Gynaecologist, Dr B
Wairarapa District Health Board

A Report by the
Health and Disability Commissioner

(Case 17HDC02004)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the Fenton's procedure performed by a gynaecologist. The Commissioner found the gynaecologist in breach of Right 7(1) of the Code of Health and Disability Services Consumers' Rights (the Code) for having performed the procedure without the woman's informed consent, and found Wairarapa District Health Board (DHB) vicariously liable for the gynaecologist's breach.

2. Following a presentation with problematic symptoms, the gynaecologist proposed to examine the woman's urethra and bladder under general anaesthetic, and — if indicated — perform surgery on her anterior vagina. The woman signed a Wairarapa DHB consent form for an "EUA [examination under anaesthetic] Cystoscopy Inject LA [local anaesthetic]/Steroid to Perineum/?Refashion Anterior Vagina". The consent form contained a standard clause stating: "I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons."

3. During the procedure, the gynaecologist noticed some abnormal transverse tethering of the posterior vagina. He performed a Fenton's procedure (a removal of scar tissue) on her posterior vagina, as he considered that this might help to alleviate her symptoms.

4. The woman told HDC that she did not consent to the Fenton's procedure. Conversely, the gynaecologist said that he genuinely believed he had consent to perform the procedure.

Findings

5. The Commissioner found that "[the gynaecologist] did not have [the woman's] consent to undertake the Fenton's procedure", and reiterated that "surgical services may be provided to a competent adult in non-emergency situations only if that patient makes an informed choice and gives informed consent, irrespective of what the doctor considers to be in the patient's best interests".

6. The Commissioner considered that "the standard clause in Wairarapa DHB's consent form had the potential to confuse or mislead its employees about the situations in which they could deviate from a consumer's express written consent". Accordingly, he found that "Wairarapa DHB did not take such steps as were reasonably practicable to prevent the gynaecologist from breaching the Code".

Recommendations

7. The Commissioner recommended that the gynaecologist apologise to the woman, review the effectiveness of his changes to practice, and undertake education on informed consent.

8. The Commissioner recommended that Wairarapa DHB apologise to the woman and review the training on informed consent that it provides to its staff.

9. During this investigation, Wairarapa DHB revised its standard consent form and prepared a "provisional revised consent form".

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint about the services provided to Ms A by Dr B and Wairarapa District Health Board (DHB).

11. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care in Month 9[1] 2016.*
- *Whether Wairarapa DHB provided Ms A with an appropriate standard of care in Month 9 2016.*

12. This report is the opinion of Mr Anthony Hill, Health and Disability Commissioner.

13. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Gynaecologist/provider
Wairarapa DHB	DHB/provider

14. Further information was received from:

The Medical Council of New Zealand (MCNZ)	Registration authority
The Accident Compensation Corporation (ACC)	Crown agent

15. HDC obtained independent expert advice from Professor Cynthia Farquhar (Appendix A).

Information gathered during investigation

Background

16. Ms A had a history of bladder prolapse[2] and stress incontinence.[3] In Month1 she met with a gynaecologist, Dr B, to discuss these symptoms. She was then aged 46 years. Dr B told HDC that they discussed the possibility of an operation on Ms A's vagina to correct her bladder prolapse, and the possibility of performing a hysterectomy.[4] Ms A signed a

[1] Relevant dates are referred to as Months 1–9 to protect privacy.
[2] Loosening of connective tissues that support the bladder, causing the bladder to descend towards the vagina.
[3] Involuntary loss of urine during physical movement or activity (eg, coughing, sneezing, heavy lifting).
[4] Surgical removal of the uterus.

consent form for Dr B to perform a "Vaginal hysterectomy", "AP repair",[5] "Monarc suburethral sling", and "LAVH?"[6].

17. Dr B operated on Ms A in Month1.

Examination on 22 Month8

18. In Month8, Dr B met with Ms A again. Dr B told HDC that she told him that she still experienced some stress incontinence, although her urinary flow was otherwise normal, and there was no indication that she had a urinary tract infection. Dr B examined Ms A's vagina and found that it did not appear to be constricted but was sensitive posteriorly. Her anterior vagina appeared puckered. Dr B was wary of examining Ms A's vagina too invasively because of the pain she was feeling there. He explained:

> "My limited examination identified unusual irregularity of the anterior vaginal wall in the area of the previous surgery which might be related to the urinary symptoms. I therefore expected that, if needed, any surgical revision would involve the anterior wall of the vagina."

