Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 20HDC00674)

Introduction

1. This report discusses the care provided to Mrs A by consultant physician Dr B at the rheumatology[1] clinic at a district health board (DHB) (now Health New Zealand|Te Whatu Ora (Health NZ)).[2]

2. Mrs A has rheumatoid arthritis (RA).[3] She was referred to the rheumatology clinic by her general practitioner (GP) for ongoing care of her RA in August 2015. Mrs A transferred to another medical centre on 7 July 2016 and was seen by multiple GPs.[4]

[1] A field of medicine dealing with rheumatic conditions, such as rheumatoid arthritis.
[2] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to the DHB now refer to Health NZ.
[3] An autoimmune disease that is usually chronic and is characterised by pain, stiffness, inflammation, swelling, and sometimes destruction of joints.
[4] Because Mrs A saw multiple GPs, I refer to her 'GP' to reflect whoever was acting as her GP at the time.

3. Typically, Mrs A experienced the worst symptoms in her knees and ankles, making mobility difficult when her RA was not managed well. In September 2015, X-rays confirmed osteoarthritis in both Mrs A's knees, with features of osteoarthritis in her hands.

4. Dr B used various drug therapies to try to manage Mrs A's RA but, unfortunately, mostly it was resistant to treatment. Between 2015 and 2018, Mrs A experienced regular flares and often felt that her pain was unmanaged, particularly in 2017 and 2018.

5. In June 2018, X-rays showed osteoarthritis[5] in both Mrs A's knees, and in October 2018 an X-ray of Mrs A's right ankle showed osteoarthritic change[6] and a non-union fracture[7] of the medial malleolus.[8]

6. Mrs A raised concerns about the level of care she received from the rheumatology clinic, particularly regarding the long-term use of prednisone,[9] and the time it took to diagnose a non-union fracture in her right ankle.

7. The following issues were identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care between 2015 and 2018 (inclusive).*
- *Whether the district health board provided Mrs A with an appropriate standard of care between 2015 and 2018 (inclusive).*

8. Independent clinical advice was obtained from rheumatologist Dr Andrew Harrison regarding the care provided by the rheumatology service.

9. In-house clinical advice was obtained from GP Dr David Maplesden regarding the GP care provided to Mrs A.

10. This report is the opinion of Deputy Commissioner Deborah James and is made in accordance with the power delegated to her by the Commissioner.

Background

Clinic staffing

11. Between 2015 and 2018, the rheumatology clinic was staffed by Dr B and Clinical Nurse Specialist (CNS) C. Dr B stated that the role of the CNS was 'an invaluable component given the significant mismatch between the demand and the available Physician FTE'. The clinical records show that more often than not Mrs A was seen by CNS C at the rheumatology clinic

[5] A condition where the protective cartilage that cushions the ends of the bones wears down.
[6] Deterioration of the protective cartilage.
[7] A non-healing broken bone. It occurs when a broken bone does not heal in the expected time period.
[8] The small prominent bone on the inner side of the ankle.
[9] A corticosteroid used to treat and prevent a variety of conditions that involve inflammation.

and had regular telephone contact with CNS C. The rheumatology clinic was also attended by rheumatologist Dr E one day every month.

Drug therapies for RA management

12. At Mrs A's first appointment with Dr B, on 4 August 2015, Dr B prescribed Mrs A a short course of 10mg prednisone daily. The intention was to see whether the prednisone reduced Mrs A's symptoms significantly. If it did, then this would indicate that an increase in disease-modifying anti-rheumatic drug (DMARD) therapy[10] was warranted.

13. While Mrs A was under Dr B's care, she was prescribed varying doses of prednisone that varied between 9mg and 60mg daily. A timeline outlining the doses of prednisone taken by Mrs A from August 2015 to December 2018 is included as Appendix C.

14. The Medsafe datasheet for prednisone states that the smallest dose that is effective or produces adequate control should be used. For adults, the initial dose of prednisone is 10–100mg daily, the maintenance dose is usually 5–20mg daily (depending on the individual patient's severity of disease and response to prednisone), and the usual adult prescribing limit is up to 250mg daily. For short-term therapy, a 20–50mg daily dosage can be used with reductions of 2.5mg or 5mg every two to four days depending on the response.

15. To summarise the pattern of prednisone doses over this period, typically Mrs A was advised by either Dr B or CNS C to increase the dose of prednisone only to treat flares.[11] When this occurred, usually a plan would be made to taper the dose back down to 20mg or less. Often Mrs A would have difficulty reducing the prednisone dose in line with the plan because inflammation and/or pain recurred as she reduced the dose. This grew to be more difficult as time went on and often meant that the taper occurred slower than planned. On several occasions, Mrs A took a higher dose of prednisone, but there is no documented clinical advice to do so. Overall, the majority of the advice from Dr B and CNS C was to reduce the dose.

16. On 7 March 2016, Dr B documented:

> '[I]t is disappointing that despite this duration of treatment with adequate doses of Prednisone there is still evidence of synovitis[12] clinically … I think we will have to move through the various oral DMARDs and open the way for anti-TNF[13] therapy.'

17. Dr B worked through various DMARDS (Plaquenil, Arava, Salazopyrin, and methotrexate), biological DMARDs[14] (rituximab and tocilizumab), and TNF inhibitors (Enebrel, infliximab, and Humira) with Mrs A to treat her RA. Unfortunately, most of these treatments were found to be ineffective, other than methotrexate, which Mrs A found of some benefit. Dr B

[10] Used to stop or slow the disease process in inflammatory forms of arthritis.
[11] Sudden increase in pain, stiffness, and swelling of the joints of the body.
[12] inflammation of the tissues that line a joint.
[13] Anti-tumour necrosis factor therapy is the use of TNF inhibitor drugs that help stop inflammation.
[14] Traditional DMARDS target the entire immune system, whereas biological DMARDs target specific steps in the inflammatory process.

also prescribed various medications to help Mrs A manage her pain and inflammation, such as ibuprofen, Naprosyn, paracetamol, amitriptyline[15] and codeine. Further, Dr B used injections of Kenacort (a corticosteroid) to help manage flares. Intra-articular[16] injections of Kenacort were administered on 24 November 2017 and 7 September 2018, and Dr B ordered an intra-muscular[17] injection of Kenacort to be administered by district nurses on 29 November 2017 when Mrs A had not felt any benefit from the intra-articular injection five days previously.

Prednisone prescribing

18. The rheumatology clinic and Mrs A's GP clinic shared care of Mrs A. As documented in the notes from Mrs A's GP clinic, in October 2017 CNS C contacted the GP clinic and clarified that prescriptions were the responsibility of the GP, not the rheumatology clinic.

19. However, most of the adjustments to Mrs A's prednisone dosage were advised by either Dr B or CNS C. They would advise the GP clinic of medication changes in letters to the GP clinic following each appointment with Mrs A.

20. CNS C told HDC that whenever Dr B was away or unavailable, she would seek advice from his colleagues. CNS C also sought advice from Dr E and would speak to his colleagues in another region when he was unavailable. CNS C advised that she always sought advice from a clinician for any increases of medication or changes to patients' treatment. She told HDC: 'I am well aware that I am unable to prescribe any medication or increase treatment for patients unless advised and prescribed by a Physician.'

21. The notes from the GP clinic frequently refer to seeking advice from Dr B on various issues. It is clear that although the GP clinic had the responsibility of prescribing the medications, they relied heavily on advice from the rheumatology clinic.

Concerns about long-term prednisone use

22. At nearly every appointment that Mrs A had at the rheumatology clinic, with either Dr B or CNS C, Mrs A was advised to reduce the dosage of prednisone she was on at the time. However, despite these attempts to wean Mrs A off prednisone, by July 2018 she had been taking doses over 10mg daily regularly for nearly three years.

23. On 18 July 2018, Mrs A had an appointment with Dr B that was dedicated to discussing the use of prednisone and Dr B's concerns about its long-term use. Dr B's documentation of the appointment notes that Mrs A tended to 'bump up' the dose of prednisone to control symptoms such as swelling, stiffness, and/or reduced range of movements but not necessarily a lot of pain.

[15] An antidepressant used to treat certain kinds of nerve pain.
[16] In the joint.
[17] In the muscle.

24. Mrs A disagreed with this statement, saying:

> 'That is not the case at all. I contacted the [rheumatology] Clinic Nurse when I was experiencing an increase in pain and/or when I was having difficulty walking. I increased the dosage only upon her advice. Usually I was advised to increase the Prednisone till the flare up had subsided and then to reduce the dose. As time went on this became a more and more frequent occurrence and more difficult to do.'

25. By 13 August 2018 Mrs A had reduced to 15mg daily but felt that her pain was not being managed. She and CNS C discussed the possibility of a second opinion, which Dr B agreed to.

Second opinion

26. Mrs A saw Dr E at the rheumatology clinic on 10 October 2018. Dr E arranged X-rays of Mrs A's right ankle, which showed osteoarthritic change and a non-union ankle fracture. Dr E referred Mrs A to the orthopaedics service for her ankle fracture. He stated that Mrs A's main problem was pain, and he did not think that this was an active inflammatory disease (RA). He said that it was difficult to know whether Mrs A's joint changes were primarily osteoarthritic, or whether the change had been influenced by previous inflammatory disease related to the positive anti-CCP.[18] Dr E considered that Mrs A's medical therapy might be able to be de-escalated once she had received orthopaedic treatment for her knees and right ankle.

Complaint to the DHB

27. On 20 December 2018, Mrs A lodged a complaint with the DHB regarding the care she received from the rheumatology clinic. However, Mrs A felt that her complaint did not receive sufficient consideration, and she lodged a complaint with HDC in the hope that lessons would be learned and would prevent a recurrence of the issues.

Further information

28. By late December 2018, Mrs A was under the care of Dr E.

29. On 25 March 2019, Mrs A saw a consultant endocrinologist, who diagnosed Mrs A with '[v]omiting, weight loss, nausea likely related to adrenal insufficiency from Prednisone dose reduction'. In July 2019, Mrs A was admitted to hospital for surgery on her right ankle. Cortisol tests showed adrenal insufficiency, and Mrs A was diagnosed with tertiary adrenal insufficiency.[19]

Opinion: Health NZ — breach

30. I have undertaken a thorough assessment of the information gathered in light of Mrs A's concerns, and I am critical of Health NZ's care of Mrs A, particularly regarding the level of service provision via the rheumatology clinic. I consider that this service provision also

[18] A type of autoantibody that is commonly produced when a person has RA.
[19] A condition in which adrenal glands do not make enough cortisol. The most common cause is suddenly stopping corticosteroids (such as prednisone) after taking them for a long time.

influenced a clinical nurse specialist to provide advice to Mrs A on prednisone dosage when not authorised to do so. I find that Health NZ breached Right 4(1)[20] of the Code of Health and Disability Services Consumers' Rights (the Code).

Level of service provision

31. In a complaint to Health NZ on 20 December 2018, Mrs A raised concerns about the resourcing of the rheumatology clinic.

32. Between 2015 and 2018, the rheumatology clinic was staffed by Dr B (0.4 FTE) and CNS C (0.6 FTE). Rheumatologist Dr E also attended the rheumatology clinic one day every month.

