Gynaecologist, Dr B

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC02166)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the gynaecology care provided to a woman by a gynaecologist at a public hospital for treatment of stress urinary incontinence and vaginal prolapse. In 2013 the woman underwent a transobturator tape (TOT) procedure, pelvic floor repair and total vaginal hysterectomy. TOT is a surgical mesh product. The woman experienced significant complications following insertion of the surgical mesh.

2. The woman raised concerns about the informed consent process prior to surgery, in particular whether the treatment options, and the clinical rationale and risks of these options, were explained adequately. Her complaint also raised concerns about the standard of surgical care provided.

Findings

3. The Deputy Commissioner found that the gynaecologist did not explain the risks of gynaecological surgical mesh to the woman adequately prior to performing the TOT procedure. On this basis, the Deputy Commissioner considered that the gynaecologist failed to provide the woman with information that a reasonable consumer in her circumstances would expect to receive and, accordingly, breached Right 6(1) of the Code. The Deputy Commissioner considered that without this information the woman was unable to make an informed choice and give informed consent. Accordingly, the Deputy Commissioner found that in proceeding with the TOT procedure, the gynaecologist also breached Right 7(1) of the Code.

4. The Deputy Commissioner considered that the gynaecologist failed to ensure that clinical documentation complied with professional standards and, accordingly, breached Right 4(2) of the Code. The Deputy Commissioner noted that the deficiencies in documentation made it difficult to assess the surgical technique retrospectively, and that therefore it was not possible to make a finding about the standard of surgical care provided.

5. The Deputy Commissioner found that Te Whatu Ora did not breach the Code.

Recommendations

6. Having considered the changes made since events, the Deputy Commissioner recommended that the gynaecologist apologise in writing to the woman, complete HDC's online learning course on informed consent, and provide a written reflection on the deficiencies in his care identified in this report.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by Dr B at a public hospital (Te Whatu Ora) (previously a district health board).[1] The following issue was identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care in 2013.*

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

9. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Gynaecologist/provider

10. Further information was received from:

Ms C	Daughter
Te Whatu Ora	District health provider
Dr D	Urologist
Medical centre	General practice

11. Independent advice was obtained from Dr Colin Conaghan, a gynaecologist, and Dr John Short, a gynaecologist, and is included as Appendices A and B.

Information gathered during investigation

Introduction

12. This report concerns the care provided to Ms A (in her forties at the time of events) in relation to a transobturator tape (TOT) procedure, pelvic floor repair and total vaginal hysterectomy[2] she underwent in 2013 to treat stress urinary incontinence (SUI)[3] and vaginal prolapse.[4]

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force and resulted in all district health boards being disestablished. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand.
[2] Removal of the uterus where the procedure is performed entirely through the vagina.
[3] Involuntary loss of urine during physical movement or activity (eg, coughing, sneezing, heavy lifting).
[4] A condition where, due to weakening of the pelvic floor muscles, one or more organs of the pelvis (uterus, bladder and rectum) slip down from their usual position and into (or in some cases, out of) the vagina.

13. TOT is a surgical mesh product (mesh).[5] The mesh tape is placed under the urethra (the tube that carries urine from the body) like a sling, to provide support and keep the urethra in its normal position to reduce or stop urine from leaking.

14. In the years following the 2013 surgery, Ms A experienced chronic pelvic pain and an increase in urinary tract infections (UTIs) that required long-term antibiotics. In 2018, the mesh was found to have eroded[6] through the vaginal wall, and Ms A underwent surgery to remove it.

15. The report discusses the following issues:

- The adequacy of the information provided to Ms A during the informed consent process for the TOT procedure and hysterectomy.
- The skill and care with which the 2013 surgery was performed.
- The postoperative care provided to Ms A in 2013.
- The standard of clinical documentation of the preoperative discussions and of the 2013 surgery.
- Whether there was indication in 2014–2018 to refer Ms A for investigation of whether the mesh was contributing to her ongoing urological issues during this period.

16. Ms A's complaint also raised concerns about her orthopaedic care in 2016–2017. The orthopaedic care provided to Ms A has been assessed, and the concerns raised by her in this regard have been addressed in separate correspondence. Ms A's orthopaedic care will therefore not be discussed in this report, except to provide context to the urogynaecological care provided by Dr B and Te Whatu Ora.

Background

17. Between 2009 and 2012, Ms A was reviewed three times at the public hospital for investigation and treatment of SUI — once by the urology service[7] and twice by the gynaecology service.[8] She had a complex medical history, including SUI associated with urethral hypermobility[9] and anterior vaginal wall prolapse,[10] recurrent UTIs, five vaginal deliveries, kidney stones, post-coital bleeding, and a gastric bypass for treatment of obesity with weight loss of 90kg. Urodynamic studies[11] were performed, which confirmed severe

[5] The term "mesh" refers to a permanent implant, usually made from a non-absorbable plastic material.
[6] Mesh erosion is where the mesh material pushes into the surrounding tissue, nerves and organs, and in some cases extrudes through pelvic organ walls and becomes exposed.
[7] March 2009.
[8] October and November 2012.
[9] A condition of excessive movement of the female urethra, which occurs when the normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping away when any downward pressure is applied, resulting in involuntary urine leakage.
[10] Anterior vaginal prolapse occurs due to weakening of the wall between the bladder and the vagina, which can cause the urinary bladder to drop or sag into the vagina.
[11] Studies to test how well the bladder, sphincters and urethra store and release urine.

SUI. Treatment options discussed included an autologous fascial sling[12] or retropubic mid-urethral sling,[13] with possible concurrent anterior pelvic floor repair for prolapse. Clinical records document that in March 2009 Ms A elected to proceed with surgery for a retropubic sling and she was placed on the surgical waitlist. However, this surgery did not proceed as Ms A subsequently relocated to another part of the country.

Informed consent process

Training and education

18. Te Whatu Ora told HDC that at the time of events, Te Whatu Ora did not provide its senior medical officers with specific training about informed consent. Dr B confirmed this, and told HDC that informed consent was part of his medical school and residency training. He explained that this training involved attendance at a formal lecture and, "more importantly", continuous monitoring of his informed consent processes over nine years of training.

19. Te Whatu Ora told HDC that at the time of events, Te Whatu Ora promoted the Medical Council of New Zealand's statement on informed consent (relevant sections of which are noted in paragraphs 89–90 of this report).

Policies and processes

20. Te Whatu Ora provided HDC with a copy of its policy on informed consent that was current at the time of events. The policy is intended to be used as a reference document for staff in meeting their obligations under various Acts and Codes when obtaining and verifying informed consent. The policy states that all staff are required to work within the framework set out in the policy, and health professionals must justify any variations from the policy.

21. Paragraph 6.4 of the informed consent policy provides that the primary responsibility for imparting information and securing informed consent lies with the person responsible for the procedure. Paragraph 8.2 requires that patients must be provided with (among other things):

- An explanation of their condition;
- The alternative options available (including no intervention);
- An explanation of the nature, status and purpose of each option (including whether each option is orthodox, unorthodox or experimental);
- An assessment of the risks, side effects, benefits, outcomes, and costs for each option (including medication);
- The likelihood of achieving the outcome that the patient seeks;

[12] A sling made from the individual's own tissue (fascia), which supports the urethra to reduce or stop urine leaking.

[13] A type of mid-urethral sling procedure for treatment of SUI involving insertion of a mesh sling behind the pubis with incisions made in the vagina and above the pubic bone. Also known as a TVT (tension-free vaginal tape) procedure.

- The physical, emotional, mental, social and sexual outcomes that may accompany the intervention;
- The consequences of not receiving treatment;
- Any results (eg, test results); and
- Any other information required by legal, professional, ethical, and other relevant standards.

22. Paragraph 8.3 outlines that there is a duty to disclose "material risks", which, while dependent on the circumstances, are considered to be those that "a reasonable person in the patient's position would attach significance to if warned about in the circumstances of the particular case". Further, paragraph 8.1 states that the higher the probability of risk or the greater the magnitude of harm, the more care and detail in giving information is required.

