General Practitioner, Dr B
Medical Centre

A Report by the
Health and Disability Commissioner

(Case 19HDC01826)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a woman who presented to a general practitioner (GP) with a respiratory complaint. In particular, the report discusses the GP's prescribing of prednisone, a steroid medication, to treat the woman's infective exacerbation of asthma. The Commissioner highlights the importance of prescribers giving clear instructions when a medication regimen is complex.

2. The GP first saw the woman on 20 June 2019. Initially he prescribed a prednisone dosage of 80mg a day for a week, to be reduced down to 40mg a day for another week. However, the woman remained unwell, and on 25 June 2019 the GP extended the length of time the woman was to take prednisone. Following this consultation, the woman began taking 100mg of prednisone a day. However, the GP stated that this was not his instruction. On 1 July 2019, the GP saw the woman again after having been told that she was taking 100mg of prednisone daily. He said that he told the woman that he had not prescribed 100mg of prednisone daily, and advised her to reduce the dosage. However, the woman stated that she did not begin reducing her prednisone dosage until a GP friend later advised her to do so.

Findings

GP

3. The Commissioner found a number of failures in the care provided by the GP to the woman. These included commencing the woman on a higher than recommended dose of prednisone, failing to measure and record her peak expiratory flow rate, his inadequate documentation for each of the three consultations with the woman, and failing to take sufficient care with a prescription. In the Commissioner's view, the GP did not provide services to the woman with reasonable care and skill, and, accordingly, breached Right 4(1) of the Code.

Medical centre

4. The Commissioner considered that it was reasonable for the medical centre to rely on the GP's experience and training, and expect that he would prescribe and maintain notes in accordance with accepted medical practice, and that the medical centre, as an employing authority, could not reasonably have done anything more to prevent the events from occurring. The Commissioner found that the medical centre did not breach the Code.

Guidelines on steroid use for asthma

5. The Commissioner noted that the New Zealand Formulary (an independent resource that provides clinically validated medicines information for health professionals) provides more refined information with respect to steroid use for specific conditions (including asthma), and that this advice is consistent with the New Zealand Asthma Guidelines. The Commissioner encouraged clinicians to use the New Zealand Formulary for accessing up-to-date prescribing information.

Recommendations

6. The Commissioner recommended that should the GP return to New Zealand, he undertake a clinical notes audit and review the New Zealand Asthma Guidelines, and report back on any changes made to his practice as a result. The Commissioner also recommended that the GP provide a written apology to the woman, and that the Medical Council consider whether a review of his competency is warranted.

7. In accordance with the recommendation in the Commissioner's provisional opinion, the medical centre provided HDC with an excerpt from its new policy in respect of issuing of medication from the supply cupboard.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her by general practitioner (GP) Dr B at the medical centre. The following issues were identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care in June and July 2019.*
- *Whether the medical centre provided Mrs A with an appropriate standard of care in June and July 2019.*

9. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	GP/provider
Medical centre/provider	

10. Further information was received from:

Dr C	GP
RN D	Registered nurse

11. Also mentioned in this report:

RN E	Registered nurse

12. In-house clinical advice was obtained from GP Dr David Maplesden (Appendix A).

Information gathered during investigation

Background

Dr B

13. Dr B is a vocationally registered GP[1] who had been working in New Zealand since 2006, mainly doing locum work. Initially he was employed by the medical centre as a locum GP from 1–12 April 2019, and was employed by the medical centre as a permanent GP from 4 June 2019.[2]

Mrs A

14. Mrs A (aged in her sixties at the time of events) had a history of asthma. She told HDC that she and her husband went on holiday from 8–15 June 2019 and, after they returned to New Zealand, they both became unwell on 17 June 2019 with symptoms of a tight chest, sore throat, and upset stomach.

20 June 2019 — initial consultation with Dr B

15. On 20 June 2019, Mrs A presented to the medical centre. Triage nurse RN E documented the following clinical notes:

> "Exacerbation of asthma? … Husband also unwell with similar. Vomiting and diarrhoea, tight chest, [shortness of breath], sore ribs from coughing, off food, drinking ok. Bladder no change, concentrated urine. No blood in bowel motions."

16. RN E recorded Mrs A's observations as: pulse 104 beats per minute; oxygen saturation 93%; blood pressure 110/56mmHg; respiratory rate 24 breaths per minute.[3]

17. Mrs A was then seen by Dr B. Dr B told HDC that on examination, which included listening to Mrs A's lungs, he diagnosed Mrs A with a chest infection. However, the only assessment notes Dr B documented were: "asthma flare up". Dr B did not record a peak expiratory flow rate (PEFR).[4] Mrs A told HDC that she recalls Dr B listening to her lungs at this consultation.

18. Dr B provided Mrs A with prescriptions for doxycycline,[5] Duolin[6] nebuliser, zopiclone,[7] and prednisone.[8] The prednisone prescription was for a total of 34 20mg tablets. Dr B told HDC

[1] Dr B was trained overseas. He was awarded the General Practice scope of practice in 2014 and is a Fellow of the Royal New Zealand College of General Practitioners.
[2] Dr B is no longer employed by the medical centre.
[3] Normal adult heart rate ranges from 60–100 bpm; ideal oxygen saturation is above 95%; ideal blood pressure is between 90/60mmHg and 120/80mmHg; normal respiratory rate is between 12 and 20 breaths per minute.
[4] A measurement of the maximum rate of air flow out of the lungs during forced expiration, used to monitor lung capacity. A normal PEFR depends on the person's gender, age, and height. For a woman of Mrs A's age, PEFR varies from 370–400.
[5] A broad-spectrum antibiotic.
[6] A medication used to treat airway diseases.
[7] A sleeping pill.
[8] An anti-inflammatory medication.

that the standard dose of prednisone to treat asthma is 1mg per kg. Dr B said that although Mrs A's weight was 120kg at the time, he prescribed an initial 80mg per day dosage of prednisone as he considered that it would be sufficient to treat her infective exacerbation of asthma. Dr B's documented instructions for the prednisone were: "20mg tab — take 2 tabl. to start with, then two tabl. twice/day (80mg/d) for one week, then reduce to 20mg twice/day (40mg/day) for another week."

19. Dr B told HDC that he also arranged for Mrs A to be provided with two 20mg tablets of prednisone from the medical centre's supply, to last her until she could get to a chemist to pick up her prescribed medication. He said that inadvertently he did not deduct the two 20mg tablets from his prescription, and therefore supplied Mrs A with 36 tablets, rather than the intended 34 tablets. However, the supply of prednisone from the medical centre was not recorded in the clinical notes. Dr B stated that he arranged for one of the nurses to provide this medication, and assumed that the nurse would document this. He accepted that he should have done it himself, but said that he did not have time, as Mrs A was an emergency walk-in and required an hour-long consultation.

25 June 2019 — second consultation with Dr B

20. On 25 June 2019, Mrs A returned to the medical centre. RN E documented that Mrs A had attended for a review of her asthma/chronic obstructive pulmonary disease (COPD). RN E noted that Mrs A's PEFR was 150.

21. Mrs A was seen by Dr B. Dr B documented the following notes:

> "[H]ere for review asthma/had nebulizer here today, states working;/still on [doxycycline]/chest still obstructive & [clinically] not better/[oxygen saturation] 94% [pulse] 98 bpm after duolin/discussed [chest X-ray] sputum culture, lab urgent & admission if not getting better. Call [hospital]."