33. Dr B stated that clinic slots were 40 minutes for a new patient and 20 minutes for follow-up. He said that because of the 'significant pressure on the limited clinic slots', it was not at all uncommon for him to see patients with urgent needs in his own time. Dr B stated that the role of the clinical nurse specialist was 'an invaluable component given the significant mismatch between the demand and the available Physician FTE'.

34. Mrs A stated:

> '[CNS C] also has a large caseload. She was usually available for questions and advice but she is unable to prescribe medications and needs access to the specialist to make any changes to treatment. I was able to contact her by telephone or by email which was a great help. I can see her role being useful once symptoms are being well managed.'

35. In her complaint to Health NZ, Mrs A stated: 'I believe my contact with [Dr B] was not frequent enough for him to keep track of my situation between large numbers of patients, holidays and conferences.'

36. Mrs A's comment regarding the frequency of contact with Dr B is supported by the fact that more often than not Mrs A was seen by CNS C rather than Dr B, and there are several documented instances where Mrs A had difficulty getting an appointment or where CNS C documented that Dr B was away and she was unable to discuss the appointment with him until his return:

- 14 January 2016 — Mrs A's GP documented that Mrs A was unable to get an appointment with the rheumatology clinic nurse for at least three weeks and so contacted the GP to see if they could refer her to see Dr B privately.
- 17 January 2017 — Reviewed by CNS C. Mrs A was having difficulty reducing her dose of prednisone and had swelling in her hands and pain in her hands and left knee. CNS C documented: '[Dr B] on leave this week so will discuss [Mrs A] with him on his return.'
- 7 March 2017 — Reviewed by CNS C. Mrs A was experiencing a 'huge flare up', which had been going on for about a week. CNS C recommended that Mrs A go on a 'high reducing dose of Prednisone' and noted: '[Dr B] is away so this cannot be discussed with him.'

[20] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

- 9 January 2018 — Reviewed by CNS C. Mrs A was struggling to reduce her dose of prednisone and was experiencing breakthrough pain and stiffness. CNS C documented: 'Will call when [Dr B] returns next week.'
- 14 May 2018 — Mrs A's GP documented: 'Currently experiencing a flare … Suggest contacting [Dr B's] nurse … [Awaiting follow-up] with [Dr B].' Mrs A's next review at the rheumatology clinic was three weeks later on 5 June 2018.
- 13 August 2018 — Mrs A was reviewed by CNS C. Mrs A felt that her pain was unmanaged. A letter was dictated on 22 August 2018 and CNS C documented: 'Unfortunately [Dr B] has been on leave, he has returned this week, I have now spoken to him and can now dictate this letter.'

37. In response to Mrs A's direct complaint to Health NZ, Health NZ stated:

> 'We would also like to apologise for the delays in accessing some outpatient appointments with the Rheumatology Service at the hospital. As you will understand when there is only one part-time Physician working in our Rheumatology Service and one visiting Rheumatologist who works one day per month, it is difficult to provide cover when these staff are away on leave.'

38. Following a meeting between Mrs A, CNS C, and the operations manager, Health NZ told Mrs A:

> 'We also discussed that there are limitations to our rheumatology resources at [Health NZ] and again apologise for any delay in you being seen and treated by a Rheumatologist.'

39. Despite the above statements, Dr B and Health NZ considered that the resources and support available to Dr B in the rheumatology clinic were sufficient. Health NZ cited Dr E's monthly visits and Dr B's ability to consult with Dr E and rheumatologists in other regions when needed.

40. I sought advice from rheumatologist Dr Andrew Harrison, who advised:

> 'This is a case where a general physician with an interest in a subspecialty working in a remote area is expected to manage a large workload with limited collegial support. More often-than-not [Mrs A] was seen by the [rheumatology] clinic nurse, most likely due to resource constraints, when more input from [Dr B], or ideally a trained rheumatologist, may have been more appropriate. The way in which available treatments were rapidly sequentially deployed over a relatively short time course while still relying on high doses of prednisone highlight the difficulties in managing treatment-resistant RA … Like much of provincial New Zealand, rheumatology services in [Health NZ] are under-resourced.'

41. Dr Harrison considered the root of the identified departures from the standard of care to be 'a resource-provision and workforce issue, which should be addressed by [Health NZ]'.

Clinical nurse specialist advising on prednisone dosage

42. As discussed above, mostly Mrs A was seen by CNS C at the rheumatology clinic, rather than by Dr B. At these appointments, or by telephone between appointments, often CNS C advised Mrs A on changes to her prednisone dosage.

43. I acknowledge that most of the time the advice was to reduce the dosage, and often CNS C consulted with Dr B on this. However, there appear to be some instances where CNS C advised Mrs A to increase her dosage without consulting Dr B. In a letter to Mrs A's GP, dated 7 July 2016, Dr B wrote:

> 'Unfortunately, her arthritis remains active and she had to recently phone up [CNS C] and was advised to increase the dose of Prednisone to 20mg daily on 29/06/16.'

44. Further, in a letter to Mrs A's GP, dated 7 March 2017, CNS C wrote:

> '[Mrs A] rang last week having a huge flare involving all of her joints. She went onto a high reducing dose of Prednisone 40mg for five days, reduced down to 30 for another five, got to 25 and flared again at the weekend so is now back on 35mg. She will try and reduce back to 30 in the next day or so. She will ring for advi[c]e if she flares again or has trouble reducing Prednisone. Unfortunately [Dr B] was away and I was not able to discuss [Mrs A] with him.'

45. I am concerned by this as Health NZ has confirmed that CNS C was not authorised to prescribe prednisone, and it is not usual practice for a clinical nurse specialist to do so. Although CNS C was not the prescriber of the prednisone (this was the role of the medical centre), I consider that because she was not authorised to prescribe prednisone, she also should not have been providing advice on dosages, particularly if the advice was to increase the dosage.

46. Given the documentation that Mrs A spoke to CNS C on the telephone on 29 June 2016 and was advised to increase the dose of prednisone, and that CNS C advised Mrs A to increase her prednisone dosage on 7 March 2017, I consider it more likely than not that CNS C was providing advice to Mrs A on prednisone dosages. However, there is no indication that Dr B viewed or raised this as an issue. Dr B also stated that the clinical nurse specialist role was 'an invaluable component given the significant mismatch between the demand and the available Physician FTE'.

47. I consider that the pressures created by insufficient resourcing of the rheumatology service directly contributed to an environment in which CNS C was able to provide advice on prednisone dosages when not authorised to do so, and I am concerned that this was not seen as an issue by the consultant physician.

Conclusion

48. I accept Dr Harrison's advice that more input from Dr B or another rheumatologist may have been appropriate in this case. Health NZ had an obligation to ensure that consumers had services provided with reasonable care and skill, and that employees had the conditions necessary to perform their work to an appropriate standard. Mrs A had difficulty accessing

care from Dr B because of the 'significant pressure on the limited clinic slots', and the 'significant mismatch between the demand and the available Physician FTE'.

49. Further, I consider that this pressure on the service directly contributed to an environment in which a clinical nurse specialist was able to provide advice on prednisone dosages when not authorised to do so, and that this was not seen as an issue by the consultant physician.

50. For the above reasons, I am critical that the rheumatology clinic resourced by Health NZ provided inadequate care. I consider that Health NZ failed to provide services to Mrs A with reasonable care and skill, and therefore breached Right 4(1) of the Code.

51. I acknowledge that after these events Health NZ received additional funding that has been utilised for locum cover and additional clinical nurse specialist hours (increased from 0.6 FTE to 1 FTE). This is discussed further below in the section 'changes made since events'. I consider that these changes are appropriate and will serve to minimise the risk of resource issues affecting the service provided in the future.

Opinion: Dr B — breach

Introduction

52. Dr B was the consultant physician who oversaw the care provided to Mrs A by the rheumatology clinic between August 2015 and December 2018 (inclusive).

53. I have undertaken a thorough assessment of the information gathered in light of Mrs A's concerns, and I am critical of Dr B's management of Mrs A's RA with prednisone, particularly the lack of critical thinking about possible alternative causes for Mrs A's symptoms, and for not seeking a second opinion earlier. I am also critical of Dr B's documentation.

54. I acknowledge that Dr B had a large caseload and was under pressure due to a 'significant mismatch between the demand and the available Physician FTE'. I also acknowledge that Dr Harrison advised that '[t]his is a case where a general physician with an interest in a subspecialty working in a remote area is expected to manage a large workload with limited collegial support'. I consider that these factors may have affected the care Dr B provided to Mrs A. However, I remain critical of the care Dr B provided to Mrs A and I find that Dr B breached Rights 4(1)[21] and 4(2)[22] of the Code.

55. Further, I have some concerns about the coordination between services regarding the consideration of Mrs A's risk of diabetes.

56. This case highlights the importance of critical thinking when treatments are not producing the expected results, and of questioning whether something else may be causing or contributing to the presenting symptoms.

[21] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'
[22] Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

57. At the end of this report, I make several recommendations for improvements and follow-up actions that could prevent similar events recurring in the future.

Management of RA symptoms with prednisone

58. Mrs A was on varying daily doses of prednisone while under Dr B's care. The doses ranged from about 9mg up to 60mg, with an average around 20–25mg over approximately three years. The exact doses taken by Mrs A over this period are set out in a timeline in Appendix B.

59. Although most of the advice given to Mrs A was to reduce the dose of prednisone, there is documented clinical advice from Dr B and/or CNS C to increase the prednisone dose on several occasions. On several occasions, Mrs A also took a higher dose of prednisone without documented clinical advice to support this. However, Mrs A is adamant that she contacted CNS C whenever she was having difficulty with pain and/or walking and increased the prednisone dosage between appointments only on the advice of CNS C.

60. I cannot reconcile the reason(s) for the increases in prednisone doses that do not have clearly documented advice to support them. However, whether or not they were advised by CNS C, ultimately, I consider that the overall responsibility for the monitoring and management of Mrs A's prednisone doses rested with Dr B as the consultant physician.

61. In March 2016, Dr B documented his disappointment that despite 'this duration of treatment with adequate doses of Prednisone', there was still evidence of inflammation in the joints. Dr B worked through a range of DMARDS, biological DMARDS, and TNF inhibitors, the majority of which did not result in any improvement in Mrs A's symptoms.

62. Mrs A's inflammatory markers remained normal over most of this time. Dr B documented: '[Mrs A] is one of those patients where there has never been a good correlation between levels of inflammatory markers and the clinical evidence of her disease activity.'

63. I sought independent advice from rheumatologist Dr Andrew Harrison, who advised: 'The doses of prednisone used from 2015 to 2018 were well above the norm for treatment of RA and represent a major departure from the standard of care.'

64. Dr B agrees that the doses of prednisone used between 2015 and 2018 were 'well above the norm'. He stated:

> 'For confirmed Rheumatoid Arthritis, I use oral steroid (Prednisone) as:
>
> - **Bridging therapy** — while awaiting a response from DMARD (Disease Modifying Anti Rheumatic Drug). Usual starting dose 10–15 mg and weaned off in 12–14 weeks.
> - **Rescue therapy** — to treat a flare; starting dose dependent on various factors including the severity of flare. Usually only a short course
> - **Long term therapy** — infrequently, there is no other option but to include prednisone in the list of long term medications. I aim for a dose no higher than 5 mg daily.

- **To determine if there is a reversible/inflammatory component** — when there is a co-existing non-inflammatory condition such as OA, Centralised Pain etc and it is unclear if escalating DMARD therapy is appropriate.'