23. Paragraph 9.3 of the policy provides that staff should use the "Agreement to Treatment" form to document a patient's informed consent. The policy also states:

> "Signed consent forms are no more than prima facie evidence that a patient has consented to the intervention. In addition to the 'Agreement to Treatment' form, full notes of the consent procedure should be taken and placed on the patient's file."

Discussion of treatment options and risks

24. Ms A told HDC that she was not informed of "less invasive" treatment options for SUI before she agreed to surgical treatment, and "nor were any risks provided to [her] [about the mesh sling procedure] to ensure [she] was fully informed of what [she] was undertaking".

25. Dr B noted that prior to his consultations with Ms A, she had had a number of consultations with other urogynaecology specialists, in which treatment options and risks were discussed (as summarised at paragraph 17). In response to my provisional decision, Ms A confirmed that in 2009 a specialist discussed the option of surgery for treatment of prolapse and advised that she would be placed on the surgical waitlist. However, Ms A said that she was not provided with any written information at that time regarding different surgical options, nor were the risks of gynaecological mesh surgery explained to her.

26. On 1 March 2013, Ms A saw Dr B at the public hospital to discuss her symptoms and suitability for surgical treatment. Dr B noted that Ms A's recent urodynamic studies indicated that she was a suitable candidate for a mid-urethral sling. He also noted that on examination Ms A's cervix appeared normal and relatively well supported, with a significant anterior vaginal wall prolapse and mild posterior vaginal wall prolapse.[14]

27. During the same consultation, Ms A told Dr B that she had been experiencing deep dyspareunia[15] and post-coital bleeding. Dr B noted Ms A's family history of cervical and

[14] Posterior vaginal wall prolapse occurs due to weakening of the wall between the rectum and the vagina, which can cause the rectum to push into the vaginal wall.
[15] Persistent or recurrent genital pain that occurs just before, during or after sex.

uterine cancer and that she had recently had a cervical smear with normal results. Dr B advised that her symptoms would need to be investigated before deciding to proceed with any type of surgery, and arranged for Ms A to have an endometrial biopsy and ultrasound. Ms A told HDC that Dr B told her that if the results "look[ed] as though [she] did have cervical cancer, then a hysterectomy could be performed at the same time as [her mesh sling] surgery".

28. On 27 March 2013, Ms A saw Dr B in the colposcopy[16] clinic. He performed a colposcopy, which appeared normal, did a repeat smear, and took cervical and endometrial biopsies. In a letter to Ms A's general practitioner (GP), Dr B advised that an ultrasound had shown a uterine submucosal fibroid,[17] and he noted that this could explain Ms A's post-coital bleeding. In response to my provisional decision, Ms A said that neither Dr B nor her GP explained the results of these investigations to her, and, in particular, that "[it is] not clear that a uterine submucosal fibroid would be the deciding factor that resulted in needing a hysterectomy nor that it was the only option".

29. In this letter, Dr B also summarised his analysis of Ms A's condition as "[vaginal] prolapse, pelvic pain, dyspareunia, post-coital bleeding and [SUI]". He documented that he had discussed "various options" with her and that they had decided to proceed with a total vaginal hysterectomy, pelvic floor repair and a mid-urethral sling.

30. Dr B acknowledged that in his letter he did not describe in detail the "various options" he discussed. He said that in this particular clinical scenario, the options would have included abstaining from surgery and offering continued observation of the prolapse, SUI, pain and bleeding; trying medication; surgically removing the fibroid; inserting a Mirena[18] for the bleeding; offering intensive physiotherapy for the prolapse and SUI, or performing only the mesh sling for SUI, as had been discussed with Ms A by previous doctors.

31. Dr B told HDC that it is his usual practice to undertake a thorough verbal discussion of surgical procedures. He said that this includes highlighting the risks of the procedure, the alternative options, immediate and long-term postoperative care, and any other concerns the patient has. Dr B said that the surgical consent form stated the major risks. The "consent to treatment" form, dated 12 June 2013, states:

> "I, [Ms A], being the proposed patient … agree that I have been able to discuss [the proposed procedures] with [Dr B] … [and he] has explained the possible benefits and risks to me of the surgery/procedure/treatment relating to my clinical history and condition. The risks include but are not limited to: [i]njury to abdominal/pelvic organs, bleeding, blood clots, infection[.]"

32. In response to my provisional decision, Ms A said that her understanding of the surgical consent form was that in signing this she was agreeing that she understood that there were risks *whilst undergoing* surgery. Ms A said that she had not been confirming that she fully

[16] A procedure in which the cells in the vagina and cervix are examined with a microscope (colposcope).
[17] A benign tumour consisting of fibrous and muscular tissue that occurs especially in the uterine wall.
[18] A contraceptive hormone-releasing intrauterine device (IUD).

understood all the risks associated with the gynaecological surgery (such as the risk of ongoing postoperative complications from the surgical mesh).

33. HDC asked Dr B to comment on the fact that there is no documentation regarding a discussion of the possible risk of mesh erosion. Dr B responded:

> "[I]t is my usual practice to verbally discuss in detail the potential risks of mesh use in surgery. I am certain that I followed my practice on this occasion as I never deviate from it."

34. Dr B also stated:

> "The risks I would routinely discuss with patients about the use of mesh in sub-urethral slings would be risk of erosion, extrusion, groin pain, suprapubic pain, failure rate, dyspareunia and voiding dysfunction."

35. In response to my provisional opinion, Ms A said that at the time of these events she was fit and healthy and exercising for three hours each day to train for a body sculpting competition. She said that if she had been advised of the above risks she would not have proceeded with the mesh procedure "due to [her] rigid fitness regime and the possibility that these risks could seriously compromise [her] health".

36. Risk factors for graft complications such as erosion, contraction and dyspareunia include obesity, previous vaginal deliveries and hysterectomy.[19] Ms A noted that she had a history of obesity and five vaginal deliveries, and the surgical plan included a hysterectomy. She said that Dr B did not take these risk factors into account when recommending the mid-urethral sling procedure.

Written information

37. Dr B noted that particular surgical pamphlets are routinely given to all surgical patients as a matter of course. He said that typically he provides these pamphlets and discusses them with the patient in the outpatient clinic, and then again prior to the consent form being signed in the surgical theatre.

38. Dr B and Te Whatu Ora provided HDC with copies of three pamphlets that were routinely given to patients at the time of events: "Urinary Incontinence" (RANZCOG[20] (2005)), "Hysterectomy" (RANZCOG (2006)), and "Pelvic Organ Prolapse" (RANZCOG (2009)).

39. The pamphlet "Urinary Incontinence" outlines the methods, risks and benefits of several surgical and non-surgical treatment options for SUI, and states:

> "Tape procedures have been linked to chronic pain in the pelvic area for some patients. In recent years, new procedures have had fewer reports of chronic pain.

[19] As noted in the literature review in Medsafe's report of surgical mesh for uro-genital adverse event reports: https://www.medsafe.govt.nz/Consumers/devices/UrogynaecologicalSurgicalMeshMedsafeReport2008.pdf.
[20] Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

> Some types of tapes may cause tissue inflammation, damage or infection many months after surgery. The tapes may need to be surgically removed. This is usually straight forward, but in some cases can be difficult."

40. The pamphlet "Surgical treatment of pelvic organ prolapse" outlines various options for surgical repair of pelvic organ prolapse.

41. The pamphlet "Hysterectomy" outlines the common reasons for a hysterectomy, including uterine fibroids, unexplained heavy or irregular menstrual bleeding, prolapse of the uterus, and cancer of the endometrium, uterus or cervix.

42. Ms A told HDC that prior to surgery she was provided with written information about hysterectomy, but was not given any pamphlets or other written information, including treatment options for SUI or the risks and benefits of mid-urethral tape procedures. Ms A's clinical record contains no documented evidence that these pamphlets were provided to her.

43. The clinic letter dated 27 March 2013 records that following discussion of the "various options", Dr B referred Ms A to the gynaecological surgical waiting list for a total vaginal hysterectomy, pelvic floor repair, TOT procedure and cystoscopy.[21]

Biopsy results

44. The results of the cervical and endometrial biopsies taken on 27 March 2013 were reported on 3 April 2013. The pathology report noted that the cervical biopsy showed surface squamous metaplasia[22] with no abnormal or malignant cells, and the endometrial biopsy showed no endometritis,[23] hyperplasia[24] or malignancy.

