General Practitioner, Dr A

Medical Centre

A Report by the

Health and Disability Commissioner

(Case 15HDC00196)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. Mr B was a patient of general practitioner Dr A at a medical centre between 2008 and 2013. Mr B had complex and longstanding psychiatric issues and a number of physical co-morbidities, including diabetes, obesity, obstructive sleep apnoea, fatty liver, and previous pulmonary embolus. When Mr B became a patient of Dr A in 2008 he was on a drug regimen that included high doses of diazepam, paroxetine, lithium and codeine. This drug regimen had been established by psychiatrists in both New Zealand and overseas.

2. Between 2008 and 2013 Mr B was prescribed lithium without regular reviews of his serum lithium levels. Serum lithium levels are taken to ensure that patients on lithium are not developing lithium toxicity.

3. In February 2011 blood tests indicated a deterioration in Mr B's renal function (his test results were outside the normal range). In November 2011 Mr B reported a hand tremor, a common side effect of lithium toxicity.

4. In November 2011 Mr B was reviewed by consultant psychiatrist Dr C, who recommended changes to Mr B's paroxetine prescription. These changes were not implemented at the medical centre until September 2012.

5. Additionally, in January 2012, the medical centre received notice from the DHB's endocrinology service that Mr B's lithium levels should be reduced. Recommended changes to Mr B's lithium prescriptions were not implemented until September 2012.

Commissioner's findings

6. It was acknowledged that Mr B's management was challenging. However, Dr A failed to assess Mr B's serum lithium levels adequately, did not document any consideration that Mr B might be suffering side effects from lithium toxicity, took no action to assess whether the lithium might be causing Mr B's tremor, and failed to ensure that specialist ordered changes to Mr B's medication regimen were made in a timely manner. Accordingly, Dr A did not provide services to Mr B with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

7. The medical centre failed to have systems in place to facilitate co-operation between providers to ensure that quality and continuity of services were provided to Mr B and, accordingly, breached Right 4(5) of the Code. [2]

Recommendations

8. The Commissioner recommend that Dr A:

   a) Provide a written apology to Mr B.

[1] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[2] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

b) Undertake training on the prescribing of psychotropic medication.

9. It was recommended that the Medical Council of New Zealand consider whether a review of Dr A's competence is warranted.

10. It was recommended, with specific reference to Royal New Zealand College of General Practitioners Foundations Standards, that the following policies are developed and finalised for the medical centre:

a) A repeat prescribing policy that includes information on patient review timeframes.

b) A policy for the robust filing of reviews and reports, including specialist advice, received by the medical centre that require action.

Complaint and investigation

11. The Commissioner received a complaint from Mr B about the services provided by general practitioner Dr A and the medical centre. The following issues were identified for investigation:

- *Whether Dr A provided an appropriate standard of care to Mr B between 2008 and 2013.*
- *Whether the medical centre (a partnership)*[3] *provided an appropriate standard of care to Mr B between 2008 and 2013.*

12. The parties directly involved in the investigation were:

Dr A	General practitioner
Mr B	Consumer
Medical centre	Provider

Also mentioned in this report:

Dr C	Consultant psychiatrist
Dr D	Psychiatrist
Dr E	General practitioner
Dr F	Psychiatrist
Dr G	Locum GP
Dr H	Locum GP
Dr I	Psychiatrist
Dr J	Endocrine registrar
RN K	Registered nurse

[3] In 2016, this partnership was dissolved. Another company was established to own and operate the medical centre. Dr A is a director and shareholder of the new entity.

Dr L	Locum GP
Dr M	Endocrinology registrar
Dr N	Nephrologist
Dr O	General practitioner
Dr P	General practitioner
Dr Q	Nephrologist

13. Information from the parties directly involved was reviewed during the course of the investigation.

14. Independent expert advice was obtained from in-house clinical advisor general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Mr B

15. Mr B, aged 49 years in 2008, had longstanding and complex psychiatric issues, which had prevented him from working since 1990. In addition, Mr B had several physical co-morbidities including diabetes,[4] obesity, obstructive sleep apnoea,[5] fatty liver,[6] and previous pulmonary embolus.[7]

16. In early 2008, Mr B enrolled as a patient of general practitioner (GP) Dr A at the medical centre. Mr B brought a letter of introduction from his previous GP, which outlined that Mr B had a long-term anxiety disorder that had been treated previously overseas with a combination of diazepam[8] and codeine.[9] The letter outlined Mr B's medication regimen, approved by psychiatrist Dr D. In response to the provisional opinion, Mr B advised that his mental health problems were concerned wholly with chronic depression and acute anxiety.

17. In early 2008, when Mr B enrolled at the medical centre, he was on approximately 20 different prescription medications. Mr B was on the following medications prescribed for psychotropic purposes:

- Diazepam (5mg tablets, 240 per month (as required 10–70mg per day)).
- Codeine phosphate (30mg tablets, 4–6 tablets per day (120–180mg per day)).

[4] Having too much glucose (sugar) in the blood as a result of the pancreas not making enough insulin.
[5] An obstruction of the upper airway that is characterised by repetitive pauses in breathing during sleep, despite the effort to breathe.
[6] The build-up of fat in the liver making it vulnerable to injury, which may result in inflammation and scarring.
[7] A sudden blockage of a major blood vessel in the lung, primarily from a blood clot.
[8] A tranquillising muscle-relaxant drug used chiefly to relieve anxiety.
[9] A sleep-inducing and analgesic drug derived from morphine — in this case used for its sedative properties.

- Paroxetine (20mg tablets, 6 tablets per day (120mg per day)). [10]
- Lithium carbonate (400mg tablets, 2 tablets per day (800mg per day)).

Lithium carbonate

18. Lithium carbonate (lithium) is used to treat bipolar disorder (manic-depressive disorder) by balancing neurotransmitters in the brain to stabilise mood and reduce extremes in behaviour. Potential adverse effects of lithium treatment include mild gastrointestinal effects (such as nausea, vomiting and diarrhoea), fine hand tremors, drowsiness and polyuria.[11] Lithium can also cause nephrogenic diabetes insipidus.[12]

19. Lithium blood levels and renal (kidney) function tests are common ways of measuring the impact of long-term lithium use. At the time of these events, it was best practice to conduct serum (blood) lithium concentrations, serum creatinine[13] levels, and renal function tests every three months.[14]

The medical centre

20. The medical centre is a small primary care health clinic with two principal general practitioners and several regular locum general practitioners. The medical centre is also staffed by one to two nurses and reception staff. At the time of the events outlined in this report, the two principal general practitioners, Dr A and Dr E, were owners through a partnership, and shared expenses but worked semi-autonomously. Patients were enrolled with either Dr A or Dr E, and were managed independently by their respective teams.

Dr A

21. Dr A qualified in medicine overseas, and is a vocationally registered general practitioner in New Zealand.[15] Dr A advised HDC that he works for a half day a week at the medical centre, and as a general practitioner for a number of community hospitals and rest homes.

Initial reviews and blood tests (February and March 2008)

22. On 14 February 2008 Mr B had his first appointment with Dr A at the medical centre. Dr A advised HDC:

> "Shortly after [Mr B] joined our clinic, I phoned [Dr D] to discuss his high doses of paroxetine, diazepam, codeine and lithium. Consistent with my discussion with [Dr D], I decided to continue treatments as they were until I got to know the

[10] A selective serotonin (a chemical thought to be responsible for maintaining mood balance) reuptake inhibitor. Paroxetine is used to treat depression, obsessive-compulsive disorder, panic disorder, generalised anxiety disorder, and social anxiety disorder, among others.
[11] Production of abnormally large volumes of dilute urine.
[12] A decrease in the ability of the kidneys to concentrate the urine. People with this condition produce excessive amounts of urine, which results in an insatiable thirst.
[13] A measure of the creatinine in the blood (a chemical waste molecule generated from muscle metabolism and transported in the blood to the kidneys for disposal in urine).
[14] Best Practice Advisory Centre (BPAC) publication, *Lithium in general practice. BPJ. 2007; Issue 3.*
[15] Dr A has been vocationally registered in New Zealand since 2002.

patient better. It was clear that [Mr B] had been on these medications for some considerable time (approximately 25 years) ..."

23. At the appointment on 14 February 2008, Dr A recorded Mr B's history in the clinical record, and noted his medication. Dr A recorded: "[A]ll meds usually 3/12ly [three monthly], but codeine and diazepam monthly scripts scripted today — and suggest come monthly to get to know a bit better." Dr A provided Mr B with a prescription for codeine phosphate and diazepam. Dr A also provided Mr B with a referral for blood tests to check Mr B's renal function. Both Mr B's serum creatinine[16] and glomerular filtration rate (eGFR) came back within the normal range.[17] A serum lithium test was not ordered at this time.

Initial referral to psychiatrist (August 2008)

24. On 25 August 2008 a locum GP referred Mr B to psychiatrist Dr F for a medication review. Dr F saw Mr B on 15 October 2008 and noted his current medication regimen, including his dependence on diazepam. Dr F wrote to Dr A stating: "I do not feel that he [Mr B] is presently capable of benefitting from cognitive therapy." A review was scheduled with Dr F for November 2008, but Mr B did not attend the appointment.

Renal function monitoring (April 2008 to August 2010)

25. On 22 August 2008 Mr B had his blood taken for renal function tests, as ordered by Dr A. The results were within the normal range.[18] A serum lithium test was also ordered, and was reported at the low end (0.41mmol/L) of the recommended therapeutic range.[19]

26. On 4 December 2008 Mr B had blood taken for renal function tests ordered by Dr A. Both Mr B's serum creatinine and eGFR came back within the normal range.[20] No serum lithium test was ordered at that time.

27. On 15 June 2009 Mr B had blood taken for renal function tests ordered by locum GP Dr G. Both Mr B's serum creatinine and eGFR results came back within the normal range.[21] No serum lithium test was ordered at that time.

28. On 19 November 2009 Mr B had blood taken for renal function tests ordered by Dr A. Both Mr B's serum creatinine and eGFR tests came back within the normal range.[22] Mr B's serum lithium was tested and found to be on the very low end of the

[16] eGFR calculation that uses blood creatinine levels, age, sex, and race to determine kidney function. In 2008 the medical laboratory advised that for serum creatinine a range of 50–120µmol/L is normal. The result also states that "GFR range for a young adult male is 87–167. From age 30, values fall by approximately 1 mL/min/year". This indicates that Mr B, aged 49 at the time of the test, should have a value of 68–148.
[17] On 19 March 2008 Mr B's serum creatinine was 84µmol/L and his eGFR was 90ml/min/1.67m^2.
[18] On 22 August 2008 Mr B's serum creatinine was 85µmol/L and his eGFR was 88ml/min/1.67m^2.
[19] In 2008 the medical laboratory advised that the therapeutic range for serium lithium was 0.40–0.8 mmol/L. Laboratory results state: "Toxicity possible at levels greater than 1mmol/L; toxicity common above 1.5mmol/L. These levels refer to specimens collected 12 hours after dose."
[20] On 4 December 2008 Mr B's serum creatinine was 86µmol/L and his eGFR was 87ml/min/1.67m^2.
[21] On 15 June 2009 Mr B's serum creatinine was 105µmol/L and his eGFR was 69ml/min/1.67m^2.
[22] On 19 November 2009 Mr B's serum creatinine was 95µmol/L and his eGFR was 77ml/min/1.67m^2.

potentially toxic range at 1.01mmol/L. The clinical notes record that Dr A reviewed the results, but no action was noted, although a further serum lithium test was ordered in April 2010.

