Obstetrician and Gynaecologist, Dr A
Private Hospital

A Report by the
Health and Disability Commissioner

(Case 19HDC00345)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided by a surgeon, and highlights the importance of following guidelines when using potentially harmful equipment.

2. On 17 December 2018, a woman underwent elective gynaecological surgery to remove fibroids from her uterus. The surgery was held at a private hospital. During the procedure, a surgical diathermy pencil was used to cut and coagulate tissue. A diathermy pencil is a hand-held unit that uses an alternating electric current of very high frequency to emit intense local heat when passed from the active "electrode" or "pencil" to the patient. Diathermy pencils come with a holster for safe placement of the pencil while not in use.

3. During the surgery, the surgeon placed the diathermy pencil on the woman instead of in the holster, causing three deep burns to the woman's abdomen.

Findings

4. The Commissioner was critical that during the surgery, the surgeon placed the diathermy pencil on the woman's abdomen instead of in the quiver as expected, putting the woman directly in harm's way. Accordingly, the Commissioner found the surgeon in breach of Right 4(1) of the Code.

5. The Commissioner made adverse comment about the surgeon's conduct during the investigation, and reminded the surgeon of her responsibilities to her patients.

6. The Commissioner considered that in this case the issue was an individual error, and not indicative of any systems issues at the private hospital. Accordingly, he found that the private hospital was not responsible for the surgeon's error.

Recommendations

7. The Commissioner recommended that the surgeon review her practice in light of this report, attend the Medical Protection Society's workshop "Achieving safer and reliable practice", and provide a written apology to the woman.

8. The Commissioner also recommended that the Medical Council of New Zealand consider whether a review of the surgeon's competence is warranted.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided by Dr A at a private hospital. The following issues were identified for investigation:

- *Whether the private hospital provided Ms B with an appropriate standard of care on 17 December 2018.*

- *Whether Dr A provided Ms B with an appropriate standard of care on 17 December 2018.*

10. The parties directly involved in the investigation were:

Dr A	Obstetrician and gynaecologist/provider
Ms B	Consumer
Private hospital	Surgical hospital/provider

11. Further information was received from:

Dr C	Obstetrician and gynaecologist
RN D	Nurse at the private hospital
RN E	Nurse at the private hospital
Manager of the private hospital	
Dr F	Specialist anaesthetist

12. Independent expert advice was obtained from an obstetrician and gynaecologist, Dr Ian Page (Appendix A).

Information gathered during investigation

Introduction

13. In November 2018, Ms B (aged in her thirties) presented to her general practitioner (GP) with suspicion that she could feel a mass in her abdomen when lying down. An ultrasound of the abdomen was arranged by her GP, which confirmed that Ms B had a multifibroid[1] uterus approximately the size of a 16–17 week pregnancy. She was referred to Dr A[2] to undergo an elective laparotomy[3] and multiple myomectomy[4] to remove the fibroids.

14. Surgery with Dr A was arranged for 17 December 2018, with assistance from Dr A's consultant colleague, Dr C.[5]

15. The surgery was to take place at the private hospital. The private hospital told HDC that clinicians (such as surgeons, physicians, and anaesthetists) operate as individual practitioners rather than employees of the hospital. As such, the clinicians have "attending rights" at the hospital in order to use the surgical and clinical services provided during the patient's admission, including equipment and nursing care. Attending rights are granted on

[1] Fibroids are abnormal and typically non-cancerous growths that develop in or on a woman's uterus.
[2] Dr A is an obstetrician and gynaecologist with an annual practising certificate from the Medical Council of New Zealand. Attending rights to the private hospital were granted to Dr A in 2013.
[3] A surgical incision into the abdominal cavity, for diagnosis or in preparation for major surgery.
[4] A surgical procedure to remove uterine fibroids.
[5] Dr C is an obstetrician and gynaecologist with an annual practising certificate from the Medical Council of New Zealand.

the basis of the practitioner's acceptance of the private hospital's by-laws, which state that the practitioner is to be familiar with, and observe, the private hospital's policies when using its surgical and clinical services.

16. This report primarily concerns the care provided to Ms B by Dr A at the private hospital. During the surgery on 17 December 2018, Ms B suffered multiple burns.

Surgery on 17 December 2018

17. In addition to surgeons Dr A and Dr C, the surgical scrub team for Ms B's procedure included Registered Nurse (RN) D as the scrub nurse, RN E as the circulating nurse, a patient nurse, an anaesthetic technician, and Dr F as the anaesthetist.

18. Prior to the surgery starting, Dr A's preference list[6] was printed out and the items on the list were assembled. RN E opened and laid out the surgical set-up while RN D did a complete scrub. RN D told HDC:

> "[W]e ensured the correct set-up was prepared, checked for any items that needed to be obtained such as patient supports, the diathermy[7] machine and the suction unit that was needed during the procedure."

19. In Dr A's first statement to HDC, she said that when the surgery commenced, the theatre nurse was still in the process of setting up all the equipment. In Dr A's second statement to HDC, she said that prior to commencing the procedure, all theatre staff were asked whether they were ready to begin, and all confirmed that they were.

