Podiatric Surgeon, Mr B

A Report by the

Deputy Health and Disability Commissioner

(Case 12HDC00347)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In 2007, Mrs A underwent ankle fusion surgery on her left ankle, which left her with a long-standing scar. She also sustained nerve damage to the left side of her left foot, which has not caused her any trouble.

2. In 2011, Mrs A developed problems with her right ankle, and subsequently consulted Mr B.

3. Mrs A first consulted Mr B on 2 August 2011, and was diagnosed with peroneal tendonitis of the right foot. At this consultation, Mr B injected Mrs A's right foot with local anaesthetic and Kenacort.

4. Mrs A's next consultation with Mr B was on 8 August 2011. The purpose of this appointment was to initiate orthotic therapy. Mr B also recorded that there was a discussion about treating the entrapment neuropathy in Mrs A's left ankle by steroid injection.

5. On 2 September 2011, Mrs A's orthotic devices were dispensed. It was noted that Mrs A had been pain free since receiving the Kenacort injection to her right foot.

6. On 18 October 2011, Mrs A returned for a six-week check of her orthotics, and Mr B administered a Kenacort injection with local anaesthetic to her left foot. Mrs A stated that Mr B did not inform her of the risks of tissue breakdown associated with having the Kenacort injection into her left ankle.

7. Mrs A said that within one week of the injection being administered, the old scar line on her left ankle became inflamed, and she had heightened sensitivity and pain. She was also experiencing problems with the orthotics dispensed by Mr B.

8. Mrs A said that at her next consultation, on 29 November 2011, she was reassured by Mr B that her left foot looked good, that she should expect pain in her left ankle, and that she did not require antibiotics. He also advised that it was normal to have difficulty wearing the orthotics, and she needed to get used to them.

9. On 8 December 2011, Mrs A consulted her general practitioner, Dr E. Dr E noted that she had an open wound on the left ankle at the site of the injection, along with a 6mm infected ulcer. Dr E cleaned and dressed the wound, and prescribed a course of flucloxacillin.

10. Over the next four months, Mrs A had her wound cleaned and dressed by the nurses at the medical clinic. On 10 January 2012, Dr F, a colleague of Dr E at the medical centre, referred Mrs A to a plastic surgeon, Mr C.

11. Mr C advised Mrs A that the steroid injection had caused her wound breakdown, and recommended surgical revision as the best treatment option.

12. On 26 January 2012, Mrs A underwent debridement and repair surgery to her left ankle, performed by Mr C. Unfortunately, the surgical wound broke down and Mrs A

continued to require follow-up care for her left ankle at the medical centre until March 2012.

13. Mrs A required new orthotics, which were dispensed to her by her previous podiatrist, and was also referred for surgery to repair the tendon and ligament in her right foot.

Commissioner's findings

14. Mr B failed in his duty to provide Mrs A with information on the risks and complications associated with a corticosteroid injection into her left foot. Accordingly, it was found that he breached Right 6(1)[1] of the Code of Health and Disability Services Consumers' Rights (the Code) by failing to provide Mrs A with information that a reasonable consumer in her circumstances would expect to receive.

15. As Mrs A did not receive sufficient information, she was not in a position to provide informed consent for the corticosteroid injection to her left ankle. Accordingly, Mr B breached Right 7(1)[2] of the Code.

16. Mrs A had a history of Type II diabetes and previous wound breakdown. These factors placed her at increased risk of tissue breakdown, and certain assessments should have been carried out and precautions taken in relation to the steroid injection in her left foot. In particular, Mr B should have considered the option of an X-ray, and should have performed a lower limb neuropathy and venous return assessment, carried out an early review of Mrs A's foot, and suggested prophylactic antibiotics following the injection and ensured that antibiotics were prescribed when Mrs A later complained of increased sensitivity in her foot and tenderness at the injection site.

17. By not carrying out these assessments and taking these precautions, Mr B failed to provide services with reasonable care and skill to Mrs A, and breached Right 4(1)[3] of the Code.

18. Mr B's documentation lacked sufficient detail, and did not provide an adequate clinical picture of Mrs A's medical history and the treatment he provided to her. His substandard clinical documentation was a breach of professional standards and, accordingly, Mr B breached Right 4(2)[4] of the Code.

[1] Right 6(1) states that "[e]very consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive".
[2] Right 7(1) states that "[s]ervices may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise".
[3] Right 4(1) states that "[e]very consumer has the right to have services provided with reasonable care and skill".
[4] Right 4(2) states that "[e]very consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards".

Complaint and investigation

19. On 16 March 2012, the Commissioner received a complaint from Mrs A about the services provided by Mr B. The following issue was identified for investigation:

- *Whether podiatric surgeon Mr B provided Mrs A with services of an appropriate standard.*

20. An investigation was commenced on 27 March 2013. This report is the opinion of Rose Wall, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

21. The parties directly involved in the investigation were:

Mrs A	Consumer
Mr B	Provider — podiatric surgeon

22. Information was reviewed from:

The Clinic	Treatment location
Mr C	Plastic surgeon
ACC Clinical Advisor	
The Podiatrists Board	

Also mentioned in this report:

Dr E	General practitioner
Dr F	General practitioner

23. Independent expert advice was obtained from a podiatric surgeon, Dr Robert Hermann (**Appendix A**).

Information gathered during investigation

Mr B

24. Mr B is registered with the Podiatrists Board, and his scopes of practice are listed as podiatrist and podiatric surgeon. Mr B studied basic medical science and zoology, and trained as a foot surgeon overseas. He is not registered as a medical practitioner in New Zealand. Mr B performs minimally invasive treatment for problems of the foot and ankle.

Mrs A

25. In 2007, Mrs A underwent ankle fusion surgery on her left ankle, which left her with a long-standing scar. Following that surgery, her wound broke down and took months to heal. As a result of the wound breakdown, Mrs A required two weeks of bed rest,

needed TENS therapy[5] to promote healing, and she also sustained nerve damage to the left side of her left foot, which she advised has not caused her any trouble.

26. Mrs A has Type II diabetes, and developed gestational diabetes during both her pregnancies. Throughout her second pregnancy she was on a high dose of insulin, but following the birth of her child she stopped taking insulin and returned to treatment with tablets.

