

# A mixed methods analysis of lithium-related patient safety incidents in primary care

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## Abstract

**Background:** Lithium is a drug with a narrow therapeutic range and has been associated with a number of serious adverse effects. This study aimed to characterise primary care lithium-related patient safety incidents submitted to the National Reporting and Learning System (NRLS) database with respect to incident origin, type, contributory factors and outcome. The intention was to identify ways to minimise risk to future patients by examining incidents with a range of harm outcomes.

**Methods:** A mixed methods analysis of patient safety incident reports related to lithium was conducted. Data from healthcare organisations in England and Wales were extracted from the NRLS database. An exploratory descriptive analysis was undertaken to characterise the most frequent incident types, the associated chain of events and other contributory factors.

**Results:** A total of 174 reports containing the term 'lithium' were identified. Of these, 41 were excluded and, from the remaining 133 reports, 138 incidents were identified and coded. Community pharmacies reported 100 incidents (96 dispensing related, two administration, two other), general practitioner (GP) practices filed 22 reports and 16 reports originated from other sources. A total of 99 dispensing-related incidents were recorded, 39 resulted from the wrong medication dispensed, 31 the wrong strength, 8 the wrong quantity and 21 other. A total of 128 contributory factors were identified overall; for dispensing incidents, the most common related to medication storage/packaging ( $n=41$ ), and 'mistakes' ( $n=22$ ), whereas no information regarding contributory factors was provided in 41 reports.

**Conclusion:** Despite the established link between medication packaging and the risk of dispensing errors, our study highlighted storage and packaging as the most commonly described contributory factors to dispensing errors. The absence of certain relevant data limited the ability to fully characterise a number of reports. This highlighted the need to include clear and complete information when submitting reports. This, in turn, may help to better inform the further development of interventions designed to reduce the risk of incidents and improve patient safety.

**Keywords:** incident reporting, lithium, medication safety, patient safety, primary care

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## Lay Summary

### A characterisation of lithium-related patient safety incidents in primary care

Lithium is an effective treatment for certain mental illnesses, but has a number of harmful side effects. Safety incidents related to medicines in the UK are reported to the National Reporting and Learning System database (NRLS), and concerns relating to lithium have previously been highlighted. This study aimed to characterise lithium incidents reported to the NRLS that occurred in a primary care setting. Reports relating to lithium and submitted between 2002 and 2013 were reviewed, and the information coded. A total of 174 reports containing the term

'lithium' were identified. Of these, 41 were excluded and, from the remaining 133 reports, 138 incidents were identified and coded with respect to incident origin, type, contributory factors and outcome. A total of 100 incidents were reported by community pharmacies (96 of which related to medicine dispensing), general practitioner (GP) practices filed 22 reports and 16 reports originated from other sources. Of the dispensing-related incidents, 39 resulted from the wrong medication dispensed, 31 the wrong strength, 8 the wrong quantity and 21 other. A total of 128 contributory factors were identified overall; for dispensing incidents, the most common related to medication storage/packaging ( $n=41$ ), and 'mistakes' ( $n=22$ ) whereas no information regarding contributory factors was provided in 41 reports. Despite the established link between medication packaging and the risk of dispensing errors, our study highlighted storage and packaging as the most commonly cited contributory factors to dispensing errors. The absence of certain relevant data limited the ability to fully characterise a number of reports. This highlighted the need to include clear and complete information when submitting reports. This, in turn, may help to better inform the further development of interventions designed to reduce incident numbers and improve patient safety.

## Introduction

Lithium has been shown to be an effective treatment for the management of bipolar affective disorder and as an augmentation strategy in unipolar depression.<sup>1,2</sup> However, the clinical use of lithium is complicated by its narrow therapeutic range and adverse effects, such as those affecting the thyroid and parathyroid glands and the kidney, all of which require regular monitoring.<sup>3</sup> Adverse patient outcomes associated with lithium in the United Kingdom were highlighted by the National Patient Safety Agency (NPSA) in 2009, with its publication 'Safer lithium therapy'.<sup>4</sup> This report identified a number of fatalities and other serious adverse events that had occurred as a result of lithium therapy using the National Reporting and Learning System (NRLS) database. This database records reports of patient safety incidents resulting from healthcare interventions made in the UK (available at: <https://report.nrls.nhs.uk/nrlsreporting/>). Following a review of incident reports involving severe harm associated with lithium, the NPSA introduced clear guidelines to help healthcare professionals to address these problems. The document suggested measures that were required to be implemented by healthcare providers by December 2010, including requirements for pharmacists prior to dispensing lithium and greater patient engagement through the Lithium Therapy Record Book.<sup>5</sup>