65. Dr B also stated that there is no clear guideline by any authority for 'rescue therapy' doses and that the intent after a rescue dose was always to bring the dose down to the 'bridging therapy' level. Further, he stated that he never endorsed the use of high doses of prednisone on an on-going basis, and all necessary actions were taken to help Mrs A to reduce the dose. He stated that he 'failed to achieve the targets not because of a lack of knowledge, experience, intent or effort but for some other reason not immediately obvious'.

66. Dr Harrison advised: 'In my experience, inflammatory pain in rheumatoid arthritis usually will respond to prednisone 20mg daily, and it is seldom necessary to go above this dose.' He explained that '[t]he apparent improvement on doses in the 40–60 mg range may have reflected the analgesic effect of prednisone in high doses'.

67. Dr Harrison also advised that the lack of success with various DMARDS created good reason to suspect that the pain Mrs A was experiencing may not always have been due to inflammation, and that it is important to consider non-inflammatory pathologies when patients have joint pain that does not respond to treatments directed at inflammation. Further, Dr Harrison advised that '[t]he lack of elevation of CRP could be a peculiarity of Mrs A, or it could have been a "red flag" signaling that her pain was not primarily due to inflammation'.

68. This advice raises a question as to whether there could have been alternative causes of Mrs A's symptoms other than RA, and whether sufficient consideration was given to this possibility.

Consideration of alternative pathologies

69. It is unclear when Mrs A suffered an ankle fracture and how recently the osteoarthritic changes had occurred in her ankle. The first documentation by the rheumatology clinic that Mrs A had pain in the right ankle was on 1 June 2017, when Mrs A saw CNS C and reported that pain in her right ankle and both knees was keeping her awake at night.

70. On 29 June 2017, Dr B examined Mrs A's right ankle and found it to be slightly bulky with a reasonable range of movement and no warmth or effusion.[23] When Dr B examined Mrs A's ankle on 10 November 2017, he found it to be swollen, mildly warm and slightly tender with a somewhat reduced range of movement. He considered that Mrs A might need a steroid injection in her right ankle but opted for a 'rescue dose' of prednisone first. By 24 November 2017, as Mrs A was reducing from the 'rescue dose', her ankle began 'playing up' again, and on examination it was slightly puffy. Dr B gave an intra-articular injection of 40mg Kenacort at this appointment. However, Mrs A received little benefit from this so Dr B arranged for a district nurse to give an intra-muscular injection of 120mg Kenacort on 29 November 2017.

[23] An excess of fluid in the joint cavity that causes pain and swelling.

The intra-muscular injection helped until early January, when Mrs A told CNS C that she was feeling stiffer again and was experiencing breakthrough pain in her right ankle.

71. Dr B said that there was no indication to obtain an X-ray of Mrs A's right ankle in November or December 2017.

72. On 5 June 2018, CNS C referred Mrs A for an X-ray of her knees. Mrs A was diagnosed with osteoarthritis of the knees, which was to be treated by the orthopaedic service.

73. At an appointment with CNS C on 13 August 2018, Mrs A said that her right ankle continued to cause her a lot of pain. On examination, it was slightly swollen. Mrs A was using codeine and Naprosyn for pain relief at this time, but these medications were not managing the pain effectively. CNS C documented that Mrs A was tearful at this appointment, not knowing what the future held for her. Dr B said that immediately after this appointment, he spoke to CNS C about contacting Mrs A in the coming days to offer her Dr E's services if she wished, as he sensed that their 'good rapport' may have been impacted. Following the discussion with Dr B, CNS C discussed a referral to Dr E for a second opinion. Mrs A was keen to go ahead with this, and when CNS C discussed it with Dr B on 21 August 2018, he agreed that it was a good idea.

74. Mrs A also saw her GP a few times in late August and early September 2018. The GP documented that Mrs A's pain at this time was an 8 or 9 out of 10, particularly in her left knee and right ankle.

75. On 7 September 2018, Dr B administered another intra-articular injection of 40mg Kenacort into Mrs A's right ankle, at her request. Unfortunately, like the first intra-articular injection of Kenacort, Mrs A found this ineffective.

76. On 10 October 2018, Mrs A received a second opinion from Dr E. At this time, Mrs A's left knee and right ankle continued to be her biggest problems. Dr E documented that there was widely spread swelling and restricted movement in Mrs A's right ankle, and that the ankle joint felt unstable. He ordered X-rays of Mrs A's right ankle, which showed osteoarthritic change and a non-union ankle fracture.

77. Dr E stated that Mrs A's main problem was pain, and he did not think that this was active inflammatory disease (RA). Dr E said that it was difficult to know whether the changes in the joints were primarily osteoarthritic or had been influenced by previous inflammatory disease (RA). He documented that the current problems would need orthopaedic input and then, once her knees and ankle had been fixed, she might be able to de-escalate her medical therapy.

78. Dr Harrison advised:

> 'According to the [rheumatology] clinic letters, [Mrs A] had complained of right ankle pain from at least 1 June 2017. [Dr B] had injected her right ankle on three occasions[24] from 1 June 2017 to 7 September 2018. Over that time she had 12 clinic appointments with the nurse or [Dr B]. While it is not possible to say with certainty when the fracture occurred, there was certainly a strong indication for an x-ray by the end of 2017 when she had had two injections [of Kenacort] and was taking prednisone 60 mg daily in addition to DMARDs and biological therapies. This would be considered a moderately severe departure from the standard of care.'

79. Dr Harrison later advised that there was a good case to be made for an X-ray of the right ankle after the second injection on Kenacort, but that not doing so would be regarded as a departure from accepted practice that is 'minor at best'.

80. Dr Harrison also advised:

> 'When patients with inflammatory arthritis have pain in a joint that has not responded to treatments directed at inflammation, it is important to consider non-inflammatory pathologies. An x-ray is an appropriate investigation to rule out erosive or degenerative arthritis, or fracture.'

81. Dr B considers that X-rays were first indicated nearly a year later than suggested by Dr Harrison, after Mrs A did not respond to the second intra-articular injection of Kenacort (administered on 7 September 2018). Dr B stated that he would have arranged this himself, except by that time, Mrs A was scheduled to see Dr E instead.

82. Dr B also stated that he would have referred Mrs A for X-rays of her right ankle at the same time as X-rays were ordered for her knees on 5 June 2018 if it had still been significantly symptomatic at that time. He said that there was no indication for earlier X-rays of the ankle as there was no accident history and the pain in the right ankle was only the primary concern twice and was otherwise 'on and off as an issue'.

83. Health NZ's response to Mrs A's direct complaint (prior to her lodging a complaint with HDC) stated:

> '[Dr B] acknowledges however that he did not provide you with the optimal standard of care as he would have expected of himself by not identifying you had a fractured ankle. He would like me to sincerely apologise to you for the ongoing issues you have experienced as a result of this fracture not being diagnosed in a more appropriate timeframe.'

84. Mrs A's GP completed an ACC treatment injury claim form in January 2019. Her GP stated that the delayed diagnosis of the ankle fracture led to 'prolonged pain and anguish and large

[24] This is correct only for two of the three injections, as one was administered intramuscularly by a district nurse.

doses of prednisone for [a] very long period of time', as well as other musculoskeletal issues as a result of Mrs A 'guarding' her right ankle due to pain. The GP also wrote:

> 'The lack of proper diagnosis and lack of early orthopaedic care led to more advanced and complex problems. Steroid injections into the broken joint would mask symptoms, not treat the fracture and likely lead to delayed healing.'

85. I note Dr B's disagreement that there was any indication for an X-ray at the end of 2017. However, given that in November 2017 Mrs A's right ankle continued to cause her pain despite being on a high reducing dose of prednisone (60–20mg) and having received an intra-articular injection of Kenacort, I accept Dr Harrison's advice that there was an indication for an X-ray of Mrs A's right ankle by this time.

86. I also consider that there was a missed opportunity for an X-ray in June 2018 when X-rays were ordered for Mrs A's knees, and I am critical of the delay in obtaining an X-ray of the ankle. I consider that this led to a delayed diagnosis and subsequent non-union of the fracture, which then required surgery, and also to further musculoskeletal issues and prolonged pain, which may have contributed to Mrs A's difficulty in tapering off prednisone.

87. I acknowledge that CNS C did arrange for both Mrs A's knees to be X-rayed in June 2018 (discussed further below). However, I am concerned that the presence of osteoarthritis did not prompt Dr B to consider whether osteoarthritis or other pathologies could be affecting other parts of Mrs A's body where pain had not responded well to prednisone or other treatments.

88. It is my view that Dr B did not consider alternative causes of Mrs A's symptoms sufficiently.

Second opinion

89. This was a complex case where Mrs A's CRP level was not a useful indicator of inflammation; her RA symptoms did not respond as expected to prednisone; she had difficulty reducing the prednisone doses due to ongoing pain and inflammation; and most of the treatments trialled did not result in any improvement in symptoms.

90. Mrs A expressed in her complaint that she felt that an earlier second opinion was warranted. She stated: 'I did not doubt my consultant's ability but as the saying goes, two heads are better than one.'

91. Dr Harrison advised:

> 'The complexity of this case would have warranted a request for a second opinion from a rheumatologist at an earlier stage, and not doing so would be seen as a moderate departure from the standard of care.'

92. Dr B stated:

> 'There had been no indication for a second opinion up to that point because:
>
> - We had clear diagnoses and plan of management

- *OA knees* (and hands) …
- *… RA* with clear clinical evidence of active synovitis, supported by mild elevations of CRP[25] on and off — that warranted a Treat-To-Target strategy — which I was totally comfortable with.
- *High prednisone use* which I was very optimistic we would be able to address

- I felt I had a very good rapport with [Mrs A].'

93. Dr Harrison advised:

> 'At the root of [the unsatisfactory aspects in the management of Mrs A's RA] is the fact that a physician with an interest in rheumatology is expected to manage treatment resistant rheumatoid arthritis without adequate peer support in a provincial hospital.'

94. However, Dr B disagreed with Dr Harrison's advice. Dr B stated that he has managed 'the entire spectrum of Rheumatological (and General Medical conditions) over the past two decades', and that he was very confident in practising in rheumatology independently. He also stated that he does not agree that the collegial support available to him was inadequate. He stated that Dr E would visit the clinic monthly and he could get a formal second opinion from him whenever necessary. Dr B also said that he knew most of the rheumatologists nearby, and he had consulted them in the past based on their areas of expertise.

95. In early March 2016, Dr B documented his disappointment that Mrs A still had evidence of synovitis, despite treatment with adequate doses of prednisone. In the following months, Dr B tried various oral DMARDs and anti-TNF therapy, but nothing worked to manage Mrs A's symptoms. Six of these treatments had been deemed unsuccessful by July 2017. Clearly this was a complex case, and I accept Dr Harrison's advice that therefore this warranted a second opinion from a rheumatologist at an earlier stage.

96. I acknowledge Dr B's experience in rheumatology and that an earlier second opinion may not have resulted in a different or better outcome. However, I am critical that Dr B did not seek a second opinion earlier in Mrs A's care.