45. On 1 May 2013, Ms A saw Dr B to discuss these results. Ms A's daughter, Ms C, was in attendance as her support person. Ms A and Dr B presented differing versions of the discussion that took place at this consultation.

46. Dr B told HDC that he discussed with Ms A that the findings of the colposcopic examination, cervical biopsy, endometrial biopsy and pelvic ultrasound were all normal aside from the finding of a uterine fibroid. Dr B referred to his clinic letter of 1 May 2013, sent to Ms A's GP, in which he wrote: "The smear was normal. The biopsy was normal and the endometrial biopsy was normal." The biopsy results were copied to Ms A's GP, but there is no record that Ms A's GP discussed these with her.

47. On the other hand, Ms A told HDC that Dr B told her and her daughter that the biopsies had come back "positive for cancerous cells". Ms A told HDC:

[21] Examination of the urinary bladder and the urethra using a cystoscope (a rigid tube-like instrument).
[22] Noncancerous (benign) changes in the squamous cells. In rare instances, squamous metaplasia can become cancerous.
[23] Inflammation and infection of the uterus.
[24] Increased cell production, which can be a sign of abnormal or precancerous changes.

> "When I went back with my daughter to see [Dr B] for the results, I was advised by him that there was evidence of white cells in my cervix which had the potential to be cervical cancer and so upon his advice, I agreed to go ahead with the hysterectomy at the same time he was to perform the [mesh surgery.] The news that I had cervical cancer was devastating both to myself and my family[.]"

48. Ms A also told HDC that she was not provided with a copy of the pathology report and did not see this until January 2020 when she requested copies of her medical records.

49. Ms C corroborated Ms A's statements in a letter to HDC:

> "In this clinic appointment I was there, [Dr B] had told my mother, and myself that she had the first stages of cancer and the best course of action was to have surgery to have a total hysterectomy (and have the prolapse bladder sling done at the same time). Naturally we were both very emotional at this time, we have a very strong family history of cervical cancers. My mother had made the decision to have the surgery based off of this information."

50. Ms C also told HDC:

> "[G]oing through all of my mother's clinic letter and test results, we have found the biopsy and smear results that is related to her total hysterectomy. In these results, it shows negative for malignant cell growth or cell evidence, we did not get these results at the time of the appointment because we didn't think we would have to."

51. Ms A also told HDC that Dr B did not explain to her that the uterine fibroid was the most likely cause of her dyspareunia and post-coital bleeding, and that if she had been made aware of the negative results of her smear and biopsies, she would not have agreed to undergo a total hysterectomy.

52. In response, Dr B told HDC:

> "I am not sure why [Ms A] thinks that I said that she had cancer where in my letter it states that I told her the results were normal. We had agreed to proceed with her surgery for prolapse and SUI. I apologise for any misunderstanding."

53. Dr B also said that he discussed with Ms A the following reasons for the recommendation of a vaginal hysterectomy:

- Utero-vaginal prolapse;
- Post-menopausal bleeding;
- Strong family history of cervical cancer;
- Persistent worrisome post-coital bleeding;
- Uterine fibroid;
- Painful sex possibly associated with the prolapse;

- Anterior vaginal wall prolapse possibly making her urinary symptoms worse;
- Having other pelvic surgery (sling, anterior vaginal wall repair) and thus the potential to take care of multiple problems at the same time.

54. Dr B said that while there is no one place in the clinical records where all of the above concerns are listed as above, each of these problems are documented and would have formulated his treatment plan. A review of the clinical records confirmed that the above issues are documented in the clinic letters of Ms A's consultations with Dr B on 1 March 2013, 27 March 2013 and 1 May 2013. In response to my provisional decision, Ms A said that Dr B indicated to her that due to her post-coital bleeding in the context of a family history of cervical cancer she had "no other options" other than to undergo a hysterectomy. She also said that her family history of cervical cancer should not have been a factor in recommending surgery as the concern about cancer had been "ruled out" by the normal biopsy results.

55. Dr B confirmed in the clinic letter of 1 May 2013 that Ms A was on the surgical waiting list and scheduled to have a vaginal hysterectomy and pelvic floor repair in June 2013.

Surgical skill and care

Training and education

56. Dr B told HDC that he has experience performing a variety of surgical treatments for SUI, including transvaginal tape (TVT)[25] and TOT mid-urethral sling procedures, and that he was trained in the TOT procedure by other gynaecological surgeons. Dr B provided a copy of an audit of the mid-urethral sling procedures he has performed. The audit shows that prior to Ms A's surgery in 2013, starting in 2008 he had performed 72 mid-urethral sling procedures, including 64 TOT procedures.

57. Dr B provided evidence of various training and education in pelvic surgery prior to Ms A's surgery in June 2013.

Surgery 12 June 2013

58. On 12 June 2013, Ms A underwent surgery for "[v]aginal hysterectomy and uterosacral fixation[,][26] [p]osterior [vaginal] wall repair, perineorrhaphy,[27] plus [transobturator vaginal tape procedure] and cystoscopy".

59. The surgery was performed by a gynaecological registrar under the supervision of Dr B as the responsible senior medical officer.

60. The type of material used for the mesh sling was Monarc® Subfascial Hammock. Ms A told HDC that at the time of her surgery in June 2013 this product had been recalled due to

[25] A method of mid-urethral sling procedure for treatment of SUI, involving insertion of the sling behind the pubis with incisions made in the vagina and above the pubic bone. Also known as a retropubic mid-urethral sling procedure.
[26] A procedure to restore the top of the vagina after hysterectomy.
[27] Surgical repair of the perineum.

known concerns. On the other hand, Dr B told HDC that as at June 2022, this product was still available.

61. The operation note dated 12 June 2013 describes the procedures. With respect to the mid-urethral sling procedure, the operation note states:

> "Mid urethral incision made … Bilateral dissection towards the obturator foramen.[28] Two small exit incisions made on each side, medial[29] inferiorly[30] of the obturator foramen. Tape applied as per instruction. Then cystoscopy performed, no bladder injury noted with bilateral ureteric jets[31] seen. Tension adjusted and vaginal wall sutured … then vaginal perforation site sutured … Catheter and vaginal pack inserted."

62. In response to my provisional decision, Dr B said that the operation note was dictated by the surgical registrar under his supervision. He accepted that as the consultant in charge, he was responsible for the standard of documentation. Dr B provided the following explanation in relation to aspects of the operation note:

- Placement of the sling: Dr B said that the description in the operation note of the mesh tape being "applied as per instruction" means that the tape was placed correctly as per the manufacturer guidelines, under the mid-urethra.
- Tensioning of the sling: Dr B said that the operation note states that the tape was tensioned properly ("Tension adjusted"). Dr B said there are many ways and techniques to tension the tape and there is no applicable gold standard. He said that some practitioners prefer to have the patient awake under spinal anaesthesia and have them cough (if any urinary leakage occurs they then tighten the sling until leaking stops), whereas some use various measurements such as a 2–5mm gap between the tape and the midurethra. Dr B stated that he places an 8mm Hegar dilator[32] between the urethra and tape and tensions the sling under that. Dr B said that he had always considered that stating in the operation note that the tape was properly tensioned was adequate.
- Vaginal perforation: Dr B stated that the vaginal skin perforation occurred at the initial placement of the trocar.[33] He said that the trocar was retracted and replaced and the perforation was repaired with a 2-0 Vicryl as stated in the operation note. Dr B said that this is a relatively common complication of sling placement, as is that of perforation, and, if repaired properly, usually does not cause any further problems.

63. The operation note documented instructions for routine postoperative care.

[28] The large opening between the ischium and pubic bones through which nerves and blood vessels pass.
[29] Toward the midline.
[30] In a lower position.
[31] Visualisation of normal periodic passing of urine from the ureter into the bladder.
[32] Hegar dilators are rod-like instruments of varying thickness, typically used to dilate the cervix.
[33] A trocar is a minimally invasive surgical instrument fitted with a cannula and used especially to insert the cannula into a body cavity as a drainage outlet or through which to pass other surgical instruments.

