Acupuncturist, Ms B

Chinese Medicine Clinic

A Report by the

Deputy Health and Disability Commissioner

(Case 15HDC01325)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 21 August 2015, Mr A visited a Chinese medicine clinic (the clinic) to receive treatment, which included acupuncture, for an injury to his left shoulder. The treatment was provided by acupuncturist Ms B.

2. On 26 August 2015, Mr A returned to the clinic for further treatment in relation to his shoulder injury. During that treatment Ms B inserted an acupuncture needle into Mr A's abdomen. Ms B left the needle in Mr A's abdomen to prolong the effects of treatment for Mr A and relieve his symptoms for a longer period. However, Ms B did not discuss this aspect of the treatment with Mr A or obtain his consent. Mr A discovered and removed the needle the following morning.

Findings

3. Ms B did not provide Mr A with information about her plan to leave the acupuncture needle in his abdomen, including information on the risks and side effects, and how to remove the needle and dispose of it correctly. This is information that a reasonable consumer would expect to receive in the circumstances and, accordingly, Ms B breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

4. Without this information, Mr A was not in a position to make an informed choice and provide informed consent for the needle to be left in his abdomen, and it follows that Ms B also breached Right 7(1) of the Code.

5. The clinic did not breach the Code.

Recommendations

6. I recommend that Ms B undertake further education and training on informed consent, review her practice in light of this report, and provide a written apology to Mr A for her breach of the Code.

7. I recommend that the clinic confirm the implementation of its new documentation policy and conduct an audit on the effectiveness of this policy. I also recommend that the clinic arrange training on its new documentation and informed consent policies for all practitioners at the clinic.

Complaint and investigation

8. The Commissioner received a complaint from Mr A about the services provided by Ms B at the clinic. The following issues were identified for investigation:

- *Whether Ms B provided Mr A with an appropriate standard of care in August 2015, including the adequacy and appropriateness of the information provided to Mr A.*

- *Whether the clinic provided Mr A with an appropriate standard of care in August 2015.*

9. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

10. An investigation was commenced on 9 June 2016.

11. Information was reviewed from:

Mr A	Consumer
Ms B	Provider, acupuncturist
The clinic	Provider

12. Independent expert advice was obtained from acupuncturist Ms Tracey Bourner (**Appendix A**).

Information gathered during investigation

Background

13. Mr A, aged 59 years at the time of these events, injured his left shoulder in 2015. Mr A presented to his general practitioner (GP), who referred him for an ultrasound scan. The ultrasound scan identified that Mr A had a damaged rotator cuff,[1] and the radiologist recommended conservative treatment to help alleviate the pain.

14. Mr A decided to go to the clinic because it was near the medical centre where his GP worked.[2] Mr A contacted the clinic and requested treatment for his shoulder injury. Subsequently an appointment with acupuncturist Ms B was scheduled for 21 August 2015.

The clinic

15. The services provided by the clinic include acupuncture and massage. Ms B is an acupuncturist at the clinic, and is a registered member of Acupuncture New Zealand.

Treatment provided to Mr A

21 August 2015

16. On 21 August 2015, Mr A presented to the clinic for treatment.

17. Ms B assessed Mr A and recorded "shoulder pain 2–3/10" and that his biceps felt sore and tight. Ms B examined Mr A and recorded Mr A's diagnosis as a sprain to his upper arm and shoulder. Ms B documented that Mr A would receive acupuncture to

[1] A group of muscles and tendons that surround the shoulder.
[2] The GP did not refer Mr A to the clinic for treatment.

the Hua Rou Men point[3] and three ashi points[4] on his shoulder, tui na massage,[5] and Teding Diancibo Pu[6] infrared heating.

18. Ms B also completed a separate form entitled "ACC treatment recorder". On the form, Ms B recorded that Mr A would receive treatment to his left shoulder for the duration of 60 minutes.

19. Ms B also provided Mr A with a patient informed consent form, which stated:

> "I acknowledge: That I have read and understood this document and that the practitioners have also verbally explained to me the procedures and possible side effects prior to any treatment being undertaken."

20. The patient informed consent form listed the procedures provided by the clinic. This included "the insertion of pre-sterilized single use stainless needles into various acupuncture points on the body". The form also listed "[t]he application of pressure and/or massage to any acupuncture point or other body areas", and the use of Teding Diancibo Pu.

21. The form also outlined the "[p]ossible reactions and side effects as a result of receiving acupuncture treatment/[traditional Chinese medicine] treatment" as:

> "
> - Stuck or bent needles, broken needles, bruising, haematoma (bleeding) and infection as a result of acupuncture.
> - It is very rare, but possible, that one can faint during the acupuncture procedure.
> - Sometimes mild pain may be experienced by the patient, or feeling of discomfort. If so please inform the practitioner immediately.
> - Burning, scarring or blistering of the skin as a result of … [Teding Diancibo Pu] lamp …"

22. Mr A signed the form, and Ms B carried out the treatment.

23. At the completion of the treatment, Ms B removed the needles and Mr A rebooked for another treatment on 26 August 2015.