29. On 8 April 2010 Mr B had blood taken for renal function tests ordered by Dr A. Both Mr B's serum creatinine and eGFR results were within the normal range.[23] Mr B's serum lithium was tested and found to be higher than the recommended range at 0.87mmol/L.

30. Between April 2008 and August 2010 Mr B was supplied with a three-monthly prescription for lithium (400mg tablets, two tablets per day).

Second referral to psychiatrist (August 2010)

31. On 20 August 2010 Mr B attended a routine appointment with locum GP Dr H at the medical centre. Following the appointment, at Mr B's request, Dr H referred Mr B to psychiatrist Dr I. Dr H's referral letter requested that Dr I review Mr B's medications. However, Mr B did not proceed with the consultation with Dr I.

Renal function monitoring (August 2010 to September 2011)

32. On 7 February 2011 Mr B had blood taken for renal function tests ordered by Dr H. Mr B's serum creatinine was higher than the recommended range, and his eGFR was lower than the recommended range.[24] No serum lithium test was ordered at that time. Dr H reviewed the results of the renal function test, and Registered Nurse (RN) K informed Mr B of the results. Mr B was booked to see a GP in early March.

33. On 1 March 2011 Mr B had an appointment with Dr A. The clinical notes record that at this appointment Mr B's diabetes management was discussed, as well as a possible colonoscopy.

34. On 25 April 2011 Dr A referred Mr B for diabetes specialist review and for gastroenterology review.[25]

35. On 14 June 2011 Mr B had blood taken for renal function tests ordered by Dr A. The results showed that Mr B's serum creatinine was higher than the recommended range, and his eGFR was lower than the recommended range.[26] No serum lithium was ordered at that time. The clinical notes record that Dr A reviewed the results of the renal function tests, and additional renal function tests were ordered.

36. On 28 June 2011 Mr B again had blood taken for a renal function test ordered by Dr A. The results showed that Mr B's serum creatinine was higher than the recommended range, and his eGFR was lower than the recommended range.[27] No serum lithium was ordered at that time. Dr A reviewed the results of the renal function

[23] On 8 April 2010 Mr B's serum creatinine was 102µmol/L and his eGFR was 71ml/min/1.67m^2.
[24] On 7 February 2011 Mr B's serum creatinine was 127µmol/L and his eGFR was 52ml/min/1.67m^2.
[25] Specialist review of the gastrointestinal tract, including the stomach, intestine and liver.
[26] On 14 June 2011 Mr B's serum creatinine was 151µmol/L and his eGFR was 42ml/min/1.67m^2.
[27] On 28 June 2011 Mr B's serum creatinine was 148µmol/L and his eGFR was 43ml/min/1.67m^2.

test and, on 8 July 2011, Mr B was referred to the district health board (the DHB) for endocrinology review.

37. Dr A advised HDC:

> "Our thoughts at this time were that the reason for [Mr B's] change in renal function was related to diabetes. There had been some fluctuations in his Hba1C,[28] some microalbuminuria,[29] some increase in his albumin/creatinine ratio,[30] and he was overweight. His initial referral to endocrinology was focused on his diabetes as was their response and advice. With hindsight however lithium levels should have been requested."

38. Between February 2011 and June 2011 Mr B continued to be supplied with a three-month prescription for lithium carbonate (400mg tablets, two tablets per day).

Endocrine review (September 2011)

39. On 30 September 2011 Mr B was seen by endocrine registrar Dr J. In a letter to the medical centre, Dr J recorded:

> "Looking at [Mr B's] biochemical work up it is of concern that his last lithium was almost 18 months ago and it was supratherapeutic. His renal function has gradually deteriorated since the beginning of this year with a creatinine of 158, eGFR 43. This may be a slight underestimate of his true GFR given his bodyweight."

40. Dr J also recorded: "[Mr B's] renal impairment is multifactorial and I would stop his non-steroidals and adjust other medication accordingly for renal impairment." Dr J further advised the medical centre: "I have attempted to contact [Dr A] at [the medical centre;] however he is not in today therefore I have conveyed the message of my concern and my advice to review his medications to [Dr H.]" Dr J also referred Mr B to the psychiatry team for review, and advised that Mr B would be reviewed at the renal endocrine combined clinic in three months' time.

41. Mr B did not attend the renal endocrine combined clinic for review at the scheduled time and was discharged from the service.

Tremor present and review at the medical centre (November 2011)

42. On 23 November 2011 Mr B was seen by Dr A at the medical centre. Dr A recorded:

> "[Mr B] comes — long chat [with] wife present about ? memory loss — [short term memory] can be very poor, also mentions tremor again which is worse — esp trying to pour drink eg, mentions [occasional] tendency to fall and unsteadiness

[28] Blood protein used to measure the amount of sugar in the blood.
[29] A moderate increase in the amount of protein in the urine.
[30] A test of the relative amount of protein in the blood. Used to determine kidney function.

and lightheaded when gets up — also pain esp L hip OE tremor sl coarse no clear cerebellar signs though heel toe poor no cogwheeling[31] no past pointing.[32]

He is due to see psychiatrist next week P: [patient] leave [with] this [problem] and consider neurological referral if they request next week."

Psychiatric review (November 2011)

43. On 28 November 2011, following the referral from Dr J, Mr B attended an appointment with consultant psychiatrist Dr C. Treatment for Mr B's anxiety was discussed, and the plan was noted as follows:

"1. to reduce the 100mg Paroxetine by 10mg every 2 weeks.

2. to be seen in 2 months.

3. to continue the rest of the medications."

44. The psychiatric examination clinical record was sent to the medical centre and received on 7 December 2011. On 7 December 2011 a receptionist at the medical centre noted in Mr B's clinical record: "IBx: 28/11/11 [the] DHB Mental Health — Psychiatric Examination."

Follow-up post psychiatric review (December 2011 to January 2012)

45. On 15 December 2011 Mr B was seen by Dr G at the medical centre for hayfever. The clinical record from the appointment does not refer to Dr C's letter.

46. On 21 December 2011 Mr B was seen at the medical centre by RN K. The clinical notes record:

"[Mr B's wife] is very concerned re [Mr B's] worsening condition ie: cognitively and medically, he has a tremor which makes life difficult and makes him now a real falls risk but also his memory is poor he misses most appointments and relies totally on [Mr B's wife] for direction. Last appoint with [Dr A] was mention of a referral but haven't heard back?"

47. On 4 January 2012 Mr B had blood taken for a renal function test and a serum lithium test. These tests had been ordered by the endocrine clinic on 30 September 2011. Mr B's serum creatinine was higher than the recommended range, and his eGFR was lower than the recommended range.[33] Mr B's serum lithium was 1.38mmol/L, which is higher than the therapeutic reference range, and within the range defined by the medical laboratory as possibly toxic. Mr B's serum creatinine, eGFR and serum lithium were not tested again until 2 October 2012, although other blood tests were ordered by the medical centre's practitioners.

[31] The "pullback", jerky or ratcheting effect in an arm or leg that the doctor perceives when moving a patient's rigid limb; it is thought to be related to tremor superimposed on limb rigidity.
[32] Misjudging the location of an object by not pointing directly at it.
[33] On 4 January 2012 Mr B's serum creatinine was 148µmol/L and his eGFR was 43ml/min/1.67m^2.

48. On 6 January 2012 Mrs B called the medical centre requesting prescriptions for Mr B's repeat medication. The notes record that Mrs B advised that she and Mr B were going overseas for a holiday and would book a review on their return. Locum GP Dr L provided Mr B with his regular prescriptions, including 540 Aropax 20mg tablets (paroxetine) six tablets once daily. This is the same amount of paroxetine prescribed to Mr B before his appointment with consultant psychiatrist Dr C on 28 November 2011.

Follow-up to high serum lithium levels (January 2012)

49. Dr L contacted Mr B on 9 January and requested that he not take lithium for one day, but should resume it the following day. Dr L also requested that Mr B have his serum lithium tested again.

50. On 11 January 2012 RN K recorded in the clinical record:

> "[Dr L] asked [practice nurse] to contact [Mr B] [regarding] his latest bloods which I have done x2 and spoken with [Mr B's wife], today they have received a letter from the specialist [endocrinology registrar Dr M] re his Lithium dose and have requested he hal[ve] his dose and repeat bloods, including INR as already organised and discussed with [Mr B's wife]. As always it is a continuing problem to get [Mr B] to attend appoints 2 @ clinic so we cannot obtain optimum results with F/U [follow-up blood tests] for health concerns."

51. On 13 January 2012 RN K recorded in the clinical notes: "Unable to contact [Mr B's wife] on cell or home phone to request [Mr B] comes in for F/U bloods prior to trip [overseas]. Message left @ [Mr B's wife's workplace for her] to contact PN." Later in the day the receptionist recorded: "[Mr B's wife] called back told her that [Mr B] needed to come before trip [overseas]. He won't!"

52. Also on 13 January 2012 the medical centre received a letter from endocrinology registrar Dr M of the diabetes clinic at the DHB, advising that Mr B had not attended the clinic. The letter also outlined:

> "I have reviewed [Mr B's] most recent blood results and I note that he has an elevated lithium level and INR. I have been in contact with your clinic nurse and it appears that this has been followed up."

Psychiatric and diabetes/nephrology service non-attendance (February 2012)

53. On 20 February 2012 the medical centre received a letter from the Mental Health Team at the DHB advising that Mr B had cancelled an appointment with Dr C.

54. On 21 February 2012 nephrologist (kidney specialist) Dr N wrote to Dr A advising that Mr B had not attended the combined diabetes/nephrology service and had not been rebooked.

Review by Dr A (February 2012)

55. On 21 February 2012 Mr B was seen by Dr A. Dr A mentioned to Mr B the timing of blood tests in relation to his lithium, as the clinical notes record:

> "Comes [with] [Mr B's wife] re not attending clinics and [symptom] assoc legs ? [osteoarthritis] ? circulatory ? myopathic [muscle weakness] when on holiday — we discussed his need to be mindful of diabetic complication and I explained these to them both. He has tremor ? cause he has just taken lithium. I explained this should be 12 hrs prior to blood test. They understood.
>
> [Patient] has an [ophthalmology appointment] next week — for review 1/3/12 here!"

56. On 1 March 2012 Mr B was seen by Dr A. The clinical notes record:

> "He made his appointment — we reviewed why he was here he had forgotten he came on his own. He is able to stand from sit without using arms. His tremor seems less. He is calmer. He has heeded the psychiatrist's advice and reduced aropax to tabs 3x daily and reduced his lithium to 1x daily and had no adverse response to that change.
>
> He is due blood test today also [with] [blood pressure].
>
> His homework is to test BSLs [blood sugar levels] qid [four times a day] 1x weekly and he is willing to see me monthly protem [for the time being]."

57. Dr A referred Mr B for a blood test that did not include serum creatinine, eGFR or serum lithium.

58. On 29 March 2012 and 18 April 2012 Mr B did not attend scheduled appointments. On 18 April 2012 Dr H provided Mr B with a one-month prescription for lithium 400mg tablets (two tablets, once daily) and Aropax 20mg tablets (six tablets daily).