22. Dr B referred Mrs A for blood tests, a sputum culture, and a chest X-ray, and noted a diagnosis of COPD.

23. Dr B told HDC that he advised Mrs A to continue with 80mg of prednisone a day for a further five days, and then to reduce this to 40mg a day for another five days (from 1 July 2019) as her condition was not improving. Dr B did not issue another prescription for prednisone and, therefore, there were not enough tablets left from the 20 June prescription to last the further 10 days. However, Dr B said that he advised Mrs A to come back for another review after her test and X-ray results were available, which he expected would be within two days. Dr B said that for this reason, he was satisfied that Mrs A had enough prednisone to take 80mg a day until she returned for another consultation. His intention was to issue another prescription at that stage.

24. Dr B told HDC that during this consultation he weighed Mrs A, and her weight was 120 kilograms. He said that therefore he discussed her BMI with her,[9] which was over 50[10] and

[9] Body Mass Index.
[10] A BMI of over 30 indicates that the person may be obese.

indicated that she was obese. He said that his rationale for advising Mrs A to remain on the dosage of 80mg of prednisone daily for another five days was because she was not improving.

25. Mrs A told HDC that during this consultation with Dr B, she was told that she was overweight and that the normal dosage of prednisone would have no effect. She stated that she was told to increase her dosage of prednisone to 100mg daily (3 x 20mg tablets in the morning and 2 x 20mg tablets at lunchtime). Mrs A said that she told Practice Nurse RN D of this as she was leaving the medical centre. Mrs A also said that Dr B provided further prednisone to her from the medical centre's cupboard. However, Dr B denies this.

26. RN D told HDC that when Mrs A was at the desk paying for the consultation, she mentioned that Dr B had told her to increase her prednisone to 100mg daily because of her weight. RN D also said that Dr B had provided Mrs A extra prednisone tablets out of the medical centre's stock cupboard, and that normally this would be recorded in the patient's medication chart and clinical notes by the doctor who issued the extra medication.

27. Mrs A's sputum culture results became available on 26 June 2019 and showed a heavy growth of *Neisseria meningitidis*.[11]

1 July 2019 — third consultation with Dr B

28. RN D told HDC that over the weekend of 29–30 June 2019, Mrs A spoke to their mutual friend, a retired GP, who "expressed her concern over the dosage of Prednisone (100mg) that [Mrs A] was taking and the length of time she was taking this". RN D said that the friend also expressed these concerns to her.

29. RN D stated that on Monday, 1 July 2019, she spoke to Mrs A on the telephone and confirmed that Mrs A was still taking 100mg of prednisone daily. RN D then sent Dr B the following electronic task message on the medical centre's patient management system:

> "Ask [Dr B] how long [Mrs A] should stay on 100mg Prednisone. Has been taking 100mg daily since last Thursday. She did not know when you wanted her to reduce the dose. I spoke with her on her cell phone this morning."

30. Dr B told HDC that after receiving this message, he told RN D that Mrs A was not to take 100mg of prednisone, and that she was never advised to take this dosage.

31. Mrs A returned to the medical centre that day to be reviewed by Dr B. Dr B noted the sputum culture results in the clinical notes, and also documented the following:

> "Temp 37.0/[oxygen saturation] 95%/chest slightly better/still SOBOE;[12] compliance good fluid intake good [chest X-ray] normal [C-reactive protein][13] & [full blood count]

[11] A Gram-negative bacterium that can cause meningitis and other forms of meningococcal disease.
[12] Shortness of breath on exertion.

normal/plan change to Cephalosporins[14]/discussed atypical pneumonia: review in 1 week or go to ED if not settling: happy with this."

32. Dr B provided Mrs A with prescriptions for Cefalexin,[15] Panadeine, and prednisone. The prednisone prescription was for 30 20mg tablets, and the documented instructions were to "take 2 tabl. max 5 days/day". The prescription allowed for one repeat.

33. Dr B told HDC that he explained to Mrs A that she was never prescribed or advised to take 100mg of prednisone daily. He said that he took extra care to ensure that she understood to start taking the reduced dosage of 40mg daily for five days. Dr B also said that the repeat prescription was valid for three months, and was for emergency use only. He stated that he "clearly recorded on the script that [Mrs A] was to take no more than two tablets per day for a maximum of five days". In response to the provisional opinion, Mrs A told HDC that at the time, Dr B did not deny prescribing 100mg of prednisone to her. She stated: "[W]e even discussed it on one occasion as to whether it would be best to take 60mgs in morning and 40mgs at lunchtime or vice versa."

34. Mrs A denied that Dr B provided her with a prednisone reduction programme. She stated that after this consultation, she was advised by her GP friend to start reducing her prednisone dose immediately, and that her friend "couldn't believe that I had been on such a high dose for so long". Mrs A said that she then reduced her dose to 60mg a day for four days, and then to 40mg a day for three days, then made further reductions of 5mg at a time.

18 July 2019 — initial consultation with Dr C

35. Mrs A returned to the medical centre on 18 July 2019. She told HDC that she was suffering prednisone withdrawal symptoms, including shaking, hot sweats, fatigue, shortness of breath, tremors, feeling blood pumping in the temporal area, a puffy face, and swollen legs.

36. Mrs A was seen by GP Dr C. Dr C recorded Mrs A's observations[16] and listened to her lungs. He noted that Mrs A had begun taking prednisone one month earlier, initially taking 100mg a day for two weeks, and then had "started coming off 13 days ago to 60mg for 4 days, then 40mgs for 3 days, then going down in 5mg since then now on 10mg for 3 days". Dr C noted Mrs A's symptoms referred to above, and recorded his impression that Mrs A was probably withdrawing from the steroids too fast.

[13] A protein produced by the liver that is normally present in trace amounts in the blood serum but is elevated during episodes of acute inflammation.
[14] A group of broad-spectrum antibiotics similar to penicillin.
[15] An antibiotic in the cephalosporins group.
[16] Temperature 36.9°C; oxygen saturation 92%; pulse 95bpm; blood pressure 160/82mmHg; weight 120kg.

37. Dr C's plan was for Mrs A to increase her prednisone dose to 20mg a day for a week, and then decrease to 15mg a day. He also referred Mrs A to an endocrinologist and requested blood tests of her cortisol[17] and BNP[18] levels.

38. Mrs A's blood test results were reported the following day. Her cortisol level was low, at 138nmol/L,[19] which was most likely due to her steroid use, while her BNP was within the normal range. RN D documented that she telephoned Mrs A to report the results and to check on how she was.

25 July 2019 — second consultation with Dr C

39. Dr C saw Mrs A again on 25 July 2019. He recorded her observations,[20] including her blood pressure of 166/66mmHg[21] (or 138/68mmHg when standing), and noted that she was still experiencing symptoms of hot sweats and tremors. His impression was that she was still in a state of adrenal insufficiency. His plan included continuing prednisone at 20mg a day. He also requested a repeat cortisol test, and for Mrs A to be reviewed in one week's time.

40. On 26 July 2019, Mrs A's cortisol level was reported as 95nmol/L. Dr C rang Mrs A and advised her to reduce her prednisone to 15mg the following day and to repeat her blood tests.

Subsequent events

41. Mrs A returned to the medical centre on 1 August 2019 and saw Dr C. He documented that her HbA1c level (blood glucose level), tested the previous day, was 63mmol/mol.[22] Mrs A's most recent HbA1c test prior to this had been on 24 August 2018, when her HbA1c level had been 43mmol/mol. Dr C's impression was that Mrs A had steroid-induced diabetes.

42. On 19 August 2019, Mrs A was reviewed by an endocrinologist. At that point, Mrs A was taking 10mg of prednisone a day. The endocrinologist noted Mrs A's recent HbA1c result and documented:

> "I note that her HbA1c was in the forties last year so I suspect she simply has steroid induced diabetes and when she comes off the Prednisone I am hopeful that her HbA1c will return to the prediabetic range."

