NHS FORTH VALLEY

Safer Lithium Dispensing Guidance

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Author / Contact	Michael Cohen	
Group / Committee – Final Approval	Primary Care Drug & Therapeutic Committee	

NHS Forth Valley

Consultation and Change Record

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Consultation Process:	Lithium Short Life Working Group Area Pharmaceutical Committee Primary Care Drug & Therapeutics Committee
Distribution:	Community Pharmacy NHS website, Forth Valley pages Community Pharmacists

Change Record

Date	Author	Change	Version
02/11/2011	MC	Pharmacist to remind the patient to take their Lithium Therapy Record Book with them when they visit clinic/GP	2
02/11/2011	MC	Pharmacist to contact prescriber if lithium levels have not been checked within the last 4 months (changed from 6 months)	2
Nov 2012	MC	Hyperlinks added	3

1. Introduction

In December 2009 the National Patient Safety Agency (NPSA) issued a Patient Safety Alert on safer lithium therapy: NPSA Patient Safety Alert – Safer lithium therapy (NPSA 2009/PSA005).

- There have been deaths, severe harm and a substantial number of reports relating to lithium therapy. Analysis of errors reported to the National Patient Safety Agency (NPSA) Reporting and Learning System suggests lithium therapy is an error-prone process. Monitoring of lithium therapy is a specific issue. A recent audit demonstrates less than optimal monitoring of lithium and a failure to adequately prepare patients to recognise therapy-induced side effects or toxicity. Some patients taking lithium have been harmed because they have not had their dosage adjusted based on recommended regular blood tests. If patients are not informed of the known side effects or symptoms of toxicity, they cannot manage their lithium therapy safely.

- Regular blood tests are important. Clinically significant alterations in lithium blood levels occur with commonly prescribed and over-the-counter medicines. The blood level of lithium is dependent on kidney function and lithium has the potential to interfere with kidney (renal) and thyroid functions.

2. Policy Statement

The National Patient Safety Agency (NPSA) has published new guidance for NHS and independent healthcare organisations to improve the safety of lithium therapy.
The Patient Safety Alert calls on frontline services to ensure that patients who are prescribed lithium are monitored in accordance with the National Institute for Clinical Excellence (NICE) guidelines. These stipulate that lithium blood levels should be assessed every three months, while thyroid and renal function tests should be undertaken every six months. In addition, the Patient Safety Alert is calling on healthcare providers to ensure that:

- There are reliable systems in place to make sure that the results of blood tests are communicated between laboratories and prescribers
- 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
- **Prescribers and pharmacists check that blood tests are being monitored regularly and that it is safe to issue a repeat prescription or dispense the prescribed lithium**
- **Systems are in place to identify and deal with medicines that might adversely interact with lithium therapy**
- The NPSA has developed a patient information booklet, lithium alert card and record book for tracking blood tests. These resources should be made available to all patients on lithium therapy and their use supported by healthcare professionals.

3. Scope

This guidance applies to all community pharmacists working within NHS Forth Valley. A template for a Standard Operating Procedure is included in appendix 1 for information or adaptation.

4. Action for Pharmacists

4.1 Ask the patient or their carer if you can see their Lithium Therapy Record Book (ask them to bring it next time if they don't have it with them, also remind them to take it when they visit the clinic/GP) which should have the following up to date information recorded:

- Current lithium blood level. This should be within the patient's blood level range (also recorded) and be checked every 3 months (blood levels are an indication of clinical efficacy or potential toxicity)

- Thyroid function test results. These should be within normal range and be measured every 6 months (lithium is associated with long-term risk of hypothyroidism)

- Renal function test results. eGFR should be monitored every 6 months (lithium is associated with long-term risk of chronic renal impairment and dose may need to be adjusted as a consequence of deteriorating renal function especially in the elderly)

- Weight and BMI. Weight should be measured every 12 months (weight loss may indicate worsening depression and weight gain may be linked to hypothyroidism)

- Consider copying this information into the pharmacy PMR or PCR

4.2 Ensure that the patient is aware of the importance of regular blood tests (above) and encourage the patient to attend for regular monitoring as described. Advise the patient to make an appointment with the prescriber if required. **Contact the prescriber if lithium levels have not been checked within the last 4 months, if the lithium blood level is outwith the normal therapeutic range or if you suspect that the patient is suffering from lithium toxicity** (severe hand tremor; stomach ache along with nausea and diarrhoea; muscle weakness; unsteady on feet; muscle twitches; slurring of words; blurred vision; confusion; feeling sleepy).