27. In 2011, Mrs A developed problems with her right ankle, and subsequently consulted Mr B as to whether she required orthotics.

First consultation — 2 August 2011

28. Mrs A first consulted Mr B on 2 August 2011. The clinical notes from this consultation document that Mrs A had been experiencing painful lateral rear pain in her right foot for several weeks. Mr B also documented that she had undergone left foot or ankle surgery in 2007, which had been unsuccessful and caused nerve damage. Mr B advised HDC that he was aware that Mrs A had suffered previous wound breakdown following her surgery in 2007, and was aware of her diabetes. This information was not documented in the clinical notes. Mr B diagnosed Mrs A with peroneal tendonitis of the right foot, and injected her right foot with local anaesthetic and Kenacort.[6]

Second consultation — 8 August 2011

29. Mrs A's next consultation with Mr B was on 8 August. The purpose of this appointment was to initiate orthotic therapy. Mr B noted that Mrs A's tendons were "much better" and that casts were taken for the orthotics. Mr B advised that it is his normal practice to perform a gait analysis at this stage. However, this information is not documented in Mrs A's clinical notes.

30. Mr B also recorded in the clinical notes that Mrs A had "pins and needles, Tinel[7] sign now" in her left ankle. Mr B advised HDC that the pins and needles were sequelae to Mrs A's failed surgery in 2007, and that the Tinel's sign at the scar confirmed entrapment neuropathy.

31. The clinical records further note: "TREATMENT — disc poss inject/decompression Sural L in future." Mr B advised HDC that this involved him discussing the tissue-wasting effect of the Kenacort compared with the more invasive surgical option of decompressing the left sural nerve.8 Mr B said that he would have gone into more detail than usual, as Mrs A was a nurse, and that corticosteroid injection with needling of the scar is a standard conservative treatment for entrapment neuropathy.

[5] Transcutaneous electrical nerve stimulation for therapeutic purposes.
[6] A corticosteroid injection with marked anti-inflammatory action.
[7] Tinel's sign is a way to detect irritated nerves by lightly tapping over the nerve to elicit a sensation of tingling or "pins and needles".
[8] The sural nerve is a sensory nerve in the leg.

Third consultation — 2 September 2011

32. On 2 September, Mrs A's orthotic devices were dispensed. It is noted that she was to return in four weeks' time for a review of the orthotics, and that Mrs A had been pain free since receiving the Kenacort injection to her right foot. The clinical notes for this consultation also state: "poss inject Sural N.L".

Fourth consultation — 18 October 2011

33. Mr B reviewed Mrs A's orthotics at this consultation and documented: "[O]rths feel OK, but [right] orth just doesn't feel as right as the [left] orth, able to run once without tendon pain."

34. Mr B administered a Kenacort injection with local anaesthetic to Mrs A's left foot. Mrs A stated that she was not fully informed of the risks and complications associated with the corticosteroid injection, as Mr B did not warn her of the risk of the tissue in her left foot breaking down. Mrs A stated that, had she known about this risk factor, she would not have had the corticosteroid injection, as her left foot was not "giving [her] any trouble at all".

35. In contrast, Mr B advised HDC that he discussed the tissue-wasting effect of the injection prior to administering it. However, Mrs A is certain that she was not given this information.

36. According to Mrs A, she had explained to Mr B that her left foot was not causing her any trouble but he recommended the corticosteroid injection for her left ankle, as "studies have shown that it can reduce the nerve damage sensitivity". Mrs A said that she believed that information. Mr B advised HDC that he could not "imagine offering an injection to any patient if there wasn't a significant complaint", as he did not charge patients for injections. Mrs A's clinical notes state, "wants injection" in relation to the left sural nerve. Mr B also performed needling[9] of the proximal aspect of the scar on her left foot.

37. Mrs A advised that in addition to not being informed about the risks of the corticosteroid injection, Mr B did not assess the venous return[10] in her left foot, which she understood to involve pressing down on the toes and seeing how fast the blood returned, and nor did he suggest the need for an X-ray evaluation.

38. In response, Mr B confirmed that he did not assess Mrs A's venous return. He also confirmed that he did not perform an X-ray, as he did not consider it was indicated.

39. Mrs A's clinical notes record that she should return in six weeks' time to check on her orthotics. There is no mention of a follow-up appointment in relation to the injection administered to her left foot.

[9] Needling is a process used to relieve symptoms related to muscle trigger points and other painful conditions. It involves inserting a needle through the skin and into the muscle trigger point.
[10] An assessment of the length of time taken for skin colour to return to normal after pressure applied to a limb causes the area to blanche.

Fifth consultation — 29 November 2011

40. Mrs A advised that within one week of treatment, the old scar on her left foot was inflamed and she had definite heightened sensitivity and pain. On 29 November Mr B recorded that Mrs A was experiencing sensitivity in the sural nerve scar, and that the injection site was more tender. Mrs A said she was reassured by Mr B that her foot looked good, that she should expect pain in her left ankle, and that she did not require antibiotics.

41. Mr B advised that he had not considered initiating prophylactic antibiotics after administering the injection, and that he had never heard that antibiotics are indicated prophylactically post injection. Additionally, he said that he did not consider prescribing Mrs A antibiotics after the consultation on 29 November. Mr B said that sensitivity is not unusual, as the scar/entrapment neuropathy resolves with the Kenacort. He explained that there were no other cardinal signs of infection and, at six weeks post injection, there was little likelihood of an infection from the injection.

42. However, Mr B also advised HDC that it was no surprise that Mrs A "got an infection from the injection" because of the poor air quality at the Clinic.

Deterioration of left foot

43. Mrs A said that the scar tissue on her left foot broke down within two weeks of her appointment on 29 November 2011, and she developed a large open infected wound at the injection site on her left ankle. She said that the wound was increasing in size every day.

44. On 8 December 2011, Mrs A consulted her general practitioner Dr E, at the medical centre. Dr E noted that she had an open wound at the site of the injection, along with a 6mm infected ulcer. Dr E cleaned and dressed the wound, and prescribed a course of flucloxacillin.[11] He also completed an ACC treatment injury claim.