19. Dr B told HDC that he explained to Ms A that her symptoms were unusual, and that he was uncertain what was causing them. He told her that it was possible that one of her suburethral slings[7] was exposed because of inadequate healing. He said that he discussed the findings with Ms A and advised her that "careful exploration of the area under general anaesthetic, including cystoscopy[8] to assess the bladder and urethra, would be helpful and that, depending on the findings, a minor surgical release of scar tissue and injection of local anaesthetic with steroid might help". Dr B stated:

> "Based on my understanding at that stage, I discussed that this might include injecting the perineum with local anaesthetic and steroid which can help with scar pain and refashioning the anterior vagina if this was deemed to be contributing to [Ms A's] dyspareunia.[9]"

20. Dr B told HDC that he explained to Ms A that primarily the procedure would be exploratory, with the intention to rectify minor problems if possible, and that given the uncertain nature of the problem, he could not predict her chances of improvement.

21. Dr B said that at this time, while he was examining Ms A, she asked him to remove a groin nodule[10] near her vagina if he could do so safely.

22. Ms A told HDC that Dr B "suggested that he could try to address [her] dyspareunia by way of a steroid injection". She said that "[h]e only discussed the possibility of minor surgery to

[5] Repair of the anterior and posterior vagina.
[6] Laparoscopically assisted vaginal hysterectomy.
[7] A device implanted to stabilise a woman's pelvic tissue and organs.
[8] Examination of the inside of the bladder and urethra.
[9] Pain during intercourse.
[10] A superficial lump.

the puckering up near the bladder sling", and "[t]here was no discussion of the potential to cut the area around the perineum".

23. Following this meeting, Dr B recorded in the clinical notes that he discussed "EUA Cystoscopy/Inject perineum/? refashion anterior vagina".

Wairarapa DHB consent form

24. At the time of these events, Wairarapa DHB had a standard consent form. The form contained a clause that stated, "I hereby consent to the operation/procedure of:", followed by an empty space for the doctor concerned to hand write a description of the proposed procedures to be performed (or contingently performed) on the patient. The consent form contained a further clause that stated: "I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons" (the "standard clause").

25. Dr B gave Ms A a standard Wairarapa DHB consent form. In the empty space, he handwrote: "EUA[11] Cystoscopy Inject LA[12]/Steroid to Perineum[13]/? Refashion Anterior Vagina." Ms A signed the consent form in Month8.

Surgery on 25 Month9

26. It is not clear whether Dr B discussed the proposed procedures with Ms A between her consultation in Month8 and her operation in Month9. Dr B told HDC that usually he meets patients prior to surgery to double-check their understanding of the proposed procedures. Wairarapa DHB provided HDC with a copy of Ms A's preoperative checklist, which contains a handwritten note that states: "Pt wants to see [Dr B] first." However, there is no record of any discussion between Ms A and Dr B.

27. In Month9, Dr B performed a cystoscopy on Ms A under general anaesthetic. He discovered that her urethra, bladder, and anterior vagina were all in a healthy condition. In particular, he observed that none of her suburethral slings were exposed as he had anticipated. However, he noticed that there was a band at the fourchette[14] with some transverse tethering of the vagina posteriorly at about 1.5cm.[15]

28. As the tethering was the only abnormality Dr B observed in Ms A's vagina, he considered that it was a likely contributor to Ms A's symptoms. He decided that a Fenton's procedure[16] to Ms A's posterior vagina would be a low-risk means of trying to address her symptoms, and went ahead with the procedure, and also removed the groin nodule that Ms A had asked him to remove.

[11] Examination under anaesthetic.
[12] Local anaesthetic.
[13] The area between the anus and the vagina.
[14] The small fold of tissue that connects the inner lips of the vagina together posteriorly.
[15] There was scar tissue connecting the inner lips of the vagina beyond what was normal.
[16] Removal of scar tissue from the vagina and suture of the edges of the new incision.