Nephrology review (May 2012)

59. On 8 May 2012 Mr B was reviewed by nephrologist Dr N. Dr N wrote to Dr A advising that Mr B had, among other things, "chronic kidney disease likely secondary to lithium". Dr N's letter was received by the medical centre on 17 May 2012. In the letter Dr N also advised:

> "With regards [to] his kidney disease he has been on lithium for approx. 10 years with concentrations that … have been relatively high. It is difficult to pin him down as he reports relatively lifelong polydipsia [abnormally great thirst] but currently has three times nocturia [waking in the night to urinate] large volume with significant fluid intake during the day and I suspect this represents nephrogenic [kidney] disease insipidus.[34] The normotension [blood pressure within the normal range] setting of chronic kidney, polyuria [abnormally large amounts of dilute urine] and lithium exposure makes lithium highly likely to be the underlying cause of his kidney disease. He has no proteinuria [abnormal proteins in urine] and no retinopathy [loss of vision] and this is unlikely to be

[34] A condition characterised by excessive thirst and excretion of large amounts of severely dilute urine, with reduction of fluid intake having no effect on the concentration of the urine.

diabetic disease. We will refer him back to [Dr C] with regards [to] attempting to maintain him on as low a dose of lithium as possible."

Care Plus review at the medical centre (June 2012)

60. On 6 June 2012 Mr B had a regular review with Dr H.[35] Dr H recorded:

> "Needs rpt [repeat] meds … on last Lithium today. has been to Nephrology — concerned to be told his kidneys are so bad. … P: [patient] repeats of all … He would [like] referral to another Psychiatrist — felt last one was just aiming to take away his Lithium and he felt challenged by that."

61. Mr B received prescriptions for his regular medication from Dr H. These prescriptions included lithium 400mg tablets (two tablets once daily) and Aropax 20 mg tablets (six tablets daily).

Psychiatry review (July 2012)

62. On 9 July 2012 Mr B was seen by Dr C at his clinic. Dr C's review note (copied to Dr A) stated:

> "I saw [Mr B] in clinic this morning. He said he had tried to reduce the Diazepam, Codeine and Lithium but could not … I did show him his test results, his creatinine level, his sugar level, and the letter from the Nephrologist [Dr N]. I believe [Mr B] understood what I explained to him and agreed to stop the Lithium and replace it with Tegretol[36] … I told [Mr B] that if he does not reduce and stop his Lithium, he will damage his kidneys more."

63. The plan as recorded in Dr C's note of the consultation was to reduce Mr B's lithium by 400mg weekly until he was no longer taking it.

Follow-up with the medical centre (September 2012 to February 2013)

64. On 27 September 2012 Mr B was reviewed by Dr G. The clinical notes record:

> "Has been on regime to reduce/stop Lithium and reduce Paroxetine with trial of tegretol as replacement. … Not happy with mood control … also has put himself back onto 400mg once daily Lithium."

65. That day Dr G prescribed Aropax 20mg tablets (four tablets per day) and lithium 400mg (one tablet per day). This was the first time Mr B's dose of both paroxetine and lithium had changed since specialists had requested dosage changes on 27 November 2011 and 11 January 2012.

66. On 2 October 2012 Mr B had blood taken for a renal function test and a serum lithium test ordered by Dr G. Mr B's serum creatinine was within the recommended range,

[35] A regular review for patients with complex health problems.
[36] Used for a number of purposes including to control bipolar mood disorder where periods of mania alternate with periods of depression, and to control diabetes insipidus.

and his eGFR was lower than the recommended range.[37] Mr B's serum lithium was 0.40mmol/L, which was within the reference therapeutic range.

67. On 2 November 2012 Mr B was reviewed by Dr A. The clinical note records that Mr B had successfully stopped lithium for three weeks, but had returned to using 400mg a day. The notes state that Mr B acknowledged his dependency on lithium.

68. Between November 2012 and February 2013 Mr B remained on one 400mg tablet of lithium per day.

Changes to codeine prescription (January 2013)

69. On 18 January 2013, following a discussion with Dr A, Mr B wrote to Dr A requesting a prescription for additional codeine:

> "I could no longer comfortably manage on a daily basis from the perspective of lumb[a]r back pain and most importantly from a psychiatric perspective. I was relying more on the codeine phosphate in particular to maintain mental stability, or what passes for it in my case I found that I did not have enough with 180 tablets per month. I asked if you would kindly increase the number of my prescription to a permanent 240 tablets per month …"

70. Dr A amended Mr B's regular prescriptions of codeine from 180 to 240 30mg tablets a month, one to two tablets, as required. Dr A also referred Mr B to an orthopaedic surgeon.

Changes to lithium (March–May 2013)

71. On 19 March 2013, following a traumatic event in Mr B's life, Dr A increased Mr B's lithium prescription to two 400mg tablets per day for one month, at Mr B's request.

72. That same day, Mr B had blood taken for a renal function test and a serum lithium test ordered by Dr A. Mr B's serum creatinine was outside the recommended range, and his eGFR was lower than the recommended range.[38] Mr B's serum lithium was 1.0mmol/L, which was higher than the recommended therapeutic range.

73. On 27 May 2013 Mr B's care was transferred to a different GP clinic. Between 19 March 2013 and 27 May 2013 no clinician at the medical centre prescribed additional lithium for Mr B.

Dr A's response

Repeat prescribing

74. Dr A advised that at the time of the events in question, the medical centre did not have a policy for repeat prescribing, although currently it is developing one. Dr A provided additional context to difficulties reviewing Mr B before repeat prescriptions were provided:

[37] On 2 October 2012 Mr B's serum creatinine was 116µmol/L and his eGFR was 57ml/min/1.67m^2.
[38] On 19 March 2013 Mr B's serum creatinine was 140µmol/L and his eGFR was 49ml/min/1.67m^2.

> "I accept that on occasion [Mr B] ought to have been reviewed before being provided with a repeat prescription. This aspect of [Mr B's] care has been discussed by the doctors and other clinical staff I work with and I am confident a similar situation would not occur in the future. It was normal practice to ask [Mr B] to come in for review when prescribing repeat medications, but he was often resistant to this and I accept that a firmer line should have been drawn with him. The combination of [Mr B's] reluctance, nonattendance and the extent to which he used his wife as a go-between resulted in [Mr B] not always being reviewed as frequently as he should have been."

Changes to Mr B's paroxetine and lithium prescriptions

75. Dr A acknowledged that appropriate changes were not made to Mr B's paroxetine and lithium prescriptions following the advice of specialists. Dr A advised that at the time of the events, prescribing doctors were not alerted to letters from specialists. Dr A considers that "[t]he way that [the medical centre] currently deals with correspondence like [Dr C's] letter ensures that matters such as recommended changes to medication are brought to the attention of treating doctors and actioned".

Additional comment

76. Dr A advised:

> "[Mr B] was a challenging patient with behaviours that made his management very difficult … Patients of all types deserve appropriate care. Looking back on events I should perhaps have questioned more closely at the time whether I was best placed to be [Mr B's] general practitioner — particularly given the need I had at the time to rely on a number of locum doctors, which made it more difficult to provide [Mr B] with a continuity of care."

77. Additionally Dr A stated:

> "I want to acknowledge that, in hindsight, the management of [Mr B's] medication and the monitoring of his lithium therapy should have been better and I apologise to [Mr B] personally and on behalf of the medical centre for this."

78. Dr A also provided HDC with advice from a GP colleague, Dr O. Dr O agreed with Dr A that the management of Mr B's medication and the monitoring of his lithium therapy should have been better. Dr O also outlined mitigating factors in the care Dr A provided, including that Mr B was a challenging patient who was difficult to engage. In addition, Dr O stated:

> "[Mr B's] tremor was long-standing and likely a side-effect of paroxetine or diazepam withdrawal (related to the regular fluctuation in the dosage that [Mr B] chose to take). From the notes it appears that [Mr B] was experiencing this tremor around the time that his serum lithium was sub-therapeutic (August 2008). I also note [Dr F's] remark that [Mr B] was experiencing withdrawal related to his erratic self-prescribing of diazepam and paroxetine. [Mr B's] longstanding tremor is therefore less likely to have been an indication of lithium toxicity and it is understandable why [Dr A] would not have reacted to this symptom."

79. Finally, Dr O outlined that the medical centre's staff and Dr A took action following Mr B's raised serum lithium level in January 2012. After the raised test result on 4 January 2012, Dr L contacted Mr B on 9 January 2012 and requested that he not take lithium that evening, but should resume it the following day. Dr L also requested that Mr B have his serum lithium tested again. Additionally, on 21 February 2012 Dr A recorded in the clinical notes that he discussed the 4 January 2012 serum lithium result with Mr B and discussed not taking lithium for 12 hours prior to the test.

80. Dr O's view also included the comment that "while [Mr B's] lithium level of 1.3[8] in January 2012 was elevated, it seems clear from [Dr A's] 21 February 2012 consultation note that he thought the blood test had been taken just after [Mr B] had taken his lithium dose — not allowing for the 12–24 hour delay required for the blood test to be accurate. This … means it cannot be safely assumed that [Mr B] was experiencing lithium toxicity."

Subsequent events

81. In June 2016 Dr P told HDC that Dr E now works as a regular sessional locum for two sessions per week. Dr H also works as a regular sessional locum, doing six regular sessions per week. Drs L and P both work five regular sessions per week. Dr P said that the new arrangement allows more crossover between the enrolled patients who are apportioned to either the Dr A practice or the Dr L/Dr P practice for administrative purposes more than medical care. Patients tend to be seen by their chosen regular part-time doctor but, if that person is not available, they will be seen by whichever doctor is free.

82. Dr P said that as soon as the medical centre was incorporated and took over ownership of the practice, there was prompt enquiry about, and subsequent commitment to, the Royal New Zealand College of General Practitioners (RNZCGP) Cornerstone process. Dr P further advised: "[W]ith the fact that different doctors would inevitably see certain patients, we had to discuss and implement policies surrounding such matters. This is a work in progress."

Relevant standards

83. The Medical Council of New Zealand publication *Good Prescribing Practice*, issued in April 2010, provides the following prescribing standards:

> "You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests …
>
> - Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe …
>
> - Periodically review the effectiveness of the treatment and any new information about the patient's condition and health if you are prescribing for an extended period of time. Continuation or modification of treatment should depend on

> your evaluation of progress towards the objectives outlined in a treatment plan …
>
> Patients receiving repeat prescriptions should be assessed in a face-to-face consultation on a regular basis to ensure that the prescription remains appropriate. Patients who need a further examination or assessment should not receive repeat prescriptions without being seen by a doctor …"

Responses to provisional opinion

Mr B

84. Mr B's responses have been incorporated into the "information gathered" section of the report where relevant. Mr B said that he was concerned that he was being portrayed as a "drug-seeker", when he was just wanting help with his depression and acute anxiety. Mr B advised that at the time he naïvely believed that if one drug was helping him, then more of them must help even more.

Dr A

85. Dr A's response has been incorporated into the "information gathered" section of the report where relevant. Dr A's lawyer stated that Dr A did not directly challenge the report's findings or recommendations, but Dr A was concerned about the way some of the report was drafted and the perceptions that could result.

