Livewell Southwest

Lithium: Policy for the Safe Initiation, Prescribing, Dispensing and Monitoring of Lithium Preparations

Version No 2.2

Review: May 2019

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

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Equality Impact Assessment	Yes

References / Source	1. National Patient Safety Agency alert NPSA/2009/PSA005 (1st December 2009) 2. NPSA 2009/PSA005 "Supporting Information" 3. NPSA 2009/PSA005 "Lithium Therapy – Important Information for Patients" 4. National Institute for Health & Clinical Excellence (NICE): Bipolar disorder: Assessment and Management *Clinical Guideline* 185, 2014. **http://www.nice.org.uk/guidance/cg185/chapter/introduction**NICE Clinical Guideline no. 90 "Depression in adults" Oct 2009 **www.nice.org.uk** 5. LSW IntraNET "Safe and Secure Handling of Medicines Guidelines" current version 6. South and West Devon Formulary and Referral, **http://www.southwest.devonformularyguidance.nhs.uk/** Chapter 4 and shared care link: http://www.newdevonccg.nhs.uk/who-we-are/medicines-and-treatments/shared-care-guidelines/western-devon-shared-care-guidelines/central-nervous-system/101099 BNF no 70, Sep 2015. 7. BNF for Children (2015-16) 8. Stockley's Drug Interactions 10th ed. (2012)
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0.2		Dec 2010	D. Reeves	Comments on initial draft
0.3		Jan 2011	S. Cooke	Comments following consultation
1.0		Feb 2011	D Reeves	Removal of Action Plan and Shared Care Guidelines
1.1	Reviewed	Feb 2014	S. Cooke	Re-formatted and presented to MGG 7/3/14
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2.0	Reviewed	Mar 16	S. Cooke	Changes as agreed by MGG
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Lithium: Policy for the Safe Initiation, Prescribing, Dispensing and Monitoring of Lithium Preparations.

1. Introduction

1.1 Lithium therapy is supported by NICE guidance, [4, 5] as an effective treatment for acute mania, prophylaxis of bipolar disorder and as augmentation of antidepressants in refractory depression. However lithium blood levels need to be maintained within a narrow range; if too low there may be a lack of therapeutic effect; if too high symptoms of toxicity occur which can be serious or even fatal in extreme cases. Lithium at therapeutic levels can also have some long term adverse effects, particularly on kidney and thyroid function. As lithium usually has to be taken for long courses, monitoring of thyroid and kidney function is also very important.

1.2 The National Patient Safety Agency alert NPSA/2009/PSA005: Safer Lithium Therapy [1] identified that some patients taking lithium have been harmed because their dosage has not been adjusted based on regular blood tests. The NPSA received 567 incident reports relating to lithium between October 2003 and December 2008, two of which were 'severe harm' and 34 of 'moderate harm' (see appendix 2 for definitions of harm). In addition the NHS litigation Authority (NHSLA) has dealt with two fatal and 12 severe harm incidents (between 1995 and 2004) and the Medical Defence Union (MDU) has been involved with 15 incidents directly related to lithium toxicity and monitoring.

1.3 An audit by the Prescribing Observatory for Mental Health (POMH-UK) in 2009 has shown that in 70% patients the NICE standard for lithium monitoring was not met and monitoring of renal function and thyroid function was similarly poor (46% and 51% respectively not met).

1.4 The NPSA alert required all organisations (NHS and private) where lithium therapy is initiated, prescribed, dispensed and monitored to complete five actions by the deadline of 31st December 2010. [1]

1.5 The South and West Devon Formulary Shared Care Guideline should be followed: **http://www.newdevonccg.nhs.uk/who-we-are/medicines-and-treatments/shared-care-guidelines/western-devon-shared-care-guidelines/central-nervous-system/101099**

2. Overall aim of the guidance

2.1 The aim of this policy is to provide robust and safe systems within LSW to manage the inherent risks to patients from the use of lithium therapy based on the recommendations of the NPSA alert.

2.2 Adoption of this policy by clinicians and other healthcare professionals will help to provide the assurance required of compliance with the NPSA alert.

2.3 The policy aims to define the local systems in place and direct the reader to other resources available where appropriate.

3. Objectives that build toward the overall aim of the guidance

These are based on the five main actions required of LSW by the NPSA alert, supplemented by the additional actions recommended in the "Supporting Information" document: [2]

3.1 **Patients prescribed lithium are monitored in accordance with NICE guidance**. This is to be achieved principally by increasing awareness of the updated advice of the Western Locality "Shared care information on the prescribing of lithium (Priadel®)"[7], which defines the responsibilities of primary and secondary care. Assurance of compliance with this guidance will be provided by audit (see section 4).