Diathermy pencil

20. For Ms B's procedure, surgical diathermy was required to cut and coagulate[8] tissue during the surgery. Surgical diathermy uses an alternating electric current of very high frequency, which emits intense local heat when passed from the active "electrode" or "pencil[9]" to the patient. The diathermy pencil is a hand-held unit with two control buttons on the device, for cutting and coagulation respectively.

21. While a diathermy pencil does not actively release heat unless the appropriate button is depressed, the pencil retains residual heat, so it comes with a quiver[10] in which to place the pencil when not in use. The diathermy pencil in Ms B's surgery was a PenEvac single-use pencil, which came in a sealed pack that included a diathermy quiver.

Set-up of diathermy quiver

22. Both RN E and RN D stated that the diathermy machine was placed behind and to the left of Dr C, who was standing on Ms B's right-hand side to allow the diathermy pencil and

[6] A list of the required and preferred items for surgery, based on the surgeon's preference.
[7] Surgical diathermy involves the use of high-frequency electric current as either a cutting modality, or to cauterise small blood vessels to stop bleeding.
[8] To change a fluid (usually blood) to a solid or semi-solid state.
[9] Diathermy "pencil" is synonymous with diathermy "pen".
[10] A diathermy quiver is a holster for the temporary storage of diathermy instruments during surgery.

suction to pass from Dr C's left hand to Dr A, who was standing on Ms B's left-hand side. RN D told HDC that as there were two diathermy quivers on her equipment table, she utilised them both. RN E told HDC that one of the diathermy quivers came with the diathermy pen in a pack, and the other diathermy quiver came in a bowl set. Both quivers were attached to the surgical drapes covering Ms B, positioned on the left-hand side of Dr C.

23. RN E told HDC that Dr C had requested that the quivers be placed to her left-hand side, as this was the best placement for her. RN E stated: "[RN D] and I have worked with both [Dr A] and [Dr C] for many years and are familiar with their surgical preferences."

24. RN D told HDC:

> "The way in which the quivers were set up in this case was exactly the same as many other open surgery cases of [Dr A's] where I have set up the theatre for her when she is working with [Dr C]."

25. RN E stated that the position of the quiver was to allow Dr C, who is left handed, ease of transfer in passing the diathermy pencil and the suction to Dr A, who was standing on the patient's left-hand side. RN D and RN E said that both quivers were easily visible, accessible, and within arm's reach of all scrubbed staff members, including Dr A and Dr C.

26. In Dr A's first statement to HDC, she said that there was no quiver set up at the beginning of Ms B's surgery. Dr A stated:

> "[O]n this occasion a quiver was not attached to the patient because while we were opening the abdominal wound, the theatre nurse was still in the process of setting up all the equipment we might need for the operation."

27. However, in her second statement to HDC, Dr A said that there was in fact a quiver attached to Ms B's drapes. She stated that she was unaware that it had been set up, as it was placed next to Dr C, which was "not where it ought to have been".

28. In her third statement to HDC, Dr A explained that the quiver used in Ms B's surgery was a laparoscopic[11] quiver, which was not the appropriate quiver for Ms B's type of procedure. Dr C agreed with Dr A, and stated: "A laparoscopic quiver had been placed next to the theatre nurse, but not next to [Dr A] as would be the usual practice."

29. RN E and RN D disagreed with Dr A's statements about the type and placement of quiver.

30. RN E told HDC:

> "No laparoscopic quiver was set up for [Ms B's] surgery. The diathermy pencil comes together in a pack with the quiver, and so there is no way that the correct diathermy quiver was not set up with the diathermy pen. It is not correct for [Dr A] to state that

[11] Laparoscopy is a minimally invasive surgical diagnostic procedure used to examine the organs inside the abdomen, and requires only small incisions.

> the pen quiver was set up otherwise than in accordance to her usual practice. If the quiver is on the same side as [Dr A], it gets in the way of her surgery."

31. RN E also stated that for the incorrect quiver to have been used, she would have had to open a separate quiver out of sterile packaging, which did not occur. RN D told HDC: "I am adamant that there was no laparoscopic quiver used in [Ms B's] surgery." She stated that both quivers were standard diathermy quivers, and were easily visible and accessible to both Dr C and Dr A. The Manager of the private hospital told HDC that it would have been "extraordinary" for a laparoscopic quiver to have been involved in this type of surgery.

32. In her third statement, Dr A said that technically the quiver was accessible to her, but she would have had to reach over the patient to use it. Dr A told HDC that the quiver was *not* accessible to Dr C, as it was placed by the scrub nurse. However, Dr C told HDC that each time she used the diathermy pencil, she placed it in the quiver, which was situated on her left-hand side.

33. In her third statement to HDC, Dr A also said that when surgery began, the diathermy pencil was already resting on Ms B's upper abdomen. Dr C, RN D, and RN E told HDC that the diathermy pencil was in the quiver before surgery began.

34. There is no mention in Ms B's clinical records, the incident report, or Dr A's surgical notes, of any issues with the quiver. The incident report noted that there was a quiver available during surgery.