26 August 2015

24. At 3pm on 26 August 2015, Mr A attended his second appointment with Ms B for further acupuncture treatment. Ms B told HDC: "[Mr A] reported that his shoulder can now abduct to 110 degrees after treatment but still sore."

25. On the "ACC treatment recorder" form used for the appointment on 21 August 2015, Ms B recorded that Mr A would receive treatment to his shoulder for the duration of

[3] An acupuncture point located on the stomach.
[4] An acupuncture point located through pain on palpation.
[5] A form of Chinese massage.
[6] An infrared lamp.

60 minutes. Ms B also documented that the acupuncture point utilised during the treatment would be the Hua Rou Men point, and that tui na massage would also be provided.

26. Ms B told HDC that Mr A returned to the clinic and stated that his shoulder movement had improved, but that his shoulder was still sore. Ms B stated that she assessed his shoulder and determined that he could abduct to 110 degrees. Ms B also stated that she palpated around Mr A's shoulder, which identified pain.

27. Mr A told HDC that he recalls Ms B describing the treatment to him, and said that he agreed to the treatment she proposed. The information provided to Mr A, and any discussions Ms B had with Mr A in relation to treatment, are not documented.

28. Ms B inserted a single needle into the Hua Rou Men acupuncture point in Mr A's abdomen. Ms B stated that the objective of this treatment was to reduce pain and improve the range of motion of Mr A's shoulder. Ms B told HDC that no needles were placed into Mr A's shoulder during this appointment.

29. Mr A recalls that the treatment involved him lying on his right-hand side for approximately 35 to 50 minutes, with his left shoulder exposed, and that "[u]p to four needles were inserted around the rear upper left shoulder blade to arm joint, and one needle [was] inserted into the belly button area".

30. Mr A said that while the needles were in place, he was left in the cubicle while Ms B was dealing with other customers in the reception area and over the telephone, and treating another client in a different room.

31. Mr A told HDC that at the completion of the treatment, Ms B returned to the cubicle and removed the needles. He said she then told him to put his shirt back on and informed him that the treatment was over for the day. Mr A then left the clinic.

32. Ms B told HDC that she intentionally left a needle in Mr A's abdomen. This was to prolong the effects of the treatment and to relieve symptoms for a longer period. She said she intended to get Mr A to come back to the clinic one or two days later for a follow-up treatment when she would remove the needle. Ms B told HDC that she secured the needle with surgical tape, and that this is the normal practice of the clinic to prevent a needle from falling out.

33. Mr A told HDC: "At no time was any information given about needles being left in or it being taped."

34. Ms B told HDC that it is her usual practice to leave needles in many of her patients. She stated that she decided to utilise the needle retention method to prolong the effects of treatment for Mr A and relieve his symptoms for a longer period. Ms B acknowledged that she failed to inform Mr A of her intention to leave the needle in his abdomen. Ms B told HDC that the reason she did not tell Mr A of her intention to leave a needle in his abdomen was that she received an abnormal number of telephone calls from other patients and was distracted.

35. Ms B did not document any details regarding the needle being left in Mr A's abdomen, including whether she taped it.

Discovery of the needle

36. The following morning, on 27 August 2015, Mr A discovered a needle still lodged in his abdomen. Mr A told HDC:

> "[Following the treatment] I dressed and went home without noticing [the needle] until the next morning when I was preparing to go to work. I believe the springy nature of the needle forced it to lay flat against the stomach by my clothing and blankets. Therefore, due to sheer good luck the needle didn't penetrate any further or cause any pain. When I removed my clothes the needle was sticking straight out as if it had just been inserted."

37. Mr A said he then removed the needle, which was not secured by tape.

38. Mr A provided the needle to HDC. Ms B's recollection of the needle was that it was 0.25mm in diameter and 25mm in length. The needle provided to HDC is 40mm in length[7] with a handle of 30mm in length.[8]

Response from the clinic

39. The sole director of the clinic told HDC that leaving a needle in place overnight is an accepted practice in China (where the practice originated), and is not harmful to the patient.

40. The clinic director also told HDC that he believes the clinic was busy on 26 August 2016, but that he does not believe this would have impaired Ms B's judgement.

The clinic — Changes following incident

41. The clinic director told HDC:

> "In view of the misunderstanding of the patient about the medical treatment method and procedures, we have redrafted the patient informed consent form. The treatment provider will endeavour to go through the treatment procedure and effects etc. so that the patient will have a fair understanding of them and be prepared for the outcomes."

42. The clinic director provided HDC with a copy of the new patient consent form. It requires the patient to agree that he or she has read and understood the document, that the practitioners have verbally explained the procedures and possible side effects prior to any treatment being undertaken, and that the patient consents to receiving the treatment. It requires the patient to sign and date the form. The form also explains the use of "longer duration needle retaining", including that this could be required for "a few hours, or longer e.g. over 2–3 days".