Postoperative care

64. Following the surgery, Ms A was monitored in hospital. She had an indwelling catheter for removal of urine. Trials to remove the catheter were attempted three times, on 13, 14 and 17 June 2013. However, each time the catheter was removed Ms A experienced urinary retention, requiring reinsertion of a new catheter.

65. Ms A told HDC that after the first failed trial removal of the catheter, Dr B told her that if she continued to experience urinary retention then "further surgery to loosen the [mid-urethral sling] should be completed". There is no evidence of this in the clinical record, although a similar plan was documented later in Ms A's care on 19 June 2013 (see paragraph 70).

66. Following the second trial removal of the catheter on 14 June 2013, Ms A was documented to be in "severe pain ++ [and] in tears". Ms A was otherwise documented to be "doing well", with "normal [postoperative] pain". Ms A's pain was documented at various times as ranging from zero to eight (out of ten), with analgesia used to good/moderate effect. The clinical notes on 14 and 15 June 2013 record that it was explained that the pain was to be expected postoperatively and would improve.

67. Clinical notes on 15 June 2013 record that a plan was discussed with Ms A for discharge home with an indwelling catheter, to be removed by a district nurse in the community one week later. The clinical notes record that Ms A preferred to trial one more removal of the catheter as she did not wish to be discharged with an indwelling catheter.

68. The third removal of the catheter was trialled at 6am on 17 June 2013, and Ms A again experienced urinary retention. The clinical notes record that there was a delay in locating a bladder scanner.[34] A bladder scanner was obtained at 2.30pm, by which time it was recorded that Ms A was "crying for pain [and] bursting". The bladder scan recorded 900ml of urine in Ms A's bladder, and a new indwelling catheter was inserted immediately.

69. Following the last failed trial removal of the catheter, on 17 June 2013 Ms A was discharged home with an indwelling catheter (the fourth since her surgery on 12 June 2013) and a plan for this to remain for one week, after which it would be removed by a district nurse in the community. The discharge summary also noted that if this was not successful, Ms A might require intermittent self-catheterisation. Ms A was scheduled for a routine postoperative gynaecological review in six weeks' time.

70. On 19 June 2013, two days after discharge and seven days postoperatively, Ms A presented to the public hospital with severe vaginal and abdominal pain and vaginal bleeding. She was diagnosed with a UTI and a small vaginal wall haematoma.[35] Ms A was reviewed by Dr B and discharged on 20 June 2013 with a script for pain relief and antibiotics, as well as a plan for the catheter to remain for a further two weeks, followed by review with a urology nurse. The discharge summary noted that if Ms A was still experiencing a high residual volume of

[34] A machine used to measure the post-void residual volume of urine in a patient's bladder.
[35] An abnormal mass of mostly clotted blood that forms in a tissue, organ or body space as a result of a broken blood vessel.

urine following urination after the catheter was removed, consideration would be given to loosening the mid-urethral sling. Ms A was scheduled for a follow-up review with Dr B in two weeks' time.

71. Ms A next saw Dr B as an outpatient on 2 July 2013 for a week three postoperative review. In a letter to Ms A's GP, Dr B noted that Ms A had had a "somewhat rocky" postoperative course, with development of a vaginal haematoma, which had drained by itself, and voiding dysfunction. Dr B documented that Ms A had had her catheter removed three days previously and had since been passing normal volumes of urine and had not experienced any leaking. It was also noted that Ms A had no further bleeding and the pain had subsided "quite a bit". In response to my provisional decision, Ms A said that no investigations were conducted at this appointment to test whether she was voiding normally, and that "to this day" she suffers from voiding issues.

72. Dr B also noted in the letter of 2 July 2013:

> "Examination showed resolution of the active vaginal haematoma. All compartments are well supported and healed. There is very good vaginal depth. There is no mesh erosion noted. [At] [t]he perineum, there was a small suture coming through a small hole. The suture was cut off below the level of the skin. This should heal well."

73. In response to my provisional decision, Ms A said that she was not given any anaesthesia or pain relief before Dr B cut the suture.

74. On 17 September 2013, Ms A was seen by Dr B for a final postoperative review. Dr B documented that Ms A was "doing very well", with "no further leaking, no prolapse, [or] bulge sensation" and that examination showed "all compartments to be healed very well". Dr B discharged Ms A back to the care of her GP.

2014–2018

75. Ms A told HDC that in the years following the insertion of the mid-urethral sling, she experienced an increase in recurrent urinary tract infections (UTIs), and that this was a result of the mid-urethral sling not having been loosened following her surgery on 12 June 2013. Ms A also said that the sling had been placed too far back and too far to the left, which, as a result, bent her urethra (Ms A's statement in this regard is based on the findings of her surgery in 2018 to remove the mesh, described in paragraph 80 of this report).

76. Ms A's clinical records show that in the years from 2014 to 2018, she had several presentations to her GP and to the Emergency Department and urology and renal services at the public hospital for investigation and treatment of recurrent UTIs and kidney stones. Ms A told HDC that she considers that the recurrent urological and renal conditions she suffered from 2014 to 2018 were a result of the mesh sling being too tight and in the incorrect position, and that she was repeatedly misdiagnosed by public hospital urology and renal services throughout these years. Ms A's relevant presentations from 2014 to 2018 are summarised in a table in Appendix C.

77. In May 2018, Ms A was reviewed by the orthopaedic service for investigation of recent worsening left hip pain. The orthopaedic service concluded that there was no clear orthopaedic cause of Ms A's pain. However, it had been noted previously that Ms A was on a long course of antibiotics for treatment of recurrent UTIs, and the service also noted that the attachment site for a mid-urethral sling is very close to the hip. On this basis, the orthopaedic service queried whether Ms A's pain could be related to her 2013 gynaecological surgery, and, in particular, the placement of the mid-urethral sling. Ms A was therefore referred to Dr B for further investigation of her left groin pain.

78. On 26 September 2018, Dr B saw Ms A in the Urogynaecology Clinic. Dr B performed a vaginal examination and noted that the mesh sling could possibly have eroded on the left side. He recommended removal of the sling and booked Ms A for surgery to remove it.

79. On 15 November 2018, Ms A was seen by a urologist in the Urology Clinic. The urologist examined Ms A and discussed with her that the mesh sling appeared to be exposed on the left side, and noted that, given Ms A's voiding dysfunction, it was likely that the sling was "a little on the tight side".

Removal of surgical mesh

80. On 21 November 2018, Ms A underwent surgery for total removal of the TOT and vaginal repair. The findings of the operation were documented as follows:

> "1. Mesh was exposed in the vagina of 5mm. Photo was taken of this and is most likely the cause of [Ms A's] dyspareunia.
>
> 2. The sling was indent[ed] in the urethra and causing obstruction of the [urethra].
>
> 3. The sling was lying too distal,[36] too close to the external urethral meatus[37] and very distal within the vaginal wall also.
>
> 4. Sling was running very horizontally in the vaginal area.
>
> 5. Low exit site of the adductor region on the left, 5cm below adductor longus which is at least 3cm lower than we would expect and similarly on the right.
>
> 6. On the left we noticed an attachment to a soft tissue entity which was able to be pushed free. This may be a small nerve which is attached to the location of the sling.
>
> …
>
> No urethral injury or bladder injury noted."

[36] Situated away from the centre of the body.
[37] The opening at the end of the urethra through which urine leaves the body.

Further information

Ms A

81. Ms A told HDC of the significant impact that the complications of her mesh surgery have had on her life. She said that the numerous vaginal investigations she has had to undergo has resulted in the loss of her dignity and privacy, and she finds it extremely challenging to attend medical appointments. Ms A stated:

> "It has affected every aspect of my life, including impacted my family. … I feel as though I have completely been robbed of my life. … I've lost jobs, relationship[s], homes and opportunities because of these issues."

Dr B

82. Dr B said that he is very sorry for the adverse outcomes Ms A has endured. He stated:

> "During the time [Ms A] was under my care, I did the utmost to ensure she was advised of her treatment options to enable her to provide adequate, informed consent. I always strive to provide a high standard of care and have taken this complaint as a catalyst to implement processes to ensure a thorough level of documentation is captured in pre-operative counselling."