Procedure

35. Once the surgical set-up was complete and all involved confirmed that they were ready to begin, surgery commenced with "knife-to-skin" time recorded as 6.50pm. Dr A began by performing a routine Pfannestiel incision[12] and muscle-splitting approach, by incising the skin with a scalpel and dissecting with the diathermy pencil down to the rectus sheath.[13] After cauterising[14] some minor blood vessels, Dr A put down the diathermy pencil and used scissors to open the rectus sheath. In her first response to HDC, Dr A stated:

> "I rested the diathermy pen on [Ms B's] upper abdomen just below her 12th rib … [Ms B] experienced three burns to her skin over the left upper quadrant of the abdomen …"

36. In her second response to HDC, Dr A stated that she placed the diathermy pencil on the drape on Ms B's abdomen. She told HDC that approximately 30 seconds to 1 minute after placing the diathermy pencil down on Ms B's abdomen, she noticed a strange smell and realised that Ms B had been burnt through the drapes. Dr C told HDC that the device was placed on the surgical drape.

[12] A type of abdominal surgical incision that allows access to the abdomen.
[13] A strong, fibrous sheet of connective tissue.
[14] Using heat to burn a part of the body in order to stop bleeding or remove tissue.

37. There is no mention of any burn marks sustained to the drapes by any of the other operating theatre staff. Dr F, the anaesthetist for the surgery, told HDC that when he was alerted to the burns, he observed the diathermy pencil body lying on the drapes, while the diathermy tip was lying on Ms B's bare skin. He documented in Ms B's clinical notes:

> "These small incisional burns to patient's abdomen done by malfunctioning diathermy! (Turned "ON" upon being plugged in!)."

38. There is no reference in Ms B's clinical records, the incident report, or Dr A's surgical notes, of burn marks on the drapes. The private hospital provided HDC with a diagram of the usual drape set-up in their surgeries. The diagram shows that the whole abdomen of the patient would be exposed and not covered by drapes. Dr A told HDC that this diagram shows how surgery is usually set up, but for Ms B's surgery the drape sat further down Ms B's upper abdomen.

39. Ms B sustained three small but deep individual burns to her abdomen, described as being 1cm long and 1.5cm deep. The burns were approximately 1cm apart from each other, with no burn marks in between.

40. When asked how the pencil caused three separate burns to Ms B's abdomen, Dr A told HDC that "the diathermy must have moved" during the time the pencil was lying on Ms B's abdomen. She stated that previously she has seen instruments move when the anaesthetist adjusts the airway or the bair hugger,[15] but she was not aware of either of these being done, as she was concentrating on the surgery.

41. The other theatre staff members told HDC that at the time Ms B sustained her burns, they were focusing on other surgical duties and were either not in the vicinity of the operating table or did not see Dr A place the diathermy pencil on Ms B's abdomen. They were alerted to the incident only once Dr A called out that the patient had been burnt.

Surgery stopped

42. After confirming that all surgical bleeding was under control, and that it was safe, surgery was stopped momentarily. The diathermy pencil was bagged with its packaging to send to the manufacturing company for investigation, and the diathermy machine was turned off and removed from theatre to be sent for testing by the electrical engineers. A plastic surgeon was contacted for immediate advice on how to treat the burns. She advised the continuous application of cool saline ice packs to the affected areas to maintain a cold temperature, and to dress the burns with Chlorsig ointment[16] once surgery was completed.

43. A new diathermy machine and pencil were obtained. In her third statement, Dr A told HDC that at this time, RN E informed RN D that the incorrect quiver had been set up, and instructed her to set up a diathermy quiver. Dr A stated that a new quiver was obtained, and was set up next to her for the rest of the surgery.

[15] A bair hugger is a temperature management system used to maintain a patient's core body temperature.
[16] An antibiotic ointment.

44. However, RN E and RN D both disagree that this occurred, and maintain that the correct quiver was set up from the beginning of surgery. RN E told HDC: "That is incorrect — I never said that [to RN D], as there was not an incorrect quiver set up."

45. RN D stated that she "totally refutes" Dr A's comment. RN D told HDC:

> "The diathermy pencil that had been set up by me was the correct diathermy pencil for use in a myomectomy. I can confirm that no comments were made to me from the senior circulating nurse suggesting that there was anything wrong with the set up in theatre, or that the wrong quiver had been used."

Completion of surgery

46. RN D told HDC that after surgery had started again, she saw Dr A place the diathermy pencil down on Ms B's abdomen again, instead of in the available quiver. RN D stated:

> "After the burn incident, once the procedure recommenced, I do recall seeing [Dr A] place the diathermy pen on the patient on at least two further occasions and saw [Dr C] return the pen to the quiver. I am certain of this, as I was concerned about any subsequent burn to the patient and so was carefully watching where the diathermy pen was being placed after each use."

47. Dr C told HDC that although she cannot specifically recall this occurring, had she seen the pencil on Ms B's abdomen subsequent to the burns, it may have been an automatic reflex response for her to place it back in the quiver.

48. Dr A disagreed with RN D's comment, and stated that as the "correct" quiver had been set up next to her by this stage, she returned the diathermy pencil to the quiver after each use.

