

Community Pharmacy Lithium Audit 2011/2012

AUDIT PACK

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Aim

To audit the monitoring aspects of lithium therapy and adherence to the "Safer Lithium Therapy" Patient Safety Alert (NPSA 1st December 2009) in Community Pharmacy.
(See Appendix)

Rationale and Background

Supported by the 2006 NICE guidelines for depression and bipolar disorder and the British Association for Psychopharmacology, lithium is used clinically for:

Bipolar disorder	Unipolar depression
<ul style="list-style-type: none">• Acute treatment of mania• Bipolar depression• Prophylaxis	<ul style="list-style-type: none">• Treatment of refractory depression

For most patients, lithium is a long-term treatment. E.g. it is recommended that patients with bipolar disorder take lithium for at least three years.

Risks

The National Patient Safety Agency (NPSA) has received a substantial number of reports relating to incidents with lithium therapy in which there has been severe harm or death. Analysis of these errors reported to the NPSA suggests lithium therapy is an error-prone process.

Lithium has a narrow therapeutic range necessitating blood levels between 0.4-1.2mmol/L. The lower end of this range is used for elderly and infirm patients and the upper end for younger patients, particularly those being treated for an episode of mania.

The NICE guidance is that when initiating long-term treatment, clinicians should aim for levels of 0.6-0.8 mmol/L, with higher levels possibly being of benefit for patients with predominantly manic symptoms.

If the concentration of lithium in the blood is too high the following may occur:-

- blurred vision
- muscle weakness
- coarse tremor
- slurred speech
- confusion
- seizures
- renal damage

Lithium treatment also increases the risk of clinical hypothyroidism up to five-fold, the risk being particularly high in women who are 40-59 years old. The clinical symptoms of hypothyroidism overlap with those of depression and may therefore remain undiagnosed and untreated unless specific screening tests are undertaken.

Monitoring of lithium therapy, therefore, is a specific issue. Maintaining patients within the appropriate therapeutic margin requires scheduled monitoring. NICE guidance requires that patients are monitored in either primary care, secondary care or both.

To minimise risks there are a number of tests that must be done during treatment:-

- | | |
|-------------------------------|----------------|
| • Lithium Blood Levels | every 3 months |
| • Thyroid Function Test (TFT) | every 6 months |
| • Renal Function Test (RFT) | every 6 months |
| • Weight/BMI | annually |

Please note that where there is a dose change the lithium levels should be monitored weekly until levels are held constant for 4 weeks. Subsequently, once levels are constant, then lithium levels can be monitored every 3 months

Communication between healthcare providers is essential and may be facilitated by patient-held records.

A patient booklet, alert card and record book have been developed to support communication between healthcare providers and empower patients taking lithium. This informs patients of key aspects of their treatment including side effects and toxicity. These materials should be distributed by the practitioner initiating treatment. However supply may also be made via the community pharmacies. These resources should be made available to all patients on lithium therapy and their use should be supported by healthcare professionals.

Further supplies of these may be obtained from:-

Sheffield FHS
Brincliffe House
90 Osborne Rd
Sheffield
S11 9BD
Tel:- (0114) 305 1800 / 305 1789

As a direct result of the risks relating to lithium therapy the NPSA issued an alert in December 2009(NPSA/2009/PSA005) stating the actions required to ensure safe prescribing of lithium, with a deadline of 31 December 2010, for all organisations in the NHS and independent sector where lithium therapy is initiated, prescribed, dispensed and monitored.

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 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;
5. Systems are in place to identify and deal with medicines that might adversely interact with lithium therapy.

This audit is based upon this alert.

Criteria and Standards

(Based on NPSA alert: Safer Lithium Therapy 2009)

Criteria	Standard
1. All patients on lithium therapy should have received three resources in a purple folder-lithium therapy: important information for patients, lithium alert card and a record book	80%
2. With every lithium prescription, the Community Pharmacist checks that the blood tests and weight measurements are being monitored regularly and that it is clinically safe to dispense the lithium prescription. <ul style="list-style-type: none"> Lithium blood levels monitored within the previous 3 months Thyroid and renal function tests within the previous 6 months BMI or weight monitored within the previous 12 months 	80%
3. Current lithium blood level is within the recorded range	80%
4. Standard Operating Procedures (SOPs) should describe a clear process for dispensing that must be adhered to if the patient's safety is compromised (Note, as a principle, therapy should not be withheld for example when no blood tests available)	100%
5. Checks are undertaken in the pharmacy to identify and deal with medicines that might inadvertently interact with lithium therapy whether prescribed or OTC medicines (SOPs, PMR, MAR Charts). Note as a minimum the following lithium interactions must be highlighted: <ul style="list-style-type: none"> Thiazides and related diuretics ACE inhibitors NSAIDs Sodium bicarbonate containing non-prescription antacids or urinary alkalisating agents 	80%

Guidance if Criteria 1, 2 or 3 are not met

- If patient does not possess a booklet then one must be provided (GP or pharmacy)
- Where it is not possible to assess monitoring then the pharmacist responsible for dispensing the prescription (or making an emergency supply) should communicate to the prescriber that the lithium medication has been provided without the blood test data being available

Guidance for Criteria 5

- The Pharmacist dispensing the prescription needs to consult with the patient and /or carer to highlight the potential lithium interactions with the OTC medications that the patient may be taking
- The Pharmacist dispensing must communicate to the prescriber the potential for lithium's interactions with the prescribed medication
- Guidance does not override the individual responsibility of community pharmacists to make appropriate decisions in the circumstances of the individual patient and/or carer

Method

- For a period of three months collect information from all patients who present with a prescription for lithium.
- Record patient details on **Table 1**, assigning a unique reference number for each patient. (The reference number will be used to record data in **Table 2**)
- Fill in data collection **Table 2**
- Complete **Table 3** to summarize adherence to audit standards and complete discussion points and conclusions.