3.2 There are reliable systems to ensure blood test results are communicated between laboratories and prescribers.

3.3 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 (see section 11).

3.4 Prescribers and pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and / or dispense the prescribed lithium (see section 12).

3.5 Systems are in place to identify and deal with medicines that might adversely interact with lithium (see section 13).

4 Description of how you will measure its effectiveness

4.1 A baseline audit of lithium monitoring was performed in one locality of Plymouth in 2006-7 then repeated in 2008-9 (see appendix 1). This showed improved lithium blood level monitoring over this period but reduced monitoring of thyroid and renal function.

4.2 An audit tool has been developed (appendix 2) that includes aspects of each of the five action points required by the NPSA alert.

5 Workforce Planning Issues

5.1 Training on the actions within this policy will be included in the following programme:

- Mental Health Junior Doctor induction training – Pharmacy sessions now include lithium prescribing & monitoring.

5.2 Clinical supervision of new or less experienced staff in these procedures by senior staff will occur as part of the routine clinical supervision in operation. The nurse in

charge of each ward or unit is responsible for ensuring this occurs in respect of the specific circumstances of their ward or unit.

6 Abbreviations

BNF	British National Formulary
BNF-C	British National Formulary for Children
LMC	Local Medical Committee
LPC	Local Pharmaceutical Committee
NICE	National Institute for Health & Clinical Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning Service
LSW	LSW
POMH-UK	Prescribing Observatory for Mental Health (United Kingdom)
SWDF	South and West Devon Formulary and Referral

7. Responsibilities

7.1 **The Chief Operating Officer** is ultimately responsible for all Livewell policies.

7.2 **The Director of Professional Practice and Patient Safety / Medical Director** are responsible for ensuring an adequate response to all safety alerts including the requirement for policy production and review.

7.3 **The Chief Pharmacist** is responsible for drafting the policy, ensuring adequate consultation and clinical scrutiny; arranging for ratification of the policy within the set deadline; operational implementation of the action points and for subsequent review of the policy.

7.4 **Consultant Psychiatrists** are responsible for all the points listed under "Secondary Care Doctor" responsibilities in the Western Locality Shared Care Information[7] Some of these actions may be delegated to junior doctors but the responsibility to ensure they are completed remains with the consultant.

7.5 **General Practitioners** working in LSW practices are responsible for all the points listed in the "Primary Care Doctor Responsibilities" section of the Western Locality Shared Care Information[7]

7.6 **Junior doctors working on inpatient units (including community & rehab) or working under consultant psychiatrists** are responsible for prescribing and monitoring lithium in accordance with the Western Locality Shared Care Information[7]. They are also responsible for ensuring the patient has a monitoring booklet that is up to date.

7.7 **Nurses on inpatient units** are responsible for ensuring that patients receive their lithium as prescribed; to check that the patient has a monitoring booklet and that this is kept up to date; the monitoring booklet is enclosed with the patient's TTAs on discharge; patients are provided with appropriate verbal and written information on

lithium; blood tests are performed 12 hours post dose; and that patients are monitored for potential adverse effects[7]

7.8 **Pharmacists on inpatient units** are responsible for clinically screening medication charts and ensuring that the lithium Western Locality Shared Care Information[7] is followed, in particular: the indication and dose are appropriate and the dose is normally given at night; the brand of lithium previously taken by the patient is maintained or the dose is re-titrated; the patient has a lithium monitoring booklet that is up to date; blood tests and biochemical tests have been performed; and that any potential drug interactions / adverse reactions or toxic effects are brought to the attention of the prescriber with recommendations for corrective action.

7.9 **Community Psychiatric Nurses** are responsible for checking the following for patients on their caseload prescribed lithium: that they have adequate supplies of the preparation of lithium prescribed; that they are taking lithium as prescribed; that they have a patient booklet that has been kept up to date; blood tests and biochemical tests have been performed in line the Western Locality Shared Care Information[7]; and reporting of any suspected adverse effects / toxic effects or non concordance with treatment to the patient's consultant and / or GP.

7.10 **Community / District Nurses** who come into contact with patients prescribed lithium should ensure that patients are concordant with treatment and have a patient booklet that has been kept up to date. Any suspected adverse effects / toxic effects or non concordance with treatment should be reported to the patient's consultant and / or GP.