49. The rest of the surgery was completed uneventfully, and Ms B's burns were dressed in accordance with the plastic surgeon's advice, to await review on the ward the following morning.

Private hospital policy

50. At the time of these events, the private hospital had an operating theatre procedure in place for the use of diathermy machines — the "[Operating Theatre] Procedure: Use of Electro-Surgical Units (Diathermy Machines)". The procedure requires the "active electrode" or "pen" of the diathermy machine to be stored in a quiver when not in use, or when not being held by a member of the surgical scrub team between active use.

51. In Ms B's surgery, the diathermy pencil was placed on Ms B's abdomen rather than in the quiver. The private hospital advised that this was a "deviation in practice from the expected standards" as set out in its policy, and that ultimately the user of the pencil is responsible for the safe use of the diathermy device.

52. Dr A told HDC that when she started working at the private hospital, she was provided with a thorough orientation on its policies and procedures. She stated that she was familiar with the operating theatre procedure in place for the use of diathermy machines.

Subsequent events

53. Open disclosure of the incident was made by Dr A on the morning after the operation, and Ms B and her partner were provided with an explanation of the events during surgery, and an apology. An incident form for the adverse event was then filled out, which stated: "Diathermy placed onto patient's abdomen after use, a quiver was available." Ms B was discharged from hospital on 21 December 2018, with follow-up appointments with both a plastic surgeon and district nurses in place.

First manufacturing report

54. The private hospital told HDC that all diathermy machines are tested annually to ensure that they meet clinical engineering requirements, and that the diathermy machine used in Ms B's operation had met all testing requirements at the beginning of 2018. An electrical safety and safe operation test was undertaken on the diathermy machine by the District Health Board's clinical engineering department on 18 December 2018. No faults were identified with the machine.

55. The single-use PenEvac pencil was sent to the American manufacturing company, I.C. Medical, to undertake testing. A report received on 14 March 2019[17] stated that the examination and functional testing of the diathermy pencil in question identified that the pencil functioned normally within all factory specifications. The report stated that no manufacturing defects were found that could have caused or contributed to the burn. The reported concluded:

> "It should be noted that after utilization of this device, the electrode remains hot, and it may be hot enough to burn the patient or burn through a drape or patient when placed on the patient instead of being stored in the supplied safety holster [quiver], when not in use … Based on available information we suspect that the most probable cause of the reported complaint may be related to failure to follow instructions provided with the product."

Internal review

56. On 22 March 2019, the private hospital completed its internal review into Ms B's injuries. Operating theatre staff were interviewed, and it was found that the correct equipment was available for the proposed procedure, and that all staff involved had received training on the diathermy device. The review concluded that the error was caused by a discrepancy between expected practice and actual practice, in relation to intraoperative utilisation of a quiver to store a diathermy pencil safely when not in use.

[17] The delay in testing and the results being available was because of closures over the holiday period, and issues with freighting contaminated equipment overseas.

Second manufacturing report

57. On 25 November 2019, as part of her third statement, Dr A provided HDC with a second manufacturing report, and stated:

> "I am also providing a further report sent to the Hospital from [the DHB] which discovered that the pencil was not water tight and this created a risk that the pencil could be reactivated without the button being depressed."

58. Dr A attached a report dated 18 September 2019 from the DHB, which stated that "the supplied pen" was found not to be fully watertight, and could potentially cause unintended activation given the right conditions.

59. On 11 December 2019, this second report was again referred to by Dr A, whose lawyer submitted on her behalf:

> "When the pen was placed back on [Ms B's] upper abdomen, it appears that it did not turn off. This pen has subsequently been discovered to be faulty, as the report attached to [Dr A's] response [of 25 November 2019] shows."

60. However, the private hospital told HDC that the "supplied pen" referred to in this second report was *not* referring to the pencil used in Ms B's surgery, and was a different diathermy pencil of the same brand.

Further information

Dr A

61. Dr A told HDC that it is not her routine practice to rest diathermy devices on a patient's abdomen. She stated that in this case, when she needed to rest the diathermy pencil, there was no quiver in the expected position, and so she placed the diathermy pencil on Ms B's stomach.

62. Dr A said that she has "no hesitation in apologising to [Ms B] for what happened to her at the time of surgery". Dr A told HDC that she has learned a great lesson as a result of this, and will now ensure that a quiver is available to her at all times and/or that the patient is protected from the device when it is not in use.

Private hospital

63. The private hospital reiterated that its nursing staff are firm in their recollection around the events that occurred in Ms B's surgery, and that the nurses' recollections have remained consistent and credible throughout the investigations carried out by both the private hospital and HDC. The hospital advised that had the theatre been set up for a laparoscopic hysterectomy when Ms B was not having that operation, this would have been a significant event noted by members of the theatre at the time.

64. The private hospital said that because it has a procedure in place, and this is known by staff, it has made no changes to its expectations around the use of diathermy machines.

Ms B

65. Ms B told HDC that it will take her longer to recover from her burn wounds than from her actual operation. She stated:

> "[These events] have influenced my day to day life but also I will now have to live with [the burns] the rest of my life both physically and mentally. Plus, I may potentially have to undergo another operation to amend the error, which may leave me scarring in other places, further time off work, and maybe further issues."