Responses to provisional decision

Dr B

83. Dr B was given the opportunity to respond to the provisional decision and his comments have been incorporated into this report where appropriate. Dr B said that he accepts the outcome and agrees with the recommendations made.

Te Whatu Ora

84. Te Whatu Ora was given the opportunity to respond to the provisional decision and advised that it had no further comment to make.

Ms A

85. Ms A was given the opportunity to respond to the provisional decision and her comments have been incorporated into this report where appropriate.

86. Ms A is of Pākehā and Māori heritage. She said that her care was not managed with the dignity and traditions of her Māori heritage, and that the care undermined her rangatiratanga and stripped her mana. Ms A said that from a physical, mental and soul level, these events have had a significant impact on her life. She stated:

> "Ko tōku rangatiratanga me tōku hōnore hei wahine kua whati tōku wairua
>
> It is my dignity and honour as a woman that has broken my soul."

Relevant standards

87. In 2008 the Medical Council of New Zealand (MCNZ) issued *Good Medical Practice*, a guide for doctors setting out standards expected of a competent doctor. These standards applied at the time of Ms A's care in March 2013. Paragraph 4, "Keeping records", states:

> "You must keep clear and accurate patient records that report:
>
> - relevant clinical findings
> - decisions made
> - information given to patients
> - any drugs or other treatment prescribed."

88. Paragraph 13 of *Good Medical Practice*, "Giving information to patients about their condition", states:

> "Give patients all information they want or need to know about:
>
> - their condition and its likely progression
> - treatment options, including expected risks, side effects, costs and benefits."

89. In 2011, MCNZ issued "Information, choice of treatment and informed consent", a statement outlining the standards of practice expected of doctors during the informed consent process (informed consent standards). These standards applied during the period of Ms A's care in 2013.

90. The informed consent standards set out the obligations of providers under the Code in relation to informed consent,[38] and state:

> "You must keep clear and accurate patient records that report information given to patients and decisions made.[39] The Medical Council recognises that every aspect of a consultation cannot realistically be noted in the patient's record. As a result we recommend that you adopt written consultation protocols that specify what information in the form of discussion, publications and questions will be given in a specific type of consultation (e.g. all patients experiencing migraines). You do not need to spend unnecessary time writing extensive notes. Instead, you can note in the patient record that the protocols were fulfilled and only outline any exceptions to the protocol. If the patient is referred or requests a copy of his or her record you should include a copy of the protocols."

[38] In particular, the standards discuss Right 4(5), Right 5, Right 6, Right 7 and Right 9 of the Code.
[39] Paragraph 4 of *Good Medical Practice* (2008).

Opinion: Introduction

91. I acknowledge Ms A's kōrero in response to my provisional opinion, that her care was not managed with the dignity and traditions of her Māori heritage, and that the care undermined her rangatiratanga and stripped her mana.

92. Following her gynaecological surgery in 2013, Ms A experienced ongoing symptoms of pain, dyspareunia and voiding dysfunction, which resulted in further surgery to remove the mesh. It is evident that this was a challenging time for Ms A. I recognise the difficulty for Ms A and her whānau in raising these concerns with this Office, and I acknowledge the ongoing mamae and healing needed for Ms A from these events.

Opinion: Dr B — breach

93. Following a thorough assessment of the information gathered in light of Ms A's concerns, I find Dr B in breach of Right 6(1)(b), Right 7(1) and Right 4(2) of the Code. The reasons for my decision are set out below.

Provision of information and informed consent — breach

94. The principle of informed consent is at the heart of the Code. Under Right 6(1)(b) of the Code, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. This includes an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option. Under Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.[40]

95. In carrying out my investigation, and endeavouring to establish what happened, I have drawn on all relevant information, including the recollections of Ms A and Dr B, as well as the clinical documentation available. I have also taken into consideration the recollections of Ms A's daughter, Ms C, when she accompanied her mother to a consultation and was party to the discussions that occurred. I have considered each piece of evidence objectively on its merits, with due consideration to the perspective of each party. In so doing, I must also acknowledge the significant passage of time since the events described in this complaint occurred, and the difficulties this presents in terms of assessing the recollections of the discussions held. In weighing up the information available, I have therefore placed great reliance on the contemporaneous clinical documentation. I acknowledge that this documentation was written by Dr B, and that there is no contemporaneous documentation written by Ms A with which to compare, and I have taken this into account in my assessment of the information. I wish to reassure Ms A that I have not discounted her recollections of the conversations where they differ from the versions documented.

[40] Except where any enactment, or the common law, or any other provision of the Code provides otherwise.

Discussion of alternative treatment options

96. Dr B documented that on 27 March 2013 he discussed with Ms A "various options" for treatment of SUI and pelvic organ prolapse, but there is no documentation of what these options were. Dr B outlined to HDC a list of alternative treatment options that applied in Ms A's clinical scenario, including non-surgical and surgical options, with the implication that he discussed these with Ms A. On the other hand, Ms A said that she was not provided with any "less invasive" treatment options for SUI before she agreed to surgical treatment.

97. Dr B and Te Whatu Ora provided HDC with copies of patient information pamphlets that outlined various treatment options for SUI and vaginal prolapse. Dr B said that these were "routinely" provided to patients. However, Ms A said that she was provided with written information only about the hysterectomy procedure. There is no evidence in the clinical records that Ms A was provided with any written material during her preoperative discussions with Dr B.

98. To assist in my assessment of Ms A's concerns, I obtained independent advice from Dr Conaghan, a gynaecologist. Dr Conaghan advised that RANZCOG identifies mid-urethral sling procedures as the treatment of choice for SUI[41] and that the mesh sling was clinically indicated for Ms A. However, he said that a discussion regarding alternative options should take place and be documented, including the risks and benefits of those alternative options. This advice aligns with the standards set out in MCNZ's publication *Good Medical Practice* (2008) and statement "Information, choice of treatment and informed consent" (2011), as well as the requirements of Te Whatu Ora's 2012 policy on informed consent.

99. On review of the clinical documentation, I accept that Dr B appears to have discussed some alternative treatment options with Ms A on 27 March 2013. However, I am unable to determine what these options were or the extent of information provided about each option. Accordingly, I am unable to assess whether Ms A was provided with adequate information about her treatment options.

100. I am critical that Dr B did not document which alternative treatment options were discussed with Ms A and what information was provided about these options. My criticism in this regard is discussed further at paragraphs 123–128 of this report.

Discussion of risks

101. Dr B told HDC that the consent form dated 12 June 2013 listed the "major" risks.[42] However, these risks appear to relate to pelvic surgery generally. Dr Conaghan noted that the consent form did not list any risks specific to the transvaginal mesh procedure (such as mesh erosion or chronic pelvic pain). Dr Conaghan advised:

[41] As recommended in RANZCOG's position statement on midurethral slings (2020): https://ranzcog.edu.au/wp-content/uploads/2022/05/Position-statement-on-midurethral-slings.pdf.
[42] As noted in paragraph 31, these were "injury to abdominal/pelvic organs, bleeding, blood clots, infection".

> "The consent document [adequately describes the surgery] but fails to document the significant risk of mesh erosion, which all surgeons undertaking this procedure were aware of in 2013."

102. I acknowledge that the surgical consent form is only a small part of the consenting process, with the bulk of the consenting process occurring in the verbal discussion between doctor and patient in the lead-up to the signing of the consent form. Dr B is certain that in this instance he followed his practice of verbally discussing in detail the potential risks of mesh use in surgery. However, in my view, it is reasonable to expect that the risks listed on the consent form reflect the content of the accompanying verbal discussion. The absence on the consent form of any risks specific to the TOT procedure is therefore concerning. Further, as per Te Whatu Ora's informed consent policy at the time of events, I would expect that when a discussion of risks takes place during a preoperative consultation, the content of this discussion, listing the risks discussed, should be documented in the clinical records. There is no evidence that a discussion of risks specific to the TOT procedure occurred. This is particularly concerning considering there was sufficient information coming to light internationally to indicate the risk to consumers of selected mesh products utilised in certain circumstances. As such it is reasonable to assume that surgeons proposing to undertake procedures involving mesh products had a heightened awareness of the importance of the consenting process.