7.11 **Pharmacists at PHNT:** Check that a pharmacist clinical screen has been done at ward level before supplying lithium against in-patient / discharge prescriptions. If this is not the case proceed as in section 12.7. Do not withhold lithium. If lithium has been stopped on admission check that this is appropriate i.e. due to toxicity (see section 12.3) or other clinical reason. If not then the prescriber should be asked to discuss the decision with the patient's consultant psychiatrist (or if not available contact the Derriford Liaison Psychiatry Team). A LSW pharmacist should be informed.

8. Initiation of Lithium

8.1 Initiation of lithium should be carried in accordance with the Shared Care Information[7].
Initiation is normally the responsibility of the consultant psychiatrist. In exceptional circumstances a GP may initiate with specialist advice.

8.2 Prior to starting lithium patients will be assessed for renal, thyroid and (where appropriate) cardiac function as defined in the shared care information – responsibilities of secondary doctors.

8.3 Monitoring as per NICE guidance / shared care information will be performed initially by secondary care then transferred to primary care after a minimum of one month.

8.4 Prior to starting lithium, patients will receive full information about the risks and benefits of treatment so that they have the opportunity to make an informed choice. In particular patients need to be informed of the side effects of lithium, signs and symptoms of toxicity and risk factors for toxicity. This can be achieved by verbal reinforcement of the information contained in the lithium patient information booklet (see section 11).

8.5 The doctor initiating lithium is responsible for issuing a patient information booklet to the patient. The doctor should explain to the patient the importance of carrying the alert card and monitoring booklet with them at all times, and keeping the latter up to date (see section 11).

9. Monitoring of Lithium

9.1 All patients prescribed lithium should be monitored according to NICE clinical guideline no. 185: Bipolar Disorder, assessment and management [4] a summary of which is included in the Shared Care Information[7]

9.2 The consultant psychiatrist who initiates lithium will ensure all monitoring has been completed until the patient is stabilised on a therapeutic dose (minimum one month).

9.3 Primary care doctors who accept shared care responsibilities for patients on lithium AND other doctors caring for patients on lithium will ensure that patients are fully monitored in line with NICE / shared care. Patients who do not attend for planned blood tests must be followed up and referred back to the consultant psychiatrist if still non-compliant with their monitoring.

9.4 Wherever possible a recent lithium blood level should be available **before** any change in dose or review of treatment is planned. Patients on lithium admitted to an inpatient unit should have their lithium levels checked on admission.

9.5 Prior to prescribing or dispensing **every** prescription for lithium, prescribers and pharmacists should check the scheduling of blood tests to reassure themselves that, given the test results, no patient harm will result (see section 12).

9.6 Guidance on of monitoring of lithium therapy can be obtained from the laboratory; please contact the Duty Biochemist on 01752 517936 (or via switchboard outside routine working hours) or alternatively Pharmacy Services 01752 434723). (ext. 34723)

9.7 For reasons of patient safety we do not advocate verbal transmission of results. All primary and secondary care areas should have access to results electronically via System 1. In rare cases where this fails 9.6 would apply.

9.8 Compliance with NICE monitoring guidelines will be demonstrated by audit as per audit tool (see appendix 1) and corporate audit plan.

10. Communication of test results

10.1 The results of initial assessment tests and all monitoring to date will be included with the referral documentation from consultant psychiatrist to primary care doctor at the point of commencing the shared care agreement.

10.2 All test results will be recorded in the patient monitoring booklet by the healthcare professional responsible or by the patient if assessed as reliable to do so.

10.3 GPs receive test results electronically from Derriford combined laboratories; however results of blood tests should always be included in discharge summaries and letters.

10.4 When requesting lithium levels for outpatients secondary care doctors should complete the GP details in the appropriate box on the form so that the results will automatically be sent electronically to the GP.

10.5 Effective communication between providers is important to achieve adequate, but not excessive, monitoring.

10.6 Compliance with agreed standards for communication of monitoring results will be demonstrated by audit (see appendix 2)

11. Patient information and record books

11.1 At the start of lithium treatment the doctor will discuss with the patient the benefits and risks of lithium therapy and the need for regular blood tests.

11.2 At the start of treatment the patient will be issued with an NPSA patient information pack, consisting of an outer wallet containing an A5 patient information booklet, A6 lithium therapy record book and a lithium alert card. The details required in the first three pages of each booklet and on the alert card should be completed with the patient. A record should be made in the patient notes of the supply of the booklet.

11.3 The information booklet should form the basis of the discussion with the patient so that they fully understand the risks and benefits of treatment and the need for close monitoring.