Responses to provisional opinion

66. The private hospital was provided with the opportunity to comment on the relevant sections of the provisional opinion, and stated that it is happy for the opinion to be finalised.

67. Dr A was provided with the opportunity to comment on the relevant sections of the provisional opinion. She submitted that the most likely conclusion is that the pencil remained active when it was placed on Ms B's stomach, and that limited weight should be placed on the manufacturer's report, as it was not conducted by an independent expert.

68. Ms B was provided with the opportunity to respond to the "information gathered" section of the provisional opinion. She told HDC that her surgery was a traumatic experience that she will not be able to forget, and stated:

> "I sincerely hope that others have not been treated and/or affected by the same mishap that I have experienced as [Dr A] has continued to practice since my surgery."

Opinion: Dr A

Introduction

69. Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code), Ms B had the right to be provided with services with reasonable care and skill. On 17 December 2018, Ms B underwent an elective laparotomy and multiple myomectomy, led by Dr A. During the surgery, Dr A placed a diathermy pencil on Ms B's abdomen instead of in a quiver. As a result, Ms B suffered three deep burns to her stomach.

70. I acknowledge that throughout the course of this investigation, this Office has been provided with many conflicting statements and recollections of events in relation to Ms B's surgery. However, the key issue — the placement of the diathermy pencil by Dr A on Ms B's abdomen — is not disputed.

Factual findings

Set-up of surgery

71. The way in which the equipment was set up for Ms B's surgery — namely the diathermy machine and quiver — has been recalled differently by the staff present in theatre on this

day. The main issues here are whether or not the correct quiver was used for Ms B's surgery, and whether or not the quiver was set up in the correct place.

72. RN D and RN E were tasked with the set-up of the equipment before surgery began. They told HDC that Dr A's preference list was printed out, and all of the necessary equipment needed was gathered. They stated that they had both worked with Dr A and Dr C many times, and were familiar with their preferences for surgery. They told HDC that accordingly, two diathermy quivers were set up next to Dr C, to allow her to pass the pencil to Dr A.

73. Dr A had several different recollections regarding the set-up for the surgery. In her first statement to this Office, she said that no quiver was attached to the patient in Ms B's surgery because the theatre nurse was still in the process of setting up all the equipment after the surgery had begun. In her second statement to this Office, Dr A said that prior to commencing the procedure, all theatre staff were asked whether they were ready to begin, and all confirmed that they were. She also said that there was a quiver attached to Ms B, but she was unaware of this, as it was placed next to Dr C, which was "not where it ought to have been".

74. In Dr A's third statement to this Office, she noted that technically the quiver was accessible to her, but she would have had to reach over the patient to use it. She also stated that the quiver used was a laparoscopic one, and was not appropriate for Ms B's surgery. Dr C agreed with Dr A that a laparoscopic quiver had not been placed next to Dr A, which would have been the usual practice.

75. In her third statement, Dr A also said that when surgery began, the diathermy pencil was already resting on Ms B's upper abdomen.

76. RN E told HDC that the diathermy pencil comes together in a pack with the quiver, and so there is "no way" that the incorrect diathermy quiver was set up with the diathermy pencil. This is confirmed by the I.C. Medical product catalogue, which shows that all pencils come with a quiver. RN E stated that the other diathermy quiver came in a bowl set, and so she would have had to open a separate quiver out of sterile packaging for an incorrect quiver to have been set up. RN D told HDC that she is "adamant" that there was no laparoscopic quiver used in Ms B's surgery. The private hospital's internal review into Ms B's injuries found that the correct equipment was available for the proposed procedure, and that all staff involved had received training on the diathermy device.

77. Considering the conflicting statements from Dr A, I do not find her evidence on this point reliable. The statements from the nursing staff around their recollection of Ms B's surgery corroborate each other, and have been consistent throughout both the private hospital's and HDC's investigations. I also note that the documentation — including Dr A's surgical notes and the incident report completed after the burns were discovered — contains no evidence of any issues with the type or placement of the quiver. I would have expected that had these problems occurred during the routine surgery, such events would have been worth documenting in Dr A's contemporaneous clinical notes or in the incident

report. As Dr C, RN D, and RN E all disagree with Dr A's statement that the diathermy pencil was already resting on Ms B's upper abdomen when surgery began, I consider it unlikely that this was the case.

78. Taking into consideration the above evidence, I find it more likely than not that the set-up for Ms B's surgery was correct, and that the correct quiver was accessible to both Dr A and Dr C at the time Dr A placed the diathermy pencil on Ms B's abdomen.

79. Irrespective of this, Dr A was the lead surgeon on this day, and had overall responsibility for ensuring that the correct equipment was set up, in the correct way, before commencement of the surgery. Even if I accepted Dr A's versions of events, I consider it would have been irresponsible for Dr A to commence non-urgent surgery without first confirming that all the equipment was set up to her satisfaction.