[7] This is the portion that is inserted into the body.
[8] This is the portion that protrudes from the body.

43. The following additional changes have been made by the clinic:

- Staff will not answer the telephone during treatment periods.
- More detailed medical records will be made in the future. These will include a description of the subjective feelings of the patient and the objective physical elements, including "the range of movement, any visible swelling, infection, growth or patient's posture, as well as the aggravating or relieving factor for the condition etc, and the goal and method of treatment".
- The clinic will be required to ensure the continual improvement of a practitioner's professional development, and better communication with patients.

44. Ms B has provided HDC with a copy of a form obtained from Acupuncture New Zealand, which staff at the clinic will use for recording treatment notes.

Responses to provisional opinion

45. Mr A received the "information gathered" section of the provisional opinion and had no further information to add.

46. Ms B and the clinic were provided with an opportunity to respond to the provisional opinion and had no further information to add.

Opinion: Introduction

47. On 21 August 2015, Mr A visited the clinic to receive treatment, which included acupuncture, for an injury to his left shoulder. I have no concerns about the care provided to Mr A during this appointment.

48. On 26 August 2015, Mr A returned to the clinic for further treatment in relation to his shoulder injury. During that treatment Ms B inserted an acupuncture needle into Mr A's abdomen. Ms B left the needle in Mr A's abdomen without advising him of her intention to do so or obtaining his consent to do so. Mr A discovered and removed the needle the following morning.

Opinion: Ms B

Standard of care — No breach

49. Ms B told HDC that her treatment of Mr A on 26 August 2015 consisted of inserting a single sterilised needle into Mr A's abdomen (using the Hua Rou Men acupuncture point). Ms B said that the purpose of using the Hua Rou Men point was to help reduce the pain, and improve the range of motion, in Mr A's shoulder. Ms B told HDC that she did not insert any needles into his shoulder during that appointment.

50. In contrast, Mr A told HDC that the treatment involved the insertion of multiple needles around his shoulder, as well as one in his abdomen.

51. The documentation relating to this appointment is recorded on the ACC "treatment recorder" form, which refers to the Hua Rou Men point. Regardless, my expert adviser, Ms Bourner, advised me that the use of a single needle would not be a departure from an accepted standard of care.

52. In relation to the use of the Hua Rou Men point, Ms Bourner advised that this was indicated for the treatment of Mr A's injury, explaining that this point is a major point in the system of abdominal acupuncture treatments used to treat pain at various body sites, including the shoulder. I accept Ms Bourner's advice and am satisfied that the use of the Hua Rou Men acupuncture point during Mr A's treatment was appropriate.

53. Following treatment, Ms B did not remove the needle from Mr A's abdomen. The following morning, while he was getting dressed, Mr A found the needle protruding from his abdomen. The needle found by Mr A was 40mm long. Ms B told HDC that leaving the needle in Mr A's abdomen was intentional, and said that, as is her usual practice, she taped the needle so that it was flat against Mr A's abdomen. However, Ms B acknowledged that she failed to inform Mr A of her intention to leave the needle in his abdomen.

54. Ms Bourner advised that leaving a needle in the body following treatment is not uncommon, and is "recommended by western and Chinese acupuncturists to prolong the effects of treatment". In relation to the size of the needle, Ms Bourner advised that when leaving in a needle for a prolonged period of time, generally small intradermal needles are used. However, for places on the body where deeper penetration is required, it would be accepted practice to use a 40mm needle, as this would allow it to be taped flat against the body.

55. I accept Ms Bourner's advice and am satisfied that the decision to leave the needle in Mr A's abdomen, and Ms B's choice of a 40mm needle, were appropriate for the treatment of Mr A's shoulder pain. However, I have concerns about the process used by Ms B when she left the needle in place.

56. Ms B told HDC that, as is her usual practice, she taped the needle flat against Mr A's abdomen. Mr A told HDC that the needle was "sticking straight out" and was not taped when he discovered it the following morning. There is no documentation detailing whether or not Ms B taped the needle to Mr A's abdomen following the treatment, and I am unable to make a finding on this.

Information provided — Breach

57. The Code of Health and Disability Services Consumers' Rights (the Code) states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available, including an assessment of the expected risks, benefits, and side effects of each option.[9] The Code also provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.[10]

58. Accordingly, having made a plan to leave an acupuncture needle in Mr A's abdomen, Ms B needed to obtain Mr A's consent to do so. She should have discussed her plan with Mr A, giving him sufficient information to be able to make an informed decision regarding whether he consented to the needle being left in his abdomen. Ms Bourner advised that had Mr A chosen to do so, the information provided should have included details about how to remove the needle and dispose of it safely.