Summary

97. I accept Dr Harrison's advice that the doses of prednisone used from 2015 to 2018 were well above the norm for treatment of RA, and that Dr B should have considered non-inflammatory pathologies when Mrs A's symptoms were not responding to a dose of 20mg daily. I accept that an X-ray of Mrs A's right ankle was indicated by the end of 2017.

98. I also accept Dr Harrison's advice that the complexity of this case warranted a second opinion from a rheumatologist at an earlier stage, and that not doing so was a departure from the accepted standard of care.

[25] C-reactive protein (CRP) testing. A blood test that checks for infection or inflammation in the body. It is used to detect the severity of inflammation or whether a person is responding to treatment. The serum CRP level in a 'healthy' person is usually less than 5mg/L.

99. I acknowledge the pressures that Dr B faced as the consultant physician for the rheumatology service, and that these pressures may have contributed to the failings in the care Dr B provided to Mrs A. However, I remain critical of Dr B for his overall management of Mrs A's symptoms, including his monitoring and management of Mrs A's RA symptoms with prednisone, and his lack of consideration of non-inflammatory pathologies as a potential cause of her symptoms. I am also critical that Dr B did not seek an X-ray of Mrs A's right ankle by the end of 2017 and did not seek a second opinion from a rheumatologist at an earlier stage. I therefore consider that Dr B did not provide Mrs A with an appropriate standard of care and breached Right 4(1) of the Code.

Documentation

100. The Medical Council of New Zealand (MCNZ) publication 'Managing Patient Records' states that doctors should maintain clear and accurate patient records, including information regarding relevant clinical findings; results of tests and investigations ordered; decisions made and reasons for them; and information given to, and options discussed with, patients.

101. Further, MCNZ's publication on 'Good Prescribing Practice' states that doctors should keep a 'clear, accurate and timely patient record', including all relevant clinical findings; decisions made; and information given to the patient about the medicines and any other treatment prescribed'.

102. In previous reports, HDC has made numerous comments stressing the importance of good record-keeping and the accuracy of clinical records.[26]

103. Dr B acknowledged that his documentation could have been more comprehensive and that the written record may not clearly substantiate the care he provided.

104. I discuss my concerns regarding Dr B's documentation below.

Documentation of information provided about risks of prednisone use

105. Mrs A stated that she has experienced side-effects of prednisone use, including 'weight gain, vision problems, probably including cataracts, full or round face, neck, or trunk', and adrenal insufficiency when tapering off.

106. In her complaint to HDC, Mrs A expressed concern about the information she was given regarding the risks of prednisone use and of tapering it off.

107. Dr B told HDC that he always explains the role of each new medication he prescribes, and the potential adverse effects. For prednisone this includes effects on 'bones, skin, eyes, weight, blood pressure, blood glucose, mood and gut', and 'the possibility of steroid deficiency when weaning off after prolonged use'.

108. Dr B said that one statement he uses with 'almost all' his patients before discussing potential adverse effects of prednisone is: 'Prednisone is a good short-term fix, but a nasty drug for long term use.' Although not on written record, Dr B stated: '[I]t is most unlikely that I would

[26] For example: 19HDC01547, 12HDC00437, and 11HDC01103.

have deviated from my standard practice of discussing the aim and the role and potential adverse effects of prednisone in my usual way.'

109. Further, Dr B stated:

> 'I have no doubt whatsoever that I repeatedly explained to [Mrs A] why there was so much focus on reducing prednisone dose … Unfortunately for me, this is not fully documented in my clinic letters.'

110. The clinic letters do not document any discussion of the reasons for reducing the prednisone doses, other than the clinic letter dated 18 July 2018, which states: 'The entire discussion during this Clinic was the use of Prednisone and the concerns with its long term use.' However, this clinic letter does not include any further information on what these concerns were.

111. Dr Harrison advised that 'the high doses of prednisone that were being taken in this case might have signalled a need to document how the patient had been briefed about the risks'. However, Dr Harrison does not consider it to be a departure from the accepted standard of care.

112. I acknowledge Dr Harrison's advice that the lack of documentation of information given to Mrs A on the risks of prednisone use does not constitute a departure from the accepted standard of care. However, as per 'Managing Patient Records', if these risks were discussed with Mrs A, then Dr B should have documented this. Further, as per 'Good Prescribing Practice', any information given to Mrs A about prednisone should have been documented. The lack of documentation makes it difficult to know what information Mrs A received about the potential adverse effects of taking and then weaning off prednisone. Given that Mrs A was repeatedly advised to reduce the prednisone dose, I consider it more likely than not that there would have been some discussion around the reason for the need to reduce, and therefore the risks associated with long-term use of prednisone. However, I am critical that Dr B did not document what information was given to Mrs A on the risks of prednisone use.

Documentation of CRP testing

113. The clinical notes from Mrs A's GP show that CRP testing occurred approximately every six weeks and that the levels were between <3mg/L and 17mg/L.[27] However, there is a lack of documentation of Mrs A's CRP test results in the notes from the rheumatology clinic.

114. Dr B stated:

> 'It is true that I did not document CRP … monitoring in my clinic letters and I agree that inclusion in the notes would have been appropriate and helpful, particularly for audit purposes … However, the non-inclusion in the [rheumatology] clinic letters does not

[27] The CRP level in a 'healthy' person is usually less than 5mg/L; 17 was an outlier on 3 January 2018, and the other occasional 'high' results were around 5–7mg/L.

> necessarily equate to absence of monitoring or its inclusion in the decision making process.'

115. Dr B also stated that Mrs A's CRP was 'also always reviewed at the time of every consultation'.

116. Dr Harrison advised:

> '[T]o neglect to document the significance of a normal or raised CRP with regard to assessment of disease activity would be regarded as a mild departure from the standard of care in this situation.'

117. Dr Harrison also advised: 'My peers would probably say that more certainty about the causes of treatment failure could have been achieved if disease activity had been better documented.'

118. I accept Dr Harrison's advice that not documenting the significance of a normal or raised CRP would be regarded as a mild departure from the accepted standard. Nonetheless, 'Managing Patient Records' is clear that doctors should document relevant clinical findings and results of tests and investigations ordered. I am therefore critical that Dr B did not document Mrs A's CRP results.

Documentation of diabetes risk (HbA1c)

119. Dr B stated that Mrs A's HbA1c[28] was checked by the rheumatology clinic at baseline, then monitored by the GP clinic in June and December 2016, omitted in 2017, then checked again in 2018. However, Dr B did not document any of the HbA1c results in his clinic letters, and there is no documentation of Mrs A's baseline HbA1c result.

120. Dr B stated:

> 'It is true that I did not document … HbA1c (Diabetes risk) monitoring in my clinic letters and I agree that inclusion in the notes would have been appropriate and helpful, particularly for audit purposes.'

121. 'Managing Patient Records' states that doctors should document relevant clinical findings and results of tests and investigations ordered. I am critical of Dr B's lack of documentation of Mrs A's HbA1c, particularly the baseline result, as this is not documented anywhere in Mrs A's clinical record.

Summary

122. I am critical of Dr B's lack of documentation of CRP and HbA1c testing and the risks of prednisone use and consider that Dr B did not comply with standards set out by MCNZ in 'Managing Patient Records' and 'Good Prescribing Practice'. I therefore consider that Dr B breached Right 4(2) of the Code.

[28] A test used to check blood sugar levels to monitor for diabetes.

Coordination of care: monitoring of diabetes risk — adverse comment

123. Corticosteroids such as prednisone have a potential side-effect of raising a patient's blood sugar, which can cause the onset of diabetes. The long-term use of prednisone therefore increased Mrs A's risk of developing diabetes.

124. Dr B stated: 'HbA1c was checked by our clinic at baseline then monitored by the GP in June and December 2016 but omitted in 2017 then again checked in 2018.'

125. Dr Harrison advised:

> 'My peers would regard the monitoring of [Mrs A's] … diabetes risk as perhaps below the expected standard, unless the testing had been undertaken but not documented in the records, which is certainly possible. The lack of consideration of diabetes risk in this situation would represent a mild-to-moderate departure from the standard of care.'

126. Dr Harrison also advised that '[t]he autoimmune clinic may have considered that they shared the responsibility of monitoring this with the GP, but this is not mentioned'.

127. I note that Mrs A's HbA1c results from June and December 2016, and September 2018, are documented in the GP clinic's notes and were within the normal range.[29] However, Dr Harrison did not have a copy of these clinical notes, and because Dr B did not document any of the HbA1c results in his clinic letters, Dr Harrison was unaware that HbA1c testing did occur.

128. I acknowledge that both Dr B and the GP clinic ordered tests to check Mrs A's HbA1c, and thus monitoring of Mrs A for diabetes appears to have been shared between the two services. However, I consider that there should have been a clear, documented plan between the services to ensure that monitoring was completed consistently. The fact that neither Dr B nor the GP checked Mrs A's HbA1c in 2017 is a good example of how important aspects of care can be missed when responsibility is spread across more than one provider and there is a lack of clear communication.

129. I am concerned that the testing of Mrs A's HbA1c was below the expected standard given that no testing occurred for approximately 21 months across 2017 and 2018. However, my criticism of Dr B regarding this is mitigated by the fact that this care was shared with the GP clinic, and I am unable to determine to what extent Dr B was responsible. I am also concerned by Dr B's lack of documentation of Mrs A's baseline HbA1c, taken by Dr B, and the lack of communication between Dr B and Mrs A's GP clinic regarding the need for regular HbA1c testing. However, because this care was shared between Dr B and the GP clinic, but without a documented plan, I have been unable to determine where the overall responsibility lay.

[29] A result of 40mmol/mol or lower is normal for people without diabetes or pre-diabetes. Mrs A's results were 30 in June 2016, 37 in December 2016, and 40 in September 2018.

Opinion: Medical centre — adverse comment

130. The medical centre provided GP services to Mrs A from 7 July 2016. It shared care of Mrs A with the rheumatology clinic and was tasked with prescribing prednisone to Mrs A, although the dosage was generally understood to be directed by the rheumatology clinic.

131. I have undertaken a thorough assessment of the information gathered in light of Mrs A's complaint, and I have some concerns about the care the medical centre provided to Mrs A regarding the coordination of care with the rheumatology clinic. My concerns centre around the monitoring of Mrs A's diabetes risk, and the prescribing of prednisone.

132. I consider that in shared-care scenarios it is crucial for all parties involved to engage in clear and effective communication regarding responsibilities and expectations.

Coordination of care: monitoring of diabetes risk — adverse comment

133. Corticosteroids such as prednisone have a potential side-effect of raising blood sugar in patients, which can cause the onset of diabetes. The long-term use of prednisone therefore increased Mrs A's risk of developing diabetes. This meant that it was important for Mrs A's HbA1c to be monitored appropriately.

134. Mrs A's HbA1c was checked by the rheumatology clinic, and then monitored by the GP clinic in June and December 2016, omitted in 2017, then checked again by the GP clinic in 2018.

135. Dr Harrison stated: 'The autoimmune clinic may have considered that they shared the responsibility of monitoring this with the GP, but this is not mentioned.'

136. Dr Harrison advised:

> 'My peers would regard the monitoring of [Mrs A's] … diabetes risk as perhaps below the expected standard, unless the testing had been undertaken but not documented in the records, which is certainly possible. The lack of consideration of diabetes risk in this situation would represent a mild-to-moderate departure from the standard of care.'