43. On 8 September 2019, Mrs A ruptured her right Achilles tendon while at home. She was reviewed on 12 September 2019 by Dr C, who noted that Mrs A was "currently still on steroid[s], which can weaken tendon in her left TA tendon as well which may be at risk of rupture as well".

[17] A steroid hormone produced by the adrenal glands.
[18] Brain natriuretic peptide — a hormone secreted in response to stretching of the heart muscle. An elevated BNP is indicative of heart failure.
[19] The reference range is 170–500nmol/L.
[20] Peak flow rate 190; oxygen saturation 97%; pulse 107bpm.
[21] High blood pressure may be considered to be 140/90mmHg or higher.
[22] The normal HbA1c range is 20–40mmol/mol.

Further information

Mrs A

44. Mrs A told HDC that she did not come off steroids completely until April 2020. She said that these events have caused "severe health issues" for her and have had financial consequences for her family. She stated:

> "[The ruptured Achilles tendon in] turn put stress on my knee (knee scooter didn't help) and I am now waiting for replacement knee surgery in November [2020]. This, in turn, has put added stress on my opposite hip due to my limping, and somewhere down the line this may need to be replaced also!"

Dr B

45. Dr B accepts that he should have taken extra care to ensure that his note-taking accurately reflected his consultations with Mrs A. However, he maintains that he "prescribed [Mrs A] the appropriate dosage [of prednisone] based on her weight and the fact that her condition did not improve as expected". He stated that Mrs A seemed happy with his approaches at her consultations and his all-round service throughout.

46. Dr B said that the medical centre was a sole GP practice and was always overbooked, and frequently would have emergency walk-ins while appointments were limited to 15 minutes. He stated that often he had to treat patients in the medical centre's "physio room", where no computer or workstation was available. This meant that he had to take handwritten notes, and issues would arise in respect of transcribing the notes into electronic form. He said that since leaving the medical centre, he has had the resources to take better clinical notes, and has consciously made an effort to improve his note-taking.

Medical centre

47. The medical centre told HDC that Dr B was given the orientation schedule, and he went through it with the Practice Manager and RN D just after he commenced employment. The medical centre stated that Dr B would have been told about the process around issuing medication from the supply cupboard.

48. The medical centre has made the following changes since these events:

- It now uses a record book to sign out medications from the supply cupboard, in addition to the usual recording of medications in patient notes.
- It is revamping the layout of the medication cupboard to make access and the accounting of drugs safer.
- It is developing a policy to govern the issue of medication from the supply cupboard.

Responses to provisional opinion

49. Mrs A, Dr B, and the medical centre were all given the opportunity to respond to the relevant sections of my provisional opinion. Where appropriate, their responses have been incorporated into this report. In addition, I note the following comments.

50. In reference to the information at paragraph 46 above, Mrs A told HDC that she was only ever seen by Dr B in "Room 2", and was never seen in the physio room.

51. Dr B told HDC that he does not wish to comment further. He also told HDC that he has left New Zealand to care for an unwell family member, and does not have plans to return in the near future.

52. The medical centre told HDC that it disputes Dr B's claim, referred to in paragraph 46 above, that the practice was always overbooked. The medical centre stated that the doctor's schedule had appointment slots for 10 patients in the morning and 10 patients in the afternoon, with breaks included. It acknowledged that sometimes there were emergencies, but stated that nurses would always triage these first.

53. The medical centre also stated that the physio room was never used as a consultation room by the doctors; it was only ever used to seat patients who were compromised by sitting in the waiting room, and these patients would be transferred to the consultation room to be seen by the doctor. The medical centre said that therefore, there would be no need to transcribe notes into electronic form, as doctors would always have MedTech available in their consultation room.

Opinion: Dr B — breach

20 June 2019 consultation

54. Mrs A was first seen by Dr B on 20 June 2019. Prior to her consultation, Mrs A was reviewed by RN E, who recorded observations that showed that Mrs A had an increased respiratory rate, slightly increased heart rate, slightly lowered oxygen saturations, and a slightly low diastolic blood pressure.

55. The only assessment note documented by Dr B was: "asthma flare up". However, both Dr B and Mrs A recall that he listened to her lungs. Mrs A's PEFR was not recorded, and appears not to have been measured. Dr B told HDC that he prescribed 80mg of prednisone a day for five days, then a reduced dosage to 40mg a day for another five days. He stated that the standard dose of prednisone to treat asthma is 1mg per kg. Mrs A's weight was 120kg at the time, but he considered 80mg to be sufficient. His instructions included with the prescription were: "20mg tab — take 2 tabl. to start with, then two tabl. twice/day (80mg/d) for one week, then reduce to 20mg twice/day (40mg/day) for another week."

Prescribing 80mg dose of prednisone

56. My clinical advisor, Dr David Maplesden, advised that national asthma guidelines state that most patients who present with acute exacerbations of asthma should have a course of oral prednisone of 40mg daily for at least five days. Dr Maplesden further advised:

> "However, I acknowledge the more general advice on steroid use provided in MIMS and the Medsafe data sheet, which includes: *The dose should be individualised*

> *according to the severity of the disease and the patient's response rather than by age or body weight,* could reasonably be interpreted as mandating a higher dose than that recommended in the asthma guideline if the patient's condition was particularly severe or the patient failed to respond adequately to the maximum dosage recommended in the condition-specific guidance. However, it appears [Mrs A] was commenced on the higher than recommended dose from the outset (i.e. response not determined), and her condition was moderate rather than severe (per clinical observations)."

57. Dr Maplesden considers that the initiation of prednisone at 80mg per day was inconsistent with accepted practice, and is mildly to moderately critical of this. I accept Dr Maplesden's advice. In my view, it is concerning that Dr B commenced Mrs A on a higher than recommended dosage of prednisone in the situation where her exacerbation of asthma was not severe, and where there had been no trial of her response to a lower dosage.

Lack of PEFR recording

58. Dr Maplesden noted that Mrs A's PEFR was not recorded. He advised that according to national guidelines, the observations recorded by RN E would be consistent with moderate asthma exacerbation, although PEFR is also used to help determine severity of an exacerbation. Dr Maplesden was mildly to moderately critical of the lack of PEFR, although he acknowledged that studies are conflicting as to the benefit of PEFR monitoring in terms of improved outcomes or reliable prediction of the need for hospital admission.[23] Notwithstanding the conflicting studies, I accept that it was expected practice to measure and record a PEFR in these circumstances, particularly in light of the abnormal observations taken by RN E. I am therefore critical that Dr B did not do so.

Documentation

59. Dr Maplesden also considered that Dr B's documentation was deficient. Dr Maplesden noted that there was no record of safety-netting advice or follow-up plan, and neither Dr B's diagnosis of chest infection, nor the diagnostic formulation or rationale, were recorded. Dr Maplesden considered that the deficiencies in Dr B's documentation constituted a moderate departure from accepted practice.

60. Dr B's notes are strikingly brief — three words only — for his assessment of a significantly unwell patient during a consultation that he said was an hour long. In addition, Dr B did not document that Mrs A was given prednisone from the medical centre's supply cupboard. I also note that the prednisone prescription was unclear — the prescription stated that the initial dose of 80mg and the subsequent reduced dose of 40mg were to be taken for "one week" each, whereas Dr B stated that the doses were for five days each. I acknowledge Dr B's comments about resourcing and time constraints at the medical centre, although I note that these claims are disputed by the medical centre. In any case, I consider that his documentation was unreasonably deficient in the circumstances.