Whereas serious patient safety incidents have been a significant driver for improving patient safety,<sup>6</sup> it has also been noted that incidents resulting in non-serious harm should not be overlooked.<sup>7</sup>

Incidents that result in mild harm or no harm have the potential to contribute to more serious harm if they are overlooked or measures not put in place to address them. The Heinrich ratio estimated that in an industry setting for every 300 no injury incidents, there would be one major injury.<sup>8</sup> In addition to assessing the effectiveness of reporting systems, these no injury incidents provide a focus for driving system change.<sup>7</sup> Despite this, there is some evidence to suggest that severity of harm was a factor in determining pharmacist led error reporting in a hospital setting.<sup>9</sup> As noted above, severe harms associated with lithium have been the subject of a previous report. However, the nature of lithium-related incidents occurring in primary care settings, with varying degrees of harm, has been less widely reported.

This study aimed to characterise all primary care lithium-related patient safety incidents submitted to the National Reporting and Learning System (NRLS) database. The intention being to identify ways to minimise risk to future patients by examining incidents with a range of harm outcomes.

## Methods

We carried out a cross-sectional, mixed methods study of patients who were the subject of a patient safety incident report related to the medication, lithium. This combined a detailed data coding process and iterative generation of data summaries using descriptive statistical and thematic analysis methods as described by Carson-Stevens *et al.*<sup>10</sup>

### Data source

The primary data for the study were extracted from an archive of the NRLS database of patient safety incident reports from healthcare organisations in England and Wales. A patient safety incident is defined as: ‘any unintended or unexpected incident that could have harmed or did harm a patient during healthcare delivery.’<sup>11</sup> Reporting began in 2003 on a voluntary basis but, since 2010, it has been mandatory to report any incident that resulted in severe patient harm or death. Each report contains structured information about location, patient demographics and the reporter’s perception of severity of harm, complemented by unstructured free-text descriptions of the incident, potential contributory factors and planned actions to prevent reoccurrence. The database was described in more detail in a study of patient safety-related hospital deaths in England.<sup>12</sup>

### Study population

The study included incidents occurring from 2003 (when the database launched) to 30 September 2013, which was the full cross-section of data available at the outset of our study. In this time, a total of 272,884 incident reports were submitted by primary care services to the central database of patient safety incidents. The free text fields of the database were searched for terms related to lithium including all common brand names (see Appendix 1 for full list). Of the incidents identified, a number were excluded either because the report was a duplicate, contained insufficient detail, or because, on detailed scrutiny, the incident was found not to have occurred in primary care or did not directly involve lithium.

### Data coding

Two clinical researchers familiar with the treatment of mental illness were trained in root cause analysis and the role of human factors in healthcare. This team reviewed the free text component of each incident report and coded the information in relation to: the type of safety incident that directly affected patient care (e.g. prescribing error) and the chain of events leading up to the safety incident (e.g. communication error between staff); the contributory factors (e.g. staff knowledge); and reported patient harm outcomes with harm severity classified according to World Health Organisation (WHO) International Classification for Patient Safety definitions.<sup>13</sup> Each report was

coded independently by both researchers and any discordance was discussed to ensure correct interpretation of codes and their definitions. Difficult cases were discussed and a third investigator arbitrated where necessary. The process has previously been described in more detail.<sup>10</sup>

### Data analyses

We undertook exploratory descriptive analysis to assess all relevant incident types, the associated chain of events and contributory factors. Vignettes were discussed as a team to identify salient themes amongst reports with similar characteristics (incident types, contributing factors, outcomes), which could be considered as targets for the prevention of future incidents.