137. I note that Mrs A's HbA1c results from June and December 2016, and September 2018, are documented in the clinical notes from the medical centre and were within the normal range. However, as Dr Harrison was asked to provide advice specifically regarding the care provided by the rheumatology clinic, he did not have a copy of these clinical notes.

138. As both Dr B and the GP clinic ordered tests to check Mrs A's HbA1c, there appears to have been an expectation of shared monitoring of Mrs A's diabetes risk. In this case, I consider that there should have been a clear, documented plan between the services to ensure that monitoring was completed consistently. There is no evidence of such a plan.

139. I am concerned that the testing of Mrs A's HbA1c was below the expected standard, given that no testing occurred for approximately 21 months across 2017 and 2018. However, my criticism of the medical centre regarding this is mitigated by the fact that this care was

shared with the rheumatology clinic, and I am unable to determine to what extent the medical centre was responsible.

140. However, this is a good example of how important aspects of care can be overlooked when responsibility is spread across more than one provider and there is a lack of clear communication.

Coordination of care: prednisone prescriptions — adverse comment

141. In October 2017, CNS C clarified that in the joint-care situation with Mrs A, the prescribing of prednisone was the responsibility of the medical centre.

142. I sought internal advice from Dr David Maplesden regarding the care provided to Mrs A by the medical centre, particularly in relation to its role as the prescriber.

143. Dr Maplesden advised that there is no record of Mrs A seeking specific prednisone dosing advice from the medical centre, but there is 'frequent reference in the GP notes to seeking of advice from the rheumatologist on various issues'. In particular, one GP on 15 May 2017 sought specialist advice regarding a flare, and on 31 May 2017, another GP documented advice to Mrs A that she 'should have detailed information from Dr B about how to go about managing her medications instead of increasing prednisone every time [rheumatoid arthritis] flares up'. It is clear that although the medical centre had the responsibility of prescribing the medications, the GPs relied heavily on advice from the rheumatology clinic.

144. Further, following each appointment with Mrs A, the rheumatology clinic would then advise the medical centre of the prednisone dose Mrs A had been advised to take, and any reduction plans in place.

145. Dr Maplesden advised:

> 'Given the variable doses of steroids recommended to [Mrs A] following her rheumatology clinic appointments (dependent to some degree on the efficacy of the other treatments prescribed) I believe it was reasonable to provide [Mrs A], at her request, a supply of prednisone that enabled some degree of flexibility of dosing with the assumption she was provided with more explicit dosing advice by the rheumatology service (which did occur) and she would follow this advice (which did not always occur). Nevertheless, with a flexible dosing schedule it might have been appropriate to prescribe with a qualifier such as: Take as recommended by rheumatology service, rather than an apparent fixed dose of 25mg daily.'

146. However, Dr Maplesden queried whether the prescribers ought to have questioned Mrs A's request for more prednisone on 12 June 2017 given that the request may have indicated use of over 45mg daily over the preceding two months. Dr Maplesden advised:

> 'Such a query would represent good practice but consideration should also be given to the fact [Mrs A] was in regular and frequent contact with the rheumatology service regarding her medication, she was very familiar with the use of prednisone, and it might

> be reasonable to expect she would adhere to the dosing regime recommended to her by her specialist in this context.'

147. Dr Maplesden considers this to have been a missed opportunity to identify that Mrs A was taking a dose of prednisone that was higher than recommended or prescribed.

148. Dr Maplesden also advised that the rationale for a prednisone prescription on 30 April 2018 was not clear. The prescription is recorded as 90x20mg tabs and 100x1mg tabs, for a 25mg daily dose. Dr Maplesden advised that this did not allow for the degree of flexibility of dosing required for gradual dose reduction. Further, this prescription was not consistent with the regimen recommended to Mrs A in her most recent rheumatology clinic appointment on 9 January 2018, in which CNS C recommended a dose of '19mg daily — reducing'. I note that the rationale for a prednisone prescription on 28 September 2016 is also unclear. Mrs A was prescribed 5x5mg tablets to be taken daily (a total of 25mg daily), but the last documented advice from the rheumatology service (dated 19 August 2016) was for 'Prednisone 20mg daily for one week, 15mg for two weeks, then 10mg thereafter'.

149. I also note that on 6 July 2018, a GP documented that Mrs A's prednisone had been increased to 25mg for several months. This appears to have been documented because it was a significant dose over a significant period. However, there is no documentation to suggest that the GP consulted with the rheumatology clinic about this or discussed the potential risks of this with Mrs A.

150. Dr Maplesden advised that the communication between Mrs A's primary and secondary care providers could have been improved in both directions to support safer use of prednisone. However, Dr Maplesden acknowledged:

> '[O]ne of the primary underlying issues appears to be that [Mrs A] gained relief of her symptoms with higher doses of prednisone and required such relief when trials of other medications were not successful. In this regard I can understand why she altered doses of the medication herself despite apparent[ly] receiving information from her providers regarding the undesirability of doing so and the preference for dose reduction.'

151. I accept Dr Maplesden's advice, and although no departures from the expected standard of care have been identified, I am concerned that there were missed opportunities where GPs who were caring for Mrs A at the medical centre could have identified that there was a discrepancy between the prednisone dosage advised and what Mrs A was taking. As Mrs A's primary care provider and prednisone prescriber, and given the risks associated with long-term use of prednisone, I would have expected the medical centre to have monitored Mrs A's prednisone use more closely. Further, if these discrepancies had been identified, I would have expected proactive steps to be taken to follow up with the rheumatology clinic to discuss and clarify Mrs A's prednisone prescriptions.

152. However, my concerns are mitigated as I consider that the rheumatology clinic, as a specialist service, held the primary responsibility for Mrs A's RA treatments. Further, it is clear that the medical centre relied on the rheumatology clinic to provide Mrs A with the necessary guidance and advice around prednisone use.

153. I also note that Dr Harrison commented: 'Prescribing restrictions should have been applied to prevent the patient escalating the dose between visits.'

Opinion: CNS C — adverse comment

154. Mrs A was seen more often by CNS C than Dr B at the rheumatology clinic, and at these appointments, or by telephone between appointments, CNS C often advised Mrs A on changes to her prednisone dosage.

155. I acknowledge that most of the time the advice was to reduce the dosage, and CNS C often consulted with Dr B on this. CNS C told HDC that she sought advice from Dr B's colleagues when he was unavailable or away on any increases in medication or changes to patients' treatment. However, on review of the clinical notes and information obtained, CNS C did not always document her discussions with Dr B's colleagues and the advice sought on prednisone medication changes for Mrs A. As such, I am unable to determine whether CNS C had sought advice on every occasion where changes were made to Mrs A's medication.

156. There appear to be some instances where CNS C advised Mrs A to increase her dosage without consulting Dr B. In a letter to Mrs A's GP, dated 7 July 2016, Dr B wrote:

> 'Unfortunately, her arthritis remains active and she had to recently phone up [CNS C], Rheumatology CNS, and was advised to increase the dose of Prednisone to 20mg daily on 29/06/16.'

157. Further, in a letter to Mrs A's GP, dated 7 March 2017, CNS C wrote:

> 'She rang last week having a huge flare involving all of her joints. She went onto a high reducing dose of Prednisone 40mg for five days, reduced down to 30 for another five, got to 25 and flared again at the weekend so is now back on 35mg. She will try and reduce back to 30 in the next day or so. She will ring for advi[c]e if she flares again or has trouble reducing Prednisone. Unfortunately [Dr B] was away and I was not able to discuss [Mrs A] with him.'

158. I am concerned that CNS C gave Mrs A advice on adjusting prednisone dosages, as Health NZ confirmed that CNS C was not authorised to prescribe prednisone, and it is not the usual practice of a clinical nurse specialist to do so. In particular, I am concerned that in the two instances described above, CNS C gave advice to increase the dosage of prednisone when the prior agreed plan with Dr B was to reduce the dose. Although CNS C was not the prescriber for the prednisone (this was the role of the medical centre), I consider the fact that she was not authorised to prescribe prednisone to mean that she also should not have been providing advice on dosages, particularly if the advice was to increase the dosage. However, my concerns regarding CNS C are mitigated as I consider that the pressures created by insufficient resourcing of the rheumatology service directly contributed to an environment in which CNS C was able to provide advice on prednisone dosages when not authorised to do so, and that this was not seen as an issue by the consultant physician.

Changes made since events

Dr B

159. Dr B stated:

> 'I will certainly endeavour to include more details in my clinic letters, including measures of disease activity. I will also extend my practice of writing down prednisone weaning plan from just those that appear to need it to also those cases where the weaning off is not going to plan.'

Health NZ

160. Health NZ stated:

> '[Health NZ] has also been allocated additional Ministry of Health (MoH) funding to support rheumatology service provisions since July 2021. This funding has been utilised by way of Locum cover and additional Clinical Nurse Specialist [CNS] hours.'

161. The additional CNS hours increased the total provided to the service from 0.6 FTE to 1 FTE.

162. A second consultant with rheumatology special interest has been employed and commenced work in March 2024. A locum rheumatologist has been contracted on a 12-month appointment to support Health NZ.

163. A second clinical nurse specialist was employed to the service and commenced work in October 2023.

164. Health NZ stated that this increased funding has resulted in 'increased clinics, increased availability to respond to GP and patient phone queries, and also supports the waitlist to ensure follow ups occur in a timely manner'.

165. Health NZ considered Dr Harrison's recommendation that the rheumatology clinic ensure that it has written information about prednisone treatment available for patients to take away. Health NZ responded that this information would be printed off and provided to the patient if it was thought to be necessary.

166. Health NZ also considered Dr Harrison's recommendation that the rheumatology clinic consider adding glycated haemoglobin to its monitoring protocols for long-term corticosteroid patients, if not currently routine. Health NZ said that this is something that the clinicians would consider as part of their clinical practice, and they do include monitoring for some patients.

Recommendations

Dr B

167. Taking into consideration the changes made since events, I recommend that Dr B:

a) Provide a written apology to Mrs A. This should be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.

b) Review the quality of his clinical documentation to ensure that disease activity and the rationale for treatment decisions are documented carefully. Evidence of this is to be provided to HDC within three months of the date of this report.

c) Provide written information about prednisone treatment to all patients who have it prescribed.

d) Review his practice in light of this report and report back to HDC on his learning and the changes made to his practice, within three months of the date of this report. In particular, when completing this review, I recommend that Dr B consider:

- The importance of managing and regularly monitoring the effects of prednisone in patients;
- The importance of obtaining X-rays when patients have joint pain that has not responded to treatments directed at inflammation;
- The benefits of obtaining a second opinion in complex cases; and
- The importance of ensuring that HbAc1 testing is completed regularly.

e) Include a forum for discussion of difficult cases in his peer review activities. Dr B is to provide confirmation of this to HDC within three months of the date of this report.

Health NZ

168. Taking into consideration the changes made since events, I recommend that Health NZ:

a) Provide a written apology to Mrs A. This should be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.

b) Share an anonymised version of this report with staff as a learning opportunity.

c) Provide HDC with any relevant policies and/or procedures in place to ensure that clinical nurse specialists cannot provide advice on prednisone dosages when not authorised to do so. This is to be provided to HDC within three weeks of the date of this report.

d) Develop and implement a policy/documented process for the role of clinical nurse specialists working in nurse-led clinics. This should include guidance on seeking specialist advice on titration of medications, and the need for documentation of all discussions with the lead clinician regarding suggested changes to medication.