[23] Fanta, C. Acute exacerbations of asthma in adults: Emergency department and inpatient management. Uptodate. Literature review current though December 2019. www.uptodate.com

25 June 2019 consultation

61. On 25 June 2019, Dr B saw Mrs A again. He noted that Mrs A's chest was still obstructive and clinically she was not better. Dr B referred Mrs A for further tests, and said that he advised her to continue taking 80mg of prednisone daily for a further five days, and reduce to 40mg a day for another five days (from 1 July 2019). Dr B said that his rationale for extending the 80mg dosage was that Mrs A was not improving. He did not provide another prescription for the prednisone or document his advice to Mrs A.

62. Conversely, Mrs A stated that Dr B told her that she was overweight and that the normal dosage of prednisone would have no effect, and therefore she was to increase her dosage of prednisone to 100mg daily (3 x 20mg tablets in the morning and 2 x 20mg tablets at lunchtime). Mrs A said that she told RN D this as she was leaving the medical centre, which RN D confirmed. Dr B denies this, but said that he did discuss Mrs A's BMI with her, which was over 50. Both Mrs A and RN D told HDC that Dr B issued further prednisone to Mrs A from the medical centre's cupboard, which Dr B denied.

Issuing prednisone from the medical centre's cupboard

63. There are conflicting accounts as to whether Dr B issued prednisone from the medical centre's cupboard on this occasion, and nothing is recorded in the clinical notes to that effect. However, as Dr Maplesden highlighted, there are incongruities in the amount of prednisone Mrs A was apparently taking versus the amount of prednisone she was given on 20 June 2019. If Mrs A had been taking the prednisone at the rate Dr B prescribed on 20 June 2019 (i.e., two 20mg tablets immediately, then four tablets daily for five days), she would have used 22 tablets as at 25 July 2019, leaving 14 of the initial 36 tablets (including two tablets Dr B provided to her from the medical centre's supply on 20 June 2019). This would have been only enough to last just over three days at the dose of 80mg a day.

64. As it happened, Mrs A did not return to the medical centre until a week later, on 1 July 2019 (discussed further below). At this point, she reported taking 100mg a day (which she further confirmed with Dr C on 18 July 2019, as recorded in the clinical notes). That she was able to maintain this dose (or any dose of prednisone) supports her and RN D's accounts that she was provided further prednisone from the medical centre's supply cupboard.

65. In these circumstances, and on the evidence before me, I consider it more likely than not that Dr B provided Mrs A with further prednisone from the medical centre's supply cupboard on 25 June 2019. As Dr Maplesden advised, Dr B should have documented this supply in the notes. I am critical that he failed to do so.

Advice about prednisone dosage

66. In light of the conflicting accounts, and the lack of further evidence, I am unable to determine exactly what instructions for taking prednisone Dr B gave Mrs A at this consultation, or what he advised her about his rationale for keeping her on a high dose. However, that there was such a divergence in the parties' understanding of what Dr B advised Mrs A highlights the need for clear instructions. As Dr Maplesden advised, clear instructions are vitally important when a medication regimen is at all complicated, and Dr

B should have documented what he told Mrs A about her prednisone dosage. Again, I am critical that he did not do so.

1 July 2019 consultation

67. On 1 July 2019, following a telephone call with Mrs A, RN D sent Dr B a message asking him how long Mrs A should continue to take 100mg of prednisone. RN D wrote in the message that Mrs A had been taking this dosage since Thursday (27 June 2019). Dr B reviewed Mrs A later that day. In addition to changing her antibiotic regimen, Dr B provided Mrs A with another prednisone prescription for 30 20mg tablets, with one repeat. The documented instructions were to "take 2 tabl. max 5 days/day".

68. Dr B stated that he explained to Mrs A that she was neither prescribed nor advised to take 100mg of prednisone a day, and that he advised her to start taking the reduced dose of 40mg a day for five days. Mrs A refuted this, and stated that she did not begin reducing her dose until she was advised to do so by her GP friend, which likely occurred after the 1 July 2019 consultation.

69. At this stage, Dr B was aware that Mrs A was taking 100mg prednisone a day. As discussed above, it is not possible to determine what advice Dr B gave her on 25 June 2019. However, assuming that Dr B's intention was not for her to take 100mg of prednisone daily, he should have explained this to her carefully and documented his advice clearly in the notes and prescription instructions. I note Dr Maplesden's comment that the difference between Mrs A's understanding of Dr B's advice and what Dr B said he advised her "emphasizes the importance of providing clear written instructions when a medication regime is at all complicated and particularly when the advised regime changes from that provided initially (and therefore changes from the instructions on the medication label)". I agree.

70. Dr B said that he did explain the prednisone regimen to Mrs A carefully; however, he did not document this discussion. Dr Maplesden commented that Dr B's prescription instructions ("take 2 tabl. max 5 days/day") were unclear. I agree. I consider that the instructions were ambiguous and could be interpreted as saying that Mrs A could take a maximum of five tablets a day. In any case, the instructions were insufficient to clarify any misunderstanding Mrs A may have had.

71. I also note that the amount of prednisone prescribed was 30 tablets (i.e., three times the amount needed to complete a five-day course of two tablets daily), plus a repeat prescription. I consider that this is an excessive amount, and am concerned by Dr B's apparent lack of care taken with this prescription.

Conclusion

72. In summary, I conclude that there were a number of deficiencies in the care Dr B provided to Mrs A in each of the three consultations. Specifically, Dr B:

- Commenced Mrs A on 80mg of prednisone a day, which was a higher than recommended dosage of prednisone in the situation where her exacerbation of asthma was not severe, and where there had been no trial of her response to a lower dosage.
- Failed to measure and record Mrs A's PEFR at the 20 June 2019 consultation.
- Failed to document each of the three consultations adequately, including:
  - His diagnosis and diagnostic formulation, and any safety-netting advice or follow-up plan, on 20 June 2019.
  - The issuing of prednisone from the medical centre's cupboard on 20 June and 25 June 2019.
  - His advice about Mrs A's prednisone regimen on both 25 June and 1 July 2019.
- Did not take sufficient care with the prednisone prescription he provided on 1 July 2019, in that:
  - His prescription instructions were ambiguous and open to interpretation.
  - He prescribed an excessive amount of prednisone.

73. In my view, these deficiencies amount to a failure to provide services to Mrs A with reasonable care and skill. Accordingly, I find that Dr B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

74. I note Mrs A's concern that Dr B's prescribing of prednisone caused her to develop diabetes and rupture her Achilles tendon. It is not possible to determine with certainty that the prednisone regimen Dr B prescribed for Mrs A caused her to develop diabetes and contributed to her ruptured Achilles tendon. However, as noted by Dr Maplesden, there is evidence to suggest that both of these events could have been related to her steroid use. It is concerning that Mrs A was exposed to this risk of harm as a result of the deficiencies in Dr B's care.

Opinion: Medical centre — no breach

75. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. Dr B was employed by the medical centre at the time of these events. As noted above, I have found that Dr B breached the Code.

76. My in-house clinical advisor, Dr Maplesden, advised: "I am unable to see that any deficiency in the medical centre processes contributed to the deficiencies identified in [Mrs A's] care." I accept this advice. In this case, I consider that the errors identified were individual failings and did not indicate broader systems or organisational issues at the medical centre. Therefore, I consider that the medical centre did not breach the Code directly.

77. In addition to any direct liability for a breach of the Code, section 72 of the Health and Disability Commissioner Act 1994 (the Act) states that an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

78. At the time of events, Dr B was a vocationally registered GP with 13 years of experience working in New Zealand, mainly as a locum. He had been through an orientation schedule with the medical centre shortly after commencing his employment. In my view, it was reasonable for the medical centre to rely on Dr B's experience and training, and expect that he would prescribe and maintain clinical notes in accordance with accepted medical practice. I do not consider that the medical centre, as an employing authority, could have reasonably done anything more to prevent these events from occurring. Accordingly, I do not find the medical centre vicariously liable for Dr B's breach of the Code.

