Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC01044)

Introduction

1. This report is the opinion of Rose Wall, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided to Ms A by Dr B,[1] a consultant obstetrician and gynaecologist at a public hospital, Te Whatu Ora[2] (formerly a district health board (DHB)).

3. The complaint concerns informed consent for pelvic organ prolapse[3] repair surgery involving surgical mesh.[4] Following consultation with Dr B, Ms A consented to a hysterectomy.[5] However, during the preoperative period immediately prior to the surgery being performed, Dr B spoke with Ms A and the procedure was changed, and Ms A received repair surgery using surgical mesh, and no hysterectomy. Ms A raised concern that the surgery was performed without her informed consent.

[1] Currently Dr B resides and works overseas and no longer holds a New Zealand practising certificate.
[2] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to the DHB now refer to Te Whatu Ora.
[3] When one or more of the pelvic organs (bladder, uterus, and rectum) drops down into the vagina, and the muscles and ligaments in the pelvic floor become stretched or too weak to hold the organs in the correct place. Prolapse can occur in the front wall of the vagina (cystocele), in the back wall of the vagina (rectocele), in the uterus, or in the top of the vagina (vault).
[4] A medical device used when repairing weakened structures with the aim of providing additional support.
[5] A surgical procedure to remove the uterus.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

4. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care between 22 May 2014 and 22 September 2014 (inclusive).*
- *Whether Te Whatu Ora provided Ms A with an appropriate standard of care between 22 May 2014 and 22 September 2014 (inclusive).*

5. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Provider/obstetrician and gynaecologist
Te Whatu Ora	Provider

6. Further information was received from:

Dr C	Provider/obstetrician and gynaecologist
Dr D	Provider/urologist
Accident Compensation Corporation (ACC)	

7. Also mentioned in this report:

Dr E	Obstetrician and gynaecologist
Dr F	Obstetrician and gynaecologist
Dr G	Obstetrician and gynaecologist
Dr H	Urogynaecologist
Dr I	Gynaecologist, ACC advisor
Dr J	Musculoskeletal physician

How matter arose

Consultation with Dr B

8. On 14 June 2013, Ms A (aged in her sixties at the time of the events) was referred to Dr B by her general practitioner (GP) due to pelvic organ prolapse. Ms A also had urinary urgency[6] and some stress urinary incontinence.[7]

9. Ms A met with Dr B on 18 November 2013 at the Women's Health Department at the public hospital. In a reporting letter to Ms A's GP dated 21 November 2013, Dr B advised that Ms A presented 'feeling a bulge', which was uncomfortable when performing activities such as physical exercise. Dr B noted that Ms A had no 'urgent or urinary symptoms, does occasionally have loss of urine with a cough or sneeze or stress incontinence' but that this was not the 'most worrisome component'.

[6] Involuntary urine leakage accompanied or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to delay).
[7] Involuntary urine leakage on effort or exertion or on sneezing or coughing.

10. Dr B noted that Ms A had done pelvic floor exercises for several years, but that she had not received any physiotherapy. On examination, Dr B confirmed the diagnosis of pelvic organ prolapse. Dr B advised Ms A's GP:

> 'After discussion of all options including continuing with pelvic floor exercises and starting ovestin cream,[8] ring pessary[9] or surgery she wishes to proceed to surgery after a trial of pelvic floor exercises … I will make a referral through to physio and placed her on the waiting list for vaginal hysterectomy anterior posterior repair[10] and sacrospinous fixation.[11] Informed consent was [obtained], including risks benefits and alternatives, no absolute contraindication to the procedure.'

11. There is no reference to surgical mesh in Dr B's letter to Ms A's GP.

12. On the same day, Dr B referred Ms A to the Physiotherapy Department at the public hospital for pelvic floor exercises.

Provision of information and consent

13. During the consultation on 18 November 2013 Ms A signed a consent form for the surgery. The consent form was also signed by Dr B on 18 November 2013. Ms A and Dr B presented differing accounts of the information that was provided to Ms A, and about the informed consent process (which is discussed under the 'Discussion immediately prior to surgery' section below).

14. Due to the passage of time, Dr B could not specifically recall seeing Ms A in the clinic. However, Dr B said that the standard consent process in the clinic was to discuss the procedure in detail, as well as the risks, benefits, and alternatives. Dr B said that the alternatives included 'doing nothing, pessary or surgery'. Dr B said that the risk of recurrence of prolapse is 'always' discussed.

15. On 18 November 2013, Dr B also provided Ms A with an information pamphlet on pelvic organ prolapse, published by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) in August 2009.

16. The general risks of surgery outlined in the RANZCOG information pamphlet are cardiovascular risks, such as heart attack, blood clots or stroke, infection of the wounds, bleeding, and anaesthetic risks.

17. The specific risks of pelvic organ prolapse surgery outlined in the RANZCOG information pamphlet are that 'the procedure fails in about five to 10 women in 100', prolapse may recur, 'up to 30 women in 100 require another operation over the ensuing years because prolapse in other areas of the vagina can develop later', stress incontinence, difficulty

[8] A hormone replacement therapy.
[9] A soft device inserted into the vagina to support the walls of the vagina and/or uterus.
[10] Surgery to repair the pelvic organ prolapse involving moving the bladder and rectum back into their normal positions.
[11] Slowly dissolving or permanent stitches are placed into the top of the vagina or the cervix and attached to one or both strong ligaments in the pelvis to provide support to the uterus or vaginal vault.

passing urine after an anterior repair, a urinary tract infection, injury to the urethra or bladder, incomplete bowel emptying after posterior prolapse repair, intercourse may be painful, damage to the rectum or small intestine, a gas embolism can rarely occur during laparoscopy, and other rare complications, which include blood transfusion and damage to a ureter. The RANZCOG information pamphlet also states that complications of the mesh 'affect about one in 10 to 20 women', such as inflammation near the mesh, failure of tissues to heal around the mesh, or mesh rejection. It states that if this complication is severe, the surgical mesh may need to be removed and, rarely, the surgical mesh can erode into other organs such as the bowel or bladder and cause pain during intercourse.

18. Ms A said that she was happy that Dr B had suggested a hysterectomy, and she signed a consent form for the surgery on 18 November 2013. Ms A stated: 'I later wondered why [Dr B] did not offer or discuss with me all of the options available to prolapse patients.'

19. Ms A said that the risk of recurrence of prolapse was not discussed with her on 18 November 2013 and that if it had been discussed, she would have remembered. Ms A also said that Dr B did not discuss with her the risks in relation to surgical mesh. Ms A stated: 'I don't believe [Dr B] discussed the use of mesh let alone the risks on 18 November 2013 or at any other time.'

Surgery on 22 May 2014

20. Ms A's surgery was scheduled for 22 May 2014, approximately six months after having signed the consent form at her consultation with Dr B.

21. Ms A was admitted to the public hospital as scheduled, but the operation performed by Dr B on 22 May 2014 varied from the surgery documented on the consent form. Dr B performed an anterior and posterior repair, sacrospinous fixation using surgical mesh, and a cystoscopy.[12] No hysterectomy was performed.

Discussion immediately prior to surgery

22. Ms A and Dr B presented differing accounts of the discussion that occurred immediately prior to Ms A's surgery on 22 May 2014.

23. Ms A stated that Dr B did not obtain her informed consent for the surgery, and Dr B did not discuss 'changing the procedure and placing a mesh'. Ms A said that she did not understand that she would not be having a hysterectomy, and she did not agree to have surgical mesh inserted. Ms A stated:

> 'I had mentally prepared and believed I was to have a hysterectomy. After being prepped and [pre-medicated] I was put on a bed and wheeled near to the theatre. A few minutes before going into the theatre [Dr B] arrived and informed me [that] she may perform a different procedure and would have a better idea once she had started the surgery. I did not comprehend that I may not have a hysterectomy … I had no time to focus on anything other than having a hysterectomy [but] after the surgery I started

[12] A procedure to look inside the bladder and urethra.

> feeling anxious and worried as I remembered parts of what [Dr B] said just prior to surgery.'

24. Ms A also stated:

> '[Dr B] did not obtain my informed consent and … did not have a clear operation plan before beginning the surgery. [Dr B] attempted to inform me of changes to the original surgery we'd previously discussed just before the operation began outside the theatre doors. I did not take on board what [Dr B] was telling me, or have any time to consider questions. I had prepared myself to have a hysterectomy and nothing else. I do not believe my presentation symptoms were to the degree that warranted the insertion of [mesh]. I would never have consented to it if I had been given the chance. No one other than myself or any other patient, should have the right to make a life changing decision for themselves, not a surgeon by themselves. I found [Dr B's] professional care of me as a woman, was full of severe lack of transparency, truthfulness and knowledge on [Dr B's] part.'

25. On the other hand, Dr B stated that Ms A was aware that she would not be having a hysterectomy, and that she would be having surgery involving surgical mesh.