29. Dr B stated that the Fenton's procedure fell within the scope of what Ms A had given him consent to do. Dr B provided several reasons for why this was the case:

a) In Month1, Ms A had consented to him operating on both her anterior and posterior vagina, alongside her hysterectomy, if appropriate, in Month1.

b) "The context of [the Month 8] discussion was that I would firstly explore the area to diagnose the problem. If the problem was minor and able to be addressed, I would fix it. I had tentatively examined [Ms A] and thought the anterior wall needed attention, but it became apparent during surgery that it was the posterior wall that was irregular. Given that consent had been obtained for vaginal surgery, I thought at the time that it would be only a minor variation (and within the consent I had obtained) to operate on the posterior rather than the anterior (as I had anticipated)."

c) He "regarded a small Fenton's procedure (applied to the posterior vagina) to release this area a low-morbidity approach which was reasonable given our previous discussion about treating possible scar tissue, albeit on the anterior vagina".

d) He believed that the standard clause in the consent form that [Ms A] had signed permitted appropriate variation of the procedure in the interests of cure.

30. Ms A told HDC that she did not at any point consent to Dr B performing a Fenton's procedure on her posterior vagina. She stated:

> "I did not go into this surgery expecting in any way to be cut near the perineum area, and had not prepared logistically or psychologically for the healing time involved with this. It was distressing to find that I had been cut all over again, when I hadn't expected to be. It was more healing and time off work than I had anticipated."

31. In 2017, Ms A submitted a claim to ACC for treatment injury. She told ACC that she continued to suffer significant ongoing perineal pain, and that she believed that this pain had been exacerbated by the Fenton's procedure. ACC accepted her claim.

Further comments — Dr B

Appropriateness of Fenton's procedure

32. Dr B told HDC that the Fenton's procedure was "carefully reasoned and well intended". He maintains that the evidence about Ms A's problems continues to suggest that her "symptoms may yet have an anatomical basis for which a surgical approach, similar to [the Fenton's] procedure, may be indicated".

33. Dr B told HDC that a Fenton's procedure is a well-established, minor intervention to release tension or narrowing at the introitus,[17] and that generally the procedure is very effective when there is anatomical distortion (which occurs most commonly after childbirth trauma to the perineum). He said that for this reason it was a reasonable

[17] The opening that leads to the vaginal canal.

approach to treating Ms A's symptoms, given what he discovered while she was under general anaesthetic.

34. Dr B told HDC that although there was no emergency reason to perform the Fenton's procedure, Ms A's continuing stress incontinence did warrant prompt attention.

Changes to practice and apology

35. Dr B told HDC that in response to this incident, he has:

a) Helped Ms A to obtain further assistance from other medical professionals;

b) Expanded clinic appointment times to facilitate longer discussion and more detailed consent;

c) Attended the MPS (Medical Protection Society) Risk Management Workshop Series; and

d) Initiated a review of the Wairarapa DHB surgical consent form.

36. Dr B stated:

> "My documentation on consent for the procedure could have been more explicit and I wish to apologise for omitting to note the possible permutation and the additional procedure to be taken."

Further comments — Wairarapa DHB

37. Wairarapa DHB told HDC that as a result of HDC's investigation into the services provided to Ms A, it revised the standard consent form used by its employees, and prepared a "provisional revised consent form".

Responses to provisional opinion

Ms A

38. Ms A was provided with an opportunity to respond to the "information gathered" section of the provisional opinion. Her responses have been incorporated into the report as appropriate.

39. Ms A was critical of Wairarapa DHB's standard consent form for not letting patients "opt out" of giving consent to procedures. She stated:

> "Most lay people would consider that 'additional procedures to be carried out in the patient's best interests' would be if you were in a life-threatening situation, that you would want the surgeon to save your life."

40. Ms A restated to HDC that she did not consent to the Fenton's procedure.

Dr B

41. Dr B was provided with an opportunity to respond to the relevant sections of the provisional opinion. His responses have been incorporated into the report as appropriate.