103. In summary, based on the information available, I am not satisfied that Dr B informed Ms A of the risks specific to the mesh procedure, including those of mesh erosion and chronic pelvic pain. Ms A said that she was not advised of any risks about the mesh procedure, and, while I acknowledge that Dr B has said otherwise, on balance I accept Ms A's version of events in light of the lack of documentation of a discussion of these risks in the preoperative consultation notes or on the consent form. While I am unable to determine whether Dr B provided Ms A with the RANZCOG pamphlets titled "Urinary Incontinence" and "Surgical treatment of pelvic organ prolapse", in any case I consider that provision of such pamphlets is not a substitute for a full discussion of the options and risks, and, as above, I am not satisfied that this occurred. In my view, a reasonable consumer in Ms A's circumstances would expect to be informed of the known risks of the TOT procedure, including mesh erosion and chronic pelvic pain. Accordingly, I find that by failing to provide Ms A with information that a reasonable consumer in her circumstances would expect to receive, Dr B breached Right 6(1) of the Code. It follows that, without this information, Ms A was not able to make an informed choice and give informed consent to the 12 June 2013 surgery. I therefore also find that Dr B breached Right 7(1) of the Code when he proceeded with surgery on 12 June 2013 without Ms A having made an informed choice to consent to the surgery.

104. In response to my provisional decision, Dr B said that while he does not accept some of the findings regarding the extent of the information he provided to Ms A, he accepts that the documentation does not corroborate his view that he provided Ms A with all information regarding the risks of surgical mesh.

Biopsy results — educative comment

105. Ms A recalled that in a consultation on 1 May 2013 Dr B told her and her daughter that the results of the cervical biopsy taken on 27 March 2013 showed that "there was evidence of white cells in [her] cervix which had the potential to be cervical cancer". Ms A's daughter recalled that Dr B told them that Ms A had "the first stages of cancer". It is apparent from Ms A's feedback that this experience had a profoundly distressing impact on Ms A and her wider family.

106. Dr B wrote to Ms A's GP that same day advising that the results of the biopsies had both been normal, and the results themselves were copied to Ms A's GP. While I do not doubt Ms A's experience of the discussion on 1 May 2013, I consider it highly unlikely that Dr B would advise a patient that her biopsies had shown signs of cancer and then advise her GP that same day that the biopsies had been normal. However, I am concerned that both Ms A and her daughter came away from the 1 May 2013 consultation with the impression that the cervical biopsy had been abnormal. In light of this, I ask Dr B to reflect on the importance of clear communication with patients when discussing biopsy results, keeping in mind the emotional aspect of these discussions, and consider whether to provide patients with a copy of their results in future, to minimise the risk of misunderstanding.

107. Patient understanding of the reasons for recommended treatment is fundamental to the informed consent process. Dr B said that he explained to Ms A the reasons for recommending hysterectomy, and these are documented in the clinical records. On the other hand, Ms A said that she understood that hysterectomy was required for treatment of cancer, and that if she had not been under this impression, she would not have agreed to have a hysterectomy. As outlined above, I am unable to determine how Ms A formed this impression, and am unable to resolve these differing accounts. Nevertheless, I am concerned that Ms A appears not to have understood the reasons the hysterectomy was recommended. I therefore ask Dr B to reflect on Ms A's experience and the importance of giving clear and full explanations for recommending surgical treatments, and then checking the patient's understanding of this information.

108. Lastly, my advisor, Dr Conaghan, advised that based on Ms A's significant vaginal prolapse and abnormal uterine bleeding, hysterectomy was clinically indicated. I accept this advice and, accordingly, I am satisfied that there were sound clinical reasons for Ms A's hysterectomy. While in no way diminishing the distress experienced by Ms A from these events, I hope that she is reassured by this finding.

Surgical technique — other comment

109. Ms A's 2013 surgery was performed by a gynaecology registrar, with Dr B assisting and overseeing as the senior medical officer. Accordingly, Dr B was responsible for ensuring that the surgical technique was of an acceptable standard, including placement and tensioning of the mesh sling, and management of any intraoperative complications, and that the surgery was documented adequately.

110. To assist with my assessment of the surgical skill and care with which Ms A's mesh sling procedure was performed, I obtained advice from an independent gynaecologist, Dr John Short.

111. Dr Short commented that the operation note from 2013 is of a poor standard, and contains limited information and little specific information. He said that based on this operation note alone, he was unable to say whether the surgery was performed with reasonable skill and care or whether the mesh sling was placed in the correct position and with the correct tension. Dr Short noted that the 2013 operation note briefly mentions a repair of a vaginal perforation, but does not describe where or how this occurred.

112. Dr Short advised that on review of the operation note for the 2018 mesh removal surgery, the findings do suggest that the surgery in 2013 was not performed appropriately. However, he cautioned that the five-year interval between the surgeries must be kept in mind when interpreting this information. On the basis of the 2018 findings, Dr Short considered that three aspects of the surgery may have been performed incorrectly — management of the vaginal perforation, tensioning of the sling, and placement of the sling. He advised that this would be a moderate departure from the accepted standard of care.

Management of vaginal perforation

113. The operation note of the 2018 mesh removal surgery documented that the mesh was found to be "exposed in the vagina of 5mm". Dr Short advised that this likely related to the vaginal perforation mentioned in the 2013 operation note. He stated that he suspected that this perforation was not managed correctly, but that he could not be sure of this due to the limited information documented in the records.

Tensioning of sling

114. The operation note of the 2018 mesh removal surgery documented that the mesh sling was found to be "indent[ed] in the urethra and causing obstruction of the [urethra]". Dr Short advised that this indicates that by 2018, the sling was too tight. However, he said that it is unclear whether this was due to incorrect tensioning at the time of the original surgery or because it had tightened over time, due to, for example, scarring.

115. Dr B's position is that the sling was tensioned appropriately.

Placement of sling

116. The findings of the mesh removal surgery in 2018 also included:

> "[Finding 3] The sling was lying too distal, too close to the external urethral meatus and very distal within the vaginal wall … [Finding 4] Sling was running very horizontally in the vaginal area … [and] [Finding 5] Low exit site … on the left … which is at least 3cm lower than we would expect and similarly on the right."

117. Dr Short advised that the above findings suggest that the sling was placed incorrectly in 2013. He explained:

> "A [Monarc®] sling should run in a slight curve, with the lowest point at the mid-urethral level and the uppermost points where the sling exits the obturator fossa. A horizontally running sling suggests incorrect placement … [The finding of the low exit sites] suggests incorrect placement and would be consistent with the sling lying horizontally. Lower exit points would mean the sling is not placed in the normal curve. It would also increase the risk of vaginal perforation."

118. Dr Short stated that the findings of the 2018 surgery "strongly suggest" that the sling was not placed correctly, and the operation note from 2013 contains insufficient information to confirm correct placement. On this basis, he concluded that "the sling was probably not placed correctly in 2013".

119. Dr B's position is that the sling was placed correctly.

Conclusion

120. I accept Dr Short's advice that if the above aspects of the surgery were performed incorrectly, this would be a departure from the accepted standard of care. However, due to the passage of time since the 2013 surgery, the changes that may have occurred during that time, and the limited clinical documentation available for the 2013 surgery, I am unable to determine with reasonable certainty whether these aspects of the surgery were in fact performed incorrectly.

121. I acknowledge Dr Short's advice that the findings of the 2018 surgery "strongly suggest" that the sling was not placed correctly, in particular that it appears that the exit sites of the sling may have been positioned too low. I find this very concerning, and I acknowledge the distress this information may cause Ms A. However, as Dr Short has noted, unfortunately the 2013 operation note does not contain sufficient detail to confirm the positioning of the exit sites of the sling. In the absence of documentation confirming where the sling was placed in the 2013 surgery, and keeping in mind Dr Short's cautioning regarding the passage of time between the 2013 and 2018 surgery, I am unable to determine whether or not the mesh sling was placed correctly.