45. Mrs A had her wound dressed regularly by the nurses at the medical centre, but after several months she felt she should obtain a second opinion about management of the wound. Subsequently, she attended the Clinic, where she was seen by a doctor who noted that she was on a course of antibiotics and that her wound was being dry dressed. It was also noted that Mrs A had Type II diabetes. Swabs were taken from the wound, and Mrs A was prescribed a further course of flucloxacillin along with phenoxymethylpenicillin.[12]

46. The results of the swab indicated that the infection was a methicillin-susceptible[13] *Staphylococcus aureus*.[14]

[11] A semi-synthetic penicillin indicated for the treatment of some infections.
[12] A penicillin antibiotic.
[13] Cannot resist methicillin, which is an antibiotic of the penicillin class.
[14] A bacterium that causes infections in humans. It is frequently found in the respiratory tract and on the skin.

Referral to Mr C

47. On 10 January 2012, Dr F, a colleague of Dr E at the medical centre, referred Mrs A to a plastic surgeon, Mr C. Dr F noted the following in his referral letter:

> "Thank you for seeing [Mrs A], normally [Dr E's] patient, who agreed to have a steroid injection into lateral left heel to 'cure nerve issue' of some 8-years duration by [Mr B], podiatrist at [the] Clinic.
>
> The result is plain to see, with deep ulceration & significant tissue damage. We have been dressing as well as antibiotics, but [Mrs A] & my nurses tell me it's worsening."

48. On 11 January 2012, Mrs A saw Mr C. He completed an assessment report and treatment plan (ARTP), which noted the following:

> "[Mrs A] has developed a chronic ulcer on her left lateral ankle. This developed following a steroid injection by a Podiatrist in November 2011. History is long standing from a scar from ankle fusion surgery eight years prior. Following the steroid injection the scar became inflamed and then broke down. It has been infected on a couple of occasions in the past two months requiring antibiotics. I note that [Mrs A] is also Type II diabetic and she is concerned that the wound is getting larger rather than smaller. [Mrs A] herself is a Registered Nurse and between herself and the GP Practice Nurses the wound has shown no evidence of improvement."

49. Mr C noted that the steroid injection had caused Mrs A's wound breakdown and ulcer development, and described the wound as follows:

> "On examination she has a long mature scar on her left lateral ankle and in the mid portion close to the malleolus there is a wound approximately 8mm in greatest extent and is roughly triangular in shape. The wound is full thickness with mildly sloughy base but no evidence of infection currently. Adjacent skin has some laxity and with some manipulation of this would allow wound closure."

Surgery

50. Mr C advised Mrs A that surgical revision was the best option for her rather than conservative management, because of the steroid administration, her Type II diabetes, and the position of the wound in a poor healing part of the body. He explained in the ARTP that conservative management would require prolonged dressings, a further course of antibiotics if infection developed, as well as wound discomfort.

51. On 26 January 2012, Mrs A underwent debridement and repair surgery to her left ankle, performed by Mr C. Unfortunately, Mrs A developed wound dehiscence[15] and superficial infection following surgery, and continued to need follow-up care for her wound at the medical centre until March 2012.

[15] A common complication of surgical wounds, involving the breaking open of the wound.

Complaint to Mr B

52. Mrs A advised that she tried to communicate her concerns to Mr B to no avail. She explained that she sent a photo of her wound to Mr B, and he left a voicemail stating that she had missed an appointment and did not require plastic surgery.[16] She explained that she did not miss an appointment but had in fact cancelled it.

Referral to Podiatrists Board

53. In May 2012, HDC referred this complaint to the Podiatrists Board of New Zealand under s59(4) of the Health and Disability Commissioner Act 1994. The Podiatrists Board carried out a competence review of Mr B's practice in December 2012.

Response to Provisional Opinion

54. Mr B was given the opportunity to comment on my provisional decision. He advised that he did not have any comments.

Opinion: Breach — Mr B

Introduction

55. Mr B is a registered podiatrist and podiatric surgeon but is not registered as a medical practitioner in New Zealand. He performs minimally invasive treatment for problems of the foot and ankle. Mr B has a responsibility to ensure that the care he provides complies with legal requirements, including the Code.

Informed consent — Breach

56. Mrs A complained that she was not fully informed of the risks and complications associated with the corticosteroid injection into her left foot. In particular, she stated that she was not warned that tissue breakdown was a possible complication of the injection. Mrs A said that she would not have proceeded with the injection to her left foot if she had been given all the relevant information.

57. Mr B asserts that he discussed the tissue-wasting effect of the injection prior to administering it. In addition, he stated:

> "[Mrs A] had a significant amount of time (3 separate visits over a 2½ month period) to think about another injection, and [having a medical background] was well equipped to understand the possible complications when I explained them to her. I always explain these, and with a nurse, I would have gone into even more detail, because of her knowledge and interest."

[16] Exact dates unknown.

58. However, Mrs A is certain that no discussion about the possible complication of tissue breakdown in her left foot took place.

59. There is no documentation of a consent process during which possible complications associated with the use of a steroid injection were explained. In response to that issue, Mr B stated that he has "never seen a documented consent for a corticosteroid injection".

Conclusion

60. Baragwanath J stated in his decision in *Patient A v Nelson–Marlborough District Health Board*[17] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter (in that case, that a patient had been specifically informed of a particular risk by a doctor). In my view, this applies to all health professionals, who are obliged to keep appropriate patient records. Health professionals whose evidence is based solely on their subsequent recollections (in the absence of written records offering definitive proof) may find their evidence discounted.[18]

61. In light of the complete absence of documentation regarding the information conveyed to Mrs A, I accept her account that the risks and complications associated with a corticosteroid injection in her left foot were not explained to her.

62. Right 7(1) of the Code states that services may be provided to a consumer only if that consumer has made an informed choice and given informed consent. Without knowledge of the risks and complications associated with the corticosteroid injection, Mrs A could not give informed consent.