Medical centre

169. I recommend that the medical centre review its management of Mrs A with respect to the repeat prescribing of steroids to determine whether there needs to be changes to its repeat

prescribing policy and/or process to ensure that steroid use by patients is monitored closely, and any inappropriate use is detected and acted upon. Consideration should also be given to prescribing restrictions. A report on the outcome of the review should be provided to HDC within three months of the date of this report.

CNS C

170. If CNS C is currently practising as a nurse in New Zealand or is not currently practising but decides to return to nursing in the future, I recommend that she reflect on the deficiencies in care identified in this case, particularly around providing advice on prednisone dosage when not authorised to do so.

Follow-up actions

171. A copy of this report with details identifying the parties removed, except the advisors on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

172. A copy of this report with details identifying the parties removed, except the advisors on this case, will be sent to the New Zealand Rheumatology Association and the Royal Australasian College of Physicians, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from rheumatologist Dr Andrew Harrison:

'**Complaint: [Dr B] at [the] District Health Board (DHB) HDC ref: C20HDC00674**
29 June 2021

Thank you for asking for advice on the complaint made to the HDC by [Mrs A] relating to treatment provided at the hospital from 2015 to 2018 while under the care of [Dr B] for the treatment of rheumatoid arthritis.

I have been provided with copies of clinic letters and other reports. I have a copy of [Mrs A's] complaint letter, dated 11 April 2020, and a copy of the response letter from [the DHB] and the clinical records from her general practitioner.

I am a rheumatologist with thirty years of experience in this speciality. I have been asked to assess the care given by applying the expected standard for a physician working in rheumatology rather than that of a rheumatologist.

I have structured my response around the matters outlined in the letter from [HDC] dated 28 May 2021.

1. The adequacy of the advice/information provided to [Mrs A], written or otherwise, prior to initiation of her prednisone and during her prednisone therapy.

On tabulating the doses of prednisone against the clinic visits between February 2016 and December 2018 it becomes clear that [Mrs A] had been taking prednisone in doses that were unusually high for treatment of rheumatoid arthritis. It is also apparent from the records that considerable effort and resources were expended in an attempt to minimise exposure to prednisone with the use of disease modifying drugs and biological therapies. In the clinic letters the advice to reduce the dose of prednisone is made at nearly every visit, and it was rare for [Mrs A] to be advised by [Dr B] or [CNS C] to *increase* the dose of prednisone. On 18 July 2018 [Dr B] states in his letter:

[Mrs A] has had a tendency to bump up the dose of prednisone to control what she calls "her inflammation". Consequently she has remained on an unacceptably high dose for a very long time.

What she calls inflammation seems to be swelling, stiffness, reduced range of movements, but not necessarily a lot of pain every time.

The recurring theme of the clinic letters was the provision of advice to reduce the dose of prednisone accompanied by intensive use of potent "steroid sparing" therapies in response to increases in the dose of prednisone between visits that overrode any progress towards steroid reduction.

a. What is the standard of care/accepted practice? The standard of care/accepted practice would be to use oral synthetic DMARDs and biological therapies to control

inflammation and allow the prednisone dose to be reduced. According to the widely accepted Treat to Target in Rheumatoid Arthritis guidelines[1], the physician and patient should agree on a goal of treatment, which in this case should have included the tapering and discontinuation of prednisone. The fact that the dose of prednisone was increased between visits suggests that agreement had not been reached, or that the patient was aware of the agreed plan but did not follow the advice given.

Also included as a standard of care in the Treat to Target in RA Guidelines is the need to measure disease activity using joint counts, C-reactive protein and composite index of disease activity.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? The doses of prednisone used from 2015 to 2018 were well above the norm for treatment of RA and represent a major departure from the standard of care. It is clear from the letters that the patient was encouraged at almost every visit to reduce the dose of prednisone, and that the targets set were seldom achieved by the time of the next visit. The use of DMARDs and biological therapies was appropriate, but unsuccessful. It is not entirely clear why this is, but there is good reason to suspect that the pain experienced by the patient, which drove the dosing increases, may not have been always due to inflammation, and may have been caused to other pathologies such as degenerative joint disease or a centrally-mediated chronic pain syndrome, or fracture, as was seen in the case of right ankle pain.

In his letter of 18 July 2018 [Dr B] raises concerns that the patient was evidently self-medicating with potentially harmful consequences. He questions whether the symptoms for which the patient was increasing the dose of prednisone were really due to inflammation, but the documentation of disease activity in preceding records is restricted to qualitative comments about the extent of swelling in the joints and in general does not contain very much evidence of quantitative measurement of the level of disease activity. Measurement of C-reactive protein was not considered helpful as [Mrs A] never had a raised CRP. This test usually serves as a guide to systemic inflammation and not measuring CRP could be seen as a departure from the standard of care. The lack of elevation of CRP could be a peculiarity of [Mrs A], or it could have been a "red flag" signalling that her pain was not primarily due to inflammation. The failure to monitor, or to neglect to document the significance of a normal or raised CRP with regard to assessment of disease activity would be regarded as a mild departure from the standard of care in this situation.

c. How would it be viewed by your peers? My peers would probably take the view that [Dr B] had provided appropriate treatment with regard to DMARD and biologic prescribing. They would agree that the prednisone dosing was excessive, and might perhaps question whether the reason that symptoms had not improved on lower doses was that inflammation may not have always been present. The apparent improvement on doses in the 40–60 mg range may have reflected the analgesic effect of prednisone in high doses. My peers would probably say that more certainty about the causes of treatment failure could have been achieved if disease activity had been better documented. They may wonder if sub-optimal communication and a lack of patient–physician collaboration may have been an important reason for failure to optimise outcome.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. This is a case where a general physician with an interest in a subspecialty working in a remote area is expected to manage a large workload with limited collegial support. More often than not [Mrs A] was seen by the clinic nurse, most likely due to resource constraints, when more input from [Dr B], or ideally a trained rheumatologist, may have been more appropriate. The way in which available treatments were rapidly sequentially deployed over a relatively short time course while still relying on high doses of prednisone highlight the difficulties in managing treatment-resistant RA. At larger centres this case may have been discussed in a peer review session. Like much of provincial New Zealand, rheumatology services in [the DHB] are under-resourced[2].

[Dr B] would be expected to undertake peer review activities as part of the RACP MyCPD requirements. It would be helpful to ensure that his current peer review activities provide a forum for discussion of difficult cases, such as this one. In addition, [the DHB] could be urged to review and improve the support provided to [the DHB] by rheumatologists from neighbouring DHBs.

2. The adequacy of information provided to [Mrs A] with respect to weaning regimes.

This is not well documented in the clinical correspondence, but it seems likely that the advice given to [Mrs A] was to taper the prednisone at the rate advised to the GP in the clinic letters. There is no record of provision of any written material.

a. What is the standard of care/accepted practice? The standard of care for DMARD and biological therapies is to provide the patient with comprehensive written information and verbal education. In contrast, there are no available guidelines on how education on use of corticosteroids should be delivered to patients with RA.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? The way that the information was provided to [Mrs A] was not a departure from standard care, however, in retrospect, it might have been wise to document the details of the information provided. This would not normally be done in cases where reduction schedules proceed as planned, but the high doses of prednisone that were being taken in this case might have signalled a need to document how the patient had been briefed about the risks.

c. How would it be viewed by your peers? My rheumatology peers would probably emphasise the importance of ensuring the patient was fully informed about the need to minimise the dose of prednisone, take as directed, taper as instructed and understand the risks as well as the benefits. If they were pressed for details about how they would provide this information they would probably say that it was usually given verbally, and that they would not normally document this in the records.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. The autoimmune clinic should ensure that it has written information about prednisone treatment available for patients to take away.

3. Would you expect provision of "sick day" advice regarding steroid management either prior to initiation of [Mrs A's] prednisone therapy or at any other point?

With long-term prednisone use it is normal for the adrenal glands to reduce cortisol secretion, which can impair the adrenal cortisol response to acute illness. "Sick day" advice in this context refers to advice provided to the patient in the event of an intercurrent illness such as infection that might necessitate a boost in the dose of prednisone. This is normally only an issue for patients taking a dose of glucocorticoid that is at or below the replacement dose, which is generally regarded to be around 7 mg daily for prednisone. The "sick day rules" that are available on the internet are generally directed at patients taking hydrocortisone for adrenal replacement.

a. What is the standard of care/accepted practice? Sick day advice is not normally given to patients attending rheumatology clinics. In fact, I had not encountered this term before now. Adjustments in the dose of prednisone during acute illness would normally be made by the doctor treating the patient for that illness, and by anaesthetists during surgery.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? In rheumatology outpatient clinics there is a difficult balance to achieve between providing informed consent and overloading the patient with information that lacks context. The "sick day" rules are just one of a very large number of cautions and advisories that could be provided to a patient taking prednisone. For [Mrs A], "sick day" dosing was not a priority as she was taking doses above the level where a boost in the dose would be required. It is seldom possible for a clinician to manage the medical priorities in the time available and provide comprehensive patient education that covers all possible aspects of the treatment.

c. How would it be viewed by your peers? My peers would probably say that patients have the right to be fully informed about all aspects of their care, but at the same time would probably admit that they prioritise the information they give on the basis of what is immediately relevant within the time available. A more "defensive" approach would increase the demands on the clinician's time and require an increase in resources.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. The autoimmune clinic should ensure that it has written information about prednisone treatment available for patients to take away.

4. Whether [Mrs A's] condition was appropriately monitored whilst she received steroid therapy.

a. What is the standard of care/accepted practice? The standard of care would be to monitor risks of treatment, including weight gain, bone mineral density, glycated haemoglobin, blood pressure and documented serious infections. Other risks such as acceleration of cataracts, thinning of the skin and bruising should be monitored and documented. Dose of prednisone should be documented at each visit.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? The patient's weight was monitored regularly, and remained stable between 2016 and 2018. Blood pressure was also monitored

and remained normal. The dose of prednisone is well documented in the clinic letters, suggesting a preoccupation with the plan of reducing the dose as quickly as possible. The blood test results are mentioned from time to time, mainly in relation to liver function, blood count and renal function. Glycated haemoglobin is not mentioned. The autoimmune clinic may have considered that they shared the responsibility of monitoring this with the GP, but this is not mentioned. Bone mineral density was measured on 17 January 2017, after somewhat more than 12 months of corticosteroid treatment. T scores were generally greater than zero, indicating low risk of fracture.

c. How would it be viewed by your peers? My peers would regard the monitoring of [Mrs A's] weight and blood pressure as above the expected standard, bone density at the expected standard, and diabetes risk as perhaps below the expected standard, unless the testing had been undertaken but not documented in the records, which is certainly possible. The lack of consideration of diabetes risk in this situation would represent a mild-to-moderate departure from the standard of care.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. The autoimmune clinic might consider adding glycated haemoglobin to their monitoring protocols for long-term corticosteroid patients, if this is not currently routine.

5. Whether, overall, pharmacological management of [Mrs A's] rheumatoid arthritis was in line with accepted practice.

a. What is the standard of care/accepted practice? The accepted practice would be to apply oral DMARDs, escalating if required to biological therapies in order to treat disease activity to the target of remission or low disease activity, ideally without the use of long-term corticosteroids[1,3].