86. Dr A's lawyer requested that Dr Maplesden's comments regarding the challenging nature of managing Mr B's conditions (see Appendix A) be stated in the report. Namely, that Mr B's condition was compounded by physical co-morbidities, and Mr B's behaviours included manipulating medications as he felt fit, resistance to recommended changes in medication, non-attendance at GP and DHB appointments, and variable compliance with requests to undertake blood tests.

87. In addition to the comments from Dr A's lawyer above, Dr A provided HDC with "personal comments from a broader perspective". In this further response to the provisional report, Dr A advised that, in his view, the overall perspective of this case focussed only on "relatively minor points (specifically lithium monitoring and communication within [the medical centre] between staff regarding specialist letters/advice …". Dr A was of the view that the report ignored the bigger perspectives arising out of the case, which he considered to be the "inadequacies/deficiencies/limitations within our health system".

88. Dr A also considered that the issues concerning renal function have been given undue emphasis, noting: "[T]he maintaining of lithium is much more important than a small rise in creatinine. I restate, the literature shows that the risk of death from suicide in such patients who stop lithium is 9%, a lot higher than ESRD which takes a long time to develop and accounts for 2% of cases."

89. Dr A said that Mr B was a patient at the clinic for five years, and was relatively settled, and that they certainly provided continuity, and for a patient such as Mr B this was paramount. Dr A was of the view that they did admirably well to keep Mr B engaged. Dr A said that the emphasis on lithium and its significance to this case was

out of proportion when considered in the context of trying to provide continuity of care to such a patient.

90. Dr O provided a response on behalf of Dr A. In particular, Dr O provided a copy of a report he formulated and provided to Dr A's legal representative, which subsequently formed the basis for Dr O's initial submission to HDC (see above at paragraph 75–77).

91. Nephrologist Dr Q was asked by Dr A to provide HDC with his expert comments on aspects of this case. Dr Q's comments included noting that Mr B had been on lithium for a number of years before becoming a patient of Dr A, and that Mr B had a number of other co-morbidities.

92. Dr Q stated:

> "Taking the results at face value without considering factors which influence a blood test result may lead to the wrong conclusion. When monitoring lithium blood concentrations, these need to be trough concentrations, taken 12 hours after the last dose and before the next dose. On the data provided to me, there is only recordings of the date and result with no evidence of the timing of the blood test or when the last dose of lithium was taken. So if the morning dose had been taken and the blood test was two hours later a result of 1.3mmol/L would not be expected. This is not enough evidence to call the result evidence of toxicity."

93. Dr Q noted that the blood lithium concentrations continued to fluctuate.

94. Dr Q was of the view that there are many other reasons for Mr B to have tremor, not least his other high dose psychotropic medications. He noted that Mr B had a number of potential contributing factors to having developed mild chronic kidney disease. Dr Q concluded that there are some very important factors that limit the ability to make any conclusions with respect to lithium toxicity.

The medical centre

95. Dr P responded to the provisional opinion on behalf of the medical centre. Dr P stated that the provisional report was, in her view, a very one-sided view of the whole treatment package that was provided to Mr B, centred on a very small part of Mr B's care, and she noted that for six years Mr B was kept relatively stable emotionally.

96. Dr P agreed that the continuation of prescribing lithium long term needs psychiatric review, but noted that Mr B failed to attend or to follow up on the referrals made to psychiatrists. Dr P commented that psychiatric review "was certainly attempted but with little success. The GPs were in a no win situation in some respects."

Opinion: Dr A — Breach

Introduction

97. Mr B had longstanding and complex psychiatric issues, which made him a challenging patient to manage. Mr B also had a number of physical co-morbidities, including diabetes, obesity, obstructive sleep apnoea, fatty liver, and previous pulmonary embolus. During his time as a patient of Dr A, Mr B was on approximately 20 different prescription medications. Mr B did not always attend his medical appointments and, at times, he adjusted the dose of his medications at will. The clinical notes also record that Mr B was reluctant to persist with changes in his medication regimen proposed by his clinicians.

98. My consideration of Mr B's care has been mindful of the overall context in which it occurred. Mr B's complex condition and behaviours are mitigating factors in my examination of his care. I also acknowledge that Dr A's care, including his support and advocacy, had provided a lengthy period of stability for Mr B.

99. When Mr B transferred to Dr A's care in February 2008 he was stabilised on a psychotropic medication regimen that Dr A did not alter, with the exception of codeine in January 2013. Dr A recognised in 2008 that Mr B was on high amounts of psychotropic medication, and contacted Dr D to confirm that Mr B should remain on those medications and dosages. My expert advisor, general practitioner Dr David Maplesden, considered that it was reasonable for Dr A to continue Mr B on the same medication regimen he had been on previously. Dr Maplesden considered that, while Mr B's medication regimen might be described as unorthodox in terms of dosages, the regimen had been approved by a senior psychiatrist and had given Mr B some stability of his long-term psychiatric condition. Dr Maplesden also noted that Dr A and clinical staff at the medical centre appropriately referred Mr B for expert psychiatric input.

100. However, while I am satisfied that it was appropriate for Dr A to continue to prescribe Mr B with high amounts of psychotropic medicine, I consider that Dr A had a responsibility to monitor Mr B for side effects related to those medications. I note that Dr A worked only one half day a week at the medical centre, and that many of Mr B's interactions with clinical staff at the medical centre were not during times when Dr A was present. However, Dr A was Mr B's primary GP and also oversaw the team covering his patients at the medical centre. I therefore consider that Dr A had primary responsibly for the care provided to Mr B.

101. I have concerns about the frequency of Mr B's serum lithium testing. I also have concerns about Dr A's failure to document any consideration that Mr B might be suffering side effects from lithium toxicity, and that Dr A took no action to assess whether lithium might be causing Mr B's tremor or the deterioration in his renal function. Finally, I am concerned that medication changes recommended by specialists were not implemented in a timely manner.

Medication management

Frequency of serum lithium testing while prescribing lithium carbonate

102. Mr B had his first appointment with Dr A on 28 February 2008. On 22 August 2008 Mr B's serum lithium levels were taken and were within the recommended therapeutic range. Mr B's serum lithium levels were next taken on 19 November 2009, at which time they were elevated. Between the serum lithium test in August 2008 and the test in November 2009, 15 months had passed and Mr B continued to be prescribed lithium.

103. On 8 April 2010, more than four months after the previous test, Mr B's serum lithium levels were taken again and were elevated above the therapeutic range. Mr B's serum lithium level was not tested again until 4 January 2012, 20 months later. The result of the serum lithium test on 4 January 2012 indicated that Mr B's serum lithium was higher than the therapeutic range and within the possibly toxic range. Mr B continued to be prescribed lithium over that period.

104. Mr B's serum lithium was tested twice more before he transferred to another medical practice — on 2 October 2012, ten months since the following test, at which time his serum lithium was within the normal range; and again on 19 March 2013, five months since the previous test, when his serum lithium level was elevated higher than the therapeutic range.

105. Guidelines in place at the time outline that serum lithium levels for patients on lithium were to be taken every three months.[39] In his advice, Dr Maplesden outlined that six-monthly monitoring for patients with stable lithium levels, and with stable renal function, was common practice during the time in question, even if it did not represent precise compliance with BPAC guidelines. However, should tests indicate concerns about renal function (ie, serum creatinine and eGFR results outside the normal range) or serum lithium levels outside the recommended therapeutic range, then testing should occur more frequently.

106. Dr Maplesden advised that, following the test in November 2009 where Mr B's serum lithium levels were at the top of the therapeutic range, "the relatively high level [of serum lithium] obtained at this point, together with Mr B's known tendency to manipulate his medications, should have led to close monitoring of his lithium level …".

107. Regarding the 4 January 2012 test when Mr B's serum lithium levels were outside the therapeutic range, Dr Maplesden advised me that the "level in January 2012 was supratherapeutic and potentially toxic at 1.38mmol/L …". Dr Maplesden considered that at this time close monitoring of Mr B's serum lithium level would have been appropriate.

108. I acknowledge the submissions received in response to the provisional report, which outline that there are factors that may influence a blood test result, including the timing of the blood test and when a dose of lithium is taken — particularly relevant in the context of a non-compliant patient — and that there are factors that limit the

[39] BPAC publication *Lithium in general practice. BPJ. 2007; Issue 3.*

ability to make any definitive conclusions with respect to lithium toxicity. I note that Dr A's 21 February 2012 consultation note makes some reference to counselling Mr B about the timing of blood testing.

109. Regardless, the issue in relation to this aspect of Mr B's care is that his serum creatinine, eGFR and serum lithium were not tested again until 2 October 2012, although other blood tests were being ordered by the medical centre's practitioners.

110. Dr Maplesden advised that "the management of Mr B following detection of a potentially toxic lithium level on [4] January 2012 was deficient, particularly the lack of monitoring subsequently irrespective of whether or not he was actually lithium toxic at the time". I agree.

111. The Medical Council of New Zealand outlines in its *Good Prescribing Practice* that practitioners are to prescribe only once they have assessed the patient's condition adequately. Between February 2008 and May 2013 Mr B continued to receive prescriptions for serum lithium without appropriate tests being undertaken (at a minimum of six-monthly intervals or more frequently if renal function deteriorated).

112. I remain of the view that Dr A failed to ensure that Mr B's serum lithium levels were assessed adequately before he was prescribed lithium. This was suboptimal.

Connection between poor renal function and lithium

113. On 7 February 2011 Mr B's blood was tested for serum creatinine and eGFR. The results for both tests were outside the normal range, indicating impaired renal function, a possible side effect of lithium toxicity. On 14 June 2011 and 28 June 2011 Mr B's blood was tested again for serum creatinine and eGFR. The results of these tests continued to show that Mr B's serum creatinine and eGFR were outside the normal range. No serum lithium tests were requested throughout this time.

114. On 30 September 2011 Mr B was seen by nephrologist Dr J, who ordered a serum lithium test to be taken. However, Mr B did not have his blood taken for testing until 4 January 2012.

115. On 23 November 2011 Dr A reviewed Mr B and noted that he had developed a hand tremor and was complaining of poor memory. At this time, Dr A did not review Mr B's serum lithium levels or determine that the serum lithium tests ordered had not been taken. Instead, Dr A deferred review of Mr B's medication until Mr B had had a psychiatric review.

116. Dr A advised HDC that in 2011 clinicians at the medical centre had concerns about Mr B's renal function, but considered that his changes in renal function were related to his diabetes and not lithium toxicity. Due to concerns about diabetes, Dr A referred Mr B to nephrology services in June 2011.

117. Dr Maplesden advised: "A deterioration in renal function was noted in February 2011 which should have triggered concurrent testing of lithium levels as lithium can both cause, and clearance be affected by, deterioration in renal function."

118. Additionally, in November 2011 when Mr B complained of a tremor and poor memory, Dr Maplesden observed: "There is nothing [in the clinical notes] to suggest [Dr A] was aware of the overdue blood tests, or that he gave consideration to the possibility the tremor was related to [Mr B's] lithium treatment and that a lithium level was well overdue." In response, Dr O outlined that a tremor may also be a side effect of paroxetine and diazepam, and noted the fact that Mr B regularly increased or decreased the amount of each he was taking. Dr O considered that it was understandable that Dr A did not consider lithium toxicity, as the tremor was longstanding and more than likely attributed to paroxetine and diazepam.