### Ethical approval

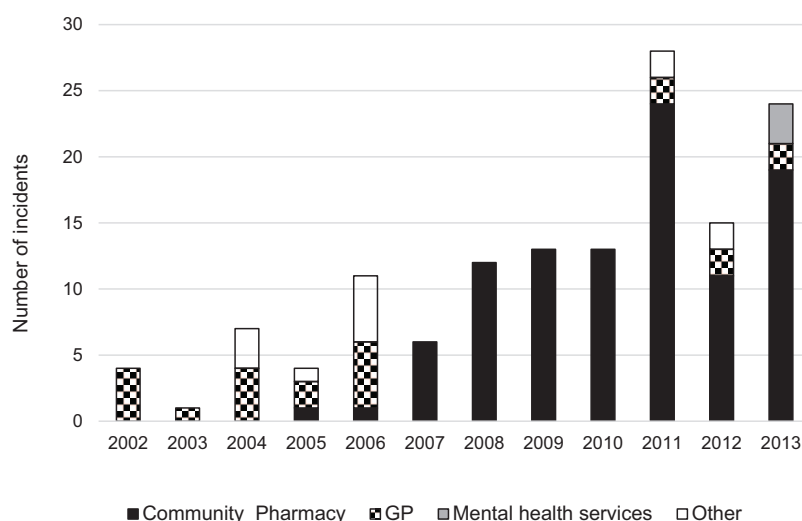
Aneurin Bevan University Health Board (ABHB) Research Risk Review Committee judged the study as using anonymised data for service improvement purposes (ABHB R&D Ref number: SA/410/13).

### Results

From the available dataset of 272,884 incident reports, 174 incident reports containing the term ‘lithium’ were identified. Of these, 41 were excluded (22 unrelated to lithium, 17 had insufficient information to allow coding and 2 duplicate reports) and, from the remaining 133 reports, 138 incidents were identified and coded (some reports included more than 1 identifiable incident). It was noted that the number of incidents reported per year increased over time, from 4 in 2002 to 24 in 2013 (see Figure 1).

### Incident origin

Incidents were grouped into those originating from community pharmacy, general practitioners (GPs), mental health services and other (including nurses and other hospital staff). Of the total, community pharmacies reported 100 (72%) incidents (96 were dispensing related, 2 relating to administration and 2 classified as other), GP practices filed 22 (16%) reports, 13 (9%) reports originated from other sources, and 3 (2%) from mental health services. The number of incidents according to reporter type and year are shown in Figure 1.



**Figure 1.** Number of primary care incidents relating to lithium, originating from different healthcare professional groups.

**Table 1.** Incident type, grouped according to reporting healthcare professional.

Incident type	Incident report origin				Total <i>n</i> = 138 (%)
	Community pharmacy <i>n</i> = 100 (%)	General practice <i>n</i> = 22 (%)	Mental health <i>n</i> = 3 (%)	Other <i>n</i> = 13 (%)	
Dispensing	96 (96%)	2 (9%)	1 (33%)	0 (0%)	99 (72%)
Prescribing	0 (0%)	3 (14%)	1 (33%)	4 (31%)	8 (6%)
Administration	2 (2%)	1 (4%)	0 (0%)	2 (15%)	5 (4%)
Monitoring	0 (0%)	8 (36%)	0 (0%)	5 (38%)	13 (9%)
Communication	0 (0%)	5 (23%)	0 (0%)	2 (15%)	7 (5%)
Other	2 (2%)	3 (14%)	1 (33%)	0 (0%)	6 (4%)

### Incident type

The 138 incidents were categorised as being related to either prescribing, dispensing, administration, lithium monitoring, communication or other (such as record keeping and decision making) (see Table 1 for details). A total of 99 dispensing-related incidents were recorded representing 72% of incidents overall. Of the dispensing incidents, 39 resulted from the wrong medication being dispensed (34 of which involved Priadel® and Plaquenil®), 31 the wrong strength, 8 the wrong quantity and 21 classified as other (see Table 2 for details). The remaining 39 (28%) incidents related to monitoring (*n* = 13), prescribing (*n* = 8), communication (*n* = 7), other (*n* = 6) and administration (*n* = 5).

