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North of England Commissioning Support

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Medicines Optimisation

Lithium Care Bundle

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1. Introduction

1.1. What is a care bundle?

A care bundle is a set of interventions that, when used together, significantly improve patient outcomes. The measures chosen reflect best practice and are based on NICE quality standards or other national guidance. Care bundles have been used extensively and successfully in Secondary Care, their use in Primary Care is more recent. This care bundle is based on the work of Healthcare Improvement Scotland and the Scottish Patient Safety Programme in Primary Care.

Reliability in health care is a failure-free operation over time. This equates to ensuring patients receive all the evidence-based care they are entitled to receive.

A care bundle is a structured way of improving processes of care to deliver enhanced patient safety and clinical outcomes. In relation to care bundles, this means ensuring that patients receive optimum care at every contact. The process for achieving reliability is to implement this set of measures (a care bundle). The key measure in a care bundle is the score which measures the level of compliance with all measures for all patients.

The care bundle data collection tool is a way of sampling whether optimum care is being delivered by applying the bundle to a sample of patients. This approach is therefore very different from traditional auditing approaches that are designed to identify whether individual measures are being implemented.

1.2. What makes up a care bundle?

- 4-5 measures
- All or nothing compliance
- Measurement done by a non-clinician if possible
- Spread over patient's journey
- Evidence based
- Creates teamwork and communication
- Multiple functions of care essential for desired outcome

1.2.1. How should a care bundle be used in practice?

A care bundle is a quality improvement tool which can be used in general practice to identify both where care is in line with best practice and where improvements are needed. Some are disease specific and some are medication specific. The latter are also known as patient safety bundles as they relate to high risk medication.

Bringing about changes in practice is not easy. To be an effective tool the results of the care bundle measurements must be discussed by ALL members of the team involved in the care of the patient. The practice team then need to take ownership of the issues identified and commit to changing the way care is provided, using tools such as the Plan Do Study Act (PDSA) cycle.

Principles of successful measurement:

- The support of all members of the practice team should be obtained
- Data should be collected anonymously
- The results should be discussed by every member of the team
- The results should be used to plan and implement improvement initiatives
- Clinician support may be needed initially by the data collector until they are familiar with the measures.

1.3. Records

The care bundle is not a performance tool and so there is no requirement to report the measures achieved. The practice should keep a reflective log of improvements.

1.4. Resources

This care bundle has the following supporting resources:

- A word document data collection form
- An excel spreadsheet data collection form with a graphing function
- A reflective log template

Further information on Care Bundles and Improvement Models can be found at NHS Scotland: https://learn.nes.nhs.scot/931/patient-safety-zone/patient-safety-tools-and-techniques/care-bundles

Evidence:

https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0670-0

The above link may need copying and pasting into web browser if struggling to access via control and click.

Further advice can be obtained from the Medicines Optimisation Team, and specific queries about this care bundle can be directed to the author (details are on the front page).

2. Lithium.

2.1. Search Criteria

Please identify a random sample of up to 20 patients prescribed lithium. Numbers in practice may actually be much lower.

This may be done by using the search within the practices clinical system. In EMIS this search may be found under: EMIS Library/Emis Clinical Utilities/Drug Monitoring/Psychiatry. A bespoke search is also available for importing/use. Please see information in appendix two if using this.

Use the data collection form to record the answer to each measure and transfer this to the Excel spreadsheet data collection form if wanting to use this. If used, the Excel spreadsheet will result in graphs being populated with ongoing scores. This should be repeated over a period of time, and the results discussed by the clinical team at regular intervals. Every three months is recommended. Use of the spreadsheet will enable changes in practice to be monitored and compliance with the care bundle to be measured.

2.2. Measures

These specific care bundle measures have been selected to focus safety improvements on local concerns. Our local Trusts Medication Safety Officer has highlighted dehydration, deteriorating renal function and interacting drugs as issues that were implicated with lithium toxicity in reported lithium incidents. We would fully expect that all safety recommendations such as ensuring patients having physical health monitoring and annual physical health checks (where clinically indicated) would be followed. The care bundle can only include 5 measures which have been prioritised to those most likely to reduce the toxicity incidents seen locally.

See Appendix 2 for further guidance about how to answer each measure.