79. I note with approval the changes that the medical centre has made following these events.

Opinion: Guidelines on steroid use — other comment

80. As noted by my clinical advisor, Dr Maplesden, and referred to above, the more general advice on steroid use provided in MIMS and the prednisone Medsafe data sheet "could reasonably be interpreted as mandating a higher dose than that recommended in the asthma guideline if the patient's condition was particularly severe or the patient failed to respond adequately to the maximum dosage recommended in the condition-specific guidance". I note that the New Zealand Formulary provides more refined information with respect to steroid use for specific conditions (including asthma), and that this advice is consistent with the New Zealand Asthma Guidelines. I encourage clinicians to use the New Zealand Formulary for accessing up-to-date prescribing information.

Recommendations

81. I recommend that Dr B provide a written apology to Mrs A for the failures identified in this report. The apology is to be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.

82. I also recommend that should Dr B return to New Zealand, he:

a) Undertake a Royal New Zealand College of General Practitioners clinical notes audit and provide to HDC the results of the audit, along with any improvement strategies he has or will implement as a result, within three months of his return to New Zealand.

b) Review the New Zealand Asthma Guidelines and report back to HDC on any changes made to his practice as a result. This information is to be provided to HDC within three months of Dr B's return to New Zealand.

83. In accordance with the recommendation in my provisional opinion, the medical centre provided HDC with an excerpt from its new policy in respect of issuing of medication from the supply cupboard. No further recommendation is necessary in this respect.

84. I recommend that the Medical Council of New Zealand consider whether a review of Dr B's competency is warranted based on the information contained in this report.

Follow-up actions

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

86. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) and the New Zealand Formulary, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

87. Dr B advised HDC that he did not agree with the findings in this report and that he would not apologise to Mrs A. HDC considered that Dr B's refusal to apologise to Mrs A, as well as his refusal to accept the findings of this Office, demonstrated a concerning unwillingness to reflect on his practice and accept responsibility for his actions, and advised the Medical Council of New Zealand accordingly.

Appendix A: In-house advice to the Commissioner

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

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her by [Dr B] of [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. Complaint from [Mrs A]; response from [Dr B]; GP notes [medical centre]; clinical notes [endocrinologist].

2. Complaint

(i) [Mrs A] is concerned at [Dr B's] prescribing of prednisone for her in 2019 following her presentation with respiratory symptoms. She states: *[Dr B] prescribed 100mgs/day (3 x 20mgs morning and 2 x 20mgs lunchtime) Prednisone and left me on this high dose without providing me with a reducing programme. I eventually saw another doctor who put me on a reducing programme after taking bloods and finding that my cortisol level was only 95.* [Mrs A] has since developed diabetes and an Achilles tendon rupture which she feels could be attributed to this prescribing.

(ii) [Mrs A] states she attended [Dr B] on 20 June 2019 with respiratory symptoms and was prescribed prednisone 80mg daily. She returned to [Dr B] on 25 June 2019 as her symptoms were not improving and she states: [*I was] told was overweight and normal dosage would have no effect. I was told to increase from 80mgs to 100mgs — 3 x 20mgs in morning and 2 x 20mgs at lunchtime. I informed [Practice Nurse] of this as I left surgery.* On 1 July 2019 [Mrs A] asked the practice nurse: *how long I should stay on 100mgs prednisone [and] … when I should start reducing because [Dr B] hadn't told me.* It is unclear from the complaint what information was then provided but [Mrs A] states that on the advice of a GP friend she reduced her prednisone *to 60mg for four days and 40mg for three days then 5mg reductions …*

(iii) By 18 July 2019 [Mrs A] was suffering from symptoms of shaking, sweats, puffy face and swollen legs which she felt might be related to withdrawal of the prednisone. She saw [Dr C] who ordered blood tests (which showed low cortisol indicating adrenal suppression) and increased the prednisone to 20mg daily for a week then 15mg daily. A referral was made concurrently to [the endocrinologist]. [Mrs A] is currently requiring treatment for her Achilles tendon rupture (cast) and diabetes (metformin) as well as requiring very slow reduction of her prednisone over many weeks.

3. [Dr B's] response and clinical records: [Dr B] notes in his response [Mrs A] had a pre-existing history of obesity (BMI > 50kg/m2 between 2016–2019), prediabetes (elevated HbA1c in February and August 2018) and asthma. Clinical notes suggest a possible COPD diagnosis with regular inhaled medications prescribed at the time of the events in question being beclomethasone, salbutamol and possibly Spioto-Respimat.

Comment: It is unclear if [Mrs A] had previously had spirometry to clarify her respiratory diagnoses, and I am unable to determine the pattern of her presentation with respiratory symptoms prior to June 2019 (including use of prednisone) or to confirm her adherence to her recommended medication regime.

4. [Mrs A] presented to [Dr B] on 20 June 2019 following her return from a holiday [overseas]. Nurse triage notes include: *Exacerbation of asthma? Has been using blue inhaler more than usual, new inhalers have been working well, just back from Holiday [overseas]. Husband also unwell with similar. Vomiting and diarrhoea, tight chest, SOB, sore ribs from coughing, off food, drinking ok. Bladder no change, concentrated urine. No blood in bowel motions. pulse 104, O2 sats 93, BP 110/56, resps 24, tripod position.* [Dr B's] assessment notes, in their entirety, are: *asthma flare up.* Prescriptions are recorded for doxycycline, Duolin nebulizer, zopiclone 3.75mg nocte and *prednisone 20mg tab — take 2 tabl to start with, then two tabl twice/day (80mg/day) for one week, then reduce to 20mg twice/day (40mg/day) for another week (34 x 20mg tabs prescribed).* An off work certificate was provided.

Comments

(i) The standard of [Dr B's] clinical documentation (and possibly assessment) is deficient. According to national guidelines[1], the vital signs recorded by the practice nurse would be consistent with a moderate asthma exacerbation although measurement of peak flow rate is also used to help determine severity of an exacerbation and has not been recorded in this case. I would expect lung auscultation to form part of the assessment of a patient with possible exacerbation of asthma. I would be at least moderately critical if lung auscultation was not performed, and mildly to moderately critical that PEFR has not been recorded (although studies are conflicting regarding the benefit of PEFR monitoring in terms of improved outcomes or reliable prediction of the need for admission[2]). There is no record of safety-netting advice or follow-up plan. [Dr B's] response includes: *Upon examination, [Dr B] diagnosed [Mrs A] with a chest infection.* This diagnostic formulation, or the rationale for the diagnosis, is not apparent from the notes. I think the standard of clinical documentation in this case (significantly unwell patient) departs from accepted practice to a moderate degree. Taking into account deficiencies noted later in this report I recommend [Dr B] consider undertaking the RNZCGP clinical notes audit[3] with results (including reflection and any improvement strategies) provided to the Commissioner for review.