Pencil placed on Ms B's abdomen after burns were discovered

80. RN D told HDC that after Ms B's burns were discovered, and the surgery recommenced, she saw Dr A place the diathermy pencil down on Ms B at least two more times. RN D stated that Dr C then returned the pencil to the quiver. RN D stated: "I am certain of this, as I was concerned about any subsequent burn to the patient and so was carefully watching where the diathermy pen was being placed after each use."

81. In response, Dr A maintained that she placed the pencil down on Ms B's abdomen only once, and that she used the quiver after the burns were discovered, as the correct quiver was in place at this time. Dr C told HDC that whilst she cannot recall this occurring, it may have been a reflex for her to place the pencil back in the quiver.

82. Dr A's explanation that after the burns were discovered she used the quiver, as the correct quiver was in place at this time, is difficult to reconcile. As set out above, I find it more likely than not that the correct quiver was in place from the beginning of surgery. Dr A had not used the quiver before the burns were noticed, despite the correct quiver being in place.

83. I consider that there is insufficient evidence available to make a finding on whether or not Dr A placed the diathermy pencil on Ms B's abdomen again after the burns were discovered. However, I would be extremely concerned if this did occur.

Placement of pencil — breach

84. Once Ms B's surgery began, Dr A used the diathermy pencil to cauterise some minor blood vessels, before using scissors to open the rectus sheath. At this moment, Dr A placed the diathermy pencil down on Ms B's upper abdomen instead of in the quiver. This fact is not disputed. Dr A told HDC that the pencil was left on the abdomen for approximately 30 seconds to one minute. Ms B sustained three small but distinct, deep individual burns to her abdomen as a result.

85. I acknowledge that there are differences in recollections around whether or not surgical drapes were on Ms B's abdomen at the time of the burns, and whether the burns were sustained through the drapes or directly against Ms B's skin. However, I do not consider it

necessary to make a finding on this issue. In my view, placing the diathermy pencil on Ms B's abdomen, regardless of whether or not the abdomen was covered by a surgical drape, was a departure from the accepted standard of care.

86. A diathermy pencil carries residual heat in the tip after use, and for that reason each pencil comes with a quiver for safe storage of the pencil whilst not in use. This is reflected in both the private hospital's "Use of Electro-Surgical Units (Diathermy Machines)" policy, and in the diathermy manufacturer's instructions, both of which state that the diathermy pencil must be stored in the quiver when not in use. My expert advisor, Dr Ian Page, told HDC that the private hospital's guidelines were very thorough, and Dr A acknowledged that she was familiar with the guidelines at the time of these events.

87. Dr Page considers that Dr A's placement of the diathermy pencil on Ms B's abdomen, instead of in the quiver, would be viewed as a moderate departure from accepted standards. I accept this advice. In my view, placing a diathermy pencil holding residual heat onto Ms B's abdomen, instead of in the supplied quiver, reflects a blatant disregard for Ms B's safety. In addition, Dr A's actions were contrary to both the private hospital's guidelines on the use of diathermy equipment, and the diathermy manufacturer's instructions.

88. I have not been provided with any convincing mitigating factors for Dr A's actions. This surgery was elective and non-urgent. Dr A told HDC that the quiver was not in the expected place when she went to place the pencil down, and so she rested it on Ms B's abdomen. I find Dr A's reasoning concerning. A series of alternative courses of action were available to her. As discussed above, if Dr A felt that the incorrect quiver had been placed in an erroneous position, it was her responsibility to ensure that such an error was rectified before the surgery began. Dr A also had the benefit of assistant surgeon Dr C or the nursing staff, who could have held the diathermy pencil or placed it in the quiver.

89. Dr A had a responsibility to provide Ms B with services with reasonable care and skill during her surgery on 17 December 2018. Dr A was the lead surgeon, and thus had ultimate responsibility for the surgical set-up and safety of her patient. I am critical that during the surgery, Dr A placed the diathermy pencil on Ms B's abdomen instead of in the expected quiver, putting Ms B directly in harm's way. Consumers put their faith and trust in their medical professionals, and it is vital that medical professionals have high regard to patient safety. I am critical that this did not occur during the surgery led by Dr A. Accordingly, I find that Dr A failed to provide services to Ms B with reasonable care and skill, in breach of Right 4(1) of the Code.[18]

90. For the reasons discussed below, I am also critical that in her responses to HDC, Dr A apportioned blame to others, when she was the lead surgeon responsible for the shortcomings. It is important that medical professionals supply accurate information to, and co-operate with, investigative bodies.

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

Issues with investigation — adverse comment

91. The statements that Dr A provided to this Office are conflicting in themselves, and differ from the recollection of theatre staff present during Ms B's surgery. Regarding the set-up for the surgery, Dr A's recollections changed with each of her three statements provided to this Office. The supposed poor set-up and incorrect equipment were still Dr A's responsibility, as the lead surgeon. If there was an issue, it was her responsibility to resolve it.

92. In her statements, Dr A made several allegations that were refuted by the nursing staff, such as no quiver being available, the wrong quiver being available, the quiver being in the wrong place, the quiver being placed on Ms B's stomach prior to the surgery commencing, and the diathermy pencil being faulty. I am concerned by Dr A's attempts to shift the blame for her actions onto others.