01

Measure	Patient's latest serum lithium levels (taken at least within the last 3-6 months as per recommendations below) are between 0.6-0.8 mmol/L (unless specified otherwise by a specialist). Y/N
Rationale	Patients prescribed lithium are monitored in accordance with NICE guidance. There are reliable systems to ensure blood test results are communicated between laboratories and prescribers. 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.

	Measure plasma lithium levels 1 week after starting lithium and 1 week after every dose change, and weekly until the levels are stable. Aim to maintain plasma lithium level between 0.6 and 0.8 mmol per litre in people being prescribed lithium for the first time. Measure the person's plasma lithium level every 3 months for the first year. After the first year, measure plasma lithium levels every 6 months, or every 3 months for people in any of the following groups: older people, people taking drugs that interact with lithium, people who are at risk of impaired renal or thyroid function, raised calcium levels or other complications, people who have poor symptom control, people with poor adherence, people whose last plasma lithium level was 0.8 mmol per litre or higher.
Source	NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy. Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence. Lithium Carbonate (Priadel® and Camcolit®) SPC.

02

Measure	The patient has an estimated glomerular filtration rate (eGFR) test recorded in the past 6 months. Where this has dropped significantly, therapy has been re-assessed. Y/N
Rationale	Patients prescribed lithium are monitored in accordance with NICE guidance. There are reliable systems to ensure blood test results are communicated between laboratories and prescribers. 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. Measure the person's weight or BMI and arrange tests for urea and electrolytes including calcium, estimated glomerular filtration rate (eGFR) and thyroid function every 6 months, and more often if there is evidence of impaired renal or thyroid function, raised calcium levels or an increase in mood symptoms that might be related to impaired thyroid function. Monitor lithium dose and plasma lithium levels more frequently if urea levels and creatinine levels become elevated, or eGFR falls over 2 or more tests, and assess the rate of deterioration of renal function.
Source	Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence. Lithium Carbonate (Priadel® and Camcolit®) SPC. NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy.

03

Measure	When starting new medicines interacting with lithium / or issuing interacting 'when required' medicines (therefore increasing the risk of toxicity), patients have had information at initiation and a review of therapy within 3 months (in line with next check of lithium level). Patients who are prescribed long-term interacting medicines have had a review of therapy within the last 12 months. Y/N/NA
Rationale	Systems are in place to identify and deal with medicines that might adversely interact with lithium therapy. Warn people taking lithium not to take over-the-counter non-steroidal anti-inflammatory drugs (NSAIDs) and avoid prescribing these drugs for people with bipolar disorder if possible; if they are prescribed, this should be on a regular (not when required) basis and the person should be monitored monthly until a stable lithium level is reached and then every 3 months. After the first year, measure plasma lithium levels every 6 months, or every 3 months for people in any of the following groups: older people, people taking drugs that interact with lithium, people who are at risk of impaired renal or thyroid function, raised calcium levels or other complications, people who have poor symptom control, people with poor adherence, people whose last plasma lithium level was 0.8 mmol per litre or higher. Be alert to the potential for drug interactions and use clinical judgement. This includes: • Metronidazole • NSAIDs, including Cyclo-oxygenase 2 (COX-2) selective inhibitors • Angiotensin converting enzyme (ACE) inhibitors • Angiotensin II receptor antagonists • Diuretics • Other medicines that affect fluid balance eg. oral or high-dose inhaled steroids • Tetracyclines
Source	Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence. NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy. Lithium Carbonate (Priadel® and Camcolit®) SPC.

04

Measure	Patient has a record of discussion of side effects relating to lithium toxicity in the last 12 months? Y/N
Rationale	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. Advise people taking lithium to: • seek medical attention if they develop diarrhoea or vomiting or become acutely ill for any reason • ensure they maintain their fluid intake, particularly after sweating (for example, after exercise, in hot climates or if they have a fever), if they are immobile for long periods or if they develop a chest infection or pneumonia Monitor the person at every appointment for symptoms of neurotoxicity, including paraesthesia, ataxia, tremor and cognitive impairment, which can occur at therapeutic levels of lithium.
Source	NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy. Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence.

05

Measure	Patient has a record of the purple lithium book being given to them and that the book was recorded as being completed within the last 6 months. Y/N
Rationale	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. Ensure the person is given appropriate national information (or a locally available equivalent) on taking lithium safely.
Source	NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy. Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence.