(ii) [Dr B's] response includes: *The standard dose of prednisone to treat asthma is 1mg per kg. Although her weight was 120kg at the time, [Dr B] prescribed [Mrs A] with an*

[1] https://www.nzasthmaguidelines.co.nz/uploads/8/3/0/1/83014052/adult_asthma_guidelines.pdf Accessed 28 January 2020
[2] Fanta C. Acute exacerbations of asthma in adults: Emergency department and inpatient management. Uptodate. Literature review current though December 2019. www.uptodate.com
[3] https://www.rnzcgp.org.nz/gpdocs/New-website/Quality/Draftv1RecordReviewAUGUST2018.pdf Accessed 28 August 2020

initial 80mg per day dosage of prednisone as he considered that it would be sufficient. He says that it is usual practice to trial patients on a lower dose first. I have assumed [Dr B] diagnosed [Mrs A] with an infective exacerbation of asthma. Prescription of an antibiotic, Duolin and prednisone was a reasonable therapeutic strategy with the previously cited guidelines stating: *Most patients presenting with acute exacerbations of asthma should have a course of oral prednisone, 40mg daily for at least five days.* A 2018 summary on oral corticosteroid (OCS) use in adult asthma exacerbations[4] (referencing international guidelines) states: *Treatment with OCS forms the backbone of management of all severe asthma exacerbations. For patients capable of asthma self-management, self-treatment with a short course of OCS (**about 1 mg/kg per day up to a maximum of 50 mg**) is clearly effective at reducing relapse, need for additional care and required dose of β-agonists. Similarly, in those patients treated in primary care or in hospital who can tolerate oral therapy, OCS **in the same dose range** are effective for the treatment of asthma exacerbations. As long as patients are able to tolerate oral therapy, there is no proven benefit of intravenous therapy. The standard duration of OCS therapy that is effective is 5–10 days.* The New Zealand Formulary lists recommended adult dose of prednisone for acute asthma as *Adult 40–50 mg once daily for 5 days* and for acute exacerbation of COPD as *Adult 40 mg once daily for 5–7 days*. No asthma guidelines I have reviewed suggest exceeding the recommended oral steroid dose if the patient weighs more than 40–50kg or is obese ([Dr B's] rationale for the large steroid dose used), and an article on determinants of glucocorticoid dosing[5] states: *Dosing of glucocorticoids in the obese patient should be based upon the ideal, rather than total, body weight*. However, doses of prednisone of the level prescribed to [Mrs A] are certainly recommended or used in other conditions (eg giant cell arteritis) and the Medsafe data sheet for prednisone includes the following information on adult dosing of prednisone:

- *The smallest dose which is effective or produces adequate control should be used since inhibition of corticotrophin secretion is related to dose and the duration of glucocorticoid therapy.*
- *The initial dose of prednisone is 10mg–100mg daily in divided doses, as a single daily dose at 8.00am or as a double dose on alternate days. The maintenance dose is usually 5mg to 20mg daily. The dose should be individualized according to the severity of the disease and the patient's response rather than by age or body weight.*
- *The usual adult prescribing limit is up to 250mg daily.*
- *Short Term Therapy: 20mg to 40mg daily with dosage reductions of 2.5mg or 5mg every 2 to 4 days depending on response.*

(iii) Based on the discussion above, my conclusion is that the prescribing of 80mg prednisone daily to [Mrs A] was excessive for the diagnosed condition and was

[4] Ramsahai J et Wark P. Appropriate use of oral corticosteroids for severe asthma. Med J Aust 2018; 209 (2): S18–S21

[5] Furst D et Saag K. Determinants of glucocorticoid dosing. Uptodate. Literature review current through December 2019. www.uptodate.com

inconsistent with recommended and accepted management of that condition. Noting [Dr B] maintained the dose of 80mg prednisone for ten days (see below) I feel [Mrs A's] management in this regard departed from accepted practice to a moderate degree. I recommend [Dr B] review the cited NZ asthma guidelines.

5. [Mrs A] returned for review on 25 June 2019. Nurse triage notes include: Came for review of asthma/COPD. *Talking 3 words per minute. PF150 on 60 mg prednisone. Started on Duolin Neb in room 3. temp 36.9 no paracetamol.* [Dr B] has recorded: *here for review asthma, had nebulizer here today, states working; still on doxy. Chest still obstructive & clin not better, So2 94% P98 after duolin. Discussed CXR. sputum culture, lab urgent & admission if not getting better call [hospital].* Prescription was provided for montelukast 10mg daily and [Mrs A] was referred for blood tests, sputum culture and chest X-ray. A diagnosis of COPD has been coded.

Comments:

(i) Management and documentation on this occasion was reasonable (putting aside the issue of the steroid management) although best practice would have been to record respiratory rate and effort in addition to the pulse, PEFR and oxygen saturations. Montelukast was a reasonable add-on therapy for management of presumed chronic asthma in addition to treatment being provided for the current infective exacerbation. Adequate safety-netting advice was provided. Possible reasons for the slow improvement in [Mrs A's] symptoms were appropriately investigated.

(ii) [Dr B] states in his response that he *advised [Mrs A] to continue the 80mg per day (2 x 20mg tablets twice daily) dosage of prednisone for a further five days and to then reduce this to 40mg per day (1 x 20mg tablets twice daily) for another five days as her condition was not improving.* This aspect of management is not evident from the clinical notes and should have been documented. Provided there was an intention to stop the steroid therapy within three weeks of commencement, and it was appropriate to do so in terms of [Mrs A's] condition, there was no need to discuss further tapering of the dose at this point. A review article on this topic[6] notes: *There is a paucity of evidence to support any particular regimen of glucocorticoid tapering. Short-term glucocorticoid therapy (up to three weeks) can usually be stopped without a taper … Short-term glucocorticoid therapy (up to three weeks), even if at a fairly high dose, can simply be stopped and need not be tapered.* However, I remain of the view that the dose of prednisone being prescribed currently (80mg daily) was not clinically appropriate.

6. [Mrs A's] chest X-ray was reported as normal. Blood count showed a mild neutrophil leukocytosis (consistent with infection, inflammation or steroid use) and CRP was normal. Sputum sample grew *Neisseria meningitidis* with the pathologist observation that this may reflect asymptomatic colonization or a potential agent of pneumonia. [Dr B] reviewed [Mrs A] with these results on 1 July 2019. Preceding nurse

[6] Furst D et Saag K. Glucocorticoid withdrawal. Uptodate. Literature review current through December 2019. www.uptodate.com

notes (same date) include: *Ask [Dr B] how long [Mrs A] should stay on 100mg Prednisone. Has been taking 100mg daily since last Thursday. She did not know when you wanted her to reduce the dose. I spoke with her on her cell phone this morning …* [Dr B's] notes include: *temp 37.0, so2 95%,* [nurse had recorded PEFR 150] *chest slightly better, still SOBOE; compliance good fluid intake good CXR normal CRP & FBC normal plan change to cephalosporins; discussed atypical pneumonia: review in 1 week or go to ED if not settling: happy with this*. There are prescriptions recorded for cephalexin, Panadeine and prednisone. A copy of the prescription records instructions for prednisone 20mg tabs as: *take 2 tabl max 5 days/day with 30 tablets prescribed and one repeat of 30 tablets.*

Comments

(i) [Dr B] states in his response that he *prescribed [Mrs A] 40mg of prednisone per day (1 x 20mg tablets twice daily), being the reduction programme dosage that he had advised [Mrs A] of at the 20 June and 25 June consultations, and a back-pocket script (1 repeat course) of prednisone in the event of emergencies and/or to last her through the winter.* [Dr B] denies ever instructing [Mrs A] to take 100mg prednisone daily, and he discussed this with her on 1 July 2019. His response includes: *At the consultation [of 1 July 2019], [Dr B] explained to [Mrs A] that she was never advised to take and/or prescribed 100mg of prednisone per day. He took extra care to ensure that she understood to stop taking this dosage and to start taking the reduced dosage of 40mg per day for 5 days, and then come in for another consultation to review her conditions. As stated above, [Dr B] prescribed [Mrs A] the reduced dose of 40mg per day and a back pocket script for the winter.* [Mrs A] did not attend for review until she saw [Dr C] on 18 July 2019 (see below).