63. I note Mr B's comments that he has never seen a documented consent for a corticosteroid injection. Informed consent is a process where the provider discusses the treatment plan options, along with the associated risks and benefits, and also gives the consumer the opportunity to ask questions. Under the Code, a signed consent is not required for a corticosteroid injection; what *is* required is the provision of full and appropriate information, and documentation of this and any ensuing discussion.

64. I find that Mr B breached Right 6(1) of the Code for failing to provide Mrs A with information that a reasonable consumer, in her circumstances, would expect to receive, in particular, information on the risks and complications associated with a steroid injection in her left foot. As Mrs A did not receive sufficient information, she was not in a position to provide informed consent for the injection, and I therefore find that Mr B breached Right 7(1) of the Code.

Standard of care — Breach

Background

65. Mrs A first consulted Mr B on 2 August 2011. Mr B diagnosed peroneal tendonitis of the right foot and injected it with local anaesthetic and Kenacort. At a further

[17] *Patient A v Nelson–Marlborough District Health Board* (HC BLE CIV–2003–204–14, 15 March 2005).
[18] See Opinion 04HDC03530, available at www.hdc.org.nz.

consultation on 18 October 2011, Mr B diagnosed entrapment neuropathy in Mrs A's left ankle, and again administered a Kenacort injection with local anaesthetic.

66. Although my independent expert advisor, podiatric surgeon Dr Robert Hermann, considered that Mr B's use of steroid injections was reasonable and indicated in the management of tendonitis of the peroneal tendon and entrapment of the sural nerve, he was concerned about the pre-injection assessment and post-injection management in relation to the risk of tissue breakdown in Mrs A's left foot.

67. Dr Hermann advised:

> "The lateral aspect of the rear foot and ankle is known to be less well perfused with blood compared to the rest of the foot and ankle. This means that incisions or steroid injections made in the lateral aspect of the foot and ankle have a higher risk of wound breakdown. Although wound breakdowns after foot and ankle surgery are not common my personal experience is that the lateral foot and ankle is the most common area where they occur."

68. Dr Hermann noted that the administration of steroid into an area of soft tissue in which previous wound breakdown has occurred may increase the chance of breakdown even further. Mrs A's history of previous wound breakdown was therefore an important consideration, as it increased her risk of complications. Mr B was aware of the previous wound breakdown.

69. Mrs A also has a history of diabetes, and Dr Hermann advised that "[p]atients with a history of diabetes are also considered to be more at risk of healing complications such as wound breakdown compared to patients with no comorbidities". Mr B accepts that Mrs A advised him of her diabetic status, but stated that, in his view, this was not a contraindication to treatment.

Neuropathy and venous return

70. Dr Hermann noted that Mrs A's clinical notes referred to her having a varus position of the feet and ankles, which he considers is highly suggestive that she had bilateral cavus feet. Dr Hermann explained that, when assessing patients with this clinical presentation, it is necessary to rule out any involvement of neuropathy, as the presence of neuropathy can inhibit wound healing.

71. Dr Hermann noted that Mr B evaluated Mrs A's arterial supply to both feet, but there is no record of an assessment of the venous return or the neurological status, which could be used to rule out neuropathy. Dr Hermann explained that confirmation that a patient has no signs of lower limb neuropathy or venous insufficiency reduces the chances of lateral foot or ankle wound breakdown after any procedure.

72. Mr B advised that, in his view, Mrs A did not have any history, symptoms or signs of neuropathy other than the sural neuropathy in her left foot, but did acknowledge that he did not assess the venous return. He explained that he is not trained to assess it, as he is not a cardiothoracic surgeon. Mr B suggested that Dr Hermann might be confusing the term "venous return" with "subpapillary venous plexus filling time". However, Dr Hermann stated that "venous return" is well established in relation to the

lower limb. He explained that in this context, "venous return" can refer only to an assessment of the length of time taken for skin colour to return to normal after pressure applied to a limb causes the area to blanche. According to Dr Hermann, this can be termed "venous return", "superficial papillary filling time", "superficial venous plexus filling time" or "papillary filling time". He advised that the test is performed as part of a vascular assessment and indicates how well an area of the foot or ankle is perfused with arterial blood and drained of venous blood. Dr Hermann stated that such information is used to assess the healing ability of the anatomical region under examination.

73. In my view, in the circumstances of Mrs A's increased risk of tissue breakdown, it was suboptimal that Mr B did not assess and document the venous return in Mrs A's left foot prior to giving the steroid injection.

X-ray

Dr Hermann advised that there is no evidence of X-ray evaluation prior to the administration of the steroid injection. He said that Mrs A's history of diabetes and previous foot and/or ankle fusions with internal fixation screws in situ necessitated ruling out any latent osteomyelitis or failure of the internal fixation, which may have been evident on radiographic evaluation.

74. Mr B stated that an X-ray was not indicated. He said that, in his view, X-rays are harmful and expensive. However, in my opinion, Mr B should have considered the value of an X-ray and discussed with Mrs A the benefits, risks and costs of an X-ray evaluation. Mrs A was not given adequate information regarding the option of an X-ray, and was therefore unable to decide whether she wanted one.

Antibiotics

75. In Dr Hermann's view, prophylactic antibiotics were indicated following the steroid injection into Mrs A's left foot.

76. According to Dr Hermann, injected steroid medication provides potent anti-inflammatory effects at the site of administration. During the process of injecting the steroid there is a small chance of wound contamination. He explained that the anti-inflammatory effect may mask any developing infection. Dr Hermann further noted that the risk of infection is considered to be higher in patients with diabetes.

77. Dr Hermann advised that in Mrs A's case, adequate precautions to prevent infection and wound breakdown should have included a five- to seven-day course of oral antibiotics.

78. Dr Hermann stated that when Mr B reviewed Mrs A on 29 November 2011 and noticed an increase in sensitivity at the left sural nerve entrapment site, antibiotic treatment was also indicated at that point. Dr Hermann advised that Mr B's failure to prescribe antibiotics on 29 November 2011 was a moderate departure from the accepted standard of care.

79. Mr B advised that he did not consider initiating prophylactic antibiotics after administering the injection. He also stated that he is not aware that antibiotics are indicated prophylactically post injection.