Appendix One: Abbreviations

Abbreviation	Definitions
eGFR	estimated glomerular filtration rate
NSAIDs	non-steroidal anti-inflammatory drugs
ACE	Angiotensin converting enzyme
BMI	Body Mass Index
QI	Quality Improvement
CNS	Central Nervous System

Appendix Two: Guidance notes

Measures 1 to 5 will help practices evidence the Prescribing Safety QI module in the 'A five-year framework for GP contract reform to implement The NHS Long Term Plan' document.

Our local Trusts Medication Safety Officer has highlighted dehydration, deteriorating renal function and interacting drugs as issues that were implicated with lithium toxicity in reported lithium incidents. These specific care bundle measures have been selected to focus safety improvements on local concerns.

Suggested evidence checks

Measure 1 - There is a recorded lithium level (dated within the last 3-6 months) of 0.6-0.8 mmol/l – respond (Y). There is a recorded lithium level (dated within the last 3-6 months) as specified by the specialist of 0.9-1.0- respond (Y). There is recorded lithium level (dated within the last 3-6 months) as specified by the specialist of 0.4-0.59 - respond (Y). Absence of a lithium level recorded in last 3-6 months - respond (N). Lithium level recorded in last 3-6 months of 0-0.39 – respond (N). Lithium level recorded in last 3-6 months 0.4-0.59 but not on specialist recommendation – respond (N).

Measure 2 – There is a recorded eGFR in the past 6 months - respond (Y). Absence of a recorded eGFR level within the last 6 months - respond (N). If there is evidence of significant decline in renal function and there is no record that therapy has been assessed – respond (N)

Measure 3 – Check patient's current medication list. Identify patient's prescribed drugs that interact with lithium.

ACE inhibitors, Non-Steroidal Anti-inflammatory Drugs (NSAIDs) and diuretics are known to increase the risk of toxicity.

Antidepressants may increase risk of CNS effects and toxicity.

Antipsychotics, Increase risk of extrapyramidal side-effects and possible neurotoxicity.

Methyldopa, phenytoin, carbamazepine, diltiazem, verapamil increase risk of neurotoxicity.

Antibiotics may elevate lithium levels.

Where there is recorded evidence there has been a review of these medicines within 12 months respond Y. When new interacting medicines have been started since the last

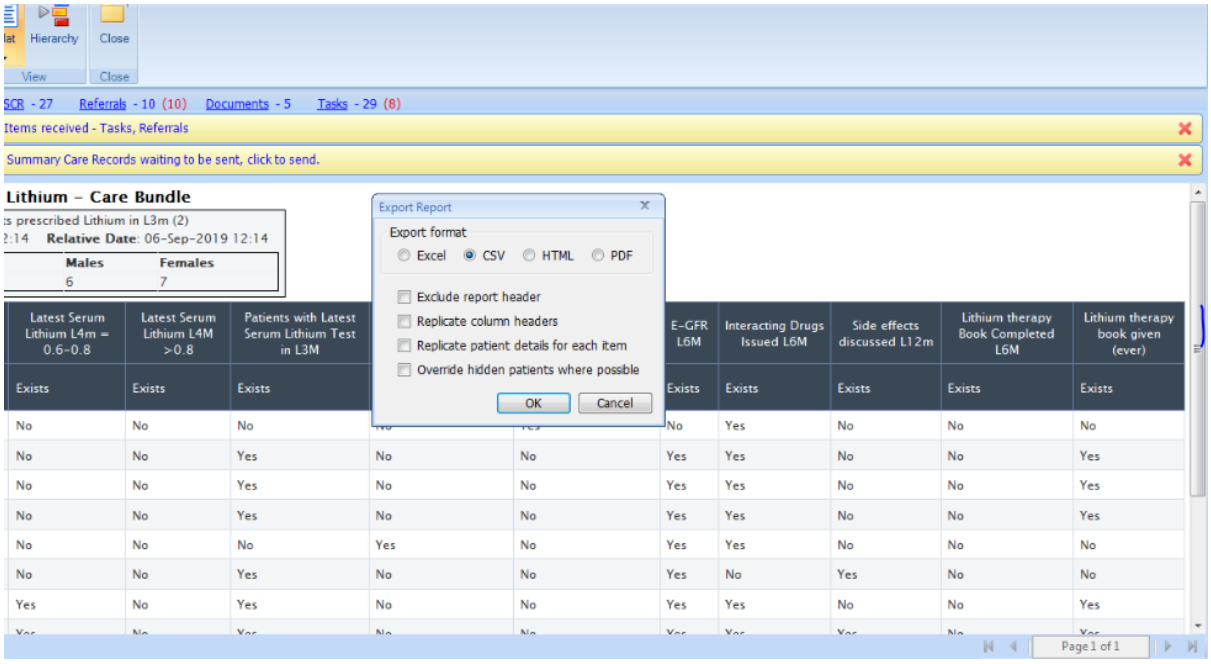
lithium level check or there has been issue of interacting “when required” medicines, if a review of therapy has been recorded within 3 months, in line with the subsequent lithium level check, respond Y. If there is no record of review, respond (N). If interacting medicines are not prescribed respond (N/A).