59. Ms Bourner noted that there are clear risks involved with needle retention, including:

- A loose needle may inadvertently be pushed deeper into the body than intended, with the risk of organ penetration.
- Retaining needles poses a risk of infection at the site of penetration, which will vary according to the patient's health, living conditions, and personal hygiene.

60. Ms B accepts that she did not inform Mr A of her intention to leave the needle in his abdomen.

61. For failing to inform Mr A of her plan to leave the acupuncture needle in his abdomen, including providing information on the risks and side effects, and how to remove the needle and dispose of it safely, Ms B failed to provide Mr A with information that a reasonable consumer would expect to receive in his circumstances. Accordingly, Ms B breached Right 6(1) of the Code. Without this information, Mr A was not in a position to make an informed choice and provide informed consent for the needle to be left in his abdomen, and it follows that Ms B also breached Right 7(1) of the Code.

Opinion: The clinic

Standard of care — No breach

62. Section 72 of the Health and Disability Commissioner Act 1994 (the Act) states that an employing authority is vicariously liable for any actions or omissions of its agents unless they are done or omitted without that employing authority's express or implied authority. In these circumstances, Ms B was acting as an agent of the clinic. In

[9] Right 6(1).
[10] Right 7(1).

addition to vicarious liability, the clinic may also be directly liable for failures in services it provides.

63. In my view, Ms B's failure to obtain informed consent to leave the needle in Mr A's abdomen, and her inadequate record-keeping, were matters of individual practice, and these failures did not occur with the clinic's express or implied authority. Therefore, I find that the clinic has not breached the Code.

Other comment

64. I note that my expert advisor, Ms Tracey Bourner, recommends that acupuncture clinics use an informed consent form. Although Ms B did obtain Mr A's written consent for the acupuncture treatment on 21 August 2015, I note that the clinic has concluded that there is a need for a more in-depth consent form, and also a need to ensure that essential details are documented in the clinical records. The clinic has adopted a new treatment record template for the recording of treatment notes, and a new informed consent form.

65. Ms B and the other individual providers were responsible for answering the telephone. She received an unusually high number of telephone calls that day, and was distracted when she answered the telephone during Mr A's treatment. The clinic director told HDC that it was an unusually busy day, but he does not believe that this would have impaired Ms B's judgement. However, I note that Ms B has stated that she was distracted.

66. Ms Bourner advised:

> "[T]he error that occurred in the treatment of [Mr A] seems to have been caused by [Ms B] being distracted by phone calls on the day of his treatment. When running a busy clinic, patient safety must be the primary concern of the practitioner. A plan should be put in place to avoid such distractions in the future."

67. I acknowledge that the clinic has changed its policies so that practitioners will no longer be required to answer telephone calls during treatment sessions with patients.

68. The changes made by the clinic following this incident are commendable.

Recommendations

69. I recommend that Ms B:

a) Undertake further education and training on informed consent, within three months of the date of this report. Ms B is to provide evidence of this training to HDC within four months of the date of this report.

b) Review her practice in light of this report, including her process for obtaining informed consent, and report back to me on her learning, within three weeks of the date of this report.

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

70. I recommend that the clinic:

a) Confirm the implementation of its new documentation policy, conduct an audit of the effectiveness of this policy, and report back to this Office within three months of the date of this report.

b) Arrange training on its new documentation and informed consent policies for all practitioners at the clinic, and provide evidence of that training to HDC within two months of the date of this report.

Follow-up actions

71. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to Acupuncture New Zealand.

72. 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 College of Chinese Medicine, and the New Zealand School of Acupuncture and Chinese Medicine, for educational purposes.

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from acupuncturist Ms Tracey Bourner:

"**Report on care provided by Ms B**

Ref: C15HDC01325

I have been asked to provide an opinion to the Health and Disability Commissioner on case number C15HDC01325. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Relevant qualifications and experience

BSc (Hons) Biochemistry (1986)
PhD Applied Biology (1993)
National Diploma in Acupuncture (2001)

I have practised acupuncture and Traditional Chinese Medicine since 2001, and was Vice President of the NZ Register of Acupuncturists (now Acupuncture NZ) from 2009 to 2012. In this role I was involved in reviewing clinical guidelines for members of the organisation, including safety guidelines.

Referral instructions

I have been asked to provide my opinion on the following issues:

- The appropriateness of the treatment (including the decision to leave the needle *in situ*)
- The lack of clinical documentation

I have been asked to advise on:

- The standard of care/accepted practice
- Whether there has been a departure from the standard of care or accepted practice, and how significant I consider this departure to be
- How this would be viewed by my peers

Information reviewed

Letter of complaint from [Mr A]
[Ms B's] response, dated 24 September 2015
Additional response form [Ms B], dated 24 December 2015
Additional information requested by myself from [Ms B] via HDC, including clinic records

Provided via email dated 4 February 2016

Additional material accessed:

Micro-Acupuncture in Practice (2009). Yajuan Wang. Churchill Livingstone.