80. Additionally, Mr B said that he did not consider prescribing Mrs A antibiotics on 29 November 2011. He stated that sensitivity is not unusual, as the scar/entrapment neuropathy resolves with the Kenacort. He explained that there were no other cardinal signs of infection and, at six weeks post injection, there was little likelihood of an infection from the injection.

81. I accept my expert's advice that, in these circumstances, where Mrs A was at a higher risk of tissue breakdown, she should have received prophylactic antibiotics, and that antibiotics were indicated on 29 November 2011 when Mrs A presented with increased sensitivity around the sural nerve and tenderness around the injection site. I consider that Mr B's care in this regard was suboptimal.

Follow-up

82. Dr Hermann is also critical of the standard of Mr B's follow-up of Mrs A following administration of the Kenacort injection to her left foot. Dr Hermann advised that due to Mrs A's previous history of wound breakdown, Mr B should have planned to review her a week after the steroid injection. I accept my expert's advice that Mr B should have carried out an earlier review of Mrs A's left foot.

Conclusions

83. I accept my expert's advice that the use of the injection was reasonable and indicated in the management of entrapment of the sural nerve. However, I am of the view that Mr B failed to provide services with reasonable skill and care to Mrs A in relation to the pre-injection assessment and post-injection management.

84. Dr Hermann advised that Mrs A was at increased risk of tissue breakdown because of her history of previous wound breakdown. Furthermore, Dr Hermann advised that steroid injections made in the lateral aspect of the foot and ankle have a higher risk of wound breakdown, and patients with a history of diabetes are also considered more at risk of healing complications such as wound breakdown, compared to patients with no co-morbidities. Mr B acknowledges that Mrs A told him about the previous wound breakdown and her diabetes. In my view, this information should have been an important consideration in the pre-injection planning, and appropriate assessments and precautions should have been taken to reduce the risk of infection at the injection site, and tissue breakdown post injection.

85. In addition, I consider that Mr B should have discussed the option of an X-ray with Mrs A and carried out a neuropathy and venous return assessment. I am also critical that Mr B allowed five and a half weeks to lapse post injection before reviewing Mrs A's foot, failed to provide for prophylactic antibiotics following the injection, and did not ensure that antibiotics were prescribed when Mrs A complained of an increase in sensitivity in her foot and tenderness at the injection site at her appointment on 29 November 2011.

86. By not carrying out these assessments or taking these precautions, I consider that Mr B failed to provide services with reasonable care and skill to Mrs A, and breached Right 4(1) of the Code.

Documentation — Breach

87. Mr B failed to document Mrs A's diabetic status, previous wound breakdown, an adequate history of Mrs A's past ankle surgery, the gait analysis carried out prior to providing orthotics, any pre-injection assessment, and the skin preparation process prior to injection administration.

88. Dr Hermann noted that Mr B did not record the skin preparation that occurred prior to the administration of the steroid injections on 2 August 2011 and 18 October 2011. Dr Hermann advised that the use of needling with the steroid injection is considered a traumatic procedure to the skin and underlying tissues, and aseptic techniques should be used when administering steroid injections in order to prevent infection, including application of an antiseptic solution such as Betadine or chlorhexidine. Dr Hermann advised that the use of aseptic techniques when administering steroid injections in order to prevent infection should be recorded in a patient's notes.

89. In response to Dr Hermann's comments, Mr B claimed that sterile skin preparation prior to corticosteroid injection is standard procedure, and is therefore not recorded. He said that it is the same as not recording that you have used a sterile needle. Dr Hermann advised that as Mrs A was at risk of developing infection, Mr B should have documented that adequate precautions had been taken.

90. Mrs A informed Mr B of her diabetic status, but there is no documented evidence of this in her clinical notes. Similarly, Mr B confirmed that he was aware of Mrs A's previous wound breakdown to her left foot. He advised HDC that he had injected her left foot because of the scars, adhesions and the nerve pain Mrs A was experiencing in that area. However, none of this information is documented in Mrs A's clinical notes.

91. When podiatrists write a prescription for orthotics and send the mould to the laboratory, they undertake a gait analysis. Mr B stated that it is his normal standard of practice always to perform a gait analysis. He stated that if this analysis is supportive of the diagnosis it is unremarkable. However, there is no reference to a gait analysis in Mrs A's clinical notes.

Conclusion

92. Failure to maintain an adequate standard of clinical documentation is a breach of professional standards. The Podiatrists Board's Ethical Principles and Standards of Conduct require a podiatrist to ensure that comprehensive, accurate and up-to-date clinical records are kept. I consider that clinical documentation should note a patient's history, a detailed description of the assessment/treatment performed, relevant findings, decisions made, and information given to patients.

93. In my view, Mr B's documentation lacked sufficient detail and did not provide an adequate clinical picture of Mrs A's medical history and the treatment he provided to her.

94. In my opinion, Mr B's substandard clinical documentation is a breach of professional standards and, accordingly, Mr B breached Right 4(2) of the Code.

Recommendations

95. I recommend that Mr B apologise to Mrs A. The apology is to be sent to HDC within three weeks of the date of this report being issued for forwarding to Mrs A.

96. I also recommend that Mr B undertake the following:

- Attend training courses, as recommended by the Podiatrists Board, on communication with patients, record-keeping, and obtaining patients' medical histories, including previous surgery and the outcome.
- Attend training courses, as recommended by the Podiatrists Board, on assessment and clinical management of at risk patients, including patients with co-morbidities.
- Arrange an independent audit of his documentation.

97. Mr B is to provide HDC with evidence of compliance with these recommendations within three months of the date of this report being issued.

Follow-up actions

98.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Podiatrists Board of New Zealand, and it will be advised of Mr B's name.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the DHB, and it will be advised of Mr B's name.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent podiatric advice to the Commissioner

The following expert advice was obtained from Dr Robert Hermann:

"9 July 2012

Re — Complaint: [Mr B] — Your ref 12/00347

This letter is in response to your email dated 3 July 2012.

I have been asked to provide advice for the Commissioner to determine whether from the information supplied there are concerns about the care provided by [Mr B] to [Mrs A] which requires formal investigation.