93. I am also concerned by the reference to the second manufacturing report that Dr A provided to this Office, which found "a supplied pen" not to be fully watertight, creating a possible risk that the pencil could be reactivated without the button being depressed. In her responses to HDC, twice Dr A referred to this pencil as being the one she used in Ms B's surgery on 17 December 2018. However, the private hospital told HDC that the "supplied pen" referred to in the second report was *not* referring to the pencil used in Ms B's surgery, and was a different diathermy pencil of the same brand, used months after Ms B's surgery.

94. As discussed earlier in this report, the diathermy machine and pencil used in Ms B's surgery were tested in December 2018 and March 2019 respectively. Both tests found that there were no faults or manufacturing defects that could have caused or contributed to Ms B's burns. Dr A's reference to the pencil in the second manufacturing report as the pencil used in Ms B's surgery, whilst failing to acknowledge that this was actually a different pencil of the same brand, could be construed as an attempt to mislead this Office.

95. This investigation has been complicated by Dr A's different versions of events. I remind Dr A of her responsibilities to her patients.

Opinion: Private hospital— no breach

96. Ms B's surgery of 17 December 2018 was carried out at the private hospital. As explained above, at the private hospital, clinicians operate as individual practitioners rather than employees of the hospital. Dr A had "attending rights" to use the hospital and its surgical and clinical services, and was expected to be familiar with, and adhere to, the private hospital policies when using its surgical and clinical services.

97. During the surgery, Dr A used a diathermy machine and placed the pen on Ms B's abdomen instead of in the available quiver. Ms B suffered three deep burns to her abdomen as a result.

98. At the time of these events, the private hospital had in place an operating theatre procedure for the use of diathermy machines. The procedure required the diathermy pencil to be stored in a quiver when not in use, or when not being held by a member of the surgical scrub team between active use. My expert advisor, Dr Page, considers that the policy was very thorough. Dr A told HDC that she was orientated to the hospital's policies and procedures and was familiar with this specific policy.

99. The private hospital also told HDC that all diathermy machines are tested annually to ensure that they meet clinical engineering requirements, and that the diathermy machine used in Ms B's operation had met all testing requirements at the beginning of 2018. Both the diathermy pencil and the machine were tested subsequently, and both were found to be functioning normally. The I.C. Medical report concluded that the most probable cause of the burns was a failure to follow the instructions provided with the product.

100. It is clear that the issue in this case resulted from an individual failure, and I do not consider that it is indicative of any systems issues at the private hospital. I have also not identified any issues with the hospital's equipment or nursing staff. Accordingly, I find that the private hospital is not directly responsible for the error that occurred during Ms B's surgery.

Recommendations

101. I recommend that Dr A:

a) Review her practice in light of this report, and report back to this Office on her learnings within three months of the date of this report.

b) Attend the Medical Protection Society's workshop "Achieving safer and reliable practice". Dr A is to report back to HDC within 12 months of the date of this report, with details of the content of the training and evidence of having attended.

c) Provide a written apology to Ms B for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms B, within three weeks of the date of this report.

102. I recommend that the Medical Council of New Zealand consider whether a review of Dr A's competence is warranted.

Follow-up actions

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

104. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and 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 an obstetrician and gynaecologist, Dr Ian Page:

"Thank you for your letter of 19 August 2019 and the enclosed documents, requesting expert advice to the Commissioner on the care provided by [Dr A] to [Ms B] on 17 December 2018. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I am a practising Obstetrician & Gynaecologist and have been a consultant for 30 years. I obtained my MRCOG in 1985, my FRCOG in 1998 and my FRANZCOG in 2002. I have been employed for the past 19 years by Northland DHB. I have been a member of the RANZCOG Expert Witness register since 2012.

Background

[Ms B] was admitted to [the private hospital] on 17 December 2018 for a planned myomectomy, to be performed by [Dr A]. During the procedure she sustained 3 burns to her abdominal wall, apparently caused by the diathermy pen used during the surgery.

Advice Requested

You asked me to review the documents and advise whether the care provided by [Dr A] to [Ms B] was reasonable in the circumstances and why. You also asked me to comment specifically on:

1. The reasonableness of [Dr A's] decision to place the diathermy pen on the patient's body whilst not in use
2. The adequacy of [the private hospital's] operating theatre procedure 'OT Procedures: Use of Electro-surgical unit (diathermy machine)'
3. Whether I had any further matters in this case that warrant comment.

Sources of Information

In assessing this case I have read:

- Letter of complaint dated […]
- [Dr A's] response dated 25 March 2019
- [The private hospital's] response dated 27 March 2019
- [Dr A's] response dated 29 July 2019
- Clinical records from [the private hospital]
- [The private hospital's] policy on the use of diathermy machines: 'OT Procedures: Use of Electro-surgical Units (diathermy machine)'

- [The private hospital's] response dated 9 August 2019
- Photographs of the burns
- Further response and diagrams from [the private hospital] dated 16 September 2019
- Response from [Dr C] dated 18 September 2019

Summary of the Case

[Ms B] was admitted to [the private hospital] on 17 December 2018 for a planned myomectomy, to be performed by [Dr A]. After general anaesthesia was instituted, and the appropriate pre-operative checks had been carried out, skin preparation was carried out with Alcohol-Chlorhexidine. Surgical drapes were then applied, light handles attached and the diathermy quiver and pencil attached.