Note:- Within the three month period the same patient may present on more than one occasion. Please collect data for each visit, using the same patient reference number

Timescales

1st August – 30th October 2011	Data collection within community pharmacies
18th November 2011	Deadline for submitting data collection forms to PCT
27th January 2012	Data analysis and production of report
2nd Mar 2012	Dissemination of report to all community pharmacies

Please submit by 18th November 2011 to:-

**Tracey Robinson,
Clinical Audit & Effectiveness Assistant,
NHS Sheffield,
722 Prince of Wales Road,
Sheffield S9 4EU**

(Please retain a copy for your records.)

Do not include patient identifiable data in any forms submitted to the PCT. However, keep records at the pharmacy as it may be necessary to follow patients up as a result of this audit.

Bibliography

1. National Institute for Clinical Excellence. Bipolar disorder: The management of bipolar disorder in adults, children and adolescents, in primary and secondary care. *Clinical Guideline 38, 2006.*
www.nice.org.uk
2. National Patient Safety Agency. Patient Safety Alert NPSA 2009/PSA005, Safer Lithium Therapy.
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=65426>

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Apply Pharmacy Name and Address Label

Table 3: Adherence to Criteria

Total Number of Patients in audit (N)

Criteria	Number of patients meeting criteria (Z)	%Adherence to criteria (100 x (Z/N))	Action points and comments
1. All patients on lithium therapy should have received lithium therapy booklet (by the initiating clinician)patients%	
3.a. Lithium blood levels monitored within previous 3 months b. Thyroid and renal function tests monitored within previous 6 months c. BMI or weight monitored within previous 12 months	a.patients b.patients c.patients	a.% b.% c.%	
3.Current lithium blood level is within rangepatients%	
4. Dispensing Standard Operating Procedures include processes that must be followed to ensure that it is safe to issue the Lithium*	YES or NO (Please delete as appropriate)	Either 0% or 100%	
5. Interacting medications (prescribed or OTC medicine) checked Y/N Note as a minimum the following must be highlighted <ul style="list-style-type: none"> • Thiazides and related diuretics • ACE inhibitors • NSAIDS • Sodium bicarbonate containing non-prescription antacids or urinary alkalisising agents 	State how many patients were checked for interactions with lithium therapy on PMR (for prescribed medicines) or verbally for OTC patients%	

* i.e. SOPs include the need to check that blood tests are monitored regularly, potential interactions are checked and that it is safe to dispense Lithium

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Patient Safety Alert

NPSA/2009/PSA005
1 December 2009



National Patient
Safety Agency

National Reporting
and Learning Service

Safer lithium therapy

Issue

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.

Patient safety incidents

The National Patient Safety Agency (NPSA) received 567 incident reports (October 2003 to December 2008) relating to lithium use. Two reports were of severe harm, 34 moderate and 531 low or no harm. The most common error was 'wrong or unclear dose or strength' (124 incidents).

The NHS Litigation Authority dealt with two fatal and 12 severe harm incidents¹ involving lithium therapy and the Medical Defence Union has been involved with 15 incidents directly related to lithium toxicity and monitoring.

An audit² found that only 42 per cent of patients on initiation of lithium therapy were documented to have been informed of risk factors for toxicity. For patients maintained on lithium therapy in the previous year, the audit found:

- one in 10 patients had no documented lithium blood level. (National Institute for Health and Clinical Excellence (NICE) standard: one blood level measurement every three months. Not met for 70 per cent of patients);
- one in five patients had no renal function tests documented (NICE standard: assessment every six months. Not met for 46 per cent of patients);
- one in six patients had no thyroid function tests documented (NICE standard: assessment every six months. Not met for 51 per cent of patients).

Supporting information

Further information and support materials to implement this guidance are available from: www.nrls.npsa.nhs.uk/alerts

Further information

Email: medicationteamenquiries@npsa.nhs.uk
Tel: 020 7927 9356

Action by all organisations in the NHS and independent sector

Action for all organisations in the NHS and independent sector where lithium therapy is initiated, prescribed, dispensed and monitored.

An executive director, nominated by the chief executive, working with relevant medical, nursing and pharmacy staff and the lead biochemist providing services to the trust, should ensure that **by 31 December 2010:**

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 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;
5. 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.

1. Between 1995 and 2004.

2. Prescribing Observatory for Mental Health. Topic 7 baseline report. Monitoring of patient prescribed lithium: baseline. Prescribing Observatory for Mental Health, CRTUO69 (data on file), 2009.