and adolescents, in primary and secondary care. Clinical guidelines 38 2006
- British National Formulary 74
- Protocol for Prescribing and Monitoring of Lithium Therapy Devon Partnership Trust, November 2017

9. Associated Documentation

- Northern Devon Healthcare NHS Trust Policies for:
  Administration of medicine SOP
  Medicines Policy