The material reviewed for this advice includes the following:

1. [Mrs A's] complaint, received [date]
2. [Mr B's] response to HDC, received 8 June 2012
3. Clinical notes from [the] Clinic
4. Clinical notes from general practitioner [Dr E]; and
5. Clinical notes from plastic and reconstruction surgeon [Mr C].

Clinical Management

[Mr B's] clinical notes indicate [Mrs A] sought his consultation on 2 August 2011 complaining of a painful right rear foot of several weeks. He notes that she underwent left foot or ankle surgery in 2007 but this was unsuccessful and there was nerve damage present.

[Mr B] evaluated the patient's arterial supply to both feet but there is no record of assessing the venous return or the neurological status. [Mr B] diagnosed peroneal tendonitis and injected the patient with Kenacort (Triamcinolone Acetonide) and local anaesthetic. The patient was then reviewed 6 days later on 8 August 2011 to initiate orthotic therapy. [Mr B] recorded an improvement in her right tendon pain and clinical signs of entrapment of the left Sural nerve with a Tinel's sign evident. Discussion about possible steroid injection and decompression of the left sural nerve occurred at that consultation.

On 2 September 2011 the patient's orthotic devices were dispensed and further discussion about a steroid injection to the left entrapped Sural nerve occurred.

10 weeks after the initial consultation (18 October 2011) the patient was reviewed by [Mr B] who noted some improvement in her right tendonitis but the orthotic devices were still somewhat uncomfortable. He administered Kenacort (Triamcinolone Acetonide) with local anaesthetic to the left Sural nerve and performed needling of the proximal aspect of the scar. He advised the patient to return in 6 weeks to check her orthotic devices.

Discomfort around the Sural nerve injection site was noted on 29 November 2011. [Mr B] was unable to provide further management of the patient as she developed a wound breakdown some time after her consultation on 29 November 2011. [Mrs A] had local wound care with a number of courses of antibiotics under the management of [Dr E] ([the medical centre]) who noted on 8 December 2011 that an internal fixation screw was still in the left ankle from previous surgery. [Dr F] ([the medical centre]) also provided care and referred the patient to [Mr C] (Plastic surgeon) for surgical debridement and wound closure.

In [Mr C's] assessment report and treatment plan dated 11 January 2012 he notes 'history is long standing from a scar from an ankle fusion surgery 8 years prior'. He further notes a wound over the lateral malleolus at the mid portion of a longitudinal scar. Due to [Mrs A's] type II diabetes and the poor healing known to occur at this particular aspect of the lower limb, [Mr C] decided to debride the area and perform a primary closure. The surgery was performed on 26 January 2012. I note that adrenalin was used within the local anaesthetic for vasoconstriction. 6 days later in a letter to [Dr E], [Mr C] reports a wound dehiscence and superficial infection following debridement and closure of the wound.

[Mr C] notes in a letter to [Dr E] on 8 February 2012 that there is improvement in [Mrs A's] wound. However the clinical notes for [Dr E] show that a month after the surgery (20 February 2012) on 26 January the wound had not healed. Although the remainder of [Dr E's] notes from the medical centre extend to 30 May 2012 there is no definitive statement about the state of the left foot wound.

Assessment

After reviewing all of the material supplied it is evident that [Mrs A] is a type II (non insulin using) diabetic. The records indicate that her right ankle had been fused previously and it is likely that the same or similar procedure was performed on the left side in 2007 to correct the cavus (high arch) foot deformity. [Dr E's] record of a screw in the left ankle supports the fact that left foot or ankle surgery had been performed. I will refer to this fact later in this letter.

The reference to a varus position of the feet and ankles is highly suggestive that this patient had bilateral cavus feet. It is necessary when assessing patients with this clinical presentation to rule out any involvement of neuropathy. This is because the presence of neuropathy can inhibit wound healing.

[Mr B's] clinical notes show no record of a neurological assessment of the lower limbs which could be used to rule out neuropathy. I also find no record of assessment of the patient's venous return. Confirmation that a patient has no signs of lower limb neuropathy or venous insufficiency reduces the chances of lateral foot or ankle wound break down after any procedure. Further there is no documented consent process in which possible complications associated with the use of a steroid injection were explained. There is also no record of skin preparation prior to steroid injections given on 2 August 2011 and 18 October 2011.

[Mr B] administered the steroid injection to the right ankle on 2 August 2011 and reviewed the patient 6 days later on 8 August 2011. However after administering the steroid injection to the left ankle on 28 October 2011 he did not review the patient for a further 5½ weeks. Although there is no report of a wound breakdown it is noted in [Mr B's] records that the site of the injection was uncomfortable. There is a concern that the patient was not followed up a week after the steroid injection to the left ankle as occurred on the right side.

[Mrs A] would be classified as an immunosuppressed patient due to her diabetes. That is to say her ability to fight infection would be lower compared to a non diabetic patient. The use of needling with the steroid injection is considered a traumatic procedure to the skin and underlying tissues. Any such procedure should be preceded by the application of an appropriate skin preparation such as Betadine or Chlorhexidine. Enough time should elapse for the antiseptic to decrease skin flora prior to injection in order to prevent infection. There is no documentation to support that this step was taken in either administration of steroid.

In addition to the application of apposite skin antiseptic the use of antibiotics prophylactically post injection was also indicated. Certainly when [Mr B] reviewed the patient on 29 November 2011 and noticed an increase in sensitivity at the left sural nerve entrapment site there may have been an indication to commence antibiotic treatment at that point in time.

Finally, I can find no evidence of plain X-ray evaluation of the patient prior to steroid injection. The patient's history of diabetes and previous foot and/or ankle fusions with internal fixation screws in situ, necessitate ruling out any latent osteomyelitis (bone infection) which may have been evident on radiographic evaluation. Without knowing if [Mrs A] developed any wound breakdown after her 2007 surgery the possibility of an underlying bone infection cannot be ruled out as a possible cause of her wound breakdown after the steroid injection.

… [Information deleted as not relevant to this case.]

It is important to realise that even under the care of a plastic surgeon the wound broke down again within the first 6 days after surgery. It would appear from the records that the wound did not heal until late in February 2012. These findings suggest that there is an underlying cause for the wound breakdown. This can range from an undiagnosed neuropathy as mentioned earlier in this report. In addition there may be a latent focus of infection within the bone (osteomyelitis) which has been undiagnosed. Further the internal fixation screws may have been a cause of irritation.