42. Dr B submitted to HDC that the realities of obtaining consent are nuanced and complex. He said:

> "Surgery is sometimes, out of necessity, exploratory. In such cases it is not always possible, or easy, to list every possible permutation of what may occur. What is more important than the written record is the content and quality of the consenting conversation between the consumer and her doctor. What is said between a doctor and consumer will enable decisions to be made that avoid exposing the consumer to the (not insignificant) risks of multiple procedures and anaesthesia."

Wairarapa DHB

43. Wairarapa DHB was provided with an opportunity to respond to the provisional opinion. It stated:

> "Wairarapa District Health Board (DHB) fully accepts the Health and Disability Commissioner's second provisional report and wishes to make no comment or addition to the document."

Opinion: Dr B — breach

44. I note that Ms A told ACC that she continued to suffer symptoms of ongoing perineal pain after Dr B's operation in Month9. For the avoidance of doubt, my role does not extend to determining causation in relation to adverse outcomes, and comments I make should not be interpreted as such.

Performance of Fenton's procedure without consent — breach

Summary of facts

45. In Month1, Ms A signed a form consenting to Dr B performing a "Vaginal hysterectomy", "AP repair", "Monarc suburethral sling", and "LAVH?". Dr B operated on Ms A in Month1.

46. In Month8, Ms A and Dr B had a broad-ranging discussion about Ms A's ongoing symptoms, possible diagnoses, and possible treatments. Dr B was wary of examining Ms A's vagina too invasively because of the pain she was feeling. Dr B and Ms A both agree that their discussion covered the possibility of Dr B placing Ms A under general anaesthetic, performing a cystoscopy on her urethra and bladder, injecting her perineum with steroids, and potentially performing minor surgery on her anterior vagina.

47. Ms A told HDC that she and Dr B "only discussed the possibility of minor surgery to the puckering up near the bladder sling", and "[t]here was no discussion of the potential to cut the area around the perineum". Conversely, Dr B told HDC that "the Fenton's procedure was within the scope of what he had discussed with [Ms A]". Given the apparently conflicting statements from Ms A and Dr B, I have had to make a finding as to whether Dr B discussed with Ms A that he might operate on her posterior vagina or perform a Fenton's procedure.

48. In resolving this apparent conflict, I have considered the following evidence:

a) Ms A has said that their discussion did not cover the possibility of cutting the area around the perineum, that she did not consent to the Fenton's procedure, and that she "did not go into this surgery expecting in any way to be cut near the perineum area".

b) Dr B's own statements suggest that the focus of their discussion was on the possibility of surgery to her anterior vagina. He has said that prior to placing Ms A under general anaesthesia, he had noticed irregularities only to her anterior vagina, and that this led him to expect that any surgery performed would involve the anterior vagina.

c) Dr B said that "[b]ased on [his] understanding", in Month8 he explained to Ms A that he could attempt to address her various issues by "injecting [her] perineum with local anaesthetic and steroid" and "refashioning the anterior vagina if this was deemed to be contributing to the dyspareunia".

d) Following the Month8 discussion, Dr B recorded in the clinical notes that he discussed "? refashion anterior vagina" with Ms A.

e) Dr B told HDC: "[I]t became apparent during surgery that it was the posterior wall that was irregular ... I thought at the time that it would be only a minor variation (and within the consent I had obtained) to operate on the posterior rather than the anterior (as I had anticipated)."

49. Having considered this evidence, I am satisfied on the balance of probabilities that at their preoperative meeting in Month8, Dr B and Ms A did not specifically discuss the possibility of a Fenton's procedure or surgery on Ms A's posterior vagina.

50. In Month8, Ms A signed a Wairarapa DHB consent form. The form contained a handwritten proposal by Dr B to perform "EUA Cystoscopy Inject LA/Steroid to Perineum/? Refashion Anterior Vagina". The form also contained a standard clause that stated: "I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons."

51. In Month9, Dr B performed a cystoscopy on Ms A under a general anaesthetic. During the procedure, he noticed a transverse tethering of the posterior vagina, which he considered would probably be contributing to Ms A's symptoms, and he decided that a Fenton's procedure would be a low-risk means of trying to address the symptoms. He believed that the procedure was within the scope of what Ms A had consented to. Consequently, he performed a Fenton's procedure on Ms A's posterior vagina.