26. Dr B said that because it had been more than 30 days since Ms A's consent had been obtained (on 18 November 2013), a discussion with Ms A took place prior to the surgery being performed, to repeat the consent. Dr B said that this discussion occurred in the 'preop' room, across the hall from the operating theatre. Dr B said that Ms A had not had any anaesthesia at that point. Dr B stated:

> 'It was during this discussion that [Ms A] was surprised or asked again about recurrence of prolapse. I said yes, that is one of the dilemmas of any prolapse repair. I specifically at this time remember her asking, "Is there anything that you can do to prevent that recurrence from happening". Again, I specifically remember her asking this when I [counselled] her on the risks of prolapse surgery. At this time, I said, well we do have a new procedure that in comparison studies does have less chance of recurrence. In this surgery, the uterus is left in place because the studies at that time showed that by leaving the uterus in place, there was less risk of erosion.[13] In addition, the mesh (Mesh A) was a newer mesh which in studies had less complications and excellent results. I do remember as I was discussing this thinking, should I be changing this before the surgery, but also thinking, if I cancel the surgery, it will be another 4–6 months before she can reschedule. I discussed this with her, and she truly wished to have a procedure that at that time anyway had been shown to have less chance of recurrence and by leaving the uterus in place, less chance of erosion.'

27. Dr B stated that this discussion with Ms A is specifically remembered because it was not common to change a procedure 'right before the surgery in question'. Dr B said that in this instance, it was believed that Ms A was being offered 'a better option to suit her requests'.

[13] When surgical mesh pushes against and into the surrounding tissue, nerves, and organs.

28. Ms A disputes that she persuaded Dr B to perform a procedure different from the procedure she had consented to on 18 November 2013. Ms A said that if she was 'surprised' about the possibility of recurrence of prolapse, as Dr B has stated, this would have been because it had not been discussed with her earlier by Dr B. Ms A said that she would have remembered if this had been discussed with her at her earlier consultation with Dr B, in which case she would not have been 'surprised' by this information. Ms A stated:

> 'No way did I consent to leaving my uterus in place or having mesh used in the surgery. If, as [Dr B] says, I did consent why did [Dr B] leave my original consent as "Vaginal hysterectomy" if [Dr B] had no intention of removing my uterus? … I had had heavy bleeding problems for years before my period stopped and had been referred to the DHB Gynaecology Department in 1999 and 2002. I had really wanted a hysterectomy on those occasions, but it was not offered to me. So when [Dr B] offered hysterectomy in 2013 there was no way I'd change from that original consent. Many of my friends had spoken about life being so much better after hysterectomy and that was what I wanted.'

29. Dr B specifically remembers discussing 'the mesh', and said that the risk of recurrence of prolapse is 'always' discussed. Dr B stated that this illustrates another good reason to repeat the consents closer to the time of the surgery, as is done now.

30. The specific risks of pelvic prolapse surgery outlined in the RANZCOG information pamphlet include that 'the procedure fails in about five to 10 women in 100', and that prolapse may recur.

Consent form

31. Initially, the consent form was signed by both Ms A and Dr B in the clinic on 18 November 2013.

32. The consent form states that Ms A agreed to have a 'vaginal [hysterectomy] [anterior] [posterior] repair B sacrospinous fixation'. This description of the procedure is handwritten on the consent form. The words 'Right side' are handwritten on the consent form above the description of the procedure, and the words '+/- mesh' are handwritten on the consent form below the description of the procedure. The consent form states:

> 'The nature, effects, common complications and risks of the above procedure and the other options available to me for this condition have been explained to my satisfaction and I understand them. I agree to the administration of anaesthetics, medicines, or other forms of treatment normally associated with this procedure.'

33. The handwritten risks listed on the consent form are 'bleeding', 'infection', '[injury] to bowel bladder [ureters]', 'blood clots', 'anaesthetic risk', 'transfusion', 'mesh erosion and permanent'. This handwritten list does not include the risk of recurrence of prolapse.

34. The consent form (signed by both Ms A and Dr B on 18 November 2013) was signed by Dr B again on 22 May 2014 (on the day of the surgery). The consent form was initialled by Ms A on 22 May 2014. Ms A said that at first, she did not remember doing so but after she had received a copy of her medical records, she remembered initialling the consent form. Ms A

stated: 'I remember looking at [Dr B] and asking why I had to initial or what was I [initialling] and [Dr B] said something that implied [Dr B would] write it in later.'

35. As there were no distinguishing features, it is unclear from the consent form what handwritten information (particularly in relation to the description of the procedure and the risks listed) was originally included in the consent form on 18 November 2013, and what information was added by Dr B on 22 May 2014, immediately prior to Ms A's surgery.

36. Dr B accepts that the consent form should have included a cystoscopy, 'or at least possible cystoscopy'. Dr B said:

> 'I am very sorry that cystoscopy, which is commonly performed after a repair is not included in the consent. [Ms A] had no complications that would warrant an unplanned cystoscopy, which would be the only reason for it to not be on the consent.'

37. Dr B said that the consent form was 'very close' to the standard consent usually obtained for anterior and posterior repair surgeries. Dr B stated that the 'standard consent for these repairs' is:

> 'After discussion of all options including doing nothing, pessary or surgical management, the plan is made to proceed to a (procedure). Risks include bleeding, infection, injury to the bowel, bladder and ureters, blood clots, [anaesthetic] risk and risk of needing a transfusion. Additional risks related to this procedure include that mesh is a permanent medical implant which sometimes needs removal, revision and there is a risk of mesh exposure[14] which may need additional procedure.'

38. Ms A said that Dr B did not discuss with her the mesh-related risks, as outlined in Dr B's 'standard consent' (that 'mesh is a permanent medical implant which sometimes needs removal, revision and there is a risk of mesh exposure which may need additional procedure').

39. On the preoperative checklist form dated 22 May 2014, the 'proposed procedure' is documented as '[anterior posterior] repair; bilateral sacrospinous fixation + [vaginal hysterectomy]'. However, on the operation data form dated 22 May 2014, the words 'Vaginal Hysterectomy +' are crossed out, and the operation is documented as 'Anterior and Posterior repair + Bilateral sacrospinous fixation + mesh + cystoscopy'.

<u>Public hospital consent form</u>

40. Dr B said that the consent form used by the public hospital at the time of the events was not appropriate. Dr B stated that at the time of the events, the public hospital used a single page consent form 'that had no lines or spaces to write in the discussion that a doctor had with the patient'. Dr B said that many surgeons simply had the patient and the doctor sign the consent form 'without writing anything in their own words'. Dr B did not feel that this was appropriate, and routinely 'wrote in the procedure and the risks'.

[14] The same as mesh erosion.

41. Dr B said that it was around this time that the public hospital discussed adopting the consent form from another hospital (Hospital 2), which consisted of five pages instead of a single page. Dr B stated:

> 'In summary, repeating the consent right before the surgery and writing the risks of the surgery in the space between the lines (because there was no dedicated space to do this in comparison to the [other hospital's] consent) shows that my consent was above the standard for the consent process at [the DHB] at this time … The consent process that I undertook was above the standard currently in place at that time at [the DHB], specifically, by first consenting in the clinic, repeating the consent if it had been over 30 days, by writing in the risks even though there was no space on the single page consent to do this, repeating this in the dictation.'

42. Dr B said that to improve the consent form, there needed to be a dedicated space for the additional risks and details of the surgery, and, at the time of the events, this was present on Hospital 2's consent form, but not on the public hospital consent form.

Surgery on 22 May 2014

43. The clinical records note that at 7.40am on 22 May 2014, prior to the surgery, Ms A was given Panadol,[15] omeprazole,[16] and naproxen.[17]

44. Dr B performed the surgery assisted by Dr E, an obstetrician and gynaecologist who was working as a senior house officer (SHO).

45. Dr B's operation note describes Ms A's procedure as: '[Mesh A] anterior mesh and sacral hysteropexy,[18] anterior repair and posterior repair.' The operation note states:

> '[Ms A] was taken to theatre, prepped and draped in [dorsal lithotomy] position[19] after informed consent obtained for the above procedure [Mesh A anterior mesh and sacral hysteropexy, anterior repair and posterior repair] including risks, benefits and alternatives. Bladder straight catheter within immediate return of clear urine. After discussing with [Ms A] prior to the surgery on either a vaginal hysterectomy and repair or conservation of the uterus with placement of the mesh, a plan was made at the time of the procedure to place the mesh extra peritoneal[20] as this was a less [invasive] procedure and injection of anterior vaginal mucosa[21] performed by opening and placement of the mesh through the mid point of each sacrospinous ligament x 2 and sutured so that it laid flat … No complications with the procedure.'

[15] Used for pain relief.
[16] Used to prevent stress-related ulceration and may reduce the risk of aspiration pneumonia.
[17] A non-steroidal anti-inflammatory drug. Side effects include dizziness, light-headedness, headache, and drowsiness.
[18] Involves lifting the prolapsed uterus back into its normal position. This is done by using surgical mesh to lift the uterus and hold it in place.
[19] Lying on the back with the knees and hips flexed.
[20] Outside the peritoneal cavity.
[21] The mucous membranes of the vagina.