[Dr A] opened the skin with a knife, and then used the diathermy pencil to continue the incision down to the rectus sheath. She opened the sheath with scissors, having rested the diathermy pencil on [Ms B's] abdomen. [Dr A] then noted what she called a strange smell, and discovered it was coming from 3 burns to [Ms B's] abdomen. The burns were exposed and cooled, and subsequently reviewed by a plastic surgeon. The operation itself was completed without further incident.

My Assessment

You asked me to review the documents and advise whether the care provided by [Dr A] to [Ms B] was reasonable in the circumstances and why. You also asked me to comment specifically on:

1. *The reasonableness of [Dr A's] decision to place the diathermy pen on the patient's body whilst not in use*

The hospital record shows that the operation started at about 6.40pm. This was elective surgery, and so there would be no urgency. Hence it would be reasonable for [Dr A] to have waited until all the equipment was ready before starting the procedure. There is a difference between [Dr A's] two accounts (her responses dated 25 March 2019 and 29 July 2019) of the events in theatre, and also between them and the account given by [the private hospital] (in their response dated 9 August 2019). I cannot determine which account is correct. The IC Medical product catalogue[1] shows that all pens come with a quiver.

There are also discrepancies with regard to the placement of the surgical drapes and the placement of the diathermy pencil. The diagram from [the private hospital] implies the whole abdomen would be exposed, while [Dr C's] statement and [Dr A's] response of 29 July say the pencil was placed on the drape. Had the issue been of residual heat in the pencil tip then there would have been burns on the drape. If the issue was of continuing electrical energy discharge then I cannot tell if there would

[1] https://icmedical.com/product-catalog/

have been burns on the drapes or not. [Dr C] notes that the diathermy quiver had been placed next to the theatre nurse, rather than next to the surgeon. The Incident Review by [the private hospital] states the quiver had been placed next to the assistant, and that placement was based on the scrub nurse's knowledge of the operating surgeon. However the diathermy pencil would usually be placed within it, and so I would think that [Dr A] would have taken it from the quiver to use it and hence known where the quiver was.

The anaesthetic note by [Dr F] states there were 'three small incisional burns to the patient's abdomen done by malfunctioning diathermy! (turned ON upon being plugged in!)' This would imply the diathermy pencil was placed on the patient's abdomen before it was plugged in, and that the burns occurred before [Dr A] used the pencil as she described. I cannot reconcile the differences. If [Dr F] believed this was a malfunction I wonder why he didn't raise the issue at the beginning of the operation when the pencil was first plugged in.

Regardless of all this [the private hospital's] Procedure about the use of a quiver when diathermy is in use is quite clear, and [Dr A] has not offered any explanation as to why she did not follow it. I think this would be viewed as a moderate departure from accepted standards and be viewed with mild to moderate disapproval by her peers.

2. *The adequacy of [the private hospital's] operating theatre procedure 'OT Procedures: Use of Electro-surgical unit (diathermy machine)'*

The document is very thorough. The only item missing from it is reference to the volume of the alarm system on the machine. However there is a process for this, as noted in [the private hospital's] response of 16 September 2019. The document notes the need to check the alarm system function prior to connecting the grounding pad to the unit, and to set the power levels to those required by the surgeon. It also notes that precautions must be taken to avoid the pooling of flammable materials e.g. skin preparation solutions.

3. *Whether I had any further matters in this case that warrant comment.*

[Dr A's] first response talks about residual heat from the diathermy pencil she had placed on [Ms B's] abdomen as causing the 3 burns. I would be surprised if the residual heat would be enough to cause one burn 1cm long and 1.5cm deep, never mind 3. The rationale for doubting residual heat as the cause is the small size of the diathermy pencil tip means that it cannot (in itself) hold that much energy. In addition, as noted beforehand, I would have expected burns to the drapes to be visible.

[Dr A's] second response states she placed the diathermy pencil on the drapes and left it there while she used scissors to open the rectus sheath. She then opened the rest of the abdominal wall and exteriorised the uterus — this took (she believes) between 30 seconds and one minute. At that point she noticed a strange smell and saw some diathermy burns through the drapes. The drapes were pulled back and skin burns

noted. A new quiver and diathermy pencil were obtained, and the rest of the operation was completed uneventfully.

The 3 burns are at least 1cm apart from each other (as far as I can tell from the photographs provided). That would imply the pencil was moved to the 3 different points whilst it was activated, or that it was activated 3 times being moved between each. There is nothing in the records or responses to clarify which it might have been.

I do not have any personal or professional conflict of interest to declare with regard to this case. If you require any further comment or clarification please let me know.

Yours sincerely,

Dr Ian Page MB BS, FRCOG, FRANZCOG
Consultant Obstetrician & Gynaecologist
Whangarei Hospital

References 1. https://icmedical.com/product-catalog/”