Expert opinion

52. HDC obtained independent expert advice from a gynaecologist, Professor Cynthia Farquhar. Professor Farquhar advised that a Fenton's procedure "is not such a common operation and should be used sparingly as the introitus is a sensitive area and prone to being a pain area in some women even without surgery", and that it "needed a preoperative discussion as it may actually increase pain especially on a background of an already sensitive introitus".

53. Professor Farquhar said that there was no emergency reason for Dr B to perform a Fenton's procedure on Ms A at the time.

Informed consent to Fenton's procedure

54. The principle of informed consent is at the heart of the Code. Under Right 7(1), "services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent". Pursuant to this right, HDC has previously determined that "surgical services may be provided to a competent adult in non-emergency situations only if that patient makes an informed choice and gives informed consent, irrespective of what the doctor considers to be in the patient's best interests".[18] If the consumer will be under general anaesthetic, the Code provides an additional safeguard that consent must be in writing.[19]

55. Dr B was responsible for ensuring that he had obtained Ms A's informed consent to any procedure he carried out in Month9. Furthermore, as Ms A was under general anaesthetic, her consent needed to be in writing. The standard consent form that Ms A signed permitted Dr B to perform a cystoscopy, inject local anaesthetic and/or steroids into her perineum, and possibly refashion her anterior vagina. It did not specify a Fenton's procedure or any procedures on her posterior vagina.

56. I have considered Dr B's submission that a Fenton's procedure is a minor intervention, and that it would be "reasonable given [his and Ms A's] previous discussions about treating possible scar tissue, albeit on the anterior vagina". I have also considered that Dr B explained to Ms A the uncertain nature of her problem, and that Dr B and Ms A broadly discussed the possibility of him addressing her problems with minor surgery to the vagina. However, I accept Professor Farquhar's advice that a Fenton's procedure is not a common operation, and that it poses risks, and therefore required a preoperative discussion.

57. In this case, I have found that the preoperative discussion between Dr B and Ms A in Month8 did not specifically cover the possibility of a Fenton's procedure or surgery on her posterior vagina. As a result, Ms A was not in a position to make an informed choice or give informed consent to the Fenton's procedure.

58. Dr B has said that one of the factors that led him to believe that he had consent from Ms A to perform the Fenton's procedure was Ms A's consent to him operating on both her anterior and posterior vagina as part of her earlier surgery carried out in Month1. However, Ms A's earlier decision is of no relevance to whether she consented to Dr B operating on her posterior vagina in Month9.

59. I have also considered the standard clause in the Wairarapa DHB consent form, and Dr B's understanding that it meant that Ms A had given him written consent to perform procedures beyond those to which she had expressly consented. However, the standard clause in the consent form cannot negate a consumer's rights under the Code to make an informed choice and to give informed consent to services. The language of Right 7(1) is

[18] 08HDC08813.
[19] Right 7(6)(c).

clear and unambiguous — in the absence of an emergency or other specified exception, no services can be provided to a consumer without first receiving the consumer's informed consent.

60. I accept Dr B's statement that Ms A's continuing symptoms (including stress incontinence) warranted prompt attention. However, I also accept Professor Farquhar's advice that these symptoms did not amount to an emergency that required Dr B to perform the Fenton's procedure, and I note that Dr B has agreed with this. Therefore, I am satisfied that Ms A's symptoms were not sufficiently serious to affect Dr B's obligation to obtain Ms A's informed consent before performing the Fenton's procedure.

Conclusion

61. I am satisfied that Dr B did not have Ms A's consent to undertake the Fenton's procedure. I am also satisfied that Ms A's symptoms did not amount to an emergency. I consider that by carrying out the procedure in the absence of informed consent, Dr B breached Right 7(1) of the Code.