46. The procedure is documented in the clinical records as: 'Placed in lithotomy position, [d]ecision for mesh repair without vaginal hysterectomy, [r]outine procedure [without complications], [c]ystoscopy post procedure …'

Events prior to discharge

47. Ms A said that following the surgery and before her discharge from hospital, she informed another doctor that she had had a hysterectomy. Ms A said that the doctor responded that she believed Ms A still had her uterus, and that all would be explained during the post-surgery check with Dr B. Ms A stated: 'I was waiting to see [Dr B] in [h]ospital, but [Dr B] never arrived … I was becoming increasingly distressed with what had and was happening to me.'

48. At 10.30am on 23 May 2014 (the day following the surgery), Ms A was reviewed by Dr E. Dr E noted that Ms A was 'sore' with 'dull pain/rectal pain'. Dr E documented that she '[e]xplained to [Ms A] [the] nature of surgery with mesh'.

49. At 9.10am on 24 May 2014, Ms A was reviewed again by Dr E. Dr E noted that Ms A was 'feeling a lot better' and that her pain had settled. Dr E's plan was to discharge Ms A with a catheter, and for Ms A to have a follow-up appointment with Dr B at Dr B's clinic within six weeks' time.

50. Ms A was discharged on 24 May 2014. On the same day, Dr E completed a reporting letter to Ms A's GP. Dr E advised Ms A's GP that the operation performed on Ms A was '[Mesh A] anterior mesh and sacral hysteropexy, anterior repair, posterior repair, cystoscopy'. Dr E reported that it was a '[r]outine procedure no complications. Cystoscopy normal post procedure.'

51. There is nothing in the clinical records to suggest that following Ms A's surgery, Dr B reviewed Ms A at any time before her discharge from hospital.

Follow-up with Dr B

52. Ms A did not have the planned follow-up appointment with Dr B within six weeks from the date of her discharge.

53. On 30 August 2014 (approximately three months following the surgery), Ms A wrote to Dr B asking when she could expect to receive a follow-up appointment. Ms A said that she had understood that she would be having a follow-up appointment with Dr B within six weeks from the date of her discharge. In her letter to Dr B, Ms A stated:

> 'When we met in December 2013, I explained my problem and understood it to be a prolapse condition. During our discussions it was stated that I would need to have a full hysterectomy … Early on 22 May when I was waiting to go into surgery you came along and asked me to re-sign consent forms as the time had lapsed by a few days. You also asked if I was currently in a sexual relationship — which I am not — and mentioned the use of mesh. I didn't fully understand, but remember stating I'd leave it up to you to do what needed to be done. All went well I understand … The Dr on the Ward asked what

> I'd had done and when I said hysterectomy she thought I still had my uterus, checked her notes and said it would all be explained at my post operation check … I phoned Women's Health on at least two occasions early into the recovery time as I was wondering if my discharge and sore stomach were normal … I phoned again in July and was advised it would be early August before I'd get an appointment … I'd like a post operation appointment and check with you please. I'd like to know what you actually did to me during surgery and the impact this may have on my future.'

54. On 22 September 2014 (approximately four months following the surgery), Ms A met with Dr B for her first follow-up appointment following the surgery.

55. Ms A said that another person was present during the meeting, whom she believed to have been a medical student. Ms A stated:

> 'It was very difficult to ask [Dr B] anything in detail as they seemed to discuss things between them. I had a lot of pain in my right hip at that time and was using a walking stick. That pain was difficult to manage. I wanted to ask [Dr B] about the surgery, what [Dr B] did to me and why [Dr B] did it, but there was no opportunity due to the interaction between them and my hip pain.'

56. On 22 September 2014, Dr B advised Ms A's GP that Ms A had presented for follow-up. Dr B advised that on examination, Ms A was 'healing well', and she had been re-commenced on oestrogen cream. Dr B also advised Ms A's GP: '[Ms A has] good support with no evidence of recurrence. Precautions were given on mesh as a permanent implant.' Dr B told Ms A's GP that, going forward, Dr B would like to see Ms A annually.

Subsequent events

Examination in 2015

57. On 14 December 2015, more than a year after her follow-up appointment with Dr B, Ms A met with Dr F, a consultant obstetrician and gynaecologist at the public hospital. Dr F advised Ms A's GP:

> '[Ms A] was operated on by [Dr B] about 18 months ago, at which time she had some pelvic support surgery performed with mesh, unfortunately the records are not available, so I am unable to ascertain exactly what was performed. At this time she is doing well. She does complain of a little bit of urinary urgency and stress incontinence, but it is not too bad for her … On physical exam, the vulva appears normal. The vagina is mildly oestrogenic. Her cervix appears normal. No evidence of any mesh erosion noted. On bimanual exam,[22] she has good anterior and posterior support with only minimal cystocoele and rectocoele. She has good uterine support as well. I will have her use the Ovestin … and this might very well help with her urinary tract issues. Other than this, nothing else to add. I don't think she needs to come back and see us unless there are other concerns.'

[22] An examination of the pelvic organs, such as the uterus and ovaries.

Examination in August 2018 — Dr G

58. On 1 August 2018 (more than four years following her surgery), Ms A met with Dr G, an obstetrician and gynaecologist at the public hospital, because a cervical smear had shown atypical endometrial cells.

59. During this consultation, Ms A mentioned the option of a hysterectomy as well as removal of the surgical mesh because she had experienced a painful speculum examination.

60. Dr G arranged for Ms A to undergo a hysteroscopy[23] D & C,[24] which showed benign[25] results.

61. On 28 August 2018, Dr G referred Ms A to Dr H, a urogynaecologist, to discuss the possibility of a hysterectomy and removal of the surgical mesh. The reason for the referral was because Ms A had previously experienced a painful speculum examination and wanted the surgical mesh to be removed.

Examination in January 2019 — Dr H

62. Ms A met with Dr H on 7 January 2019. Dr H advised that he questioned whether the procedure performed by Dr B on 22 May 2014 was a sacral hysteropexy, or whether it was a transvaginal sacrospinous hysteropexy.[26] Dr H explained that a sacral hysteropexy is done 'from an abdominal approach' with surgical mesh, whereas a transvaginal sacrospinous hysteropexy is done through the vagina and is usually performed without surgical mesh.

63. Dr H said that without the operation note, he was unable to provide accurate advice, as he was unable to comment on 'exactly what was done or know exactly what implants' were in place. Dr H advised Dr G:

> 'I have requested these operation notes from [the public hospital], but obviously, I do not have these available for review with [Ms A] today. Please, in the future, for such cases, include this information, as I am not able to access [the DHB's] operation dictate reports [in this location].'

64. Dr H said that Ms A had a 'very painful speculum examination during the work up for her abnormal smear results' and, for this reason, she wanted the surgical mesh removed. Ms A said that this was not the first time that she had had pain in relation to speculum examinations and that 'severe pain' was present with each examination. Ms A said that she first started to experience pain at Dr B's examination on 22 September 2014, and that it worsened over time.

65. On examination, Dr H noted that there did not appear to be any significant pelvic organ prolapse, and there was no cervical mass or surgical mesh erosion or exposure.

[23] A procedure to examine the inside of the uterus.
[24] Dilation and curettage is a minor surgical procedure used to diagnose and treat conditions that affect the inside of the uterus.
[25] A condition or growth that is not cancerous.
[26] An operation performed through the vagina that involves supporting the uterus using stitches to fix it to a strong ligament inside the pelvis.

66. Dr H advised that he suspected that Ms A had had a transvaginal sacrospinous hysteropexy and that she may have had pain and tenderness related to the fixation points.

67. Dr H advised that he would be 'very reluctant' to recommend removal of the anterior surgical mesh because this was not what was contributing to Ms A's pain, and she did not have any 'significant difficulty' related to this. Dr H said that this advice was consistent with what professional societies were recommending for women who had had surgical mesh implants without significant ongoing complications or concerns. Regarding Ms A having a hysterectomy, Dr H advised Dr G:

> '[A] hysterectomy, in this situation, with the distorted anatomy, could be somewhat challenging and has increased risk of complications compared to the usual hysterectomy patient. If you are satisfied with your evaluation for the atypical endometrial cells seen on a cervical smear, then I would recommend conservative management due to her increased risk of complications, if hysterectomy were to be performed.'

68. On 15 February 2019, Dr H reviewed the operation note of Ms A's surgery on 22 May 2014. Dr H confirmed that Ms A had had a transvaginal sacrospinous hysteropexy, and not a sacral hysteropexy as documented on the operation note.