Summary

My concerns about the care provided by [Mr B] which I believe require further investigation are listed below:

1. No documented evaluation of the patient's lower limb venous return and lower limb neurological status.

2. No documented discussion about possible complications and/or consent process.
3. No documented use of skin preparation before administration of the steroid injection.
4. No documented assessment of bony pathology using pre injection plain X-rays.
5. Lack of antibiotic management post administration of steroid injection and needling.
6. No antibiotic management after the recognition of pain at the site of the injection 29 November 2011.

Recommendation

While I agree with the initiation of management using orthotic therapy and steroid injections, I am concerned about the pre injection assessment, preparation and post injection management regarding recognising developing infection and wound breakdown. Due to these findings I would recommend further investigation.

If I can be of further assistance in regard to this matter please contact me.

Yours faithfully

Dr Rob Hermann (Podiatric surgeon)"

Further advice

Further expert advice was obtained from Dr Robert Hermann as follows:

"**Expert Advice to the Health and Disability Commissioner provided by Dr Rob Hermann (Podiatric surgeon)**

13 August 2013

Introduction

I have been asked to provide an opinion to the Commissioner on case number 12/00347 regarding care provided by [Mr B] (podiatric surgeon) to [Mrs A]. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I am a podiatric surgeon and qualified for Fellowship of the Australasian College of Podiatric Surgeons (ACPS) in 1991. The ACPS Fellowship is recognised by the Podiatry Board of Australia (PBA) as a qualification for the purposes of registration as a specialist surgeon. I am also endorsed by the PBA to prescribe from a national list of s3, 4 and 8 medicines according to State legislature in the practice of podiatric surgery.

I qualified as a podiatrist in 1986 with an Advanced Diploma in Science (Podiatry) from the University of South Australia. My experience includes 9 years in general podiatry and 22 years in reconstructive podiatric foot and ankle surgery.

I received a Graduate Certificate in Research Methodologies from the University of South Australia in 2005. Currently I am completing a professional doctorate at the Queensland University of Technology. Due for completion in late 2014 this research will see the development of the first foot and ankle web based surgical audit tool. The objective of this research is to improve the quality and safety of foot and ankle surgery provided in Australia.

The referral instructions provided are:
Provide independent advice about whether [Mr B] provided an appropriate standard of care to [Mrs A].
Complaint

[Mrs A] complained that:

1. The cortisone injection in her left ankle was unnecessary and inappropriate;
2. [Mr B] did not provide adequate information (including the risk that the tissue could break down) in relation to the injection;
3. [Mr B] did not respond appropriately in light of increased sensitivity and pain at the injection site; and
4. She was not able to use the orthotics which [Mr B] had arranged for her and that these caused tendon and ligament damage to her right foot.

Please review your preliminary advice provided and amend as necessary in light of further information provided:

1. Report dated 9 July 2012
2. Email dated 10 July 2012
3. Phone call 3 July 2012
4. Email dated 31 October 2012.

List of documents provided

Documents emailed on 3 July 2012:

1. [Mrs A's] complaint, received [date];
2. [Mr B's] response to HDC, received 8 June 2012;
3. Clinical notes from [the] Clinic;
4. Clinical notes from general practitioner [Dr E]; and
5. Clinical notes from plastic and reconstruction surgeon [Mr C].

Further documentation emailed on 25 June 2013:

1. Email from [Mrs A], 29 March 2012;
2. File note of phone call with [Mrs A], 1 May 2012;
3. File note of phone call with [Mrs A], I July 2012;
4. HDC letter to [Mr B], dated 17 July 2012;
5. Response from [Mr B], dated 12 September 2012;
6. File note of phone call with [Mrs A], 2 October 2012;

7. Letter from [Mr B], dated 11 October 2012;
8. Email from [Mrs A], dated 29 November 2012;
9. Response from [Mr B], dated 6 December 2012;
10. Notification of investigation letters, dated 27 March 2013; and
11. Response from [Mr B], dated 4 May 2013.

Please comment generally on the standard and appropriateness of care that [Mr B] provided to [Mrs A].

If not covered above, please answer the following questions, with reasons for your views.

In relation to the Kenacort injections on 2 August 2011 and 18 October 2011:

1. Were the injections indicated in light of [Mrs A's] presentation?
2. Please detail the risks associated with this kind of procedure.
3. Please comment on the adequacy of the precautions/steps taken prior to administering the injection.
4. Was [Mrs A's] history of wound breakdown a relevant consideration? If so why?
5. What Information should [Mr B] have provided to [Mrs A] prior to administering the injections?
6. The adequacy of care and reviews following the administration of the injections.

In relation to the orthotics provided by [Mr B]:

1. Please comment on the adequacy of care provided.
2. Please advise if you require further in formation in order to comment.

If in answering any of the above questions, you believe that [Mr B] did not provide an appropriate standard of care, please indicate the severity of his departure from the standard.

Some experts approach the above question by considering whether the provider's peers would view the conduct with mild, moderate or severe disapproval.

Are there any aspects of the care provided by [Mr B] that you consider warrant comment?

Podiatric Surgery Expert Advice
In preparing this advice I have read the Guidelines for Independent Advisors document supplied to me.

1. Were the injections indicated in light of [Mrs A's] presentation?

The use of steroid injections is reasonable and indicated in the management of tendonitis of the peroneal tendon and entrapment of the Sural nerve.

2. Please detail the risks associated with this kind of procedure.

The following comments are limited to the risks of local effects of steroids injected into soft tissue.

A steroid induced inflammatory flare can occur within the first 24 to 48 hours after administration of the injection. This is a reaction to crystals that may form within the injected tissues. It is usually short term and managed with anti-inflammatory drugs and or ice packs.

Injected steroid medication provides potent anti-inflammatory effects at the site of administration. This means steroid injections can be used to reduce inflammation in soft tissues (e.g. nerve, muscle, tendon, capsule & ligaments) and within joints. However during the process of injecting steroid there is always a very small chance of wound contamination. In the unlikely event that infection does occur it is likely to be masked by the anti-inflammatory effect of the injected steroid. For this reason infection is a possible risk of steroid injections. The risk of infection is considered to be higher in patients who have any form of immunosuppression such as diabetes.