122. I am also concerned that the tension of the sling may have been too tight on placement. However, I accept that the sling may have tightened over time and, given the passage of time between insertion and removal of the mesh sling, it is not possible to know whether it was too tight on placement. Further, while I am concerned that the vaginal perforation mentioned in the 2013 operation note may not have been managed correctly, unfortunately I am unable to assess whether this was the case due to the poor documentation of the 2013 surgery.

Documentation — breach

123. Right 4(2) of the Code provides that every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards. In previous

reports, HDC has made numerous comments stressing the importance of good record-keeping and the accuracy of clinical records.[43]

124. I am critical that the 2013 surgery was documented poorly, and note that this has made it difficult to assess the standard of the surgical technique. In particular, I am critical that the 2013 operation note contains no specific information about the placement or tension of the sling, nor about where or how the vaginal perforation occurred.

125. In my view, adequate documentation of surgical procedures, including occurrence and management of intraoperative complications such as vaginal perforation, is essential to providing appropriate patient care. As highlighted by Dr Short's advice, if the 2013 surgery had been described adequately in the operation note, this would have provided more information for the specialists involved in Ms A's subsequent care in considering the cause and treatment of her postoperative symptoms.

126. In response to my provisional decision, Dr B said that he considered that the description of the placement of the sling "as per instruction" and "[t]ension adjusted" was sufficient to document that the sling had been placed correctly and tensioned appropriately. However, I remain concerned about the paucity of information, and accept Dr Short's advice that the operation note, including those descriptors, did not provide sufficient detail to enable him to assess whether the mesh sling was placed and tensioned correctly. On this basis, I remain of the view that the operation note did not contain sufficient detail about these aspects of the surgery.

127. Further, as discussed at paragraph 100, I am critical that Dr B did not document which alternative treatment options were discussed with Ms A preoperatively, nor did he document what information was provided about these options.

128. In conclusion, I consider that in failing to ensure an adequate standard of documentation with respect to the 2013 operation note and the preoperative discussions about treatment options, Dr B failed to comply with Te Whatu Ora's policy on informed consent and the MCNZ standards applicable at the time of events. Accordingly, I find that Dr B breached Right 4(2) of the Code by failing to provide services that complied with professional standards.

Use of Monarc® Subfascial Hammock — other comment

129. Ms A raised concerns that at the time of her surgery in 2013, concerns had been raised about the Monarc® sling and it had been recalled. Dr B told HDC that as at June 2022, this product was still available.

130. My independent advisor, Dr Short, stated:

> "Safety concerns had been expressed about all surgical mesh products before 2013. The Monarc device became unavailable in New Zealand in about 2016. This was a decision by the manufacturer and not due to any regulatory issues. The monarc was a brand of mid-urethral sling (MUS), made from polypropylene mesh. The two subtypes of these

[43] For example: 19HDC01547, 12HDC00437, and 11HDC01103.

> are 'retropubic' and 'transobturator', depending on the method of placement. The monarc is in the latter subtype. Use of these types of MUS is now discouraged due the higher complication rates and they are now used very rarely. Retropubic MUS are still used."

131. Given the significant complications Ms A experienced following the insertion of the Monarc device, it is understandable that she would be concerned to learn that subsequently the product had been withdrawn from the market, and to assume that this was due to safety concerns. I also appreciate that it may be distressing to learn that the transobturator tape used in her surgery is no longer recommended due to the higher rate of complications. However, I am obliged to assess the care provided based on the information available at the time of events. In this case, I accept Dr Short's advice that at the time of events the Monarc device was still available in New Zealand and, accordingly, I consider that it was not unreasonable for Dr B to have used this device in Ms A's surgery in 2013.

Postoperative care — no breach

132. Following her surgery on 12 June 2013, Ms A experienced postoperative complications with urinary retention, for which she required an indwelling catheter for approximately two and a half weeks. Ms A said that Dr B should have loosened the mesh sling after the first postoperative trial removal of the catheter failed on 13 June 2013.

133. Dr Conaghan noted that Ms A had a complex surgical procedure and advised that it is very common to have an element of bladder dysfunction following such surgery. He said that it may take up to six to eight weeks for urine flow to be well established, and that in some circumstances this may require the patient to have intermittent catheterisation at home.

134. Dr Conaghan advised:

> "[A]lmost all of these situations resolve and do not require surgery to release the sling. This would be a last resort and one would not embark upon surgery under six weeks. There is still significant [postoperative] recovery to take place and a further surgical procedure within six weeks could be a difficult procedure."

135. I accept this advice. While I acknowledge that Ms A had a challenging postoperative period, I am satisfied that her postoperative care was reasonable. Ms A told HDC that after the first failed trial removal of the catheter, Dr B told her that if she continued to experience urinary retention then "further surgery to loosen the [mid-urethral sling] should be completed". However, there is no evidence of this in the clinical record, and, guided by the advice from Dr Conaghan, I accept that loosening of the sling would not have been advised at this early stage.

136. When Ms A presented to the Emergency Department on 19 June 2013, two days after her discharge from hospital, Dr B documented that consideration would be given to loosening the mesh sling if, upon removal of her catheter in two weeks' time, she continued to experience a high residual volume of urine following urination. When Ms A was reviewed by Dr B two weeks later, following the removal of her catheter three days prior to the

appointment, she was noted to be passing normal volumes of urine with no leaking. I am satisfied that at this point, Ms A's urinary dysfunction appeared to have resolved, and loosening of the sling was therefore no longer indicated.

Opinion: Te Whatu Ora — no breach

137. As a healthcare provider, Te Whatu Ora is responsible for providing services in accordance with the Code.

138. I am satisfied that Te Whatu Ora had adequate policies in place setting out the expectations of employees with respect to the informed consent process, and that Dr B had had adequate training and experience to perform Ms A's surgical procedures on 13 June 2013, as required at the time of events.[44]

139. I have considered whether Te Whatu Ora is directly responsible for any of the departures in Dr B's care identified in this report. After careful consideration, in my view the departures identified are independently attributable to Dr B and are not symptomatic of broader systems or organisational issues at Te Whatu Ora. I therefore find that Te Whatu Ora did not breach the Code.

Care from 2014–2018 — other comment

140. Ms A told HDC that she considers that the recurrent urological and renal conditions she suffered from 2014 to 2018 (as outlined in Appendix C) were a result of the mesh sling, and that repeatedly she was misdiagnosed by the urology and renal services throughout 2014 to 2018. I acknowledge how distressing and frustrating it must have been for Ms A to have experienced these recurrent issues throughout these years and to have discovered later that the issues may have been a result of the mesh sling.

141. To summarise, the clinical records show that Ms A's urinary symptoms were infrequent in 2014 and 2015. She had one UTI treated in primary care in 2014 (January) together with one Emergency Department attendance (June) and one GP attendance with right flank pain (July). An ultrasound in June 2014 showed a non-obstructing right kidney stone, which was thought to explain her right flank pain. There are no further references to UTIs or renal symptoms throughout the rest of 2014 or in 2015. Ms A appears to have experienced an increase in UTIs in 2016, with five attendances at her GP for UTI symptoms between January and July 2016. In February 2016, Ms A was prescribed a one-month course of prophylactic antibiotics, after which her symptoms appeared to resolve until a recurrence in July 2016. An ultrasound in September 2016 showed non-obstructing kidney stones in both renal tracts.

[44] Since these events, significant sector changes have been made to reduce the future risk of mesh complications. These changes are discussed at paragraphs 152–157.

142. From May to November 2017, Ms A was reviewed five times by the urology and renal services at the public hospital for UTI/renal symptoms. Throughout this period she was frequently prescribed therapeutic and prophylactic antibiotics. An X-ray in May 2017 showed a right kidney stone, for which lithotripsy[45] treatment was performed. Following surgery in the private sector in October 2017 to remove kidney stone fragments, in November 2017 Ms A was reviewed by the renal service and her history of recurrent UTIs and kidney stones was noted. A long course of therapeutic and prophylactic antibiotics was prescribed. The impression was of recurrent UTIs and kidney stones, but no consideration of the cause was noted.

143. In May 2018, Ms A was reviewed by the urology, orthopaedic and renal services. The orthopaedic and renal services noted the possibility that Ms A's mid-urethral sling could be contributing to her groin pain and recurrent UTIs. Ms A was referred to Dr B, who recommended removal of the sling.