69. On 22 February 2019, after having reviewed the operation note of Ms A's surgery on 22 May 2014, Dr H wrote a further letter to Dr G. Dr H advised:

> '[Ms A] had undergone a pelvic organ prolapse operation with [Dr B] … on the 22nd May 2014. The exact details of this procedure are still a little bit unclear to me, but from reviewing the text of the operation note, it does appear that [Ms A] had an anterior [Mesh A] mesh prolapse repair and a transvaginal sacrospinous hysteropexy, as well as a posterior repair. I have deduced this from the description of the procedure, which is in conflict with the procedure that was listed in the operation name, which includes sacral hysteropexy. It does make sense now that she did have a transvaginal sacro-hysteropexy and this is consistent with the findings on my clinical examination.'

70. Dr H said that he stood by his previous recommendations, and advised that he would 'avoid a hysterectomy, pretty much at all costs, with the exception being the indications of malignancy'.

71. Dr H did not arrange any further follow-up for Ms A, and her ongoing care was to be managed by Dr G.

72. On 18 April 2019, Dr G reported to Ms A's GP on the outcome of the referral to Dr H. Dr G advised Ms A's GP that Ms A had pain only during speculum examinations or intercourse. At that point, Ms A did not have a partner and was not having intercourse. Dr G advised that in addition to this pain, Ms A had leg and back pain. He advised that while potentially this could

be due to the surgical mesh, it could also be due to spinal stenosis,[27] which Ms A had been diagnosed with in 2016.

Examination in September 2019 — Dr C

73. Prior to September 2019, Ms A underwent surgery for a hip replacement. Ms A said that after the hip replacement surgery, she was again left with back and pelvic pain, which had increased considerably. Ms A stated: 'I was so concerned wondering if my situation would ever change and started asking for advice from others in the health field that I came across.'

74. On 6 September 2019, Ms A met with Dr C, an obstetrician and gynaecologist, to seek another opinion on whether the surgical mesh could be the cause of her back pain. Ms A still had vaginal pain but only when she was being examined.

75. On examination, Dr C found that the majority of Ms A's pain was posteriorly, and that this related to the posterior repair surgery performed by Dr B on 22 May 2014. This was consistent with Dr H's findings on 7 January 2019. On examination, Dr C also found a normal cervix and no evidence of prolapse. Dr C advised:

> 'Based on my assessment on 6 September, there was tenderness in the posterior vaginal wall, where there was tightness of the levator[28] muscles from the posterior repair performed in 2014 and pain associated with a tight ridge of mesh in the distal margin where it attaches to her cervix and at the mesh arms as they extend around the cervix towards the sacrospinous ligament. This type of pain is usually due to the mesh being placed overly tight, placing excessive tension on the tissues. Excessive tightness on the mesh also distorts its shape which can lead to an abnormal inflammatory reaction and consequent pain. The posterior vaginal pain is a result of posterior repair done with sutures. I felt this would have been done quite "tight" and this means that the tissue is under excessive tension and scarring and muscular pain arises as a result. These are phenomena relating to the technique of the surgery and, I would suggest, are the cause of her vaginal pain (but not the back pain).'

76. Dr C advised, however, that Ms A's 'biggest problem' was her back pain, and not her vaginal pain. Dr C considered it unlikely that Ms A's back pain would improve if her gynaecological surgery was reversed. Dr C suggested that Ms A see her GP regarding further and ongoing management of her back pain.

77. Dr B disagrees with Dr C's assessment that the surgical mesh had been placed 'overly tight, placing excessive tension on the tissues'. Dr B said that Ms A had postoperative examinations, which were normal.

[27] A narrowing of the spinal canal.
[28] A broad muscle group that forms the greater part of the floor of the pelvic cavity and takes part in supporting and raising the pelvic floor.

Complaint to Te Whatu Ora

78. On 17 September 2019, Ms A made a complaint to Te Whatu Ora about her surgery on 22 May 2014. In her complaint to Te Whatu Ora, Ms A said:

> 'I am very unhappy about the changes [Dr B] made to the surgery in 2014, particularly at a time when I was incapable of receiving and considering the information [Dr B] was giving me … My experience would have been better if I had been fully informed about [Dr B's] plans to change my surgery and given time to consider it. At the time [Dr B] spoke to me on 22 May I was prepared and very happy to be receiving a hysterectomy and couldn't take on board anything different … I really hope other people have many days to consider changes to surgery and not the few minutes I was given …'

79. Following Ms A's complaint, Te Whatu Ora met with Ms A and assisted her with a referral for a hysterectomy, and removal of the surgical mesh. Ms A told HDC:

> 'The meeting ended positively with discussions about referring me for [mesh] removal and hysterectomy. It was agreed [Dr G] would make the referral which he did to [two] Urologists.'

Pelvic ultrasound — 19 April 2021

80. Due to the surgical mesh complications from her surgery on 22 May 2014, Dr D, a urologist, referred Ms A for a pelvic ultrasound on 19 April 2021.

81. The ultrasound showed:

> 'There is a broad synthetic anterior mesh identified, with the inferior margin located approximately 2 cm below the bladder neck and extending superiorly to within 1.6 cm of the cervix. This passes smoothly laterally before being obscured by shadowing along the sidewall … The inferior portion of the mesh appears to have eroded through the vagina wall …'

82. Based on the ultrasound findings, the radiologist stated:

> 'Anterior vaginal wall mesh in situ, with the inferior portion appearing eroded through the vaginal wall with marked associated pain in this region on transvaginal ultrasound, despite the use of lignocaine gel. The mesh is providing good support and otherwise has standard appearance ...'

83. Dr B said that the ultrasound showed that the surgical mesh was in the correct place, but it showed mesh exposure. Dr B stated that mesh exposure occurs in 17% of transvaginal mesh implants, and this is a known complication of surgical mesh implants for prolapse. Dr B is sorry that Ms A had a mesh exposure.

84. Dr B considers that based on the notes, there is evidence that Ms A had 'high tone pelvic floor dysfunction'. Dr B explained that this is where the pelvic floor muscles are in a constant

state of contraction or spasm, and the presenting symptoms are 'groin pain, back pain, vaginal pain, difficulty emptying, urgency, constipation, and [dyspareunia[29]]'. Dr B stated:

> 'I agree that the surgery I performed has exacerbated high tone pelvic floor dysfunction because the way this procedure is performed is by placement of mesh arms through the sacrospinous ligaments bilaterally. However, I would like to point out that this risk of pain with placement of sutures through the sacrospinous ligament is a known risk with these vaginal procedures regardless of whether mesh is used … Placement of sutures or the mesh arms through the sacrospinous ligament may exacerbate pelvic floor dysfunction. Her hip and back pain most certainly contributed to her pelvic floor dysfunction, and this was present prior to the surgery.'

Removal of surgical mesh and hysterectomy

85. On 20 April 2021, Ms A met with Dr D to discuss the surgical options. Dr D proposed surgery for 'a total complete removal of the upper anterior vaginal mesh +/- concurrent fascia lata[30] harvest and fascial sacrocolpopexy[31] with a total abdominal hysterectomy'.

86. On 15 October 2021, Dr D performed the eight-hour-long surgery assisted by a urologist. The surgery is described in the operation note as: 'Harvest of fascia lata from right thigh, [r]obotic assisted removal of [Mesh A] vaginal mesh + total abdominal hysterectomy + bilateral salpingo-oopherectomy[32] + fascial sacrocolpopexy + cystoscopy.'

87. Following the removal of the surgical mesh, Ms A's back pain improved, but she had stress urinary incontinence as well as urge incontinence. Urodynamic studies [33] showed dysfunctional voiding. Dr D believed that Ms A's stress urinary incontinence could be improved with pelvic floor relaxation through physiotherapy. Dr D suggested Bulkamid[34] and Botox[35] injections if the pelvic floor physiotherapy did not improve Ms A's condition.

88. On 21 December 2021, Dr D injected Ms A with Bulkamid and Botox for urge incontinence.

89. On 13 January 2022, Dr D reported to Ms A's GP that she had been 'very well' since her Bulkamid and Botox injection on 21 December 2021. Dr D noted that Ms A was no longer using any pads, and that she had no stress urinary incontinence.

[29] Painful intercourse.
[30] Deep, strong, connective tissue of the thigh, which can be harvested and used to reinforce weakened tissue during pelvic organ prolapse or stress incontinence surgery.
[31] A procedure that suspends the vagina or uterus back to its normal position, using a synthetic graft of native tissue (fascia lata).
[32] Removal of the ovaries and fallopian tubes.
[33] To examine and assess the function of the bladder.
[34] A minimally invasive and long-lasting treatment option for bladder leaks caused by stress urinary incontinence.
[35] Botulinum toxin, used to treat urge incontinence or an overactive bladder.

Te Whatu Ora's Adverse Event Report

90. Following Ms A's complaint, Te Whatu Ora conducted a review of the events and completed an Adverse Event Report (AER).