The essential guide to Acupuncture in Pregnancy & Childbirth (2006). Debra Betts.

The Journal of Chinese Medicine Ltd.

Guidelines for Clinical Notes (July 2006). New Zealand Register of Acupuncturists Inc.

Factual summary

On 27 August 2015, [Mr A] discovered a needle still lodged in his abdomen from acupuncture treatment received the previous day from [Ms B]. The treatment was for an injury to his left shoulder. The needle was removed with no pain or other adverse effects.

[Ms B] stated that the treatment consisted of the use of a single needle, and the objective was to reduce pain and improve range of motion in [Mr A's] shoulder. She explained that leaving needles *in situ* is normal practice in her clinic. No clinical documentation was provided by [Ms B]. [Mr A] stated that the treatment included deep massage (tui na) and muscle exercises in addition to the acupuncture treatment.

[Mr A] commented that [the clinic] was busy, and that the two practitioners also take phone calls. [Ms B] also commented that on the day of the treatment in question she was distracted by an abnormal number of phone calls from patients, and omitted to inform [Mr A] of the retained needle in his abdomen. She has apologised for this omission.

Appropriateness of the treatment received

[Mr A] was being treated for an injury to his left shoulder. The acupuncture component of the treatment consisted of one needle inserted into the abdominal point Hua Rou Men (ST-24). This may seem unusual, as the area where the needle was inserted is not obviously connected to the shoulder. However, there is a system of abdominal acupuncture treatments for pain at several body sites, such as tennis elbow, carpal tunnel syndrome, osteoarthritis of the neck, and shoulder pain. Hua Rou Men is the major point used in this system, either alone or in conjunction with other abdominal points (Wang, 2009). The point selection was therefore appropriate for the condition being treated.

I believe that many western-trained acupuncturists would regard a single-needle treatment as unusual, but not a departure from accepted practice. This is particularly true when the treatment has involved other components of Traditional Chinese Medicine, such as tui na and exercises, as in this case.

Regarding the needle being left *in situ*, this is not an uncommon practice, and is recommended by western as well as Chinese acupuncturists to prolong the effects of treatment. However, it is more common, particularly outside of China, to use small intradermal needles, such as those shown below, rather than standard acupuncture needles. These needles are only a few millimetres long, and can easily be completely covered by tape to hold them in place. An example of their

use would be in the treatment of pregnant women to relieve symptoms for several days following treatment (Betts, 2006).

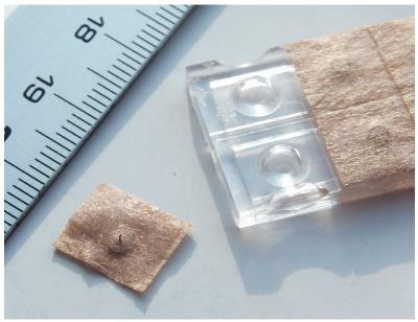

Fig. 1. A typical small intradermal acupuncture needle.

In this case the needle left *in situ* was of a standard size — 0.25mm diameter and 25mm shaft length.

Contrary to the letter of support provided, there are clear risks involved with needle retention:

- A loose needle may inadvertently be pushed deeper into the body than intended, with the risk of organ penetration
- Retaining needles poses a risk of infection at the site of penetration, which will vary according to the patient's health, living conditions, and personal hygiene
- Hepatitis C virus is very easily transferred between individuals through microscopic amounts of blood. A patient may not be aware that they have Hepatitis C. If a needle falls loose in a public place or in the patient's home, it could pose a risk of infection to anyone suffering a needle-stick injury from handling it.
- Regardless of the risk of infection, acupuncture needles could cause injury to children who pick them up, or to pets that may try to ingest them.

[Ms B] is correct in saying that it is normal practice to tape a needle in place to prevent it from being dislodged. However, the needle used in this case was relatively short and thick, and would have been difficult to tape flat to the body compared with a longer thinner needle which would bend more easily. If the needle had been taped in place [Mr A] would probably have been aware of it on dressing following the treatment.

[Ms B] has accepted that she failed to inform [Mr A] that a needle had been left in place, but states that it was her intention to leave the needle in overnight.

If the needle were left *in situ* deliberately but not taped in place, this would be regarded as a significant departure from accepted practice for the reasons discussed above regarding the risks from loose used needles. This would generally be regarded as an unsafe practice.

Needle retention in general is safe as long as the patient is fully informed of the fact that a needle has been left in place, and is given instructions on how to remove the needle and safely dispose of it if they wish to do so. Ideally a container should be supplied for the needle to be returned to [the clinic] and placed in a sharps container on the next visit.

I believe that the majority of acupuncturists would prefer to use small intradermal needles as discussed above, as these are designed to be left *in situ*, and are easier to secure and safer than using standard needles. However, I appreciate that these may not achieve the same results using abdominal points in patients of a larger build, as the depth of penetration may be insufficient.