Measure 4 – There is a record of discussion of side effects relating to lithium toxicity in the last 12 months – respond (Y). Where there is no record of discussion of side effects relating to lithium toxicity in the last 12 months – respond (N).

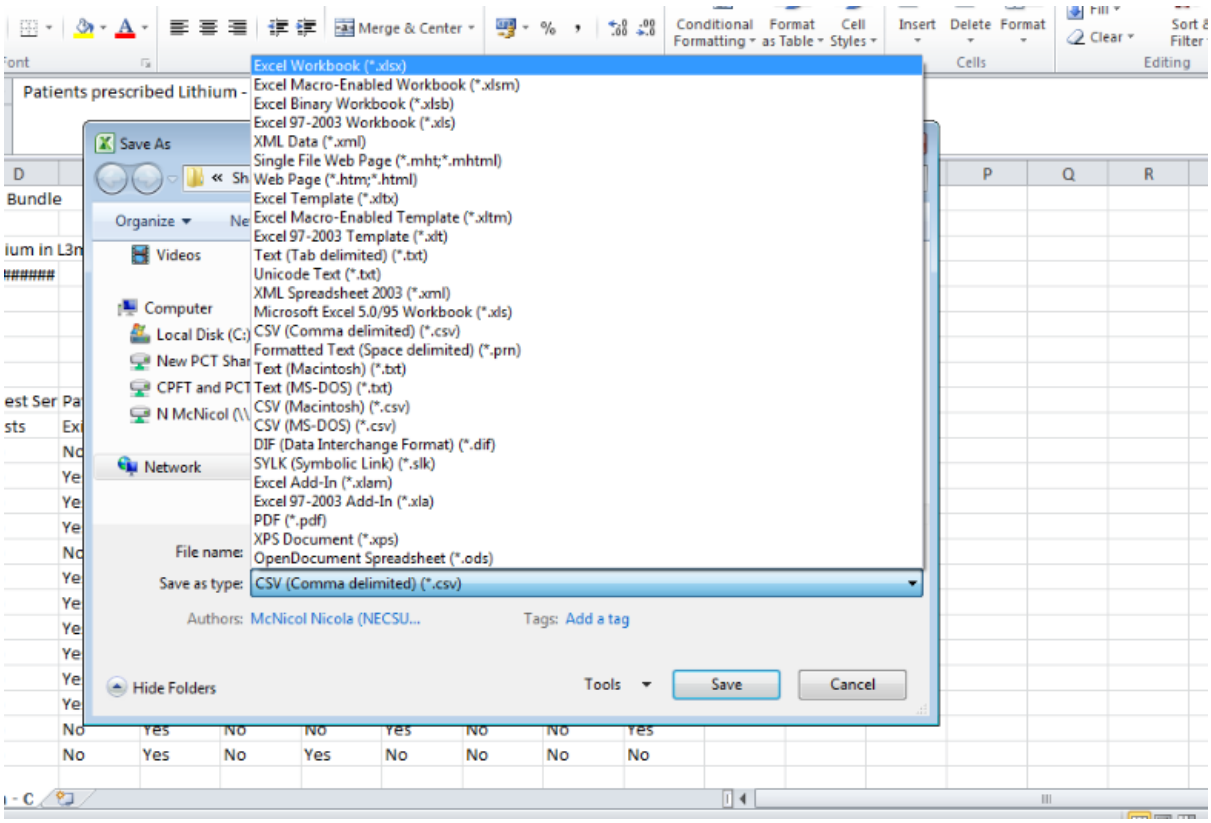
Measure 5 – There is a record of the purple lithium book being given to the patient and that the book was recorded as being completed within the last 6 months – respond (Y). Where there is no record of the purple lithium book being given to the patient or that there is not a record the book was recorded as being completed within the last 6 months – respond (N).