91. The AER notes that Dr B had left the country and that Te Whatu Ora was unable to locate Dr B to explain the care provided. The AER was therefore completed without any involvement from Dr B.[36]

92. The AER states that on 18 November 2013 Ms A consulted Dr B for pelvic organ prolapse and consented to a vaginal hysterectomy on the same day. The AER also states that on the day of the surgery (22 May 2014), Ms A was informed of a new suspension surgery to fix her problem, after she had been given sedation. The AER notes that after the operation, Ms A was not fully informed of the nature of surgery performed. The AER states:

> 'The procedure consent form used at the time was re-written and altered to fit Mesh, date and time of alteration is not clear. As per the two Urogynaecologist[s] who have reviewed the patient, the documented description of the surgery is not consistent with the surgery previously consented for or what was expected of the surgery done. The expected standards of care were not followed for obtaining informed consent for this major surgery.'

93. The main conclusions outlined in the AER are:

- 'Standards were not followed for obtaining consent for the surgery.'
- 'Documentation for surgery is not consistent with expected standards for surgery.'
- 'Standard of care were not met for the patient as she clearly wanted and expected a hysterectomy at the time.'
- 'Going [forward], patient needs to be supported to access care for pelvic pain, backache, psychological effects and occupational needs as well as needed further complaint process.'
- 'The surgeon is not available for explanation — no longer working or registered in New Zealand.'

94. The AER states that the 'root cause(s)' were:

> 'Expected standard procedures for obtaining informed consent were not followed resulting in patient not getting her expected operation which was a hysterectomy when the surgery was changed on the day of surgery.'

95. The AER states that the contributory factors were a '[l]ack of perioperative review by surgeon', a '[d]elay in post operation follow up by [the] surgeon', and '[a]mendments to the consent form were not recorded on the standard consent form'.

[36] HDC was able to locate Dr B and Dr B has provided input into HDC's investigation process.

96. The following recommendations for changes were made, as set out in the AER:

> '• [Ms A] wanted a hysterectomy and is distressed that she did not get a hysterectomy but instead she underwent a procedure that she was not aware of or had explained 12 weeks after the surgery. Informed consent was therefore not obtained. The Women's Health Department should therefore accept responsibility and apologise to [Ms A] for the medical misadventure …
>
> • Processes for obtaining consent in the Women's Health [D]epartment should be reviewed if this has not happened since 2013 with the use of a consent form that captures more information and has a portion for comprehensive documentation if the surgery has been changed.
>
> • Surgical procedure for an elective patient should not be changed on the day of surgery neither should it be changed in the anaesthetic room or in theatre.
>
> • The Women's [H]ealth [D]epartment should ensure the process time for postsurgical review of patients is within 6 to 8 weeks.
>
> • The DHB's Women's Health Service should ensure that a referral is made to the appropriate services for Ms A's back and mesh pain and a psychologist. ([Ms A] said that she was referred to a psychologist by ACC in early 2022, when she became distressed after a fall, and not by the Women's Health Service.)
>
> • Keep options open for review with [accredited] mesh removal gynaecologists — have to be specifically credentialed for mesh removals.'

ACC

97. Following the events, a treatment injury claim was submitted to ACC. ACC obtained clinical advice from a consultant gynaecologist, Dr I.

98. Dr I advised that Ms A's initials on the consent form, as well as Dr B's reference in the operation record about the discussions immediately prior to the surgery, indicate that there was 'some degree' of consent from Ms A to Dr B's recommendation for a surgical mesh repair, rather than a hysterectomy. Dr I advised, however, that Ms A did not specifically consent to the particular surgical mesh (Mesh A) being used, where the surgical mesh would be placed, the amount of surgical mesh that would be used, to bilateral sacrospinous fixation being included in the surgical mesh placement, or to a cystoscopy (cystoscopy is not included on the consent form).

99. Dr I described Dr B's operation note as 'confusing and disordered and not consistent with usual clinical documentation/surgical procedure descriptions'. Dr I advised that there are inconsistencies in the documentation, eg, 'sacral hysteropexy', which is documented on the operation record. Dr I explained:

> '[Sacral hysteropexy] is not a procedure that is approached vaginally, (sacro-hysteropexy is an abdominal procedure supporting a uterus to the sacral promontory). This surgery would be more correctly titled "[m]esh sacrospinous hysteropexy".'

100. Dr I advised:

> 'The description in the clinical record indicates the final decision on surgery was determined intraoperatively,[37] not preoperatively whether a hysterectomy would be performed … Examination under anaesthesia with decision intraop is not documented as a preop plan on the consent.'

101. Dr I advised that if surgical mesh is being recommended, it would be usual to provide 'case specific justification'. Dr I stated:

> 'Mesh has never generally been considered as indicated for first vaginal prolapse surgery. [Dr B's] reasoning for considering mesh remain unexplained. (The patient's only understanding was that this would avert [the] need for hysterectomy and that it was [a] "new procedure".) Postoperative risks are listed on the formal consent form including "erosion", however pain, dyspareunia, and long-term surgical challenges if there are complications are not mentioned … The timing of the change in surgical plan, when [Ms A] was alone, prepped, in her surgical gown and just outside the theatre typically pressured/nervous was in my opinion entirely inappropriate, and would not have supported informed consent and decision making.'

102. ACC approved Ms A's treatment injury claim. In summary, ACC concluded that there was a failure to gain informed consent for a surgical procedure, including insertion of mesh. ACC also concluded that the 'surgery has resulted in a consequential injury of tissue tension and distorted anatomy from incorrectly placed surgical mesh leading to vaginal pain'.

Relevant policies, procedures, and guidelines

Informed consent policy

103. Te Whatu Ora's Informed Consent for Health Care Procedures Policy (Informed Consent Policy) at the time of the events stated:

> 'Informed consent is the result of an interactive process involving communication between a clinician or clinical team and patient.
>
> - The communication must occur in an environment that enables the parties to communicate openly, honestly, and effectively.
> - Clinicians must therefore provide the information in relation to a proposed procedure in a form, language, and manner that the patient can understand.
> - The patient has the right to consider fully the information given and to seek further opinion.
> - The patient, free from coercion, then consents to the procedure.
> - The patient has the right to refuse or withdraw consent at any time …

[37] During a medical operation.

> The provider undertaking the health care procedure has primary responsibility for ensuring full and correct information is given regarding that procedure … In general, the person who is performing the health care procedure should be the person gaining consent.'

104. Since the events, Te Whatu Ora has updated its Informed Consent Policy, which is discussed below (under 'Changes made since events').

RANZCOG guideline

105. In July 2007, RANZCOG developed its guideline 'Polypropylene vaginal mesh implants for vaginal prolapse'[38] (RANZCOG guideline). The guideline provides advice on the use of mesh for the treatment of vaginal prolapse.

106. In March 2013, RANZCOG provided recommendations for the consent process in relation to surgical mesh. It stated that the consent process should be wide ranging and cover issues such as:

> '• The patient should be informed that very limited robust data is available on the efficacy and safety of many of the transvaginal mesh products available in Australasia …
>
> • Complications discussed of transvaginal mesh must include mesh exposure/erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or pelvic pain which may require additional intervention and may not be completely resolved even with mesh removal. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest should be discussed.'

Further information

Ms A

107. Ms A told HDC about the impact these events have had on her life. She stated:

> 'It has been a long and difficult journey since May 2014 and to date has resulted in me no longer being able to work due to my own increased symptoms of PTSD.[39] My GP is supportive and prepared a Medical Certificate initially for 2 [weeks], but increased it for 3 [months] up to [22 December 2023]. This [brought] my Private Practice business … to an abrupt end earlier than I'd hoped and planned …'

108. Ms A provided HDC with a copy of a report from Dr J, a musculoskeletal physician, dated 4 December 2023. Dr J's report states:

> '[Ms A] … has chronic low back pain, bilateral buttock and ischial pain, bilateral achy pain posterior legs and numbness toes, these problems developed following a failed pelvic floor repair with mesh on [22 May 2014], requiring further surgery, as well as abdominal post surgical incision hernia … Internal disc disruption lower 4 lumbar discs

[38] First endorsed by RANZCOG in July 2007, and due for review in March 2026.
[39] Post-traumatic stress disorder.

> likely present prior to pelvic surgery but because she was keeping herself very fit did not give significant problems. The pelvic floor failed surgery and subsequent problems has accelerated lumbar disc pathology, she has developed significant spinal stenosis at L3/4, right lateral recess and foraminal narrowing at L4/5 compromising the right L4 nerve foot …'

109. Ms A said:

> '[Dr J] is the first medical professional to acknowledge the surgery on [22 May 2014] contributed to the pain and fatigue in my lower back, buttocks and all the way down the backs of both legs. Others have suggested [it's] degenerative and related to my spinal stenosis diagnosis … The injuries and effects from that surgery on [22 May 2014] just seem to keep on going … I definitely don't want others to go through this and hope there is a way to stop it.'

110. Ms A stated:

> 'It is very important to me that my voice is heard … to help other [mesh] harmed women and women suffering from pelvic floor prolapse to have more choices, informed consent, transparency and more information offered to them.'