Lack of Clinical Documentation

[Ms B] is a member of Acupuncture NZ (formerly the NZ Register of Acupuncturists), and so is obliged under the organisation's clinical guidelines to keep detailed clinical notes for each treatment provided (NZRA, 2006). Also, when providing treatment which is covered by ACC, it is an absolute requirement of ACC that treatment notes are kept, and these must be in English.

The clinical notes provided in this case are minimal, and are more a record of treatment than full treatment notes.

The treatments provided to [Mr A] were not invoiced to ACC, but the form provided indicates that this is the way ACC treatments are generally recorded at [Ms B's] clinic. These would be inadequate for ACC's requirements.

It would be a serious departure from accepted practice if no treatment notes were being written at this clinic. Most acupuncturists would regard this as poor practice. More importantly it breaches the clinical guidelines of Acupuncture NZ, and does not meet ACC requirements. Failure to maintain treatment notes in English could result in loss of ACC provider status.

I would recommend that [Ms B] contact Acupuncture NZ for guidance on how to provide an informed consent form to give to patients to sign when she or her co-workers intend to leave needles *in situ*. Patients must be informed of the potential risks involved. Acupuncture NZ can also provide advice regarding the information that should be included in treatment notes to comply with their and ACC's requirements.

Finally, the error that occurred in the treatment of [Mr A] seems to have been caused by [Ms B] being distracted by phone calls on the day of his treatment. When running a busy clinic, patient safety must be the primary concern of the practitioner. A plan should be put in place to avoid such distractions in the future. Encouraging people to leave a message and calling them back between patients, or employing someone on a casual basis to answer the telephone during busy periods may be necessary to maintain a high standard of patient care.

Tracey Bourner, 12 February 2016

Report on care provided by [Ms B] Ref: C15HDC01325

I have been asked to provide an opinion to the Health and Disability Commissioner on case number C15HDC01325. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Relevant qualifications and experience

BSc (Hons) Biochemistry (1986)
PhD Applied Biology (1993)
National Diploma in Acupuncture (2001)

I have practised acupuncture and Traditional Chinese Medicine since 2001, and was Vice President of the NZ Register of Acupuncturists (now Acupuncture NZ) from 2009 to 2011. In this role I was involved in reviewing clinical guidelines for members of the organisation, including safety guidelines.

Expert advice required

I have previously submitted a report on this case (February 2016), and have been asked to consider some additional information regarding the care provided by [Ms B] to [Mr A], and to comment in particular on:

1. whether the additional information provided changes my preliminary advice in any way
2. the adequacy of the relevant policies and procedures in place at the time of the events complained of, and
3. the adequacy of the relevant policies and procedures currently in place at [the clinic], including any further changes that may be considered appropriate.

For each of these issues I have been asked to advise:

1. what the standard of care/accepted practice is,
2. if there has been a departure from the standard of care or accepted practice, and
3. how the care provided would be viewed by my peers.

Information reviewed

1. Complaint from [Mr A] dated 28 August 2015.
2. Clinical notes relating to the treatment under consideration.
3. Photocopy of the needle that was left in place after treatment.
4. Response from [Ms B], 4 Feb 2016.
5. Response from [Ms B], 24 Sept 2015.
6. Response from [Ms B], 23 Dec 2015.
7. Response from [the clinic] 7 July 2016.
8. Patient informed consent form from [the clinic].
9. Minutes of General Meeting, [the clinic] 28 June 2016.
10. Email to HDC from [Mr A], 9 May 2016.
11. Summary of telephone conversation between HDC and [Mr A], 9 March 2016.

12. Letter to HDC from [Mr A], 28 Feb 2016.
13. HDC's Guidelines for Independent Advisors.

Effect of additional information on preliminary advice

The additional information regarding [Mr A's] treatment relates to the size of the needle that was left in his abdomen, and his recollection of the treatment, including the number of needles used at each site (the rear of his left shoulder and his abdomen).

The needle appears to be longer than the size stated by [Ms B]. In document number 4 she states that it was a 0.25 x 25mm needle. If the photocopy is a true life-size copy then it is a 40mm needle. The diameter cannot be assessed from the photocopy.

A 40mm needle would be more suited to being taped in place than a 25mm needle, as it could more easily lay flat against the skin. However, if it were to come loose and penetrate the body as far as the handle, there is obviously a higher risk of organ penetration, depending on the build of the patient. In my opinion, most acupuncturists would use a 40mm needle when intending to leave a needle taped in place after treatment, if the location were not suitable for a small intradermal needle.

However, it seems that the needle had not been taped in place in this case, so the risk of it penetrating the body deeper than intended was increased. There was also a high probability that the needle would fall out, in which case it could have penetrated the body at another site, or caused a hazard to any other person who came into contact with it.

This additional information does not change my preliminary advice regarding informed consent and the need to focus on patient safety and avoid distractions at busy times in [the clinic].