11.4 Patients should be instructed to carry the alert card with them at all times and to ensure they have the record book with them whenever they see their Consultant or GP, when requesting a prescription or having one dispensed, or when admitted to hospital.

11.5 An initial supply of patient booklets was sent to all mental health units / wards and to other inpatient areas. Further supplies may be obtained from Pharmacy Services 34725 (ext.: 01752 434725)

11.6 Compliance with agreed standards to confirm that patients have been issued with patient booklets and that the record book has up-to-date records of blood test results and health checks will be demonstrated by audit (see appendix 1). It is recognised that patients on lithium are often unreliable in retention and use of patient booklets.

12. Checks at the point of prescribing, dispensing and administration

12.1 Prior to prescribing or dispensing **every** prescription for lithium, prescribers and pharmacists should check the scheduling of blood tests to reassure themselves that, given the test results, no patient harm will result.

12.2 There should be a process in place to ensure that repeat lithium requests are brought to the attention of a GP so they can be assured that the necessary monitoring has taken place before signing the prescription. This might be similar to the system in place for warfarin requests.

12.3 For clarity, prescriptions should not be issued if **any** of the following apply:

- If the current blood level is above 2mmol/L or above 1.5mmol/L and the patient has symptoms of toxicity (see shared care guideline) - arrange for the patient to be transferred to Accident and Emergency.
- For elderly patients if the current blood level is above 1mmol/L and the patient has symptoms of toxicity - arrange for the patient to be transferred to Accident and Emergency.
- If the current blood level is above the target range and the patient has symptoms of toxicity - refer the patient immediately to the consultant or, if the patient is unlikely to be seen promptly, to Accident and Emergency.

12.4 If any of the following apply the prescription may be issued but the remedial action indicated must be taken:

- If the current blood level is below the target range or above the target range but the patient has no symptoms of toxicity - inform the consultant at the earliest opportunity.
- If the lithium blood level has not been checked within the last three months (or within one week following a dose change) – ensure a repeat blood test is performed without delay and make any dosage adjustment necessary.
- If the patient refuses to cooperate with blood tests – refer to consultant.
- If kidney or thyroid tests are overdue – ensure they are performed without delay.

12.5 Pharmacists on inpatient wards when clinically screening prescriptions should ensure that lithium levels have been performed appropriately and are within the range for the patient. They should also ensure that kidney and thyroid tests have been performed according to schedule and that all results are entered in the patient booklet. Any discrepancies or problems should be brought to the attention of the duty doctor or consultant.

12.6 **Pharmacists at PHNT:** Check that a pharmacist clinical screen has been done at ward level before supplying lithium against in-patient / discharge prescriptions. When this does not appear to have taken place on the ward, the pharmacist should make the supply and then telephone LSW Pharmacy Services on 34723 (or 39006 for Glenbourne) to inform us that a supply has been made without the appropriate assurance of monitoring being available. If there is no reply on this number a voicemail message should be left to include: the supplying pharmacist's name;

patient's name; NHS / Hospital number; ward; strength, preparation and quantity of lithium supplied; and the date of supply. Lithium should not be withheld unless the pharmacist has reason to believe that the patient has toxic lithium levels (see section 13).If lithium has been stopped on admission check that this is appropriate i.e. due to toxicity (see section 12.3) or other clinical reason. If not then the prescriber should be asked to discuss the decision with the patient's consultant psychiatrist (or if not available contact the Derriford Liaison Psychiatry Team). A LSW Pharmacist will pick up this message on the next working day and ensure the appropriate checks are made and the supplying pharmacist at PHNT is informed.

12.7 Nurses should not administer lithium to any patient who is showing signs of toxicity and / or for whom the current blood level is above 1.5mmol/L (or above 1mmol/L in elderly patients). The duty doctor or consultant should be contacted immediately for advice.

12.8 Where patients are unwilling to accept and use a record system for personal monitoring, and it is not possible to otherwise perform this check, the patient should be referred back to the consultant for a review of lithium therapy. In this situation shared care may not possible and consideration should be given to whether lithium is still the most appropriate treatment for the patient.

12.9 Notwithstanding the above, patients stabilised on lithium should not have their lithium withheld due to insufficient monitoring or lack of information (e.g. patient forgets to bring in record book). Action should instead be taken to ensure that the correct monitoring is achieved as soon as possible.

12.10 The audit tool (see appendix 1) will monitor the checking process and identify where this has not been possible.

13. Identification of adverse reactions, toxicity and drug interactions

13.1 Please refer to the shared care information[7] for information regarding adverse drug reactions, symptoms of toxicity and potential drug interactions.