Te Whatu Ora

111. Te Whatu Ora has provided a formal written apology to Ms A for the distress she has suffered as a result of her experience at the public hospital. Te Whatu Ora said that it acknowledges Ms A and understands that this has been a very traumatic experience for her. Te Whatu Ora said that it would like to reiterate the sincere apology that was made to Ms A previously.

112. Te Whatu Ora also met with Ms A following her complaint and referred her to an accredited mesh removal specialist, as well as to the Pain Service for treatment of her ongoing pain.

113. Te Whatu Ora said that it was of the view that Dr B was 'very well qualified and had an appropriate range of experience', and it was on the basis of Dr B's 'extensive obstetrics and gynaecology experience, training and skills' that Dr B was employed by Te Whatu Ora as a consultant obstetrician and gynaecologist. Te Whatu Ora said that it did not have any concerns about Dr B's performance.

114. Te Whatu Ora stated that Dr B did not have a supervisor assessing Dr B's processes of obtaining informed consent and performing surgical mesh surgeries. Te Whatu Ora said that in 2013 Dr B was promoted, reflecting that Te Whatu Ora was confident in Dr B's abilities. Te Whatu Ora said that this role involved clinical leadership alongside providing patient care.

115. Te Whatu Ora advised that it has not received any other complaints relating to surgical mesh procedures performed by Dr B.

Dr B

116. Dr B stated:

> 'In summary, I am sorry that [Ms A] has had pain contributed to by my pelvic floor surgery. I am sorry that she had a mesh exposure. In addition, I am sorry that the consent did not include cystoscopy as it should have.
>
> I believe that I provided an appropriate standard of care and was appropriately trained and provided care addressing her specific requests at that time to reduce the risk of recurrence.'

Responses to provisional opinion

Ms A

117. Ms A was given an opportunity to respond to the 'Introduction', 'How matter arose', and 'Changes made since events' sections of the provisional opinion.

118. Ms A's comments have been incorporated into this opinion where relevant and appropriate.

Dr B

119. Dr B was given an opportunity to respond to the sections of the provisional opinion that relate to the care Dr B provided.

120. Dr B apologised to Ms A that her expectations were not met with the surgery Dr B performed in May 2014. Dr B stated:

> 'Although at that time I thought that I was offering a better procedure to suit a specific clinical situation, I, like all urogynaecologists understand more fully the issues with transvaginal mesh procedures outweigh the benefits of less prolapse recurrence. Given the mesh issues, I accept that it was unwise to change to a procedure with a mesh right before the surgery. Although I would never perform a surgery on someone if I didn't think they were adequately consented, as patient choice and especially women's choice and shared decision making are of utmost importance to me, I acknowledge that this was a new procedure and this decision to do this new procedure should not have been made without more time to consider.'

121. Dr B also apologised that a review of Ms A did not occur six weeks following the surgery. Dr B is unsure why no follow-up occurred and said that it is standard practice to see patients six weeks following surgery, or prior to this, if necessary.

Te Whatu Ora

122. Te Whatu Ora was given an opportunity to respond to the provisional opinion.

123. Te Whatu Ora's comments have been incorporated into this opinion where relevant and appropriate.

Opinion: Dr B — breach

124. First, I acknowledge the challenges Ms A has been confronted with following her surgery in 2014. Ms A experienced persistent pain over an extended period, and eventually, in 2021, she underwent an eight-hour-long surgical procedure to remove the surgical mesh. The psychological impact of this experience should not be underestimated, and clearly the ramifications of the surgical mesh insertion continue to affect Ms A's physical wellbeing on a day-to-day basis.

125. I have undertaken a thorough assessment of the information gathered in light of Ms A's concerns, and I consider that Dr B breached Right 6(1)(b) and Right 7(1) of the Code of Health and Disability Services Consumers' Rights (the Code). The reasons for my decision are set out below.

Informed consent process

Information provided

126. Right 6(1)(b) of 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, side effects, benefits, and costs of each option.

127. Ms A initially signed the consent form on 18 November 2013. On 22 May 2014, immediately prior to the surgery, Ms A initialled the consent form but does not remember doing so. According to the AER report she had been sedated at the time Dr B informed her of the new suspension surgery to fix her problem.

128. The consent form states that Ms A agreed to a 'vaginal [hysterectomy] [anterior] [posterior] repair B sacrospinous fixation'. The words 'Right side' and '+/- mesh' are also handwritten on the consent form. The consent form states:

> 'The nature, effects, common complications and risks of the above procedure and the other options available to me for this condition have been explained to my satisfaction and I understand them. I agree to the administration of anaesthetics, medicines, or other forms of treatment normally associated with this procedure.'

129. The RANZCOG guideline at the time of the events stated that the consent process should be wide ranging, and that the complications of transvaginal mesh to be discussed must include:

> '… mesh exposure/erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or pelvic pain which may require additional intervention and may not be completely resolved even with mesh removal. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest should be discussed.'

130. The consent form shows that the only documented risks discussed were 'bleeding', 'infection', '[injury] to bowel bladder [ureters]', 'blood clots', 'anaesthetic risk', 'transfusion', 'mesh erosion and permanent'.

131. There is no reference to any of the other risks specific to the particular procedure, which included the risks associated with surgical mesh, such as vaginal scarring/stricture, fistula formation, and persistent pelvic pain (which may be unprovoked). Except for dyspareunia (pain during intercourse), these other mesh-related risks are also not referred to in the RANZCOG information pamphlet that was provided to Ms A on 18 November 2013.

132. Based on the documentation, insufficient information was provided to Ms A about the risks of surgical mesh surgery for vaginal prolapse.

133. While the risk of recurrent prolapse is mentioned in the RANZCOG information pamphlet that was provided to Ms A on 18 November 2013, and while Dr B may have discussed some of the risks with Ms A ('mesh erosion and permanent'), Dr B did not discuss all the surgical mesh-related risks and complications, as recommended by RANZCOG in March 2013. This view is supported by Dr I, who advised:

> 'Postoperative risks are listed on the formal consent form including "erosion", however pain, dyspareunia, and long term surgical challenges if there are complications are not mentioned …'

134. I appreciate that the consent process is 'more nuanced' than merely what is written on the consent form, and that the most important aspect is the verbal discussion that occurs between the surgeon and patient.

135. In this case, Dr B and Ms A have different recollections of the discussions. Ms A stated that she did not consent to surgical mesh being used, whereas Dr B specifically remembers discussing 'the mesh'.

136. As the clinical records do not contain any other details about what Dr B discussed with Ms A about the risks, it is not possible for me to determine exactly what information was provided to her during their verbal discussions. However, in most cases, it is reasonable to assume that the items written on the consent form at least summarise the content of discussions.

137. Based on the available documentation (being what is documented on the consent form), Dr B did not provide sufficient information to Ms A about the risks and complications of using surgical mesh to allow an informed choice.

Consent to procedure

138. On 22 May 2014, Dr B performed an anterior and posterior repair, sacrospinous fixation using surgical mesh, and a cystoscopy on Ms A. No hysterectomy was performed.

139. There are numerous inconsistencies in the clinical records in relation to the procedure. The procedure performed by Dr B differs from what is documented on the consent form, as well as the operation note.

140. The procedure documented on the consent form is a 'vaginal [hysterectomy] [anterior] [posterior] repair B sacrospinous fixation', with the words '+/- mesh' documented below the description of the procedure.

141. The operation note describes the procedure as '[Mesh A] anterior mesh and sacral hysteropexy, anterior repair and posterior repair'.

142. On the preoperative checklist form dated 22 May 2014, the 'proposed procedure' is documented as '[anterior posterior] repair; bilateral sacrospinous fixation + [vaginal hysterectomy]'. However, on the operation data form dated 22 May 2014, the words 'Vaginal Hysterectomy +' are crossed out, and the operation is documented as 'Anterior and Posterior repair + Bilateral sacrospinous fixation + mesh + cystoscopy'.

143. Ms A did not receive a hysterectomy, as documented on the consent form. Ms A consented to and received a sacrospinous hysteropexy, but this was recorded inaccurately in the operation note as a sacral hysteropexy. Ms A had a cystoscopy, but this is not documented on the consent form.

144. Ms A and Dr B have different recollections of the discussions and the procedure that Ms A agreed to. Ms A stated that she did not consent to surgical mesh being used and to having no hysterectomy. Dr B stated that a discussion with Ms A occurred about leaving the uterus in place (ie, no hysterectomy) and using surgical mesh. Dr B accepts, however, that the procedure was changed just before Ms A's surgery.

145. Having considered the evidence available, on balance, I find that Ms A did not consent to having no hysterectomy on 22 May 2014. While 'vaginal hysterectomy' has been crossed out on the operation data form, it has not been crossed out on the consent form, or on the preoperative checklist form.

146. It is clear from the evidence that even after the surgery, Ms A did not comprehend that she did not have a hysterectomy, and she had no understanding of the procedure that had been performed on her.