119. The Medical Council of New Zealand outlines in its *Good Prescribing Practice* that practitioners must be familiar with medication side effects when prescribing. In 2011, when Mr B's renal function was deteriorating, there is no record of Dr A considering a possible diagnosis of lithium toxicity. Furthermore, in November 2011 when Mr B presented with a tremor — a side effect of lithium toxicity — there is no record of a possible diagnosis of lithium toxicity or of Dr A attributing the developing tremor to paroxetine or diazepam. I consider it suboptimal that Dr A did not document any consideration that Mr B might be suffering side effects from lithium toxicity, and took no action to assess whether the lithium was the cause of Mr B's tremor or deteriorating renal function.

Medication amendments following specialist review

120. On 28 November 2011 and 11 January 2012 specialists recommended that the dosage of Mr B's medication be amended.

Paroxetine

121. On 28 November 2011 Mr B was seen by psychiatrist Dr C, who advised that Mr B should reduce his dose of paroxetine by 10mg every two weeks. The clinical note advising this was sent to the medical centre and filed electronically on 7 December 2011. However, Mr B's prescription for paroxetine remained the same until 27 September 2012. Between 28 November 2011 and 27 September 2012 Mr B was seen by Dr A on two occasions after the recommended change.[40] Mr B was also seen by two members of Dr A's medical team after the recommended change (Dr G[41] and Dr H[42]). Mr B was prescribed paroxetine three times over that period by Dr L[43] and Dr H.[44]

Lithium

122. On 11 January 2012 a clinical note by RN K recorded that Mr B's dose of lithium was to be halved, following discussion with endocrinology registrar Dr M. Changes to Mr B's lithium prescription did not occur until 27 September 2012, following a letter of 9 July 2012 from Dr C indicating that Mr B was to titrate his lithium levels down until he was no longer taking any lithium. As above, between 11 January 2012 and 27 September 2012 Mr B was seen on two occasions by Dr A and on two other occasions

[40] 21 February 2012 and 1 March 2012.
[41] 15 December 2011.
[42] 6 June 2012.
[43] 9 January 2012.
[44] 18 April 2012 and 6 June 2012.

by members of Dr A's team. Furthermore, on 1 March 2012 Mr B reported to Dr A that he had reduced his lithium to once daily (400mg total) from twice daily (800mg total). However, Mr B continued to be prescribed his "standard" (800mg daily) dose of lithium.[45]

123. I am critical that the recommended changes to Mr B's medication regimen were not made in a timely manner. As Mr B's primary GP, overseeing the team covering his patients at the medical centre, I consider that Dr A had primary responsibility for the care provided to Mr B, and should have ensured that the recommended changes were made when he met with Mr B.

Conclusion

124. I provided Dr Maplesden with Dr A's responses to the provisional opinion. Dr Maplesden emphasised that he considered that the difficulty managing complex patients like Mr B is a mitigating factor when considering the failures set out below. I accept that advice.

125. I acknowledge that Mr B's conditions and management were complex. Dr A nevertheless failed to assess Mr B's serum lithium levels adequately (see paragraphs 107-109). Dr A did not document any consideration that Mr B might be suffering side effects from lithium toxicity, and took no action to assess whether the lithium might be the cause of Mr B's tremor or deteriorating renal function. Finally, Dr A failed to ensure that specialist ordered changes to Mr B's medication regimen were made in a timely manner. Dr Maplesden considered that together these deficiencies in care would be considered by his peers to be a moderate departure from accepted standards. I accept Dr Maplesden's advice. In my view, and after taking into account the mitigation further set out above, Dr A did not provide services to Mr B with reasonable care and skill, and breached Right 4(1) of the Code.

126. I note that Dr A has accepted his errors in the management of Mr B's medication and appropriately undertaken steps to ensure that the errors do not happen again.

Opinion: Medical centre — Breach

127. At the time of these events, the medical centre was a partnership, with both Dr A and Dr E as partners. While Dr A and Dr E shared administrative costs, they ran independent enrolled patient lists at the medical centre and managed patients in relative isolation from each other. The management of Mr B's care was shared between Dr A, several locum GPs, and nurses at the medical centre. Dr A organised locum GPs to cover his practice while he was not present.

128. While Mr B was a patient at the medical centre his serum lithium levels were not tested in a timely manner, repeat prescriptions were not processed appropriately and, in addition, dosage changes recommended by specialists were not reviewed and

[45] On 18 April 2012 and 6 June 2012 Dr H prescribed Mr B with 800mg of lithium daily.

implemented in a timely manner by staff members. Staffing at the medical centre appears to have made continuity of care difficult. In those circumstances it was essential that the medical centre had robust processes to ensure effective communication between its staff, particularly around the review and actioning of reports and results, and repeat prescribing.

129. On 28 November 2011 Mr B was seen by psychiatrist Dr C, who advised that Mr B's dose of paroxetine should be reduced by 10mg every two weeks. The clinical note was sent to the medical centre and filed electronically on 7 December 2011. The note in the electronic clinical record states: "28/11/11 [DHB] Mental Health — Psychiatric Examination." Between 7 December 2011 and 27 September 2012 Dr L, Dr G, Dr H and Dr A all reviewed Mr B at the medical centre, but his prescription for paroxetine was not changed. It was not until 27 September 2012 that Dr C's recommended changes were made, and Mr B's prescription for paroxetine was reduced.

130. As outlined in the Medical Council of New Zealand's *Good Prescribing Practice*, individual prescribing clinicians have a responsibility to review new information about a patient's condition and health before prescribing. Clinicians working for the medical centre had an individual responsibility to review Mr B, and the notes in his clinical file, and action amendments to Mr B's medication appropriately.

131. However, between 7 December 2011 and 27 September 2012 three clinicians[46] at the medical centre failed to review Dr C's letter and amend Mr B's medication. In my view, the fact that these errors occurred multiple times indicates a wider systemic communication issue at the medical centre.

132. Similarly, on 11 January 2012 a clinical note by RN K records that Mr B's dose of lithium was to be halved, following discussion with endocrinology registrar Dr M. In addition, on 1 March 2014 Mr B self-reported that he had reduced his lithium. However, changes to Mr B's lithium prescription did not occur until 27 September 2012, following a letter of 9 July 2012 from Dr C indicating that Mr B was to titrate his lithium levels down until he was no longer taking lithium. Between 11 January 2012 and 27 September 2012 Mr B was seen by two different clinicians working for the medical centre, yet the prescribing clinicians failed to amend Mr B's lithium dose.

133. Dr Maplesden advised:

> "[Mr B] saw multiple providers and had multiple prescribers and I feel this situation may have contributed to some of the suboptimal aspects of his management … While staffing at [the medical centre] may have made such continuity of care difficult, this situation necessitated effective communication between providers and robust processes particularly around review and actioning of reports and results, and repeat prescribing, and I feel there were significant deficiencies in these areas."

134. I accept Dr Maplesden's advice. I note that Dr A considered that his need to rely on a number of locum doctors made it difficult to provide Mr B with continuity of care.

[46] Dr A (21 February 2012 and 1 March 2012), Dr G (15 December 2011) and Dr H (6 June 2012).

135. I also note that at the time of the events in question the medical centre did not have a policy for repeat prescribing to guide patient review requirements and management processes with regard to changes in patient medication regimens. Similarly, at the time of the events in question the medical centre did not have a process for managing correspondence received by the medical centre that included matters to be brought to the attention of the treating doctor. Without processes in place, appropriate communication between providers did not occur, and appropriate changes were not made to Mr B's medication regimen.

136. Dr A has identified that this was a systemic problem at the medical centre, and advised that prior to February 2016 the medical centre put in place a process to ensure that correspondence such as Dr C's letter is brought to the attention of treating doctors and actioned.

Conclusion

137. I consider that the medical centre failed to have in place systems to facilitate co-operation between providers to ensure that quality and continuity of services were provided to Mr B and, accordingly, breached Right 4(5) of the Code.

Recommendations

138. I recommend that Dr A:

c) Provide a written apology to Mr B for his breach of the Code. The apology should be sent to HDC, for forwarding to Mr B, within three weeks of the date of this report.

d) Undertake training on the prescribing of psychotropic medication. Evidence of this training should be sent to HDC within three months of the date of this report.

139. I recommend that the Medical Council of New Zealand consider whether a review of Dr A's competence is warranted, and report back to HDC on the outcome of that consideration.

140. As noted above, the medical centre is under new ownership. I note the positive changes made by the new owner. I recommend, with specific reference to the Royal New Zealand College of General Practitioners Foundations Standards assessment, that the following policies are developed and finalised for the medical centre:

c) A repeat prescribing policy that includes information on patient review timeframes. A copy of the policy is to be sent to HDC within three months of the date of this report.
d) A policy for the robust filing of reviews and reports, including specialist advice, received by the medical centre that require action. A copy of the policy is to be sent to HDC within three months of the date of this report.

Follow-up actions

141. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, the Royal New Zealand College of General Practitioners, and the DHB, and they will be advised of Dr A's name.

142. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden on 15 April 2015:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Mr B]; response from [Dr A] of [the medical centre]; response from [Dr E] — dual practice owner [the medical centre]; statement from [the receptionist]; [the medical centre's] clinical notes for [Mr B] from 2008–2013.

2. [Redacted as unrelated to issues under investigation and for reasons of privacy].

3. [Dr A] has provided a comprehensive response which is supported by the contemporaneous clinical documentation. I will not reiterate his response in detail here. …

4. It is evident [Mr B] had very longstanding and complex psychiatric issues although his precise diagnosis appears to have varied over the years. He also had physical co-morbidities including diabetes, obesity, obstructive sleep apnoea, fatty liver and previous pulmonary embolus. His psychological state had prevented him from working since 1990. Many medication regimes had been trialed both in the [country] where [Mr B] previously resided, and in New Zealand with varying degrees of effectiveness. When [Mr B] transferred to the care of [Dr A] in February 2008 he had been stabilized on a medication regime under the auspices of [psychiatrist Dr D]. The medications [Mr B] was taking are accurately outlined in [Dr A's] response. The regime does appear somewhat unorthodox, particularly in terms of the high doses of diazepam and paroxetine being prescribed, but [Dr D] is an expert in his area and noting the complexity and persistence of [Mr B's] symptoms I think it was reasonable for [Dr A] to assume there were strong clinical grounds to persist with [Mr B's] current medication regime. I think it was also reasonable for [Dr A] to assume that, after almost twenty years of having a psychological condition treated by various clinicians including experts in the field, all appropriate treatment modalities had been considered. Furthermore, I note [Mr B] requested increased doses of his various medications at times and, when changes or reductions in his regimes were suggested at times (see below) he was generally most reluctant to either trial or persist with these changes. I note [Dr A] states he discussed [Mr B's] regime with [Dr D] shortly after taking over [Mr B's] care and he evidently received a reassuring response from [Dr D]. While it is apparent [Mr B] was dependent on benzodiazepines and codeine there is nothing in the prescribing pattern to suggest he was abusing or diverting the medications [redacted for privacy reasons]. Some thought might have been given to referring [Mr B] to a structured drug withdrawal programme noting his dependence [redacted for privacy reasons]. However, this comment must be regarded in the context of there being apparent 'expert' authorization of [Mr B's] regime and his complex and unstable psychiatric history ie there was a potential risk of destabilisng his condition should such changes be made. As noted previously,

there is documentation on file that suggests [Mr B] expressed reluctance at any suggestion his regime be altered.