Groin nodule excision — adverse comment

62. During the consultation in Month8, Ms A asked Dr B to remove a superficial groin nodule near her vagina.

63. The standard consent form that Ms A signed stated: "EUA Cystoscopy Inject LA/Steroid to Perineum/? Refashion Anterior Vagina"; it did not refer to Dr B removing Ms A's groin nodule. However, in Month9, while Ms A was under general anaesthetic, Dr B removed the nodule.

64. Professor Farquhar advised HDC that removal of a groin nodule is a small procedure, and she does not regard Dr B's omission to obtain written consent to remove Ms A's groin nodule as a major oversight.

65. However, as Ms A was under general anaesthetic at the time, Dr B was required to obtain her written consent to the removal of the nodule. Although he did not do this, I am mindful that Dr B did have Ms A's verbal consent to remove the groin nodule. I am also mindful of Professor Farquhar's advice that removal of a groin nodule is a small procedure, and that Dr B's failure to obtain written consent was not a major oversight.

66. Accordingly, I am critical of Dr B's omission to obtain prior written consent to the removal of Ms A's groin nodule.

Opinion: Wairarapa DHB — breach

67. In Month9, Dr B was an employee of Wairarapa DHB. As set out above, I have found that Dr B breached Right 7(1) of the Code for performing a Fenton's procedure on Ms A without her informed consent. Under section 72(2) of the Health and Disability Commissioner Act

1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

68. At the time of these events, Wairarapa DHB had a standard consent form for use by its employees. The form contained a clause that stated, "I hereby consent to the operation/procedure of:", followed by an empty space for the doctor concerned to hand write a description of the procedures that he or she proposed to perform (or contingently perform) on the patient. The form contained a further clause that stated: "I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons."

69. Dr B told HDC that one of the reasons he believed he had Ms A's consent to perform the Fenton's procedure was that "appropriate variation of the procedure in the interests of cure is explicit in the text of the consent form".

70. Professor Farquhar advised HDC that she reviewed the standard consent forms of several other DHBs, and that none contained standard clauses such as the one used by Wairarapa DHB. She advised that such a standard clause could encourage surgeons to deviate from the express written consent given to them by their patients.

71. I accept this advice. On Dr B's own evidence, the wording of Wairarapa DHB's consent form was one of the factors that led him to believe that he could perform the Fenton's procedure on Ms A. It is clear that the standard clause in Wairarapa DHB's consent form had the potential to confuse or mislead its employees about the situations in which they could deviate from a consumer's express written consent. As noted above, it is the consumer's right to decide and, in the absence of an emergency or certain other requirements, clinical judgement regarding best interests does not apply. Accordingly, I find that Wairarapa DHB did not take such steps as were reasonably practicable to prevent Dr B from breaching the Code, and that it is vicariously liable for Dr B's breach.

72. I note that since these events, Wairarapa DHB has reviewed its consent form and prepared a "provisional revised consent form".

Recommendations

73. I recommend that Dr B:

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

b) Confirm the implementation of his new practice of expanding clinic appointment times to facilitate longer discussion and more detailed consent, conduct a review of

the effectiveness of this practice, and report back to HDC within three months of the date of this report.

c) Provide evidence to HDC, within three months of the date of this report, that he has attended the MPS Risk Management Workshop Series.

d) Undertake further education and training on the application of consumers' rights to give informed consent to health services, preferably with a focus on consumers under general anaesthetic, within three months of the date of this report.

74. I recommend that Wairarapa DHB:

a) Provide a written apology to Ms A. The apology is to be sent to this Office within three weeks of the date of this report, for forwarding to Ms A.

b) Provide HDC with a review of training provided to staff in relation to informed consent, and evidence that all relevant staff have been trained in informed consent, within three months of the date of this report.

Follow-up actions

75. A copy of this report with details identifying the parties removed, except the expert who advised on this case and Wairarapa DHB, 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 B's name.

76. A copy of this report with details identifying the parties removed, except the expert who advised on this case and Wairarapa DHB, 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 Professor Cynthia Farquhar:

"27 March 2018

Complaint: [Ms A]

Ref: C17HDC02004

I have been asked to provide advice on the following issues in regard to the care of [Ms A] at the time of surgery at Wairarapa [DHB] by [Dr B] [in] [Month 9].