13.2 Chronic lithium toxicity has been reported to have 9% mortality, whilst acute toxicity has 25% mortality. However, patients with chronic lithium toxicity are more likely to experience severe symptoms at lower serum levels. Concurrent medication, older age and prior neurological illness may increase susceptibility to lithium toxicity.[10]

13.3 Many of the interactions involving lithium occur because of altered serum lithium concentrations related to its excretion by the kidney. Therefore drugs that affect renal excretion, e.g. diuretics, or those affecting electrolyte balance, e.g. sodium compounds, are likely to interact. [10] In many cases these interactions can be managed by close monitoring, but where possible alternative drugs that do not interact should be used.

13.4 In addition there are several lithium neurotoxicity interactions with centrally active drugs e.g. antipsychotics, antidepressants and carbamazepine. Importantly these can occur when serum lithium concentrations are within the normal range. [10]

13.5 If side effects or symptoms of toxicity are suspected the patient should be referred to their consultant, or in an emergency situation, e.g. serum levels 2mmol/L or more, to Accident and Emergency.

13.6 If a new drug (or change in dosage) is to be prescribed for a patient on lithium the potential for drug interaction should be checked in the shared care information[7] and the latest version of the BNF[8]. If an interaction is listed then advice on management should be sought from either the Consultant, Pharmacy Services (int.: 34723; ext.: 01752 434723) or Medicines Information, Derriford Pharmacy (int. 39976, ext.: 01752 439976).

13.7 Community pharmacists and secondary care pharmacists will inform the prescriber (GP or consultant as appropriate) if an interacting drug is prescribed, and advise on management strategies if required.

13.8 If an interacting drug is to be used then all involved (patient, consultant, GP, pharmacist and nurse as appropriate) should be informed of the additional monitoring requirements and who to contact should the patient develop symptoms of toxicity or worsening mental state.

13.9 Patients should be warned to check with their doctor or pharmacist before taking any additional medication 'over the counter' and to follow the advice in section 6 and 7 of the patient booklet with regard to diet, dehydration and signs of toxicity.

13.10 The audit tool (see appendix 1) will monitor communications and subsequent actions where clinically important interactions are identified.

Approval by Medicines Governance Group (MGG)

Chief Pharmacist (Chair of MGG)

Name: Steve Cooke

Signature:…

Date: 27/07/16

Final Approval by Livewell Southwest

Medical Director

Name: Dr. Adam Morris

Signature…

Date: 27/07/16

Appendix 1: Audit Tool

NPSA Patient Safety Alert 2009/PSA005; Safer Lithium Therapy Audit Tool: For period …….. to ……

First 2 letters of Surname……. Initial of first name…… Hospital Number…….. DoB……

1. Monitoring has been performed in accordance with NICE CG 185:	Yes	No	N/A	Comments:
1.1 Initial plasma level within 7 days of starting treatment and each dose change				
1.2 Plasma lithium level every 3 months for 1st year then 6 monthly except at risk groups to continue 3 monthly (see guideline)				
1.3 Additional plasma lithium level if interacting drug added or stopped				
1.4 U&E/Renal function at initiation then every 6 months				
1.5 TFT at initiation then every 6 months				
1.6 Weight and Height at the start of treatment then if patient gains weight rapidly				
1.7 ECG prior to initiation if CVD or risk factors present				
2. Timeliness of communication of test results	No. days:			Comments:
2.1 Time lapse between lithium plasma level request and result issued	Yes	No	N/A	
2.2 Test results communicated between secondary and primary care	No. Days:			
2.3 Time lapse between test results received in secondary care and communicated to primary care				
3. Patient Information/Booklets	Yes	No	N/A	Comments:
3.1 Patient has been issued with a lithium booklet				
3.2 Patient details / treatment pages completed				
3.2 Patient's lithium booklet is up-to-date with test results				

. Blood tests are checked before prescribing/dispensing lithium	Yes	No	N/A	Comments:
4.1 There is evidence that blood tests have been checked before prescribing				
4.2 There is evidence that blood tests have been checked before dispensing (in Secondary Care)				
4.3 There is evidence that appropriate action has been taken when serum levels are found to be out of range.				

5. Interacting Medicines	Yes	No	N/A	Comments:
5.1 Significant potential interactions have been communicated to prescriber				
5.2 Correct action taken and documented				
5.3 Changes to monitoring frequency or blood level range communicated to patient, GP, pharmacist and nurse as appropriate				

Completed by:…… Date…….