147. In addition, I consider that Ms A did not agree to surgical mesh being used. Due to the lack of detail on the consent form, I am unable to determine when Dr B first discussed with Ms A the option of having surgery involving surgical mesh, and whether this occurred in the clinic on 18 November 2013, or immediately prior to the surgery on 22 May 2014. Dr B's letter to Ms A's GP dated 18 November 2013 states that Ms A had been placed on the waiting list for a 'vaginal hysterectomy anterior posterior repair and sacrospinous fixation'. The letter makes no reference to surgical mesh. This suggests that it is more likely than not that Dr B did not discuss surgery involving surgical mesh with Ms A in the clinic, and that it was first discussed immediately prior to the surgery on 22 May 2014.

148. Te Whatu Ora acknowledged that the consent form was 're-written and altered to fit [m]esh', and that the date and time of the alteration is not clear.

149. Nevertheless, even if Ms A had agreed to the surgery involving surgical mesh and no hysterectomy, I am critical that Dr B changed the elective procedure immediately prior to the surgery being performed on 22 May 2014. In my view, anticipating that a consumer is in a position to make an informed choice and give informed consent in such a circumstance is a fundamental failing, and should not have occurred in any circumstance.

150. This was contrary to Te Whatu Ora's Informed Consent Policy at the time of the events, which stated that the patient had the right to consider fully the information given and to seek further opinion.

151. This was also contrary to the Medical Council of New Zealand's statement on 'Information, choice of treatment, and informed consent',[40] which states that the patient must have the opportunity to consider and discuss the relevant information with the treating doctor.

152. Informed consent is an ongoing process where there are multiple opportunities for the consumer to receive information and ask questions of the healthcare provider concerned. To help a consumer decide whether they agree to a particular treatment or procedure, the healthcare provider must give the consumer all the information they need in an understandable format to enable them to consider it and make an informed decision.

153. In my view, providing Ms A with significant new information just before undergoing major surgery was inappropriate. I agree with Ms A's comments that she was 'incapable of receiving and considering the information' that Dr B had provided to her just before the surgery. Ms A had insufficient opportunity to fully consider the information to which she was entitled, before consenting to the procedure. This view is supported by Dr I, who advised:

> 'The timing of the change in surgical plan, when [Ms A] was alone, prepped, in her surgical gown and just outside the theatre typically pressured/nervous was in my opinion entirely inappropriate, and would not have supported informed consent and decision making.'

154. Te Whatu Ora acknowledged that the 'expected standard procedures for obtaining informed consent were not followed'.

Conclusion

155. Dr B did not provide Ms A with adequate information to allow her to make an informed choice, as she was not provided with information about all the mesh-related risks and complications. This was information that Ms A could reasonably have expected to receive in the circumstances. In addition, Ms A had insufficient opportunity to fully consider the information to which she was entitled. Accordingly, I find that Dr B breached Right 6(1)(b) of the Code. It follows that Ms A was unable to give informed consent to the surgery that occurred, and that Dr B also breached Right 7(1) of the Code.

[40] March 2011.

Follow-up care — adverse comment

156. Following the surgery on 22 May 2014, Dr B did not review Ms A at any time before she was discharged from hospital.

157. Following her discharge, Ms A was meant to have a follow-up appointment with Dr B within six weeks' time, but this did not occur. On 30 August 2014 (approximately three months following the surgery), Ms A wrote to Dr B requesting a follow-up appointment. Ms A had her first follow-up appointment with Dr B on 22 September 2014 (approximately four months following the surgery).

158. I am concerned about Dr B's lack of follow-up and after care of Ms A. As the consultant, Dr B was responsible for overseeing Ms A's recovery following her surgery. Instead, it was left to Ms A to contact Dr B to arrange a follow-up appointment. As a result of the follow-up appointment not being arranged, Ms A was subjected to further delay in her clinical situation being clarified. I acknowledge how distressing this would have been for Ms A, particularly given the uncertainty and questions around the surgical procedure that had been performed on her.

159. Te Whatu Ora acknowledged that there was a lack of perioperative review, and a delay in post-surgery follow-up by Dr B.

160. This Office has previously made adverse comments about a healthcare provider who failed to arrange a six-week follow-up appointment for a patient following a surgical procedure.[41]

161. Dr B should have reviewed Ms A prior to her discharge from hospital and should have arranged follow-up with Ms A earlier to ascertain whether the surgery had been successful, and that there were no complications. I am concerned that this did not occur. Timely follow-up was particularly important in this circumstance where Ms A's operation had changed at late notice.

Placement of surgical mesh — other comment

162. When Ms A met with Dr C on 6 September 2019, Dr C advised that the type of pain Ms A was experiencing was usually due to the surgical mesh being placed 'overly tight'. Dr B disagrees with this assessment. Dr B said that Ms A's postoperative examinations were normal. Dr B also said that the ultrasound on 19 April 2021 showed that the surgical mesh was in the correct place, but that there was mesh exposure.

163. There is an innate difficulty in retrospectively reviewing the standard of care in surgical mesh cases where questions are raised about the appropriateness of the surgical mesh placement at the time the surgery was performed. Due to the passage of time (from the surgical mesh insertion in 2014 until the surgical mesh removal in 2021), and the unavailability of any prior imaging, it is not possible for me to determine whether the mesh was inserted correctly.

[41] 15HDC00312.

164. I also acknowledge that the ultrasound on 19 April 2021 was not available to Dr C at the time of his assessment.

Opinion: Te Whatu Ora

Follow-up care — adverse comment

165. Dr B did not review Ms A following the surgery and prior to Ms A's discharge from hospital. Following the surgery, Ms A was unsure what surgical procedure had been performed, and whether or not she had undergone a hysterectomy.

166. On 23 May 2014, on the day following the surgery, Ms A was reviewed by another gynaecologist and obstetrician on the ward, who documented that she provided Ms A with an explanation of the nature of the surgery with surgical mesh.

167. On 30 August 2014, approximately three months following the surgery, Ms A wrote to Dr B requesting a follow-up appointment. Ms A advised Dr B:

> 'The Dr on the Ward asked what I'd had done and when I said hysterectomy she thought I still had my uterus, checked her notes and said it would all be explained at my post operation check …'

168. Ms A also advised Dr B that she contacted the hospital on at least two occasions as she was unsure about her recovery, and the surgery that was performed.

169. I am concerned that Dr B did not review Ms A prior to her discharge from hospital. In addition, I am concerned that none of the staff took any action to address Ms A's concerns about the procedure that was performed, or her recovery, when it was raised with them.

170. The doctor on the ward took no action when she became aware that Ms A did not have a clear understanding of the surgery that had been performed. I would have expected the doctor to have followed up on this promptly to ensure that Dr B was made aware of Ms A's confusion about the procedure.

171. Similarly, when Ms A contacted the hospital on two occasions following her discharge, the staff took no action to ensure that Dr B was made aware of Ms A's concerns. Ms A's concerns about her procedure and recovery should have been addressed with urgency and I am concerned that this did not occur.

172. Because multiple staff members (the doctor on the ward and the other hospital staff) had the opportunity to ensure that Ms A's concerns following the surgery were addressed promptly but did not do so, in my view, this deficiency in the follow-up care was a service delivery failure, and responsibility rests with Te Whatu Ora.

173. I commend Te Whatu Ora for the steps it took and the support it provided to Ms A following receipt of her complaint. Te Whatu Ora has made changes to its Informed Consent Policy and consent form. Te Whatu Ora also assisted Ms A by referring her to Dr D for the removal of the surgical mesh and a hysterectomy.

Other comment

174. On 14 December 2015, more than a year after her follow-up appointment with Dr B, Ms A met with Dr F at the public hospital. Dr F advised Ms A's GP that he was unable to determine with certainty what surgery had been performed by Dr B because the clinical records were not available.

175. On 7 January 2019, Ms A met with Dr H, but Dr H was also unable to provide Ms A with advice in relation to the surgery that was performed by Dr B because he did not have access to the operation note.

176. I am concerned that both Dr F and Dr H were not equipped with the information they required to be able to manage the consultations with Ms A as the full clinical records were not available or accessible. Without the information contained in the clinical records, any consultation would have been of limited value for Ms A.

177. Since the events, Te Whatu Ora has made changes to its systems, which now enable consumers' clinical records to be accessed and shared across the hospital network.

Changes made since events

Te Whatu Ora

178. Te Whatu Ora said that it takes its obligations and responsibilities 'very seriously'. Te Whatu Ora stated that following the incident with Ms A, it has taken considerable time and effort developing and updating its policies. Te Whatu Ora said that it carried out a thorough investigation into the incident and that appropriate policies and procedures have been implemented as a result.

179. Te Whatu Ora updated its Informed Consent Policy in 2015, 2017, 2019, and again in 2022. Te Whatu Ora said that its current Informed Consent Policy is 'substantially more thorough' than the policy that was in place at the time of the events. Te Whatu Ora stated that its current Informed Consent Policy 'places specific emphasis on the use of surgical mesh, directing patients to a copy of the Ministry of Health's surgical mesh publication which the patient is required to discuss with their surgeon before consenting to surgery'.