Background to the case was provided by the HDC. [In Month 1] a vaginal hysterectomy, anterior repair, Monarc suburethral sling and perineorrhaphy were performed by [Dr B]. At 6 week follow up [in Month 3] there were no significant symptoms. No examination was considered necessary and the patient was discharged.

[In Month 8], [Ms A] was again seen at a gynaecology outpatient clinic at Wairarapa DHB. From the notes '1. unprovoked urinary leakage any time, no UTI, normal flow and complete emptying, 2. dyspareunia, sensitive perineum' and O/E 'normal volume introitus but sensitive perineum. Vagina healthy, *c ..... (meaning unclear)* anterior wall, on palpation? Vaginal fistula -1.5 cm for EVO, not seen but felt. Discussed: EUA cystoscopy, inject perineum, ?refashion anterior vagina'. Signed at the end of the consultation but as no name written clearly I cannot be clear who the doctor was.

On the same day the consent form was signed for 'EUA cystoscopy inject LA/steroid to perineum ?refashion anterior vagina'. Signed by the same individual who signed for the outpatient visit. I assume that this is [Dr B] as he also dictated a letter which is dated [Month 9] for the outpatient clinic [in Month 8]. In that letter the following findings are described. 'On examination the introitus is of adequate volume but slightly sensitive and she has some irregular scarring around the suburethral area where I inserted the sling and I am not sure what is going on. To get some more information I have arranged an EUA and cystoscopy. We are going to inject the perineum with some local anaesthetic and steroid and possibly refashion the anterior vagina …'

[In Month 9] on the form with the title OPERATION RECORD under Diagnosis 'EUA cystoscopy urethral dilatation Fenton's procedure and excision nodule left groin'.

The issue that I have focused on is the performing of a Fenton's procedure (which is the posterior vagina) and excision of nodule in the left groin as neither of these procedures were consented.

a. What is the standard of care/accepted practice?

I have sought guidance on the standard of the consent process from the HDC website.

'The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint: *RIGHT 7 Right to Make an Informed Choice and Give Informed Consent* Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.'

And from a case documented on the HDC website.

'As discussed in case 07HDC11318, surgical services may be provided to a competent adult in non-emergency situations only if that patient makes an informed choice and gives informed consent, irrespective of what the doctor considers to be in the patient's best interests. In the absence of adequate consent preoperatively, "inadequate consent [cannot] be cured retrospectively".'

In my view the care for [Ms A] clearly does not meet the standard as the patient did not provide consent for the Fenton's operation or the excision of the left groin node.

Neither procedures are emergency procedures.

1. Fenton's procedure. A Fenton's procedure is on the posterior wall and involves incision of tissue and suturing. It is not such a common operation and should be used sparingly as the introitus is a sensitive area and prone to being a pain area in some women even without surgery. The purpose of a Fenton's operation is to increase the capacity of the lower part of the vagina by releasing or removing scar tissue. As a perineorrhaphy had been part of the overall surgical procedure [in Month 1] then this is the likely explanation for the sensitive perineum. There is no mention of a sensitive introitus prior to the original surgery.

It should have been possible to identify the need for a Fenton's procedure at the time of the outpatient appointment [in Month 8]. This needed a preoperative discussion as it may actually increase pain especially on a background of an already sensitive introitus.

2. Groin excision. The need for the left groin excision is not clear and it was not mentioned by the patient or the doctor at the outpatient visit [in Month 8]. It is possible it had developed in the interim weeks into something that needed removing. That seems unlikely that it would develop in only 4 weeks given the time since the surgery was 7 months earlier. However, it was at the site of the sling insertion and examination in a post operative patient with urinary leakage probably warranted inspection. The reason for the unconsented excision of the left groin nodule is not provided on the surgical record although the words punctum is mentioned so I assume it was puckered in some way. The sample was discarded and there is no histology. Once again additional surgery can result in more discomfort in a patient with pain symptoms even if in a different location.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be.

This is a moderate departure and breaches the code of the patient being able to make an informed decision. [Dr B] has explained that he thought the following sentence in the consent form used by Wairarapa covered his change in the surgery where the second bullet point says 'I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons'.