4.3 Remind patients of the following:

- That they need to maintain a consistent intake of fluid and specifically not to become dehydrated
- To swallow tablets whole and not crush or chew
- To take lithium doses at the same time each day. Lithium doses are normally taken in the evening to facilitate monitoring (lithium levels must be measured at least 12 hours after last dose)
- Women of child bearing potential being prescribed lithium should adopt adequate contraceptive methods.

4.4 Advise patients to contact their prescriber if they have concerns about lithium side effects

Side effects of lithium	Signs of lithium toxicity
Upset stomach – particularly at the start of treatment Fine shake (‘tremor’) of hands Metallic taste in mouth Weight gain Swelling of ankles Feeling of thirst and passing a lot of urine Reduction in thyroid activity Alteration of renal function	Severe hand shake (‘tremor’) Stomach ache along with nausea and diarrhoea Muscle weakness Being unsteady on feet Muscle twitches Slurring of words Blurred vision Confusion Feeling sleepy

4.5 Check PMR for any newly prescribed or deleted medication which may alter lithium levels e.g. ACE inhibitors, Angiotensin II receptor antagonists, NSAIDs, thiazide diuretics or sodium containing antacids. Check any OTC medication that the patient would like to purchase does not affect lithium blood levels e.g. NSAIDs and sodium containing products (e.g. antacids, effervescent preparations, health salts). **Contact the prescriber if you have any concerns about interacting medication** (bear in mind that it will be difficult to titrate lithium doses if interacting medication is taken intermittently).

4.6 Copy contact details of health professionals found on lithium card or record book into pharmacy PMR. Also ensure that current brand, formulation and dose of lithium is recorded in PMR (lithium brands are not interchangeable).

5. Resources and Further Information

The Patient Safety Alert, supporting documentation and PDFs of a Lithium Therapy Record book, *Lithium Therapy – Important information for patients* booklet and Lithium Alert Card can be accessed and downloaded from the NPSA website at http://www.npsa.nhs.uk.

The contact for the Alert is:
Dr David Gerrett
Senior Pharmacist
National Patient Safety Agency
4-8 Maple St
London
W1T 5HD
david.gerrett@NPSA.NHS.UK

National Institute for Clinical Excellence (NICE 2006). Bipolar Disorder: The management of bipolar disorder in adults, children and adolescents in primary and secondary care. Clinical Guideline 38, www.nice.org.uk

National Patient Safety Agency (NPSA), Patient Safety Alert NPSA/2009/PSA005, www.nrls.npsa.nhs.uk/alerts

National Institute for Clinical Excellence (NICE) indicator guidance for QOF-Mental Health, July 2010, www.nice.org.uk

British National Formulary Edition 59, March 2010, www.bnf.org

Further References

- Ward ME, et al. Clinical pharmacokinetics of lithium. J Clin Pharmacol 1994;34:280–5.
- Reiss RA, et al. Lithium pharmacokinetics in the obese. Clin Pharmacol Ther 1994;55:392–8.
- Thomsen K, Schou M. Avoidance of lithium intoxication: advice based on knowledge about the renal lithium clearance under various circumstances. Pharmacopsychiatry 1999;32:83–6.
- Sproule BA, et al. Differential pharmacokinetics of lithium in elderly patients. Drugs Aging 2000;16:165–77.
- Kripalani M, Shawcross J, Reilly J, Main J. Lithium and chronic kidney disease. BMJ 2009;339:b2452
- Livingstone C, Rampes *J.* Lithium: a review of its metabolic adverse effects. *Psychopharmacol* 2006;20(3):347-55.

The Mental Health Pharmacy Team can be contacted at FVRH (01324 566728) for further guidance if required.