5. During the period in question, five referrals were made to mental health services by various clinicians for assistance with [Mr B's] management:

(i) August 2008 — referral by [Dr A's] locum to psychiatrist [Dr F]. Seen 15 October 2008. Current medication regime noted together with the fact [Mr B] took additional medications outside the prescribed regime when he felt he needed them (including paroxetine). Benzodiazepine dependence noted. Behavioral plan discussed but *I do not feel that he is presently capable of benefitting from cognitive therapy.* Recommendation to take a medium dose of diazepam regularly (50mg daily) rather than higher dose (up to 100mg per day) intermittently with a goal to adjust other medications, and consider slow reduction in diazepam, once [Mr B] was stable on the regular dose. Review scheduled for November 2008 but [Mr B] declined to return for review. On 4 December 2008 [Dr A] recorded *asking about ECT — encouraged to get back to psych services and ask to see a different psychiatrist.*

(ii) September 2010 — referral by locum [Dr H] to psychiatrist [Dr I] requesting medication review. [Mr B] did not proceed with consultation following the referral.

(iii) September 2011 — Endocrine registrar [Dr J] referred [Mr B] for psychiatric medication review following concerns about deteriorating renal function and high doses of psychoactive medication. Pertinent to later discussion on [Mr B's] drug monitoring is [Dr J's] comment: *Looking at his biochemical work-up it is of concern that his last lithium was almost 18 months ago and it was supratherapeutic.* [Mr B] was seen by psychiatrist [Dr C] on 28 November 2011. Reduction of diazepam and paroxetine doses were discussed but there is no reference to lithium. The agreed plan was *to reduce the 100mg paroxetine by 10mg every 2 weeks … to be seen in 2 months … to continue the rest of the medication … I also advised him to use an irregular dose of diazepam 10 to 20mg every day.* On 15 February 2012 a letter was sent to [Dr A] noting [Mr B] had not attended scheduled follow-up appointments and then had declined any further input, and he was being discharged from the service.

(v) May 2012 — referral from nephrology service ([Dr N]) back to [Dr C] for medication review, particularly lithium. Clinic letter includes: *With regards to his kidney disease, he has been on lithium for approx. 10 years with concentrations that … have been relatively high … I suspect* [current symptoms of excessive thirst and polyuria] *represent nephrogenic diabetes insipidus. The normotension setting of chronic kidney disease, polyuria and lithium exposure makes lithium highly likely to be the underlying cause of his chronic kidney disease. He has no proteinuria and no retinopathy and this is unlikely to be diabetic disease. We will refer him back to [Dr C] with regards to attempting to maintain him on as lower dose of lithium as possible.* The clinic note from [Dr C] dated 9 July 2012 refers to frank discussion with [Mr B] regarding the risks of continuing lithium therapy and an agreement to slowly reduce it and replace it

with carbamazepine. [Mr B] informed [Dr C] he had reduced his previous paroxetine dose by 20mg (to 80mg) but had been unable to make the other medication reductions previously recommended. The agreed management plan (outlined in the letter to [Dr A]) included:

1. to reduce lithium by 400mg weekly to zero

2. to replace by 200mg Tegretol weekly up to 400mg nocte

3. to reduce the paroxetine by 10mg every 2 weeks

4. to continue with the rest of the medications …

…7. The next step is to reduce the diazepam and codeine slowly

8. to be seen monthly

On 9 October 2012 [Dr C] sent [Dr A] a note informing him he had discharged [Mr B] from his care at [Mr B's] request and following [Mr B's] non-attendance at his last three appointments.

(v) July 2012 — referral by [the medical centre] locum [Dr H] to psychiatrist at [a private clinic] for medication review. Included in the referral letter is the comment: *He has recently been found to have kidney disease likely secondary to his long term high use of Lithium. However, he feels very threatened by attempts to reduce his medications and does not want to go back to see [Dr C] …* [Mr B] did not attend any consultations at [the private clinic].

6. I have reviewed GP notes more closely from February 2011 when deterioration in [Mr B's] renal function was first noted (see tabulated result in Attachment 1) and I make the following observations:

(i) The abnormal renal function tests of 8 February 2011 were filed by [Dr H] with no specific action points documented. On 1 March 2011 he was seen by [Dr A] and discussion was documented regarding elevated liver function and suboptimal glycaemic control. On 26 April 2011 [Dr A] referred [Mr B] for diabetes specialist review and for gastroenterology review. Serum lithium had not been tested since April 2010 at which time renal function was normal.

(ii) Renal function had deteriorated further in bloods taken 28 June 2011 although [Mr B] was awaiting his endocrinology review at this stage. Serum lithium was not checked. [Mr B] did not see a GP at [the medical centre] from 26 April 2011 to 23 November 2011 although he saw endocrinology registrar [Dr J] on 30 September 2011 (see 5(iii)). Regular prescriptions were provided by a variety of [medical centre] clinicians over this period with provider [Dr G] noting on 21 July 2011 that [Mr B] should be seen three-monthly for his scripts (this message conveyed to him) but script provided by [Dr G] the following day (three months) as [Mr B] was travelling to [another region]. Further three-month script provided on 21 October 2011.

(iii) On 31 October 2011 the endocrinology clinic letter was filed (([staff member]). This letter referred to [Mr B's] suboptimal lithium monitoring, previous high levels and that bloods were being ordered. However, it appears [Mr B] did not get the requested tests undertaken until January 2012 (see 5(iii) and Attachment 1). On 23 November 2011 [Dr A] has recorded [Mr B's] concerns regarding a coarse tremor (apparently longstanding) and poor memory. Any medication review is deferred until an imminent psychiatrist review. There is nothing to suggest [Dr A] was aware of the overdue blood tests, or that he gave consideration to the possibility the tremor was related to [Mr B's] lithium treatment and that a lithium level was well overdue.

(iv) The clinic letter from [Dr C], outlining the recommendation to reduce paroxetine and specifying a reduction regime, was filed on 7 December 2011 ([staff member]). On 15 December 2011 [Mr B] saw provider [Dr G] for a steroid injection for hayfever. On 21 December 2011 [the practice nurse] has recorded a conversation with [Mr B's] wife: *re [Mr B's] worsening condition, he has a tremor which makes life difficult and makes him now a real falls risk but also his memory is so poor he misses most appointments …* It is not clear what action was taken on this message. I note that when [Mr B] was prescribed his medications on 9 January 2012 (see below) no change was made to his paroxetine dosage which was continued at six 20mg tabs daily (540 ie it does not appear [Dr C's] recommendations were followed nor was there any record the dose reduction regime was discussed further with [Mr B] (although see section (vi) below).

(v) On 4 January 2012 results of blood tests ordered the previous September at endocrinology clinic, and finally undertaken by [Mr B], were received at [the medical centre] and filed by provider listed as [**Dr A**]. These showed a supra-therapeutic and potentially toxic lithium level at 1.38 mmol/L. Next to the result is the comment *omit tonight then continue as before (vo).* On 9 January 2012 provider [Dr L] has documented instructions for [Mr B's] warfarin therapy and also *hold lithium x 1 day and resume, check both* [presumably referring to INR and lithium level] *again 1 wk.* Three-month supply of all medications (including usual lithium dose of 800mg daily) was provided on this date. In the interim, [Mr B] had apparently received a letter from the endocrinology clinic advising him to halve his dose of lithium and repeat the blood tests (discussed with [the practice nurse] on 11 January 2012). [Mr B] was advised to attend in person for review but refused to do so. I could not find any outbox document suggesting a repeat lithium level had been requested. [Mr B] evidently then went on holiday [overseas].

(vi) On 21 February 2012 [Dr A] reviewed [Mr B] and discussed his recent non-attendance at DHB clinics (diabetes and nephrology). Notes include: *he has tremor ? cause. he has just taken lithium. I explained this should be 12 hrs prior to blood test. They understood.* A blood request form had been provided on 2 February 2012 but did not include serum lithium. In fact there are no results on file for renal function or serum lithium until October 2012 although there are several INR results filed in the interim. [Dr A] reviewed [Mr B] next on 1 March 2012 and notes include: *His tremor is less, he seems calmer. He has heeded the*

psychiatrist's advice and reduced aropax to tabs 3x daily and reduced his lithium to 1x daily and had no adverse responses to that change. He is due blood test today (INR only performed) *… he is willing to see me monthly protem.*

(vii) Three-monthly script for [Mr B's] medications was provided on 18 April 2012 ([Mr B] cancelled or had not attended at least two scheduled GP appointments since last seeing [Dr A]). Script was provided by [Dr H]. Lithium continued to be prescribed at 800mg daily (when previous notes and specialist recommendation was for 400mg daily) and paroxetine was prescribed as *6 tabs once daily* when it was previously noted [Mr B] had reduced his dose to three daily and was meant to be on a reducing regime per previous specialist recommendations.

(viii) On 17 May 2012 a clinic letter was received from the DHB nephrology service (see 5(v)) noting the likelihood of nephrotoxicity secondary to lithium therapy and the need to reduce the dose to the absolute minimum required. Some concern was also expressed at the high doses of [Mr B's] neuroleptic medications in the face of impaired renal function. The letter was filed by [a staff member]. By this stage [Mr B] had not had his renal function or lithium levels rechecked since January 2012 despite the lithium level in January being potentially toxic. However, it is apparent [Mr B] was taking a lower dose of lithium than that prescribed for him, and he was relatively asymptomatic (his tremor, if it was related to lithium, was improved).

(ix) On 6 June 2012 [Mr B] was reviewed by provider [Dr H]. He requested repeats of all his medications. Notes include *He would like referral to another psychiatrist — felt last one was aiming to take away his Lithium and he felt challenged by that.* There is no reference to [Mr B's] paroxetine dose reduction regime or current dosage. Scripts were provided including lithium at 800mg daily and paroxetine at *6 tabs once daily.* A blood test form was provided for INR only.

(xi) On 13 July 2012 a clinic letter was received from [Dr C] and filed by [staff member] (see 5(v)). This gave quite explicit instructions regarding recommended changes to [Mr B's] medication regime although there is nothing in the clinical notes at this time reiterating these recommendations for those providers not viewing the clinic letter. On 27 September 2012 [Mr B] was seen by provider [Dr G] who recorded: *Has been on regime to reduce/stop Lithium and reduce paroxetine with trial of tegretol as replacement … not happy with mood control on lower paroxetine, has put himself back on 80mg per day, also has put himself onto 400mg once daily lithium …* pain control was discussed ([Mr B] had chronic back and ankle pain — one of the documented reasons for prescribing of codeine despite the assertions in [Mr B's] complaint). A more gradual reduction in paroxetine was discussed and written instructions provided but *he is loathe to do this … I have said this is optional …* At this visit [Mr B] also requested an increase in his codeine dose and for a supply of morphine tablets and barbiturates to help him sleep. These requests were declined by [Dr G] and deferred to [Dr A]. Repeat medications were provided with lithium now recorded as 400mg daily and paroxetine as four tablets daily. Blood test form was provided including lithium

levels and renal function and was undertaken on 2 October 2012 (renal function stable, lithium level lower level of therapeutic range). This was the first assessment of renal function and serum lithium for 10 months.