Accepted practice when leaving a needle *in situ* after treatment is to ask the patient if it is acceptable to leave the needle in place, and to securely tape the needle flat against the skin. The patient should be informed how long to leave the needle in place, and how to safely remove and dispose of it if they wish to remove it sooner, for example if it becomes uncomfortable before the next treatment is due.

In this case [Mr A] was not informed that the needle was to be left in his abdomen, and it was not taped securely to his body. This caused a degree of physical risk to him, and clearly distressed him when he discovered the needle the following morning. This is a significant departure from accepted practice, most likely caused by the practitioner being distracted at a busy time in [the clinic]. In my opinion this would be regarded as poor practice by other acupuncturists.

The adequacy of relevant policies and procedures in place at the time of the complaint

At the time of [Mr A's] treatment [the clinic] did not appear to use a patient informed consent form that covered the variety of treatments carried out by the practitioners there. In a busy clinic dealing with people of different cultures who may not be familiar with Chinese medicine practices it is important that patients understand what may be involved when they come for treatment, particularly if the practitioners do not have the time to explain every procedure with new patients. In this respect the information given to [Mr A] was inadequate.

It also seems that at the time of [Mr A's] treatment [Ms B] was very busy and was possibly distracted by having to answer [the clinic] telephone during the time of his treatment. It is not clear whether this was the general procedure at [the clinic], or whether this was an unusual occurrence, but in this case it probably contributed to the error that led to this complaint. In this respect the procedures followed on the day were inadequate to ensure patient safety.

Not all acupuncturists provide an informed consent form for patients, but it is recommended to do so, particularly where there may be time constraints in a busy clinic, or where linguistic differences make verbal explanations of procedures difficult. Therefore this is not a significant departure from accepted practice, but the treatment procedures should have been explained verbally to [Mr A]. To provide neither written nor verbal explanation of the course of the treatment to a patient who is not familiar with Chinese medicine practices is, in my opinion, a significant departure from accepted practice and would be viewed as such by most acupuncturists.

With regard to answering the telephone while treating a patient, this is not an uncommon practice in some clinics. This is not a significant departure from accepted practice, but many acupuncturists would consider this as not ideal, and to be avoided as much as possible.

Regarding the treatment notes supplied by [Ms B], these would be regarded as too brief for the requirements of ACC, as they do not include details of the injury being treated, the patient's signs and symptoms, and the exact treatment applied. It is generally considered to be good practice to maintain detailed notes for all patients. The notes supplied would be a significant departure from accepted practice for ACC cases, and in my opinion most acupuncturists would consider them inadequate for non-ACC patients as well.

The adequacy of relevant policies and procedures currently in place at [the clinic]

The minutes of the Company General Meeting of [the clinic], dated 28 June 2016 (Document 9), show that the members of [the clinic] have taken action to improve each of the procedures discussed above, and have sought support from their professional body to improve their practice.

The informed consent form (Document 8) is thorough and deals specifically with retained needles.

Agenda item 2 states that practitioners should no longer answer [the clinic] telephone whilst treating a patient, which will enable the practitioners to work with fewer distractions.

Agenda item 3 lists the information that should be included in clinical notes for each patient, which will ensure compliance with ACC requirements and improve record-keeping.

These changes to [the clinic's] policies and procedures will ensure that in these areas [the clinic] will operate according to accepted practice, and provide a standard of care that most acupuncturists would approve of.

My only additional recommendation would be to emphasise the importance of recording the treatment provided during each session as exactly as possible, including the names or numbers of every acupuncture point used. This not only provides useful information if a different practitioner needs to treat one of [the clinic's] patients for any reason, but also provides a definitive record of treatment in case of future disputes or complaints.

Tracey Bourner
4 August 2016"

Additional expert advice

Ms Bourner was asked to comment on:

1. What factors would make a treatment location unsuitable for an intradermal needle.

2. Previous advice obtained stated that if the needle had been taped, probably [Mr A] would have been aware of it when he dressed. Would it have been less likely for [Mr A] to have noticed the needle upon dressing if it had not been taped?

"1. Intradermal needles are very short, penetrating only a few millimetres. They are therefore ideal for use on acupuncture points close to the surface of the skin, for example around the wrists and ankles. For acupuncture points that are normally needled more deeply, say one to one and half inches, some acupuncturists would prefer to use a longer needle and tape it in place. An intradermal needle may be considered unable to penetrate deep enough to stimulate the point effectively. When using abdominal points it is easy to tape a needle in place. For acupuncture points close to a joint this is more difficult as movement of the joint would move the needle, so an intradermal

needle may be preferred. Individual acupuncturists will have their own preferences according to their training and subsequent experience.

2. This is difficult to answer. It would depend on how the needle was positioned when he was dressing after the treatment, which is not known. If it was sticking out from the body then it may have been more easily noticed than a needle taped in place. It depends on so many factors, such as the type of tape used, the amount of tape used, whether the tape pulled on the skin, etc. I really don't think there is a clear answer to this question."