Lithium search and report.

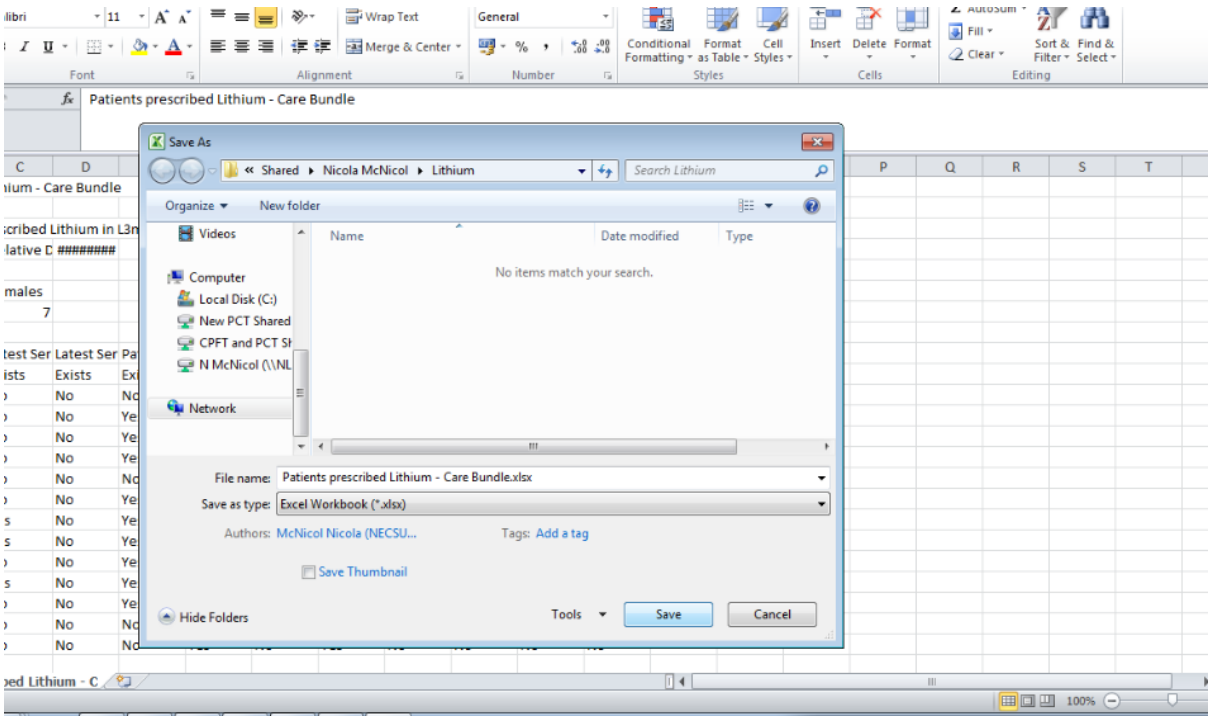
When exporting the report select the CVS option to save. This saves the Yes/No responses.



Open the saved file and change to excel format.



And save in excel format.



Interpretation of the spreadsheet.

With regards measure 3 the report will pick up the main groups of interacting drugs, but the list is not exhaustive so please remain vigilant that the patient still may be taking an interacting drug even if there is a 'No' in the spreadsheet. The presence of 'Yes' in this column is highlighting the patient has one of the more common interacting drugs co-prescribed. It will still be necessary to check the patient record in order to determine if the patient has been given information at initiation and have had the medication combination reviewed within 3 months to ensure the patient is clinically stable.

When starting new medicines interacting with lithium / or issuing interacting 'when required' medicines (therefore increasing the risk of toxicity), patients have had information at initiation and a review of therapy within 3 months (in line with next check of lithium level). Patients who are prescribed long-term interacting medicines have had a review of therapy within the last 12 months. Y/N/NA

References:

Bipolar disorder: assessment and management (CG185). NICE National Institute for Health and Care Excellence. https://www.nice.org.uk/guidance/cg185#

Lithium. Coventry and Warwickshire Partnership Trust
https://www.covwarkpt.nhs.uk/download.cfm?doc=docm93jijm4n1732.pdf&ver=2290

NHS National Patient Safety Agency – Patient Safety Alert NPSA/2009/PSA005 – Safer Lithium Therapy.

Lithium Carbonate (Priadel® and Camcolit®) SPC.