(ii) There is no reference to the above conversation in the clinical notes, and the details of [Mrs A's] intended prednisone regime is not clear from the clinical notes or the prescription. These are deficiencies in clinical documentation. The quantity of prednisone 20mg tabs dispensed per the prescription dated 20 June 2019 was presumably 34 tablets as prescribed. Assuming [Mrs A] took the tablets initially as directed, by the time of the consultation on 25 June 2019 she would have used 20 tablets (2 stat then 4 daily for four days and 2 on the morning of the consultation). However, the nurse notes dated 25 June 2019 suggest [Mrs A] was taking 60mg (3 tablets) daily at the time of the consultation. In any case, it seems unlikely there would have been sufficient residual tablets to maintain the apparently intended dose of 80mg (4 tablets daily) for a further five days, and certainly insufficient to maintain a dose of 100mg (5 tablets daily) without a further prescription being provided on 25 June 2019, and I could find no reference to a further supply of prednisone being provided on this date. This lack of clarity is reflective of the poor contemporaneous documentation regarding changes to the initial intended prednisone regime. However, while I think many of my colleagues would have chosen to undertake a more gradual and clearly defined/described weaning regime for a patient who had been taking around 80mg prednisone daily for ten days, I am aware of the previously cited information regarding such withdrawal (reference 5). Noting [Dr B] had a

documented intention to review [Mrs A] in a week, and assuming he gave her clear instructions to reduce her dose of prednisone to 40mg daily for five days and then stop, it is not possible to say his management (in terms of the withdrawal advice) was inconsistent with some guidance. In any event, it appears [Mrs A] sought advice from a GP friend and did undertake a withdrawal programme of sorts as noted at the consultation on 18 July 2019 (see below). I am unable to say whether extending the course of prednisone beyond the apparently intended 16 days contributed to subsequent events.

(iii) It appears [Mrs A's] understanding of the advice provided to her regarding dose and duration of prednisone use differed to the advice [Dr B] states he provided to her. I feel this emphasizes the importance of providing clear written instructions when a medication regime is at all complicated and particularly when the advised regime changes from that provided initially (and therefore changes from the instructions on the medication label). The directions on the prednisone prescription dated 1 July 2019 appear somewhat unclear. If the intention was to provide a five day course of prednisone 40mg daily with a 'back-pocket' script of one course for use in emergencies (as stated in the response), this would be very reasonable management in terms of dose, duration and provision of emergency treatment. However, the script request dispensing of 30 tablets with one repeat which implies one course for completion of the current regime and up to five 'emergency' courses which could be regarded as excessive.

7. On 18 July 2019 [Mrs A] was seen by [Dr C] who noted she was currently taking 10mg prednisone and *was started on 1/12 ago up to 100mg for 2 weeks started coming off 13 days ago to 60mg for 4 days, then 40mgs for 3 days, then going down in 5mg since then now on 10mg for 3 days. finished antibiotics 6 days ago, saturday morning was shaking had a hot sweat, fatigue and shortness of breath at present, sleeping no different at present …* Physical assessment was unremarkable and [Dr C] attributed [Mrs A's] symptoms to steroid withdrawal which was managed by increasing the prednisone dose back up to 20mg daily then undertaking a more gradual withdrawal. Subsequent blood tests confirmed a degree of adrenal suppression most likely due to steroid use. [Dr C] referred [Mrs A] to [the endocrinologist] who diagnosed likely steroid withdrawal symptoms and steroid induced diabetes (see below) and concurred with [Dr C's] plan of more gradual steroid withdrawal.

Comment: [Mrs A's] management by [Dr C] was consistent with accepted practice.

8. Development of diabetes: It is well known that glucocorticoids such as prednisone have a powerful impact on glucose metabolism, contributing to hyperglycaemia and a predisposition to diabetes[7]. Risk factors for developing steroid induced diabetes relevant to [Mrs A] include high BMI, increasing age, prior impaired glucose regulation

[7] Morris D. Steroid-induced diabetes and hyperglycaemia. Part 1: mechanisms and risks. Diabetes & Primary Care. 2018;20(4): 151–153

(prediabetes) and dose, potency and duration of steroid therapy. There is reference in the notes to an increase in [Mrs A's] HbA1c from pre-diabetes levels of 44 and 43 mmol/mol (15 February 2018 and 24 August 2018) to a level consistent with a diagnosis of diabetes (63 mmol/mol recorded in notes 1 August 2019 — original lab result not on file). Clinic letter from [the endocrinologist] dated 19 August 2019 includes the comment: *I suspect [Mrs A] simply has steroid induced diabetes and when she comes off the prednisone I am hopeful that her HbA1c will return to the pre-diabetic range …* Based on this information, I think it is quite possible the development of [Mrs A's] diabetes is related to her steroid use (a recognized complication of steroid use) but it is not possible to exclude the possibility she had already reached an HbA1c threshold for diagnosis of diabetes (as progression of her pre-diabetes associated with persistent markedly increased BMI) before being prescribed steroids. The original plan for the steroid use was a short course (less than three weeks) albeit at high dose. A transient increase in average daily glucose levels with this therapy might have been expected with gradual return to pre-treatment levels following cessation of therapy.

Achilles tendon rupture: [Mrs A] ruptured her Achilles tendon on 8 September 2019 while on 10mg prednisone as part of her steroid reduction regime. An article on steroid use and risk of tendon rupture includes: *oral glucocorticoid (GC) therapy increases the risk of tendon rupture in a dose-response relationship. A single short-term high-dose GC treatment course may be sufficient transiently to increase the risk of tendon rupture*[8]. A review article on Achilles tendon rupture includes glucocorticoid and fluoroquinolone use as risk factors for tendon rupture and also older age and obesity. It is quite possible that steroid use contributed to [Mrs A's] tendon rupture, but given she had additional risk factors for such an injury it is not possible to quantify the degree to which her various risk factors contributed to development of the injury, or to state that had she not been prescribed steroids the injury would not have occurred. I note an ACC claim has been submitted for the injury and I presume this was accepted by ACC."

The following further advice was obtained from Dr Maplesden:

"I have reviewed the additional information obtained since provision of my original advice dated 28 January 2020.

1. Comment from [Mrs A]: In a further response dated 26 May 2020, [Mrs A] states again that [Dr B] prescribed her 100 mg prednisone daily without a reduction regime or advice, and that on two occasions he supplemented the prescribed quantity of steroids with additional tablets from his surgery but failed to record this.

2. [Dr B's] response per [lawyer]:

(i) Points 12–14: This issue was addressed in sections 4(ii) and 4(iii) of my original advice. I have not been presented with any asthma specific guidance which

[8] Spoendlin J et al. Oral and inhaled glucocorticoid use and risk of Achilles or biceps tendon rupture: a population-based case-control study. Ann Med. 2015;47(6):492–8

recommends steroid doses in excess of 50 mg per day. However, I acknowledge the more general advice on steroid use provided in MIMS and the Medsafe data sheet, which includes: *The dose should be individualised according to the severity of the disease and the patient's response rather than by age or body weight*, could reasonably be interpreted as mandating a higher dose than that recommended in the asthma guideline if the patient's condition was particularly severe or the patient failed to respond adequately to the maximum dosage recommended in the condition-specific guidance. However, it appears [Mrs A] was commenced on the higher than recommended dose from the outset (i.e. response not determined), and her condition was moderate rather than severe (per clinical observations). While I do not believe initiation of the steroid therapy at 80 mg per day was consistent with accepted practice, I acknowledge there are some circumstances where subsequent increase in dose might be considered appropriate and I therefore downgrade my criticism of [Dr B's] initial prescribing, as discussed in section 4(iii) of my original advice to mild to moderate from moderate.