180. The Informed Consent Policy now includes requirements in relation to the timing of the consent, and states:

> 'Consent should be gained within a reasonable timeframe to the commencement of treatment. However, the consumer must have sufficient time to consider the information provided, their options, potential risks and consequences of the treatment and any alternative options.
>
> If there has been significant delay from when consent was obtained and treatment is to be provided, the consumer's health status changes, or if there are significant changes to the planned treatment, then further information must be provided before, and the consumer's consent, obtained again.'

181. The Informed Consent Policy also states:

> 'As a general rule, consent remains valid until withdrawn by the person concerned. However, the consent may no longer be valid and it may be necessary to reconfirm a consumer's consent in the following circumstances:
>
> - Significant changes to the consumer's health status or circumstances.
> - Significant changes to the planned services.
> - New information becomes available regarding the proposed service (i.e. new evidence of risks or new service options emerge).'

182. In relation to the use of surgical mesh, the Informed Consent Policy states:

> 'The Ministry of Health notes that each type of mesh procedure carries its own risks and benefits. As part of the informed consent process, patients should be fully informed about what is involved in the procedure, the possible benefits and risk of complications, as well as any alternative treatment options (both surgical and non-surgical) …
>
> Patients have the right to seek a second opinion if they are not satisfied with the information they receive or would like further advice on [their] treatment options. [The DHB] assesses surgeons undertaking urogynaecological surgical mesh procedures against credentialling guidance developed by the Australian Commission on Safety and Quality in Health Care, and surgeons must ensure rigorous informed consent processes that include understanding of the associated risks.'

183. In addition to its Informed Consent Policy, Te Whatu Ora updated its consent form, which was implemented in August 2023. The updated consent form is comprehensive and contains a separate section that is required to be completed if there are significant changes to the planned procedure and/or a delay in undertaking the procedure.

184. Te Whatu Ora said that following the release of the AER and the recommendations made, it undertook a review of the time frame for postsurgical review of patients. Te Whatu Ora said that due to a resourcing issue at the time of the events, it was unable to implement the recommendation to ensure that patients were reviewed within six to eight weeks following surgery. Te Whatu Ora stated that this resourcing issue has now been resolved, and the recommendation has been completed.

185. As recommended in the provisional opinion, Te Whatu Ora has provided HDC with an update on the changes that have been made to its systems as part of the health system transformation that will enable consumers' clinical records to be accessed and shared across the hospital network. Te Whatu Ora said that since 2016, it has utilised a digital platform that links and provides access to clinical information for all its hospitals in the region. Te Whatu Ora said that this platform includes operation notes, investigation results, imaging, ED clinical notes, clinical correspondence, and certain progress notes. Te Whatu Ora stated that if the digital platform had been available at the time when Ms A had her surgery (in 2014), the operation note would have been available to Dr H when he saw Ms A in 2019.

Dr B

186. Dr B told HDC that transvaginal mesh procedures are no longer performed because they have been 'banned and taken off the market'. Dr B stated that mesh contracture with pain, as well as mesh exposure, are two known complications with transvaginal mesh implants, which have resulted in the recall. Dr B has not performed transvaginal mesh implants since 2014 or 2015 but continues to perform laparoscopic mesh sacrocolpopexies[42] and mesh sling procedures, which have not been 'taken off the market' in the country where Dr B currently practises.

187. Dr B said that if pelvic floor dysfunction is diagnosed in patients who also have pelvic organ prolapse and who wish to have surgical management, Dr B counsels them that the surgery may exacerbate or 'flare' their pelvic floor dysfunction. Dr B stated that the patients may opt to treat the pelvic floor dysfunction in the first instance, or it is discussed with them the need for additional physical therapy after the surgery. Dr B said that in some women with concurrent pelvic floor dysfunction and prolapse, laparoscopic procedures have been recommended instead of transvaginal procedures with sacrospinous fixations.

Changes in medical practice

188. Due to the high risk of complications associated with surgical mesh, several changes have been made since the events.

189. In 2019, more than 600 people shared their stories of surgical mesh harm with Manatū Hauora|the Ministry of Health (the Ministry) through a restorative process. In response, the Ministry committed to certain actions on behalf of the health system, which formed a mesh work programme.

190. In 2018, the Director-General of Health wrote to the district health boards requiring them to implement rigorous informed consent processes for mesh procedures. Following the restorative process, resources for consumers to understand their rights around informed consent were more widely available. HDC also wrote to all district health boards and the Private Surgical Hospitals Association to improve understanding of informed consent processes in relation to mesh surgery.

191. Currently, the Ministry is working on a process to credential surgeons who undertake pelvic floor procedures. This means that a committee of experts will check that surgeons have the right skills, experience, and education to perform complex surgeries such as those using surgical mesh. The Ministry is also working to establish specialist service centres for mesh complications and is designing education packages to ensure that health professionals understand their role in preventing and reducing harm from surgical mesh.

192. HDC, as a member of the Surgical Mesh Roundtable[43] (the MRT) alongside representation from several other agencies, including Te Tāhū Hauora|Health Quality & Safety Commission

[42] Surgery to lift the vagina or uterus back into its normal position by attaching a piece of synthetic mesh between the top of the vagina and a bone in the lower part of the spine.
[43] https://www.health.govt.nz/system/files/documents/pages/terms_of_reference_surgical_mesh_roundtable_updated_march_2021.pdf.

(HQSC), is overseeing and monitoring the surgical mesh work programme led by the Ministry. The work programme includes the actions and recommendations arising from the Health Committee and Restorative Justice reports.[44]

193. In 2017, Medsafe also took action that resulted in no surgical mesh products for pelvic organ prolapse being supplied in New Zealand. Medsafe has also been monitoring adverse event reports associated with mesh and has provided information and guidance to support its use.

194. In December 2022, HDC and HQSC jointly wrote to the Ministry and Te Whatu Ora about a lack of progress implementing the 2019 restorative process recommendations. HDC and HQSC called for urgent action to be taken to reduce patient harm in the meantime. This letter prompted intensive engagement with the Ministry and the MRT about next steps.

195. In June 2023, HDC and HQSC again jointly wrote to the Ministry expressing strong support for a pause.

196. In August 2023, the Director-General of Health supported a time-limited pause on the use of surgical mesh for stress urinary incontinence. The use of surgical mesh to treat stress urinary incontinence will be paused while steps are being taken to minimise harm linked to the procedure.

197. The MRT recommended a pause until four specified conditions have been met to minimise harm linked to the procedure for women. The four specific conditions are:

- Mandatory credentialling of clinicians to the National Credentialling Framework Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures;
- Setting up a mesh registry for female pelvic floor procedures including surgical mesh;
- A structured informed consent process using a patient decision aid; and
- Patient case discussion at a multi-disciplinary meeting.

198. There will be a high vigilance process to monitor the use of alternative procedures for the management of stress urinary incontinence during this pause. There will be exceptions in cases where no other appropriate options are available.

[44] In 2014, Carmel Berry and Charlotte Korte petitioned Parliament for an inquiry into the use of surgical mesh in New Zealand. The Health Committee's report on this petition, with seven recommendations, was presented to the House in 2016. In December 2019, the Ministry released a report prepared by the Diana Unwin Chair of Restorative Justice at Victoria University, 'Hearing and Responding to the Stories of Survivors of Surgical Mesh'. The report included several actions agreed to by stakeholder representatives in response to the harms and needs heard and identified the Surgical Mesh Roundtable as an appropriate group to oversee the delivery of the workstreams.

Recommendations

Te Whatu Ora

199. In light of the apology already provided to Ms A and the significant changes made by Te Whatu Ora to its Informed Consent Policy and consent forms, and as the issue of accessibility of clinical information has been addressed, I consider that no further recommendations are necessary.

Dr B

200. As recommended in the provisional decision, Dr B has provided a formal written apology to Ms A for the deficiencies in the care provided. Taking into account that Dr B is no longer practising in New Zealand, I recommend that should Dr B return to medical practice in New Zealand, Dr B (a) develop and implement a system for ensuring that all treatment options and their associated risks are discussed clearly with patients, and documented on consent forms or in clinical letters, including the day when these discussions occurred; and (b) consider how to improve the informed consent process to ensure that patients are provided with sufficient time to fully consider the information to which they are entitled, before seeking their consent.

Follow-up actions

201. A copy of this report with details identifying the parties removed will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

202. A copy of this report with details identifying the parties removed will be sent to Dr Joe Bourne, Chief Medical Officer of Manatū Hauora|Ministry of Health and Chair of the Surgical Mesh Roundtable, Te Tāhū Hauora|Health Quality & Safety Commission, the Accident Compensation Corporation, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, to highlight systemic learnings that can be taken from this case. Te Tāhū Hauora|Health Quality & Safety Commission will be asked to consider referring to this report in future quality improvement work Te Tāhū Hauora undertakes with the Health and Disability sector relating to informed consent processes.

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