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? The use of DMARDs and biologics has been in line with guidelines and Pharmac funding regulations. The doses of prednisone were unacceptably high for the length of time they were prescribed. The records indicate that the clinicians at the autoimmune clinic put considerable effort and resource into minimising the dose of prednisone.

c. How would it be viewed by your peers? I would expect my peers to have a similar opinion to my own.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. With regard to the pharmacological management of rheumatoid arthritis, the main practice improvement points to take from this case is to document disease activity carefully to provide rationale for treatment decisions.

6. Whether [Dr B's] standard of written communication with [Mrs A's] GP was in line with accepted practice.

a. What is the standard of care/accepted practice? Written communication from a rheumatology service should contain clear identification of the patient, with an up-to-date record of the medical problems and current treatment. It should include an assessment of the status of the patient, usually with regard to inflammatory disease activity, and a

summary of the monitoring tests undertaken since the last visit. If any of these components have not changed since the last visit it would be acceptable to state this rather than to reiterate the clinical or laboratory data. The treatment plan should be clearly stated.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? Overall, the correspondence with [Mrs A's] GP meets the standard of care. The letter documenting the rationale for the decision to start Humira in August 2016 is lacking in detail with regard to joint counts, and CRP is seldom if ever mentioned, other than in a comment from [Dr B] that in her case CRP is not a good reflection of disease activity.

c. How would it be viewed by your peers? The standard of correspondence is similar to that of many of my peers, and better than some. It would be viewed as acceptable.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. I strongly recommend clear documentation of the evidence that a patient meets the criteria for any Special Authority medication, as this is useful for future care and for determining whether the response was sufficient for renewal of the Special Authority. It is also useful for Pharmac audits of prescribers.

7. Whether there was any clinical indication for imaging of [Mrs A's] ankle prior to her review by Dr E in October 2018.

a. What is the standard of care/accepted practice? When patients with inflammatory arthritis have pain in a joint that has not responded to treatments directed at inflammation, it is important to consider non-inflammatory pathologies. An x-ray is an appropriate investigation to rule out erosive or degenerative arthritis, or fracture.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? According to the clinic letters, [Mrs A] had complained of right ankle pain from at least 1 June 2017. [Dr B] had injected her right ankle on three occasions from 1 June 2017 to 7 September 2018. Over that time she had 12 clinic appointments with the nurse or [Dr B]. While it is not possible to say with certainty when the fracture occurred, there was certainly a strong indication for an x-ray by the end of 2017 when she had had two injections and was taking prednisone 60 mg daily in addition to DMARDs and biological therapies. This would be considered a moderately severe departure from the standard of care.

c. How would it be viewed by your peers? Experienced rheumatologists would have a degree of sympathy for [Dr B]. Most of us have will have faced a similar situation where, with the benefit of hindsight, we might have ordered an x-ray or another investigation earlier. There is a tension between investigating adequately and using health resources wisely. It is likely, however, that my peers would see this as an error of judgment, and would see it as a moderately severe departure from the standard of care.

d. Recommendations for improvement that may help to prevent a similar occurrence in future. In his response to the complaint [Dr B] apologised for failing to diagnose the fracture and will, no doubt, have learned from this incident. The importance of obtaining x-rays in this situation should be emphasised to him.

8. Any other matters you consider warrant comment with regard to the management of [Mrs A's] arthritis or the provider response. There are a number of unsatisfactory aspects in the management on [Mrs A's] arthritis. At the root of these is the fact that a physician with an interest in rheumatology is expected to manage treatment resistant rheumatoid arthritis without adequate peer support in a provincial hospital. This is a resource-provision and workforce issue, which should be addressed by [the DHB].

There is the fact that the patient had access to high doses of prednisone, which she used inappropriately for management of non-inflammatory joint pain, the notable example being the right ankle fracture. In my experience, inflammatory pain in rheumatoid arthritis usually will response to prednisone 20 mg daily, and it is seldom necessary to go above this dose. Prescribing restrictions should have been applied to prevent the patient escalating the dose between visits. [Dr B] does appear to have emphasised the importance of dose reduction to [Mrs A], in keeping with his philosophy regarding prednisone use as stated in his response letter. The complexity of this case would have warranted a request for a second opinion from a rheumatologist at an earlier stage, and not doing so would be seen as a moderate departure from the standard of care.

Yours sincerely,

Andrew Harrison FRACP PhD
Rheumatologist
Associate Professor in Medicine, University of Otago Wellington

References.

1. Smolen, J. S. *et al.* Treating rheumatoid arthritis to target: 2014 update of the recommendations of an international task force. *Ann. Rheum. Dis.* **75,** 3–15 (2016).
2. Harrison, A. A., Tugnet, N. & Taylor, W. J. A survey of the New Zealand rheumatology workforce. *N. Z. Med. J.* **132,** 70–76 (2019).
3. Lau, C. S. *et al.* APLAR rheumatoid arthritis treatment recommendations. *Int. J. Rheum. Dis.* **18,** 685–713 (2015).'

Further advice received 22 November 2022:

'Thank you for asking to review the responses to my report on this case.

I have reviewed my report dated 21 June 2021 and the responses from [Dr B] and [the DHB]. I do not believe any new information has been provided that would lead me to change my opinion. [Dr B] appears to agree with most of my recommendations.

He has devoted a large portion of his response to establishing his credentials. I did not mean to give the impression that I think he is underqualified to perform his role. He

may not have completed the RACP rheumatology training program, but undertook training under the supervision of rheumatologists and has extensive experience providing rheumatology services at [the DHB]. I am unsure about the relevance of this part of his response as it does not influence the assessment of the case.

He has taken issue with my comments about the level of peer support with which he is provided. This was meant in a supportive way, and while his wordy rebuttal of this point is again of questionable relevance, I would have significant concerns if [Dr B] thought that he was not disadvantaged with regard to day-to-day collegial support and regular peer review, in comparison to rheumatologists working in large main-centre departments.

My assessment of the management of the right ankle pain over the course of 2017 and 2018 was based on the clinic letters. [Dr B] has provided his own interpretation of the letters, which argue that the ankle was intermittently symptomatic over this time. As stated in my original report, it is not possible to determine with certainty when the fracture occurred, but I think there was a good case to be made for an x-ray of the right ankle after the second injection. Not doing so would be regarded as a departure from accepted practice, minor at best.

Yours sincerely,

Andrew Harrison FRACP PhD
Rheumatologist
Associate Professor in Medicine, University of Otago Wellington'

Appendix B: In-house clinical advice to Commissioner

The following in-house advice was obtained from GP Dr David Maplesden:

'**TO** : [HDC]

FROM : David Maplesden

CONSUMER : [Mrs A]

PROVIDER : [Medical centre]

FILE NUMBER : C20HDC00674

DATE : 24 April 2023

1. I have stated in my previous file steer: There may be an issue with communication provided to [Mrs A] regarding management of her steroids, the steroid therapy per se (including awareness of risk of adrenal suppression and checking for this — eventually done by GP September 2018) and delayed detection of her ankle fracture. However, on review of the GP notes I cannot find any notes referring to GP initiated increase in prednisone doses but rather recognition that [Mrs A] was adjusting the doses herself and required more explicit direction from her rheumatologist. There is no prescription provided from the GP for doses higher than prednisone 25mg daily, and most prescriptions are for somewhat lesser doses. There is frequent reference in the GP notes to seeking of advice from the rheumatologist on various issues. There is no reference to complaint to the GP of ankle pain until 5 September 2018. The GP has expressed awareness of the risks of prolonged steroid therapy to bone health and initiated follow-up Dexa bone scan and possible Aclasta (not required after bone scan normal). [Mrs A] was followed up in [the DHB] rheumatology clinic more frequently than she attended her GP over the period in question. Taking into account the likelihood that many of [Mrs A's] prednisone dose increases and changes to her recommended regime were self-directed rather than prescribed, it could be difficult to criticise her overall management.

2. You ask how [Mrs A] was able to take higher than recommended doses of steroids for a prolonged period of time.

I have reviewed the GP notes including all reports received by them from the [DHB's] rheumatology service. There is no response on file from the practice. There are several factors apparent from the information reviewed:

3. [Mrs A] had a complex rheumatological condition that was proving difficult to control despite extensive and ongoing specialist input and multiple medication trials under the auspices of the specialist service. Reports received by the GP from the rheumatology service would generally refer to [Mrs A's] current medications (including prednisone) and advice provided to her regarding dose adjustments. These reports have already been summarised in [Dr B's] response. There is frequent reference to [Mrs A] self-

adjusting her prednisone dose in response to her pain levels and it is evident this behaviour continued despite advice provided to her from the rheumatology service recommending gradual dose reduction on a number of occasions and providing advice that was sometimes general (eg. reduce dose as able or "x dose reducing") and sometimes more specific in this regard.

4. [Mrs A] had regular face to face and telephone contact with the specialist service. The extent of telephone contact is unclear but there are references in clinic letters to telephone advice having been sought and provided on a number of occasions including in relation to prednisone dosing. From February 2016 to September 2018 there were at least 21 reported face to face reviews with the rheumatology service and there was sometimes a lag of several days between the clinical review and receipt of the report. Over the same period there were 12 face to face GP consultation when [Mrs A's] anti-rheumatic therapy was mentioned although rheumatoid medication review was not the primary purpose of most of these consultations. There is no record of [Mrs A] seeking specific steroid dosing advice from her GPs although on 15 May 2017 provider [X] sought specialist advice regarding a current flare in [Mrs A's] symptoms and on 31 May 2017 provider [Y] noted: *I suggest that she should have detailed information from [Dr B] about how to go about managing her medications instead of increasing prednisone every time Rh Art flares up*. In October 2017 the rheumatology clinical nurse specialist (CNS) contacted [the medical centre] noting [Mrs A] *has continuously range about* [her prescriptions] *and these should be fulfilled by …* An appointment was scheduled with [X] for a *medication review and so as to rectify prescription errors* [not otherwise specified] *and ensure future scripts to be GP responsibility and not specialists*. On 27 October 2017 there is reference to review and meds updated [X] with prednisone prescription provided at that stage being 5mg BD (60 tabs) and 1mg tabs as required (x 100 tabs). This is consistent with the dose most recently recommended in the clinic letter dated 25 September 2017 of 13mg daily reducing as able.

5. Prior to this review [Mrs A] generally requested repeats of her various medications via telephone. Prescriptions for prednisone 5x5mg tabs daily (150 and presumably two repeats) were provided to [Mrs A] on 29 September 2016, 31 January 2017 (average of 3.6 tabs per day over this period) and 24 April 2017 (average of 5.4 tabs per day over this period). Another prescription for the same amount was provided at [Mrs A's] request on 12 June 2017 (an average of 9.2 tabs per day) and this high use is consistent with the doses recorded in the clinic letters from January, March, April, May and June 2017. However, it is apparent from the clinic letters that the rheumatology service was aware of [Mrs A's] steroid use over this period, and that the severity of [Mrs A's] symptoms and lack of response to trials of various adjunctive medications over this period is what led to her maintaining a higher than desirable intake of steroids. Given the variable doses of steroids recommended to [Mrs A] following her rheumatology clinic appointments (dependent to some degree on the efficacy of the other treatments prescribed) I believe it was reasonable to provide [Mrs A], at her request, a supply of prednisone that enabled some degree of flexibility of dosing with the assumption she was provided with more explicit dosing advice by the rheumatology service (which did occur) and she would follow this advice (which did not always occur). Nevertheless, with

a flexible dosing schedule it might have been appropriate to prescribe with a qualifier such as: *Take as recommended by rheumatology service* rather than an apparent fixed dose of 25mg daily. Appropriate changes were made to prescribing regime on 27 October 2017 as noted above. The question arises as to whether prescribers ought to have questioned [Mrs A's] request for more prednisone on 12 June 2017 when the request might have indicated use of over 45mg daily over the preceding two months. Such a query would represent good practice but consideration should also be given to the fact [Mrs A] was in regular and frequent contact with the rheumatology service regarding her medication, she was very familiar with the use of prednisone, and it might be reasonable to expect she would adhere to the dosing regime recommended to her by her specialist in this context.