(xii) On 1 November 2012 [Mr B] returned for review by [Dr A]. Notes refer to [Mr B's] unsuccessful attempts to stop lithium (currently taking 400mg daily) and paroxetine (managed to reduce to two tabs daily but felt unwell so increased dose back to four tabs daily (originally on six tabs daily). *He finds he manages on diazepam at current high levels but needs more codeine to manage his pain. He acknowledges that he is dependent on these.* The outcome of this discussion is not clear from the notes although it appears [Mr B] was under the impression his supply of codeine was going to be increased from 180x30mg per three months to 240x30mg per three months. On 18 January 2013 [Mr B] wrote to [Dr A] expressing concern that the dose increase had not occurred and on 22 January 2013 [Dr A] provided a script to effect the dose increase. Concurrently there was referral made to an orthopedic surgeon for review of [Mr B's] ankle condition which was the apparent cause of his increased pain levels. On 5 February 2013 a three-month repeat of all medications was provided including 240x30mg codeine tabs, lithium 400mg daily and paroxetine four tabs daily.

(xiii) Subsequent events are as reported by [Dr A] in his response. There was involvement of the DHB emergency psychiatric service following [events on] 6 March 2013 but the service did not offer a hospital admission despite concerns expressed by [Dr A] and his team. On 19 March 2014 [Dr A] saw [Mr B] and noted he had recommenced (of his own volition) his previous dose of lithium (800mg daily) to try and help stabilize his mood …, and requesting a script for lithium to make up the current deficit. [Dr A] provided this on the condition [Mr B] had blood tests done and lithium level and renal function were done that day (see Attachment 1). Subsequent notes relate to the … support offered to [Mr B] by the medical centre in terms of assisting him to find a new GP and ensuring supplies of medication in the interim.

7. Comments

(i) From the outset I acknowledge [Mr B's] conditions made him a particularly challenging patient to manage. He enrolled at [Dr A's] practice on a pre-existing medication regime that might be described as unorthodox in terms of the dosages of some of the medications prescribed, particularly paroxetine, but with that regime having been initiated or at least approved by a senior psychiatrist and having given [Mr B] some stability of his long-term psychiatric condition. [Dr A] did not initiate any of the medications complained about by [Mr B] nor did he increase doses of these medications beyond the levels [Mr B] was already taking when he enrolled, with the exception of codeine in January 2013. The increase in that dose was made in response to repeated requests from [Mr B] who was complaining his chronic ankle pain was not being controlled on the current dose. [Dr A] was clearly uneasy about the medication regime [Mr B] was on at the time of his enrolment and he sought, and obtained, reassurance from [Dr D] that the regime was appropriate. Additional expert psychiatric input was sought from several sources over the period in question. [Mr B's] management difficulties

were compounded by his physical co-morbidities (he was taking around twenty different prescription medications) including diabetes, this giving a possible explanation for the deterioration in renal function observed from February 2011. I note [Mr B] was referred to various specialists (including respiratory, endocrinology, gastroenterology and nephrology) over the period in question and that his physical conditions were actively managed. General management was also made more difficult by [Mr B's] behaviours including a tendency to manipulate his medications as he felt fit rather than on medical advice, resistance to recommended changes (reductions) in his medication regime, frequent non-attendance at both GP and DHB appointments and variable compliance with requests to undertake blood tests. These issues have been regarded as mitigating factors in my comments below. However, for these reasons I believe also that particular effort was required to ensure [Mr B] received continuity of care through a single provider — that provider responsible for issuing prescriptions and monitoring [Mr B]. Instead he saw multiple providers and had multiple prescribers and I feel this situation may have contributed to some of the suboptimal aspects of his management commented on further below. While staffing at [the medical centre] may have made such continuity of care difficult, this situation necessitated effective communication between providers and robust processes particularly around review and actioning of reports and results, and repeat prescribing, and I feel there were significant deficiencies in these areas.

(ii) Repeat prescribing: Repeat prescriptions were provided for [Mr B] by different providers and on occasions without timely review. This was evident particularly in 2011 (see 6(ii)). Following changes made to [Mr B's] medication regime by [Dr C] in November 2011 there was no appropriate change made to his prescription until September 2012 ie incorrect instructions and doses of paroxetine continued to be provided on repeat prescriptions over this period. A similar situation occurred with prescribing of lithium following a recommended dose reduction in January 2012 (see sections 6(iv), (v), (vii), (xi)). **These deficiencies in medication management I feel would be met with moderate disapproval by my peers.** A contributing factor to these oversights appears to be deficiencies in clinical documentation in that once the letter from [Dr C] had been filed, it was not possible for providers to recognize, from the clinical notes alone, that the patient was supposed to be on a reducing dose of paroxetine unless all providers had read [Dr C's] letter before it was filed.

(iii) [Mr B] was on long-term lithium therapy. Recommendations regarding monitoring of patients on lithium therapy are presented in Attachment 2. I cannot determine when [Mr B] had last had a lithium level taken prior to enrolling with [the medical centre] or what that level was but for the purposes of this advice I will assume a satisfactory level had been obtained just prior to transfer. Relevant results are tabulated in Attachment 1. Following transfer to [the medical centre] in February 2008 [Mr B] did not have a lithium level performed until November 2009 although prior tests of renal function were normal. This was well outside the recommended monitoring interval. The lithium level in November 2009 was what might be regarded as the top of the therapeutic range for someone not being treated for acute mania but there is no record [Mr B] was suffering from adverse

effects of the medication at this time. Nevertheless, I think the relatively high level obtained at this point, together with [Mr B's] known tendency to manipulate his medications, should have led to close monitoring of his lithium level, that need heightened even further when a deterioration in renal function was first noted in February 2011 and concerns about lithium and renal function raised by [Mr B's] physicians in 2011 and early 2012 (see 5(iii) and 5(v)). I note [Mr B] complained of tremor (a possible adverse effect of lithium therapy) from at least November 2011. On reviewing the results, it was 20 months from the time of enrolment before the first serum lithium was ordered. Despite this being at the high end of the therapeutic range it was five months before another level was ordered, with that level being more acceptable. A deterioration in renal function was noted in February 2011 which should have triggered concurrent testing of the lithium level as lithium can both cause, and clearance be affected by, deterioration in renal function. While renal function was monitored (and continued to deteriorate) over the next seven months, it was not until [Mr B] was seen in endocrinology clinic that a serum lithium was ordered (by them) although [Mr B] did not get this done until January 2012. [Dr A] continued to see [Mr B] between September 2011 and January 2012 and noted him to have a tremor yet did not review his lithium levels or determine the tests ordered by the endocrine clinic had not been performed. The level in January 2012 was supratherapeutic and potentially toxic at 1.38 mmol/L and inappropriate advice was initially given to [Mr B] by [medical centre] staff (skip one dose of lithium then restart at the usual dose and retest in a week) although appropriate advice was given by the endocrinology clinic. This episode should have resulted in very close monitoring of lithium levels even though [Mr B] had had a dose reduction — the reasons being his potentially toxic level, variable compliance with medication and impaired renal function. Nevertheless it was ten months before another check of renal function or lithium level was undertaken despite [Mr B] having regular blood tests for his INR in the interim. Taking all of these factors into account, and despite the mitigating factor of [Mr B's] variable compliance with instructions, I think the events outlined suggest serious deficiencies in [medical centre] processes around monitoring and management of patients on lithium therapy including recognition of the interaction between lithium and renal function, and tracking of important tests to ensure they have been undertaken. **I feel these aspects of [Mr B's] management would be met with moderate to severe disapproval by my peers**.

Attachment 1: Summary of available renal function and lithium levels undertaken from March 2008 to March 2013. It must be noted [Mr B] had multiple additional blood and urine tests performed over this period relating primarily to assessment of glycaemic control, complications of diabetes and INR monitoring.

Date	Serum creatinine[1]	eGFR[2]	Serum Lithium[3]	Clinician ordering test
19 Mar 08	84	90	Not ordered	[Dr A]
22 Aug 08	85	88	Not ordered	[Dr A]
4 Dec 08	86	87	Not ordered	[Dr A]
15 Jun 09	105	69	Not ordered	[Dr G]
19 Nov 09	95	77	1.01	[Dr A]
8 Apr 10[4]	102	71	0.87	[Dr A]
7 Feb 11	127	52	Not ordered	[Dr H]
14 Jun 11	151	42	Not ordered	[Medical centre clinician]
28 Jun 11	148	43	Not ordered	[Medical centre clinician]
4 Jan 12[5]	148	43	1.38	Endocrine Clinic
2 Oct 12[6]	116	57	0.40	[Dr G]
19 Mar 13	140	49	1.00	[Dr A]

[1] Units µmol/L, normal range 50–120.

[2] Units ml/min/1.67m^2 determined by calculation based on patient age and serum creatinine. Pathologist comment on Mr B's results: *The GFR range for a young adult male is 87–167. From age 30, values fall by approximately 1ml/min/year.*

[3] Units mmol/L. Reference range given as 0.40–0.80. Pathologist comment in 2009: *A range of 0.6–1.4 has been suggested in the treatment of acute mania. Toxicity possible at levels greater than 1 mmol/L; toxicity common above 1.5 mmol/L. These levels refer to specimens collected 12 hours after dose.* For later lithium results the pathologist comments had changed to: *Sometimes toxic 1.0–1.5 mmol/L; usually toxic >1.5 mmol/L … Chronic Therapy: values higher than the quoted range* [0.40–0.80] *may be needed in some patients while others may remain well with serum concentrations as low as 0.4mmol/L. For those on therapy, serum lithium concentrations should be checked every 3 months and when clinically appropriate. Renal and thyroid function tests should be performed every 6 months. Note: Lithium clearance is reduced in renal impairment.*

[4] Mr B had been supplied with the test request form on 16 February 2010.

[5] Request form had been supplied to Mr B at his Endocrine Clinic appointment on 30 September 2011.

[6] Dr A provided Mr B with a request form including renal function but not serum lithium on 2 December 2012 which Mr B did not action. Between 1 March 2012 and 2 October 2012 Mr B was provided by Dr A with test request forms for INR only.

Attachment 2: Lithium monitoring recommendations (from the BPAC publication *Lithium in general practice. BPJ. 2007; Issue 3*):

(i) Recommended baseline tests and ongoing monitoring are described in Table 2 (reproduced below). There may be slight local variations in these guidelines. As well as biochemical monitoring it is important to look for and educate patients about physical signs and symptoms associated with adverse effects and toxicity. These include tremor, tiredness, lethargy, nausea, vomiting and diarrhoea, dehydration, polydipsia, polyuria and nocturia. Although baseline tests will be carried out when lithium is initiated by a specialist, check that the results are complete and readily available for reference.