### Contributory factors

A total of 128 contributory factors were identified for 82 of the incidents reported, whereas no information was available for 56 incidents. Overall, the most common contributory factor was medication storage or packaging in relation to dispensing incidents (*n* = 41), followed by a cognitive error (such as a mistake or inattention), which occurred in the context of most error types. A total of 97 contributory factors were identified for 58/99 of the dispensing incidents (some incidents had more than 1 identified contributory factor), whereas no information was available for 41/99, as the relevant section of the NRLS data collection form was left blank. The most commonly cited contributory factor for dispensing incidents

**Table 2.** Details of dispensing incident types.

Dispensing incident type	Number <i>n</i> = 99 (%)
Wrong medicine	39 (39)
Wrong strength	31 (31)
Wrong quantity	8 (8)
Wrong patient	4 (4)
Wrong dose timing	4 (4)
Wrong formulation	4 (4)
Wrong label	3 (3)
Wrong dose	3 (3)
Contraindicated medication dispensed	1 (1)
Discontinued medication dispensed	1 (1)
Out of date medication dispensed	1 (1)

was medication storage or packaging ( $n=41$ ), where the similarity of the packaging between two medicines with similar names (Priadel® and Plaquenil®) was commonly noted. Other factors were cognitive errors ( $n=23$ ), working conditions ( $n=18$ ) (where being busy and being interrupted were commonly noted), process not followed ( $n=8$ ), continuity of care ( $n=3$ ), lack of protocol ( $n=2$ ) and other ( $n=2$ ).

#### Outcome and harm

No outcome (as the relevant section of the NRLS data collection form was left blank) or an unclear outcome with insufficient detail to allow coding was reported for 84 (61%) incidents. A total of 74 outcomes were reported for the remaining 54 coded incidents (more than 1 outcome was possible for each incident). The most frequently reported outcomes were requirement for repeated visit to a health care provider ( $n=24$ ; 32%), hospital admission ( $n=10$ ; 14%), unplanned change in dosing ( $n=9$ ; 13%), treating of the patient with insufficient information ( $n=6$ ; 8%) and need for repeated tests ( $n=5$ ; 7%).

Patient harms resulting from the incidents were reported for only 63/138 incidents. Where harm was reported, it was classified as no harm ( $n=8$ ),

no harm due to mitigating action ( $n=32$ ), mild ( $n=10$ ), moderate ( $n=9$ ) and severe ( $n=4$ ; two reports with four incidents). The severe harms all required hospital admission (three of the four resulted from medication overdose) and all occurred prior to 2011.

#### Discussion

This study investigated incidents relating to the use of lithium in primary care in England and Wales, reported to the NRLS database between 2003 and 2013. A total of 174 reports were identified and, from these, 133 reports detailing 138 incidents were reviewed and coded. The frequency of reporting increased over time, with the largest number of incidents reported in 2011. This was broadly in line with the increased level of reporting seen in the NRLS database.<sup>14</sup> The majority of the primary care reports submitted to the NRLS database and reviewed in this study related to errors made in the dispensing of lithium. Reports came largely from community pharmacy and incorrect medicine or incorrect strength dispensed were the most common incidents.

Although most incidents were associated with the dispensing process, this perhaps reflected the number of lithium reports submitted by community pharmacies compared with other professional groups. Community pharmacists reported 100 (72%) of the coded incidents, starting with a single report in 2005, followed by a significant increase in reporting from 2007 onwards. The timing of this initial reporting, and the subsequent increase in reporting coincided with a change to the terms of the NHS Community Pharmacy Contractual Framework in 2005, which required all pharmacy contractors to report incidents to the NRLS.<sup>15</sup> It has been suggested that the effectiveness of a reporting system can be based upon the ratio of severe to less severe harm reporting.<sup>7</sup> Using the assumption that where no harm was reported a severe event had not occurred, the ratio of severe to less severe harms (1:99) reported by community pharmacies might be considered somewhat encouraging. However, briefing document 034/14 issued by the Pharmaceutical Services Negotiating Committee (PSNC) in 2014,<sup>15</sup> indicated that the level of reporting to the NRLS by community pharmacies was low, and put measures in place to address this. Given the estimated 1–3% incidence of

dispensing incidents in community pharmacies and number of prescription items for lithium dispensed in Wales in 2012 alone (approximately 75,500 items data from the Comparative Analysis System for Prescribing Audit; NHS Wales Shared Services Partnership),<sup>16</sup> these concerns over under-reporting appear well substantiated despite it being a contractual requirement.