6. Following the prescribing review undertaken by [X] on 27 October 2017, [Mrs A] evidently had a flare of her symptoms and was advised by [Dr B] to take 60mg prednisone daily for one week, 40mg for one week, 20mg for one week then 15mg and reduced as able (clinic report 8 November 2017). On 24 November 2017 [Dr B] reported [Mrs A] had been unable to reduce her prednisone below 40mg daily. He administered a steroid injection into her ankle and more gradual prednisone reductions was advised (clinic report 24 November 2017). Clinic report dated 9 January 2018 indicated [Mrs A] was taking 19mg prednisone daily with advice to continue reduction by 1mg per week. Prescription was provided by [the medical centre] provider [Z] on 5 March 2018 for prednisone 5mg BD x 60 (and presumably two repeats). The next prednisone prescription was provided by [X] on 30 April 2018 and is recorded as 90 x 20mg tabs with dose of 25mg once daily, and 100 x 1mg tabs to take as required. The rationale for this prescribing is not clear (it would be expected [Mrs A] was taking somewhat less than 20mg prednisone daily and a 20mg tab did not allow for the degree of flexibility of dosing required for gradual dose reduction). On 5 June 2018 the CNS reported [Mrs A] was currently taking 25mg prednisone daily (and she may therefore have requested this dose in the 30 April 2018 phoned prescription request) with no dose reduction advised but follow-up due by [Dr B] in six weeks. On 25 June 2018 [X] noted [Mrs A's] lack of response to recently commenced infliximab treatment and *prednisone has been increased to 25mg for several months, not on any bony protection*. Dexa bone scan was arranged (normal) and prescription provided for prednisone at 15mg daily reducing to 10mg (other instructions obscured) implying gradual reduction of prednisone dose was discussed and implemented. On 18 July 2018 [Dr B] reported having an extensive discussion with [Mrs A] about her ongoing steroid use and self-adjustments with strong advice to decrease her dose and reducing regime advised. Subsequently it appears [Mrs A] did slowly reduce her prednisone dose and prednisone prescribing was consistent with dose reductions.

7. There was a missed opportunity to identify [Mrs A] was taking a higher than recommended or prescribed prednisone dose in June 2017 (s5), and the prescribing by [X] in April 2018 did not appear consistent with the regime recommended to [Mrs A] in her most recent rheumatology clinic appointment preceding that prescription (s6). It may be that communication between [Mrs A's] primary and secondary care providers could have been improved in both directions to support safer use of prednisone but one

of the primary underlying issues appears to be that [Mrs A] gained relief of her symptoms with higher doses of prednisone and required such relief when trials of other medications were not successful. In this regard I can understand why she altered doses of the medication herself despite apparent[ly] receiving information from her providers regarding the undesirability of doing so and the preference for dose reduction. I think it is reasonable to recommend the practice review its management of [Mrs A] with respect to the repeat prescribing of steroids to determine whether there need to be changes to their repeat prescribing policy or process to ensure possible inappropriate use of oral steroids is detected and acted upon.'

Appendix C: Timeline of prednisone doses while under Dr B's care

Aug 2015	Started on **10mg**[1] by Dr B.
Sep 2015	Reduced to **9mg** by Dr B with a plan to reduce at a rate of 1mg per week.
Dec 2015	Increased to **20mg** by GP[2] on the 7th to manage a flare. GP reduced this to **15mg** on the 14th with a plan to reduce to 10mg after a week.
Jan 2016	GP documented on the 11th: '[Mrs A] has been altering the dose of steroid according to [severity of symptoms in her] knee.' Actual doses taken at this time were not documented. GP documented on the 28th that Mrs A was now taking **30mg** and advised a reduction to 20mg.
Feb 2016	Mrs A had reduced to **25mg** early Feb, but increased back to **30mg** by the 5th because her left knee became 'puffy and tender' and she did not feel she could reduce further. CNS C suggested Mrs A call the rheumatology clinic on the 10th and if she was feeling well they could reduce to 25mg.
Mar 2016	By the 7th Mrs A had reduced to **17.5mg** and was continuing to reduce as able. Dr B noted there was still evidence of inflammation in the joints despite the use of prednisone.
Apr 2016	Symptoms were controlled and Mrs A had reduced to **9mg**. Dr B planned for her to reduce at a rate of 1mg per week.
Jun 2016	On the 29th CNS C advised an increase to **20mg** to manage a flare.
Jul 2016	On the 7th Dr B advised to continue with **20mg** for another week, then reduce to 15mg for two weeks, then 10mg after that. Mrs A also enrolled as a patient at the medical centre on the 7th.
Aug 2016	Mrs A had not felt able to reduce as planned due to ongoing flares, so remained at **20mg**. CNS C advised on 19th to stick with the plan to reduce to 15mg for two weeks, then 10mg after that.
Sep 2016	GP prescribed **25mg** on the 28th. Unclear rationale given last advice from the rheumatology clinic.
Nov 2016	Dr B was surprised on the 17th to see Mrs A was now on **25mg**. Plan to reduce to 20mg for a week, then 15mg for two weeks, then 10mg thereafter.

[1] Doses of prednisone are daily amounts and doses in bold are the amounts that were being taken.
[2] Mrs A transferred to another medical centre on 7 July 2016.

Jan 2017	Mrs A had reduced to **15mg** but CNS C documented that she did not feel she could reduce further due to pain.
Feb 2017	On the 14th CNS C advised to increase to **40mg** until the 17th to manage a flare. Mrs A was still sore on the 17th so continued on **40mg** until the 21st when she was able to reduce to **30mg**. Further reduction to **25mg** by the 28th. These reductions appear to have been supported by CNS C via phone calls.
Mar 2017	On the 7th CNS C documented that Mrs A was back to **35mg** following a flare over the weekend. Unclear if this was clinically advised or not. Plan from CNS C was to try to reduce back to 30mg in the following few days and CNS C documented: '[Mrs A] will ring for advice if she flares again or has trouble reducing Prednisone.'
Apr 2017	By the 4th Mrs A was still on **35mg**. She had not been able to reduce due to ongoing flares. CNS C documented: '[Mrs A] knows to touch base with us regarding the reduction in prednisone.' Mrs A was able to reduce to **30mg** on the 9th but was sore and inflamed in her knees and ankles so went back to **35mg**. There is no evidence she contacted the clinic at that time as CNS C had recommended.
May 2017	Mrs A was still on **35mg** on the 5th when reviewed by CNS C. On the 7th Mrs A increased to **45mg** due to swelling in her knees and ankles. She called the rheumatology clinic and spoke to CNS C on the 9th. No record of what was advised in that call.
Jun 2017	Mrs A was at **45mg** on the 1st and felt that her pain was not being managed. On the 8th Mrs A increased the dose to **55mg** due to inflammation in her ankles and left knee. On the 29th she was reviewed by CNS C and Dr B. CNS C documented: '[Mrs A] understands if anything gets worse, if any of her joints blow up, [Dr B] is happy to bring her in at her request for a joint injection.' Plan made to reduce to 50mg for a week then reduce by 5mg per week.
Jul 2017	Mrs A had reduced to **40mg** by the 14th, in line with reduction plan.
Aug 2017	Mrs A had reduced to **14mg** by the 29th. New plan documented by CNS C to reduce by 1mg per week until 10mg is reached, then reduce by 1mg per fortnight.

Sep 2017	Mrs A had reduced to **13mg** by the 25th but reported arthritis and pain worsening again. CNS C discussed this with Dr B, who advised to stay at the dose that is comfortable.
Nov 2017	Dr B gave a 'rescue dose' of **60mg** on the 10th for one week with a plan to reduce to 40mg for a week, 20mg for a week, 15mg for a week, then reduce as able. By the 24th Mrs A had reduced to **40mg** but had been unable to reduce to 20mg as her right ankle was 'playing up'. Dr B injected 40mg of Kenacort[3] into the right ankle and advised she reduce the prednisone to 20mg for a week, then 15mg for two weeks, then 10mg until reviewed. NB: Mrs A did not get much benefit from this injection of Kenacort so a 120mg dose was injected into the muscle by district nurses on the 29th.
Jan 2018	By the 9th Mrs A had reduced to either **20mg** or **10mg**. Clinical notes say 20mg and had not been able to reduce further. After speaking with a doctor, CNS C advised a reduction of 1mg per week. Mrs A recorded: 'Reported taking 20mg Prednisone but have only 5mg pills, have been taking 2 pills only, therefore 10mg. Noticed this when told to reduce by 1mg at a time. Took 9mg total. Ankle is swollen and sore, took another 5mg, some improvement but still swollen … Will call when [Dr B] returns next week. Start **19mg** Prednisone.'
Feb 2018	Mrs A increased to **20mg** on the 13th then **25mg** on the 16th. No evidence of clinical advice.
Jun 2018	Mrs A increased to **30mg** on the 7th due to worsening pain. No evidence of clinical advice.
Jul 2018	Appointment on 18th with Dr B was dedicated to discussing his concerns about the long-term use of prednisone. He documented that Mrs A has a tendency to 'bump up' the dose of prednisone to control symptoms such as swelling, stiffness, and/or reduced range of movements but not necessarily a lot of pain. Dr B emphasised the need to reduce the dose as soon as possible and made a plan to reduce to 20mg and then reduce by 5mg per fortnight. Dr B documented: 'To help her achieve this I have suggested that if she ever feels that there is a need to increase the dose of Prednisone again then she should

[3] A corticosteroid used to suppress inflammation and swelling and relieve pain.

	make contact with us and we will endeavour to actually review her here before making a decision as to where to go.'
Aug 2018	Mrs A had reduced to **15mg** by 13th and **10mg** by the 27th. However, feeling her pain is not being managed. Referral for second opinion made. GP documented plan to reduce by 1mg monthly now she is at 10mg.
Sep 2018	Mrs A remained at **10mg** until end of September, as planned, but rates pain 8/10, particularly in right ankle. Dr B injected 40mg of Kenacourt into [Mrs A's] right ankle on the 7th, but this did not help.
Oct 2018	Mrs A had reduced to **9mg**. Seen by rheumatologist Dr E, who made a plan to speed up reduction to 1mg every three weeks (as opposed to monthly) due to need for surgery to fix non-union of right ankle.
Nov 2018	Mrs A had reduced to **8mg** by 2nd.
Dec 2018	Mrs A had reduced to **6mg** by 18th and was 'totally under the care of [Dr E] since late December 2018'.