My response to this is that no justification was given for the additional two procedures. The HDC code recommends that if there was an emergency then undertaking procedures without consent could be justified. This was not an emergency. The HDC case 07HDC11318 mentioned above, also says 'surgical services may be provided to a competent adult in non emergency situations only if that patient makes an informed choice and gives informed consent, irrespective of what the doctor considers to be in the patient's best interests'.

This sentence in the consent form (see above) is not found in the other DHB consent forms I reviewed ([three district health boards]). None of them have a statement such as in the Wairarapa consent form.

The impact of the breach of the code is that the patient is left with vaginal pain which could have been exacerbated by the surgery. The issue of the groin nodule does not seem to have resulted in any major harm.

c. How would it be viewed by my peers?

I consider that my peers would be concerned by what was planned [in Month 9] as the patient had a sensitive perineum and also in the change in the planned operation during the surgery. The change from the consent form (refashioning the anterior vaginal wall) to what actually happened (Fenton's operation which is on the posterior wall) would also be a concern. It was not clear from the notes what was the concern with the anterior vagina wall. The sensitive perineum was mentioned and injection of LA and steroid was part of the planned operation. This did not happen. Perineal pain is often chronic and complex, especially if it arises in an area where there has been prior surgery such as for [Ms A]. It may be that the pain is a neuropathic pain. The area was described as sensitive. Further surgery in this area is unwise as further neural damage is likely. A trial of neuromodulating agents such as amytriptyline or gabapentin may have been more appropriate.

Furthermore the left groin nodule excision was also not consented and yet this would have been most likely to have been present four weeks earlier as it was 7 months since the original surgery. The tissue was discarded so there was no clinical concern about chronic granuloma or other pathological processes.

The documentation would also be considered inadequate as the signatures are illegible and there is no full name provided or role given. There isn't even space for this on the consent form.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Wairarapa DHB should urgently review their consent form. In particular they should remove the sentence that says 'I understand that procedures additional to that specified above may be carried out if it is in my/the patient's best interests and can be justified for medical reasons' as it could encourage surgeons to deviate from the written operation. The Wairarapa DHB form should reflect the guidance of the HDC.

They should also allow space for the surgeon's name to be written in full and the role.

Finally, consideration should be given to the development of a national consent form that all DHBs can use and that meets the guidance of the HDC.

Professor Cynthia Farquhar

27 August 2018

Complaint: [Ms A]

Ref: C17HDC02004

I have been asked to respond to the additional information provided by [Dr B] that the patient gave verbal consent to the excision of the nodule in the left groin at Wairarapa [DHB] by [Dr B in Month 9].

1. Was the care undertaken by [Dr B] clinically appropriate in the circumstances?
[Dr B] excised the nodule in the left groin at the request of the patient but failed to document this in the notes or on the consent form. It is a small procedure and so it was accidentally overlooked. This is not a major oversight.

The surgery on the posterior wall on the vagina (the Fenton's operation) was not consented and my comments on that procedure as given in my report on the 27th March 2018 stand. I acknowledge that this was likely done in the patient's best interest. Surgeons are in a difficult position once they detect something while the patient is under anaesthesia. Should they proceed or should they defer doing so and wait until they can discuss with the patient. That may involve a second procedure. However, the HDC code is clear that unconsented surgery should only be undertaken if it is an emergency.

2. If there has been a departure from the standard of care; how significant is the departure?

It is a departure according to the HDC code as stated above. Although the procedure is small the site of the surgery is a sensitive one. The alternative to surgery might have

been stretching and desensitization exercises provided by physiotherapists. I am not aware of how much ongoing pain the patient has. The significance is **minor to moderate** depending on the extent of ongoing pain. For example has there been an exacerbation and has this adversely affected her ability to have satisfactory sexual relationships.

3. How would the care provided be viewed by your peers?

I think that many of my peers would have been in a similar situation of trying to decide what to do. I think that most of them would not proceed with an unconsented procedure.

I note that [Dr B] is apologetic and has given this case a great deal of thought including expanding his consulting time and undertaking MPS Risk Management Workshops which he is to be commended for.

Professor Cynthia Farquhar"