Whereas the number of reports submitted by community pharmacies in relation to the number of items dispensed was relatively low, it was significantly greater than that observed for other healthcare professionals. This may in part reflect the contractual obligation for community pharmacies to report using the NRLS database. It has been documented that all stages of the medication management process from prescribing to administration are associated with a risk of error.<sup>17</sup> However, only 38 reports of lithium-related incidents originated from other healthcare professionals. Furthermore, only 39 were associated with aspects of the medicines management process other than dispensing. A number of factors have been identified as barriers to the reporting of medication errors,<sup>18–20</sup> which may have contributed to the limited quantity of reporting observed in our study. These include a lack of feedback to the reporter following incident submission, time constraints in completing reports, the complexity of navigating reporting systems and fear of blame. The low level of reporting and the focus on a single medicine were limitations of the study, and impact on the generalisability of the findings. Overall, the level of detail contained within the reports could have been improved. In a significant number of cases, there was insufficient detail to allow coding of the incident or of contributory factors, and in some cases no details were provided for key aspects such as resulting outcomes and harms. This lack of information prevented full coding of these incidents and a similar lack of data quality has been reported elsewhere.<sup>21</sup> Without a full description of the incident, it becomes more difficult to attempt to develop strategies such as driver diagrams and harness learning to facilitate change.<sup>22,23</sup>

Despite the established link between medication packaging and the risk of dispensing and other errors,<sup>24–26</sup> our study highlighted medicine storage or packaging as the most commonly cited contributory factor. The WHO ‘Medicines without harm’ initiative identifies look-alike sound-alike medicine

names, and labelling and packaging as frequent sources of error and harm that can be addressed.<sup>26</sup> It was notable that the lithium brand Priadel<sup>®</sup> and the medicine Plaquenil<sup>®</sup>, both of which were manufactured by Sanofi Aventis and have similar names and packaging were the most frequently confused medicines. Strategies to address confusion of look-alike sound-alike names include the use of ‘Tall-Man’ lettering on medicine labels.<sup>27</sup> Tall-Man lettering utilises capitalisation for parts of the text of the medicine name, to highlight differences between similar names. Evidence to support this approach remains somewhat mixed, with little definitive evidence of a beneficial effect.<sup>28</sup> A limitation in the evaluation of this strategy is the limited number of published studies; particularly those conducted in real-world settings (see Larmené-Beld *et al.* for review).<sup>27</sup> Nevertheless, adoption of lists of medicines recommended for Tall-Man lettering<sup>29,30</sup> may represent a possible driver for reducing similar dispensing errors. Medication storage and packaging is likely to be an ongoing source of error in the dispensing process involving manual selection of medicines. Whereas automation has been shown to reduce some of the errors associated with dispensing,<sup>31</sup> other aspects of the medicines management process from prescribing to administration will undoubtedly continue to be subject to human error.

### Conclusion

Despite lithium being a drug with a narrow therapeutic range that has been associated with serious harm, the number and quality of the primary care reports submitted to the NRLS database and reviewed in this study was limited. Although community pharmacy made a significant contribution to lithium-related incident reporting, the absence of certain relevant data limited the ability to fully characterise a number of reports. This highlighted a need for better understanding amongst reporters to include clear and complete information (e.g. contributory factors such as packaging and work environment) when submitting reports. This, in turn, may help to better inform the further development of interventions designed to reduce incident numbers and improve patient safety.

### Conflict of interest statement

The authors declare that there is no conflict of interest.

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#### Appendix 1: field searched and search terms

Free text fields searched:

Description of what happened

Actions preventing recurrence

Apparent causes

Search terms related to lithium: Lithium; priadel; camcolit; Li; Li-, Li+; Liskonum; purple book; purple-book