The link to NHS Forth Valley Guideline for the Management of Patients on Lithium can be found on the NHS Forth Valley Intranet, http://intranet.fv.scot.nhs.uk/home/Depts/PrimaryPharmacy/Pharm_Clinical_Documentation/pharm_guidance.asp

6. Appendix 1: Standard Operating Procedure Template

Standard Operating Procedure for Dispensing of Lithium Therapy

Name of Pharmacy:	
Purpose To reduce the risk of patients being harmed by lithium therapy To ensure that all patients have been appropriately counselled To ensure that patients are aware of the importance of regular blood tests To ensure all patients know what dose to take and when to take it	**Scope** This procedure relates to the supply of lithium therapy and includes actions which must be followed in addition to those contained in other SOPs relating to the dispensing process

Procedures/ Process	**Responsibility**
1) Ask the patient or their carer if you can see their Lithium Therapy Record Book (ask them to bring it next time if they don't have it with them, also remind them to take it when they visit the clinic/GP) which should have the following up to date information recorded: • Current lithium blood level. This should be within the patient's blood level range (also recorded) and be checked every 3 months (blood levels are an indication of clinical efficacy or potential toxicity) • Thyroid function test results. These should be within normal range and be measured every 6 months (lithium is associated with long-term risk of hypothyroidism) • Renal function test results. eGFR should be monitored every 6 months (lithium is associated with long-term risk of chronic renal impairment and dose may need to be adjusted as a consequence of deteriorating renal function especially in the elderly) • Weight and BMI. Weight should be measured every 12 months (weight loss may indicate worsening depression and weight gain may be linked to hypothyroidism) Consider copying this information into the pharmacy PMR or PCR.	

2) Ensure that the patient is aware of the importance of regular blood tests (under 1) above) and encourage the patient to attend for regular monitoring as described. Advise the patient to make an appointment with the prescriber if required. **Contact the prescriber if lithium levels have not been checked within the last 4 months, if the lithium blood level is outwith the normal therapeutic range or if you suspect that the patient is suffering from lithium toxicity** (severe hand tremor; stomach ache along with nausea and diarrhoea; muscle weakness; unsteady on feet; muscle twitches; slurring of words; blurred vision; confusion; feeling sleepy).	
3) Remind patients of the following: • That they need to maintain a consistent intake of fluid and specifically not to become dehydrated • To swallow tablets whole and not crush or chew • To take lithium doses at the same time each day. Lithium doses are normally taken in the evening to facilitate monitoring (lithium levels must be measured at least 12 hours after last dose). • Women of child bearing potential being prescribed lithium should adopt adequate contraceptive methods.	
4) Advise patients to contact their prescriber if they have concerns about lithium side effects (upset stomach, fine hand tremor, metallic taste, weight gain, ankle swelling, thirst and passing a lot of urine, reduction in thyroid activity, alteration of renal function).	
5) Check PMR for any newly prescribed or deleted medication which may alter lithium levels e.g. ACE inhibitors, Angiotensin II receptor antagonists, NSAIDs, thiazide diuretics or sodium containing products. Check any OTC medication that the patient would like to purchase does not affect lithium blood levels e.g. NSAIDs and sodium containing products (e.g. antacids, effervescent preparations, health salts). **Contact the prescriber if you have any concerns about interacting medication** (bear in mind that it will be difficult to titrate lithium doses if interacting medication is taken intermittently).	

6) Copy contact details of health professionals found on lithium card or record book into pharmacy PMR. Also ensure that current brand, formulation and dose of lithium is recorded in PMR (lithium brands are not interchangeable).	

Review Procedure This procedure will be reviewed when there are any new professional recommendations or in the event of critical incidents. In the absence of any of these events, it will be reviewed every two years	**Prepared by:**
	Signature:
	Date of preparation:
	Date effective from:
	Version number:
	Date of review:
Known Risks Incorrect dose taken; patient not being monitored; patient not present in the pharmacy; lithium toxicity	

I have signed to say that I have read the procedure and understand its implications.

Name	Signature	Date

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