Further expert advice obtained

"**Report on care provided by [Ms B] Ref: C15HDC01325**

I have been asked to provide an opinion to the Health and Disability Commissioner on case number C15HDC01325. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Relevant qualifications and experience

BSc (Hons) Biochemistry (1986)
PhD Applied Biology (1993)
National Diploma in Acupuncture (2001)

I have practised acupuncture and Traditional Chinese Medicine since 2001, and was Vice President of the NZ Register of Acupuncturists (now Acupuncture NZ) from 2009 to 2011. In this role I was involved in reviewing clinical guidelines for members of the organisation, including safety guidelines.

Expert advice required

I have previously submitted two reports on this case (February 2016 and August 2016). For this report I have been asked to consider some additional information regarding the care provided by [Ms B] to [Mr A], and to comment in particular on:

1. whether the additional information provided changes my preliminary advice in any way

I have also been asked to comment on any other aspects of the care provided to [Mr A] that I feel warrant such comment.

I have been asked to advise:

1. what the standard of care/accepted practice is,
2. if there has been a departure from the standard of care or accepted practice, and how significant any departure is considered, and
3. how the care provided would be viewed by my peers.

In the event of any conflict in the evidence I have been asked to comment on the appropriateness of the care provided for each alternative scenario.

Information reviewed

1. Response from [Ms B] dated 10 October 2016
2. [Mr A's] clinical notes:
   a. Treatment notes — two pages
   b. Signed patient informed consent form for 21 August 2015 treatment
   c. Ultrasound report
3. New patient informed consent form
4. New patient clinical notes form
5. Photo of point location of Hua Rou Men (ST-24)
6. Photo of the surgical tape used
7. Abdominal acupuncture point wall chart
8. Abdominal hologram chart
9. Abdominal Bakuo graph chart
10. HDC's Guidelines for Independent Advisors.

Effect of additional information on preliminary advice

The important additional information provided for this report consists of a more detailed account of [Mr A's] treatment from [Ms B], and the intake form signed by [Mr A] at his first treatment. The latter also contains the treatment notes for this first treatment.

The inclusion of [Mr A's] intake form and initial treatment notes changes my preliminary advice regarding the inadequacy of [Ms B's] clinical notes, insofar as these notes are adequate for this treatment. However if the only clinical notes for the second treatment are those on the second page, entitled 'ACC Treatment Recorder', then these are still inadequate for ACC's requirements. This issue has since been addressed by [Ms B's] clinic by the adoption of a clinical note template provided by their professional body.

There is some discrepancy regarding the size of the needle that was left in [Mr A's] abdomen. [Ms B] has reiterated that the needle was a 0.25 x 25mm standard needle. The photocopy provided to me of the actual needle indicated that it was a 40mm needle, if the photocopy were a true life size image. The length of the needle used does not significantly affect my preliminary advice. In my opinion a 40mm needle, being more flexible, would be easier to tape to a patient's abdomen than a shorter needle, but without knowing the individual patient's build it is difficult to judge which would be most suitable. Individual practitioners would have their own preferences. It is not standard practice to record on patient notes the length and diameter of the acupuncture needles used in a treatment.

[Ms B] states that she intended to leave the needle in [Mr A's] abdomen to prolong the effects of the treatment, and says that she taped the needle in place with surgical tape. In [Mr A's] account of finding the needle the following morning he does not mention whether any tape was found on the needle, or on his body, or if any tape was subsequently found that could have been the tape used to secure the needle. The accepted standard of care for retaining a needle would be to ask the patient if it were acceptable to them to have the needle retained. If so, the needle should be securely taped in place, and the patient given advice on how to safely remove the needle if they

need to do so before their next appointment. They should also be advised how do either dispose of the needle safely, or how to keep it to return it to [the clinic] on their next visit. If [Ms B] had taped the needle in place but forgot to inform [Mr A] of this and to give him instructions regarding its removal because she was distracted by answering the telephone, then this would be a departure from accepted practice. However the risk to the patient would have been low if the needle were securely taped in place, so the departure would be moderate. If the needle had not been taped in place then the risk to the patient or to another person finding the needle would have been higher, from accidental needle-stick injury or from the needle penetrating more deeply than was intended. In this scenario the departure from accepted practice would have been more significant.

I believe that most acupuncturists would accept that leaving a needle in a patient after treatment is poor practice, but that many acupuncturists would have done this at some time in their career. Fortunately in most cases the needle is noticed as soon as the patient moves, as it generally causes some pain, or the patient notices the needle when dressing immediately after treatment. In my opinion it is quite rare for a needle to remain unnoticed until the following day, and the risk to the patient and to others is increased in this situation.

In my opinion [Ms B] has accepted responsibility for the error that resulted in this complaint, and her clinic has now introduced improved practices, both to prevent practitioner distraction during treatments and to improve their clinical notes to acceptable standards.

Tracey Bourner

2 November 2016”