Lithium baseline tests and monitoring.[6,9] (adapted from Livingstone, 2006; Waitemata DHB 2006)

	Baseline	Routine maintenance	Comments
Serum lithium concentrations	Important to establish reliable steady state concentration associated with therapeutic response	3-monthly	Monitor more frequently in high risk patients, e.g. those on potentially interacting drugs, poor compliance, elderly, unstable renal function, physical illness
Thyroid Function	Baseline thyroid function (T4, TSH)	TSH 3 months after initiation and then 6-monthly	T4 not routinely required. Monitor for symptoms of hypothyroidism
Electrolytes	Baseline	Check with lithium serum levels every 3 months	Particularly important to monitor sodium as it competes for reabsorption in proximal renal tubule
Serum creatinine and renal function	Exclude renal disease. Baseline creatinine and estimation of renal function	Check at same time as lithium levels, at least every 3 months	Estimate renal function using the Cockcroft and Gault Equation* based on ideal body weight
Serum calcium and magnesium	Baseline	Check every 2 years	Lithium may rarely cause hypercalcaemia and hypermagnesium
Parathyroid Hormone (PTH)			Measure only if serum calcium is elevated. PTH must be interpreted relative to serum calcium measurement on the same specimen
Weight	Baseline weight	Monthly, reduce frequency after 6–12 months if weight is stable	Encourage self-monitoring and weight control measures
Pregnancy Test	Baseline in women of childbearing age		
ECG	Baseline in patients with cardiac problems or aged over 45 years	12-monthly in patients with cardiac problems or aged over 45 years	Conduct more frequently if clinically indicated

*The bpac creatine clearance calculator is based on the Cockroft-Gault equation

(ii) Adverse effects are usually related to serum lithium concentrations and are infrequent at levels below 1.0 mmol/L. Mild gastrointestinal effects (mild nausea, vomiting and diarrhoea), vertigo, muscle weakness and a dazed feeling may occur initially, but frequently disappear after stabilisation. Fine hand tremors, polyuria and polydipsia (mild thirst) may persist. Mild polyuria may not be of concern but may be troublesome and the possibility of diabetes insipidus should be considered. Skin conditions including acne, psoriasis, generalised pustular psoriasis, rashes and leg ulcers can be aggravated by lithium treatment. Lithium has several less common but important metabolic adverse effects. Prevention and avoidance of risk factors are important keys to management (Table 1). Patients and their families/carers should be educated about early warning signs of all adverse effects, and the need for immediate advice if clinical signs of lithium toxicity such as severe or persistent diarrhoea, vomiting, tremor, mild ataxia, drowsiness or muscular weakness occur.

(iii) Nephrogenic diabetes insipidus: Lithium is the most common drug cause, affecting 10% of patients treated for 15 years or more. Risk correlates with duration of lithium treatment. Presents as polydipsia and polyuria (24 hour urine volume > 3 L). Dehydration, lithium intoxication and deteriorating renal function may occur and renal impairment may be permanent. Risk factors include long term treatment, concurrent use of long term NSAIDs, chronic physical illness and increasing age. Avoidance includes careful monitoring and awareness of risk factors. Management may include shared care with renal specialist and switch to alternative treatment.

(iv) There is debate in the literature about how long mood stabiliser treatment should be continued and various criteria have been proposed. Local consensus is to continue treatment for at least six months after a first manic episode. The criteria for long-term maintenance treatment varies but commonly includes at least two episodes of mania or depression … Discussion about discontinuing lithium treatment will usually be done in consultation with a specialist. Indications for discontinuing treatment include:

- Lack of response, given an adequate dose for an adequate time period.
- Renal failure or worsening renal insufficiency.
- Cardiac insufficiency.
- Ongoing poor compliance with medication (where interventions to improve compliance have been ineffective).
- Intolerable adverse effects to lithium.
- Remission of bipolar disorder for an adequate period of time in liaison with specialist

Attachment 3: Extracts from the Medical Council of New Zealand publication *Good Prescribing Practice 2010*:

(i) You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests. Alternatively you may prescribe on the instructions of a senior colleague or a practice colleague who can satisfy the above criteria, as long as you are confident that the medicines or treatment are safe and appropriate for that patient and the patient has given his or her informed consent. Medicines or treatment must not be prescribed for your own convenience **or simply because patients demand them**.

(ii) Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe.

(iii) Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. In such circumstances, it might be

useful to discuss the proposed treatment with a senior colleague before completing the prescription.

(iv) Periodically review the effectiveness of the treatment and any new information about the patient's condition and health if you are prescribing for an extended period of time. Continuation or modification of treatment should depend on your evaluation of progress towards the objectives outlined in a treatment plan.

(v) Where a patient's care is shared between clinicians, the doctor with the responsibility for continuing management of the patient has a duty to keep him or herself informed about the medicines that are prescribed.

(vi) If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur.

(vii) In most circumstances there should be timely and full information flow between general practitioners, hospital doctors and other relevant health practitioners about the indications and need for particular therapies. If you are the prescribing doctor and you make a change to treatment, you must notify your colleague(s) of the change and the rationale for it. If the change has significant implications for the patient and his or her care, you must also make sure that this information is received by your colleagues.

(viii) It is important that any system for issuing a repeat of an earlier prescription issued to a patient takes full account of the obligations to prescribe responsibly and safely and that the doctor who signs the prescription takes responsibility for it. Before signing a repeat prescription you must be satisfied that secure procedures are in place to ensure that: the patient is issued with the correct prescription; each prescription is regularly reviewed so that it is not issued for a medicine that is no longer required; the correct dose is prescribed for medicines where the dose varies during the course of the treatment."

Additional advice

Dr Maplesden provided the following further advice on 5 October 2015:

> "I have reviewed additional documentation provided by [Dr A] and a letter of support from colleague [Dr O]. I make the following comments:
>
> 1. I accept [Mr B] had a lithium level undertaken on 22 August 2008 and this result was 0.41 although I could not find this result in the initial documentation provided to me. This makes redundant the comment in section 7(iii) of my original advice: *Following transfer to [the medical centre] in February 2008 [Mr B] did not have a lithium level performed until November 2009 …* It is correct to state there was a period of 15 months between the August 2008 and November 2009 lithium tests and I note [Mr B's] serum creatinine was within the normal range over this time although there was some deterioration in eGFR.

2. [Dr O] states that guidelines for serum lithium monitoring have altered with six-monthly monitoring now recommended. He quotes a BPAC publication from July 2014 which is somewhat later than the events in question. Nevertheless, I accept six-monthly monitoring for patients with stable lithium dose and levels and with stable renal function was common practice during the time period in question even if it did not represent precise compliance with local guidelines (at the time). In fact, I would not have been overly critical if [Mr B] had had annual checks of serum creatinine if he had been physically and mentally stable with stable renal function, lithium intake and lithium levels. My issue is that [Mr B] had erratic monitoring of his lithium levels which cannot be wholly attributed to non-compliance with requests for blood tests as he had multiple unrelated blood tests performed between the time of his lithium levels. [Mr B] was also noted to be somewhat non-complaint with recommended doses of his medications and his renal function was unstable. These factors also indicated a need for some structured form of lithium level monitoring. I maintain the view that the management of [Mr B] following detection of a potentially toxic lithium level on [4] January 2012 was deficient, particularly the lack of monitoring subsequently, irrespective of whether or not he was actually lithium toxic at the time.

3. There is no new information affecting my factual observations of [Mr B's] prescribing including the delays in updating prescriptions following specialist recommendations and prolonged periods when [Mr B] was prescribed medication without review.

4. Both [Dr A] and [Dr O] comment on the challenges of managing a patient such as [Mr B] and this situation was addressed to some extent in 7(i) of my original advice. The complexity of [Mr B's] conditions and management, including his variable compliance with clinical recommendations (in particular attending for reviews and blood tests) meant it was important early on to agree the 'rules' around issues such as repeat prescribing and to ensure these 'rules' were complied with. However, there was always a risk that had treatment been suddenly withdrawn, even if this was due to [Mr B's] refusal to comply with recommendations regarding review before repeat prescriptions would be provided, the outcome for him might have been catastrophic. In hindsight, I feel I may not have given this issue adequate consideration as a mitigating factor and I have reassessed the degree of departure from expected standards relating to [Mr B's] overall management (including lithium monitoring and medication management) from 'moderate to severe' to 'moderate'.

4. [Dr A] has described remedial measures undertaken since this complaint and these appear appropriate particularly with respect to repeat prescribing (draft policy reviewed and this appears consistent with those I have viewed from other practices), administration of specialist letters, and use of patient alerts to aid lithium monitoring. I am also reassured that a recent practice audit of lithium monitoring did not raise any issues with other patients taking the drug. I note [Dr A's] practice is preparing for a RNZCGP Foundations Standards assessment and this should ensure relevant written clinical and administrative policies are in place.

5. I have no further comments or recommendations."

Dr Maplesden provided the following further advice on 13 June 2016:

> "Thank you for providing the responses to your [provisional report] from various stakeholders.
>
> 1. Very much of the academic discussion presented appears to be based on an assumption that I felt [Mr B] was lithium toxic at one stage, that I felt [Mr B's] tremor was due to lithium toxicity, and that I felt [Mr B's] impaired renal function was secondary to the effects of lithium. On re-reading my original advice I think I made it quite clear that these were all potential (not actual) situations which heightened the need for structured monitoring of [Mr B's] lithium levels as best as was possible under the circumstances. None of my adverse comment was based on an assumption that [Mr B's] lithium treatment had caused him actual harm. I remain of the view that there was a need for structured monitoring of [Mr B's] lithium levels to minimise the potential risks of harm in the clinical scenarios described (impaired renal function, previous elevated lithium level with timing of test not confirmed, persistent tremor of uncertain aetiology, tendency to self-medicate).
>
> 2. Comment has been made in one of the responses that guidelines (with respect to lithium monitoring) and specialist advice (with respect to recommendations made by renal physician) do not necessarily need to be followed by the GP who has a better overall knowledge of his patient and can consider such recommendations and advice in an holistic context. However, I am unable to determine that any such consideration was made with respect to [Mr B's] management but rather that it was deficiencies in communication which led to identified oversights in altering [Mr B's] prescriptions in response to specialist advice, and in his lithium monitoring. I agree with comments made in the responses, and which were made in my original advice, that any alteration in [Mr B's] treatment regime needed to carefully balance the risks of destabilisation of his psychiatric condition (which carried with it a significant risk of self-harm) against known adverse effects of the regime itself.
>
> 3. Comment has also been made that the [provisional report] focusses on one small aspect of management of an extremely complex patient and I agree that the difficulty managing a patient [such as Mr B], particularly a patient with the traits exhibited by [Mr B], needs to be emphasised as a mitigating factor as does the fact that the care provided by [Dr A] did result in a significant period of stability for [Mr B]. Personally, I have found providing care to such patients to be mentally exhausting, frustrating and rarely professionally fulfilling and some of the research cited in the responses emphasises how such patients often find it difficult to find and retain consistent primary care support. I think those aspects of [Mr B's] management which have been the subject of adverse criticism in the [provisional report] were deficient for the reasons outlined in my advice (and revised as moderate departures from expected standards of care). However, while these deficiencies were 'visible' because they could be identified from the clinical documentation, the positive aspects of the care provided to [Mr B] by [Dr A] by way of emotional support and advocacy under very trying circumstances are somewhat less 'visible'. The response from [Dr A] to the [provisional report] I think illustrates the emotional and professional investment he made in attempting

to maintain [Mr B's] psychological stability, and I can identify with the frustration and unease he must have felt at times when [Mr B] insisted on manipulating his own medications, often to potentially unsafe levels, and resisted the efforts made by [Dr A] (and other providers) to seek appropriate specialist care and support."