(ii) I make no change in my comments on the standard and clarity of [Dr B's] clinical documentation. Accurate recording of changes in medication doses or advice is critical for patient safety. I regularly review clinical notes from a wide variety of rural and urban practices and I am not aware of a significant difference in overall standard of clinical documentation between such practices. I note [Dr B] has stated he did auscultate [Mrs A's] lungs at the time of his assessments of her and I cannot dispute this assertion.

(iii) Point 20: [Dr B's] prescribing of prednisone remains somewhat unclear to me despite this attempt at clarification, further complicated by [Mrs A's] assertion that [Dr B] supplemented the prescribed medication with additional supplies from his surgery. If it is assumed the pharmacist dispensed the number of tablets prescribed by [Dr B] (see [the medical centre] response), some discrepancies remain:

a. The prescription dated 20 June 2019 was for prednisone 20 mg tabs, *Take 2 tabl to start with, then two tabl twice/day (80 mg/d) for one week, then reduce to 20 mg twice/day (40 mg/d) for another week. Mitte: 34 tabs*. By my reckoning, to complete the prednisone course as directed would require 44 x 20 mg tablets leaving a shortfall of 10 tablets.

b. At review on 25 June 2019 [Dr B] states he instructed [Mrs A] to maintain her dose of prednisone at 80 mg daily (4x20 mg tabs) for a further five days before dropping to 40 mg (2 x 20 mg tabs) for a further week. There was no additional prescription for prednisone provided on this date. If [Mrs A] was following the current instructions and those provided with the previous prescription, and assuming 34 x 20 mg prednisone tablets had been dispensed on 20 June 2019, [Mrs A] would have only 12–14 tablets of prednisone remaining (depending on whether she took 40 mg or 80 mg as the total dose on 20 June 2019) — sufficient for only a further 3–4 days at 80 mg daily dose. This supply would not have lasted until the next review on 1 July 2019 at 80 mg/day and certainly not at 100 mg/day — the instruction [Mrs A] claims was provided and

which she followed. There needs to be some clarity over where the additional supply of prednisone which [Mrs A] apparently took over this period was sourced — specifically did [Dr B] provide [Mrs A] with additional prednisone from the practice supply and if he did, how much was supplied and why was this not documented (see section 6(ii) of my original advice). If the statements from [Mrs A] and practice nurse [RN D] (see below) are confirmed by [Dr B], I would be moderately critical that provision of prednisone from the practice supply was not recorded in the clinical notes and comment that the actual prescriptions can no longer be relied upon to give an accurate picture of the instructions provided to [Mrs A] regarding her prednisone regime.

c. The prescription for prednisone 20 mg tabs dated 1 July 2019 had unclear instructions as previously discussed (*take 2 tabl max 5 days/day* (30 tablets with one repeat of 30). According to [Dr B], the management plan at this point was for [Mrs A] to continue prednisone at 40 mg daily for one week (14 tabs total) as per the original plan and then stop. While the intended plan as described by [Dr B] was reasonable, the instructions on the prescription were unclear and not consistent with the plan.

(iv) The comments in section 6(iii) of my original advice remain unchanged.

(v) I have no further comments or additional alterations from my original advice.

3. Responses from [the medical centre]

(i) Statement from practice nurse [RN D] refers to [Dr B] providing [Mrs A] with additional prednisone 20 mg tabs from the practice supply on 25 June 2019, and [Mrs A] stating to [RN D] on that date that [Dr B] had told her to increase her dose of prednisone to 100 mg daily because she was 'fat'. It is unclear if [RN D] observed [Dr B] supplying prednisone 20 mg tabs to [Mrs A] or whether her statement is based on the conversation with [Mrs A]. [RN D] states she confirmed with [Mrs A] in a phone call on 1 July 2019 that she was still taking a dose of 100 mg prednisone daily and was unsure when and how to reduce the dose, and it was arranged for her to see [Dr B] for review. See my comment in 2(iii)b regarding provision of prednisone from the practice supply.

(ii) The practice has supplied dispensing records from [the] Pharmacy.

20 June 2019: 34 x 20 mg prednisone dispensed
2 July 2019: 60 x 20 mg prednisone dispensed

(iii) I am unable to see that any deficiency in [the medical centre] processes contributed to the deficiencies identified in [Mrs A's] care.

4. Statement from [Dr C]

There is no new information provided by [Dr C]. I feel [Dr C's] management of [Mrs A] was conscientious and consistent with accepted practice.

5. In conclusion, while I have downgraded my criticism of [Dr B's] prescribing of 80 mg prednisone to [Mrs A] from moderate to mild–moderate, I remain concerned at the deficiencies in clinical documentation, particularly those in relation to [Mrs A's] intended or actual prednisone regime. I remain of the view that there were deficiencies in [Dr B's] communication with [Mrs A] which resulted in her perceiving 100 mg prednisone daily was the appropriate instruction for her even if that was not the intended instruction. It must also be of significant concern that if [Dr B] did provide [Mrs A] with additional prednisone tablets from the practice supply he has been less than forthcoming about this aspect of the care he provided to her."

The following further advice was obtained from Dr Maplesden:

"I have reviewed the response from [Dr B] per his legal representative dated 10 July 2020.

Point 4.1: I accept the intention of [Dr B's] prescribing as noted in the response (40mg stat then 80mg BD for five days then 40mg BD for five days) but point out again that the prescribing recorded in the notes referred to 40mg stat (evidently supplied from practice stock) then 80mg BD for one week then 40mg BD for one week. It remains of concern that the clinical documentation was inaccurate.

Points 6–7: I accept it is common and accepted practice to provide a stat dose of prednisone from surgery stock (MPSO) in the clinical situation described. It is best practice to document direction for administration or provision of the medication if it is to be administered by the practice nurse. If the medication was administered under practice standing orders, this should have been documented. There is no reference in the [the medical centre] response or [Mrs A's] statements to staff other than [Dr B] administering [Mrs A] prednisone tablets from practice stock.

Point 8: My comment regarding [Dr B] being less than forthcoming regarding administration of prednisone from practice stock does not relate to his failure to document this action in the clinical notes but more to the omission of this action from his responses to HDC until the issue was specifically raised.

Point 9: I am unable to prefer either version of events but refer the reader back to point 2(iii)b of my advice dated 16 June 2019. It remains unclear from where [Mrs A] obtained the prednisone tablets on 25 June 2019 that sustained a dose of 80mg per day (as advised by [Dr B]) or 100mg per day (as stated by [Mrs A]) for a further five days between 25 June and 1 July 2019. If additional prednisone tablets were supplied by a staff member of [the medical centre] over this period and this was not documented, I would be mildly to moderately critical.

Point 14: as noted in my original advice dated 28 January 2020, while back pocket prescribing in the situation described is perfectly acceptable, on this occasion the written prescribing instructions, as recorded, were unclear and confusing.

Final comment: The additional information supplied does not influence me to change the content of my previous advice. I remain of the view that [Dr B's] clinical documentation was deficient to a moderate degree and this has contributed to it being impossible to determine from the clinical notes precisely what his intended and actual management was of [Mrs A] in relation to her steroid regime. I remain mildly to moderately critical of the steroid dosing regime [Dr B] states he advised for [Mrs A] and the reasons for this have been discussed previously. I recommend [Dr B] reflect on the clarity of his communication with [Mrs A] regarding her steroid regime such that she perceived his intention and advice was for her to take 100mg daily for the period noted in the complaint even if that was not his intention. I have no further comments or recommendations."