The administration of steroid into an area of soft tissue in which previous wound breakdown has occurred may increase the chance of further breakdown.

The above risks should prompt a practitioner to review a patient who has been injected with steroid a week after administration.

3. Please comment on the adequacy of the precautions/steps taken prior to administering the injection.

Aseptic technique should be used when administering steroid injections in order to prevent infection. This includes application of an antiseptic solution such as chlorhexadine or betadine to the skin and allowing it to dry for 3 to 5 minutes prior to injection. I note in [Mr B's] letter dated 12 September 2012 he reports that chlorhexadine was applied prior to the steroid injections but it was not recorded as it is a standard procedure. I can only respond to [Mr B's] comments by stating my standard procedure is to record the application of antiseptic solution at all times prior to administering injections or performing surgery and to record such activity in the case notes. If [Mr B] did apply chlorhexadine prior to administering the steroid injections then adequate precautions to prevent infection were taken. If he did not apply chlorhexadine then adequate precautions were not taken. In any case such activity should be recorded in the case notes.

If [Mr B] was aware that [Mrs A] had previously developed wound breakdown after her left ankle surgery adequate precautions should have included a 5–7 day course of oral antibiotics. In addition a plan to review the patient a week after the steroid injection should have occurred. On the other hand if [Mr B] was unaware of the previous history of wound breakdown it would be difficult to expect him to prescribe antibiotics or review the patient earlier than 5 weeks after the injection.

4. Was [Mrs A's] history of wound breakdown a relevant consideration? If so why?

[Mrs A's] history of wound breakdown was a relevant consideration for the following reasons.

The lateral aspect of the rear foot and ankle is known to be less well perfused with blood compared to the rest of the foot and ankle. This means that incisions or steroid injections made in the lateral aspect of the foot and ankle have a higher risk of wound breakdown. Although wound breakdowns after foot and ankle surgery are not common my personal experience is that the lateral foot and ankle is the most common area where they occur. Patients with a history of diabetes are also considered more at risk of healing complications such as wound breakdown compared to patients with no comorbidities. The risks of steroid injections include wound breakdown as mentioned above in point 1. These causes of wound breakdown were also noted by [Mr C] (plastic surgeon) in his assessment report and treatment plan dated 11 January 2012.

5. What information should [Mr B] have provided to [Mrs A] prior to administering the injections?

Any patient who has a steroid injection should be informed to contact the consulting practitioner if there is inflammation and/or pain that does not settle 24 to 48 hours after the injection and before the next consultation.

6. The adequacy of care and reviews following the administration of the injections.

As mentioned in point 3 if [Mr B] was aware of the previous history of wound breakdown the patient should have been reviewed at 1 week after the injection. However as [Mr B] noted on 29 November 2011, the patient presented with increased sensitivity around the sural nerve and tenderness around the injection site. Prescription of antibiotics at this time was indicated for the reasons listed in point 2.

In relation to the orthotics provided by [Mr B]:

1. Please comment on the adequacy of care provided.

The case notes do not provide much detail regarding this aspect of the care given by [Mr B]. It is certainly reasonable to treat peroneal tendonitis with orthotic therapy. I also note that [Mr B] was aware of irritation caused by the right orthotic on 18 October 2011. I assume that the orthotic devices were adjusted so that they were more comfortable but cannot ascertain this without more information.

2. Please advise if you require further in formation in order to comment.

To comment about this aspect of the care provided by [Mr B] is difficult without examining the patient and the orthotic devices prescribed. I would need to at least review the case notes, orthotic devices, any clinical pictures and imaging (plain X-rays C.Ts etc).

Additional comments

As explained in my previous report [Mrs A] had a history of previous left ankle surgery. Internal fixation still in situ was noted by [Dr E] ([the medical centre]) on

8 December 2011. Her history also included type 2 diabetes and wound breakdown following surgery. These facts are all reasons to order plain X-rays as part of an assessment prior to any intervention. Such assessment can rule out the presence of infection or failure of internal fixation. This omission in pre-injection assessment is important as both of these findings can cause wound breakdown.

My previous report also refers to no documentation of venous return assessment prior to the steroid injection. I note in a letter from [Mr B] dated 12 September 2012 he states that I may be confused about what 'venous return' means. He cites an article about central venous pressure, 'Assessment of venous return curve and mean systemic filling pressure in postoperative cardiac surgical patients, Maas et al 2009'. This is to suggest I was referring to venous return in the context of cardiac surgery. In the matter of [Mrs A] I believe the context is well established as referring to the lower limb. In this context venous return can only refer to an assessment of the length of time taken for normal skin colour to return to normal after pressure applied to a limb causes the area to blanche. This can be termed venous return, superficial papillary filling time, superficial venous plexus filling time or papillary filling time. The test is performed as part of a vascular assessment and indicates how well an area of the foot or ankle is perfused with arterial blood and drained of venous blood.

Such information is used to assess the healing ability of the anatomical region under examination. It is reasonable to document the assessment of venous return cases such as [Mrs A].

The lack of documentation of the following indicates inadequate record keeping:

1. Evaluation of the patient's lower limb venous return and lower limb neurological status;
2. Possible complications and/or consent process;
3. Skin preparation before administration of the steroid injection;
4. Assessment [of] any pathology using pre injection plain X-rays.

Findings
In my view there was a mild departure from the standard of care by [Mr B] in his management of [Mrs A] by the lack of documentation of:

1. Evaluation of the patient's lower limb venous return and lower limb neurological status;
2. Possible complications and/or consent process;
3. Skin preparation before administration of the steroid injection;
4. Assessment [of] any pathology using pre injection plain X-rays.

The lack of review at 1 week post left ankle steroid injection, prescription of antibiotics at the time of injection and/or on 29 November 2011 represent a moderate departure from the standard of care in my view.
Please inform me if you require further advice.

Yours faithfully
Dr Rob Hermann (Podiatric surgeon)"