144. My independent advisor, Dr Conaghan, reviewed the care provided to Ms A by the public hospital in the years following her mesh surgery in 2013. He noted that Ms A had one Emergency Department attendance (in 2014), at which time her flank pain was believed to be referred renal pain due to kidney stones and recurring UTIs, and that she had several attendances with various services at the public hospital in 2017 and 2018. On review of the clinical records, Dr Conaghan considered that it appears that Ms A was well cared for, and that an acceptable standard of care was provided in 2017 and 2018.

145. I acknowledge that as a gynaecologist, Dr Conaghan is not a peer of the Emergency Department, Urology and Renal specialists who provided care in 2016–2018. I am nevertheless reassured that he has not identified any "red flags" that would be an indication to seek further advice from a peer of those specialists.

146. I appreciate that with the benefit of hindsight, Ms A may question whether the specialists who reviewed her in 2016 and 2017 should have considered whether the mesh sling was contributing to her symptoms. However, I am obliged to assess the care with the information that was available at the time of events. On review of the information, it appears that in 2014 and throughout 2016 and 2017, Ms A's symptoms were reasonably explained by the persistent kidney stones evident on imaging in 2014, 2016 and 2017, and consideration was not given to the mesh as a contributing cause, as other pathology was considered the most likely contributor. When Ms A was referred to the gynaecology and urology services in 2018, mesh erosion was identified, and surgery to remove it was arranged promptly.

147. For the reasons outlined above, I have decided not to continue my assessment of this aspect of Ms A's complaint.

[45] A procedure to break up stones inside the urinary tract.

Changes made since events

Dr B

148. Dr B told HDC that in 2016 he transitioned from using the TOT to the TVT method following the increasing data available from 2015 regarding the benefits of TVT, including possible longer term success rates, lower reoperation rates for SUI, lower rates of postoperative pain, and less difficulty in removal of the mesh sling if necessary. Dr B also advised that since 2018, predominantly he has used the autologous fascial sling.

149. Dr B also said that since the events described in this complaint, he has "markedly increased [his] level of documentation in regard to [preoperative] counseling" and "markedly reduced TOT procedures as of 2015, [and as of 2017 has] stopped doing TOT procedures … and markedly reduced TVT procedures".

Te Whatu Ora

150. Te Whatu Ora told HDC that in 2019 Te Whatu Ora developed an online course for staff that provides an overview of informed consent, and that since 2019, informed consent awareness has been included in the Gynaecology Department junior induction programme.

151. Te Whatu Ora also told HDC that in 2019 its urogynaecology team (including Dr B) developed new patient information booklets on treatment options for stress urinary incontinence and pelvic organ prolapse and for the management of complications, including options for mesh removal. Ms A was part of the consumer working group involved in the development of these booklets. Te Whatu Ora confirmed that these booklets are provided to patients by the senior medical officer at outpatient appointments.

Changes in medical practice since events

152. Due to the high risk of complications associated with urogynaecological procedures involving surgical mesh, a number of changes have been made, or are in the process of being implemented, since the events of this complaint to reduce future harm.

153. In 2018, the Director-General of Health wrote to district health boards (DHBs) reminding them that surgical mesh remains an important clinical issue, updating them on developments, and requiring them to implement rigorous informed consent processes for mesh procedures.[46]

154. In 2019, more than 600 people shared their stories of mesh harm with the Ministry of Health through a restorative process. In response, the Ministry committed to certain actions on behalf of the health system, which formed a mesh work programme. Following the restorative process, resources for consumers to understand their rights around informed consent (including those discussed at paragraph 151) were available more widely. HDC also

[46] See https://www.medsafe.govt.nz/hot/alerts/surgical-mesh-letter-to-NZ-College-of-Surgeons%20May%202018.pdf.

wrote to all DHBs and the Private Surgical Hospitals Association to improve understanding of informed consent processes in relation to mesh surgery.

155. Currently, the Ministry is in the process of creating a national credentialling framework for surgeons who undertake pelvic floor reconstructive procedures and urogynaecological procedures involving mesh.[47] This means that a committee of experts will check that surgeons have the right skills, experience and education to perform complex surgery 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 mesh.

156. HDC is a member of the Surgical Mesh Roundtable,[48] alongside a number of other agencies, including the Health Quality & Safety Commission (HQSC). The Roundtable is responsible for overseeing and monitoring the surgical mesh work programme led by the Ministry of Health, including the actions and recommendations arising from the Health Committee and Restorative Justice report.[49]

157. Medsafe continues to monitor adverse event reports relating to the use of surgical mesh implants for the treatment of pelvic organ prolapse, stress incontinence, and hernia repair, and continues to review published information on the use of surgical mesh.

Recommendations

158. Taking into account the changes that have been made, and are continuing to be made, since the events, I recommend that Dr B:

a) Provide a formal written apology to Ms A for the deficiencies identified in this report. The apology should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this decision.

b) Complete HDC's online learning course on informed consent (Module 2: What you need to know about informed consent). Evidence of completion is to be provided to HDC within two months of the date of this decision.

[47] See https://www.health.govt.nz/publication/national-credentialling-framework-pelvic-floor-reconstructive-urogynaecological-and-mesh-revision.

[48] https://www.health.govt.nz/system/files/documents/pages/terms_of_reference_surgical_mesh_round-table_updated_march_2021.pdf.

[49] 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*. This report included a number of 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.

c) Reflect on the deficiencies in his care with respect to his documentation standards and informed consent process, and provide a written report to HDC on the changes he has instigated to his practice since, or as a result of, this case, to ensure that all treatment options and their associated risks are discussed clearly with patients, and documented on consent forms or in clinic letters. Dr B's report should include reflections on Ms A's experience, the importance of clear communication with patients when discussing biopsy results, and the importance of providing and documenting full explanations for recommending surgical treatments, including the risks and benefits of these options, and checking the patient's understanding of this information. Dr B's report is to be provided to HDC within two months of the date of this decision.

Follow-up actions

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

160. A copy of this report with details identifying the parties removed, except the advisors on this case, will be sent to Dr Joe Bourne, CMO of Manatū Hauora and Chair of the Surgical Mesh Roundtable, the Accident Compensation Corporation, and the Health Quality & Safety Commission, to highlight systemic learnings that can be taken from this case. Dr Bourne will be asked to table a copy of this decision at the next meeting of the Surgical Mesh Roundtable.

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

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr Colin Conaghan, a gynaecologist:

"**Complaint [Ms A] [District Health Board] ([the DHB]) Your Ref C19HDC02166**

I can confirm that I have no personal or professional conflict in this case. I do not know the individuals involved in the delivery of care at [the] District Health Board.

My qualifications and experience

1. I confirm I am registered with the Medical Council of New Zealand in the vocational scope of practice of Obstetrics and Gynaecology. I am a Fellow of the Royal College of Obstetricians and Gynaecologists (FRCOG) (1997) and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) (1988).
2. I am a practising obstetrician and gynaecologist in Christchurch New Zealand. For 19 years I worked as a Senior Medical Officer in obstetrics and gynaecology at the Christchurch Women's Hospital for the Canterbury District Health Board. I currently work fulltime in private practice in the area of obstetrics and gynaecology. I am a visiting clinical lecturer for the Otago Medical School, lecturing in the area of obstetrics.
3. I am on the RANZCOG expert witness register.
4. I attach to this report a copy of my curriculum vitae.

Documents provided

1. Letter of complaint dated 18 November 2019.
2. Reply from [the DHB] dated 5th February 2020 from [the] Chief Medical Officer.
3. Reply from [the DHB] dated 5th of February 2020 from [Dr B], Consultation O & G Specialist.
4. Clinical records from [the DHB] from 2013 to 2019 in 21 digital attachments and consisting of 389 pages.

Background

[Ms A] has a complex medical history identified throughout the medical records consisting of

- Morbid obesity with bariatric surgery November 2006
- Laparoscopic cholecystectomy in 2007
- Sphincter of Oddi dysfunction in March 2012
- Recent admission with Fitz-Hugh-Curtis Syndrome
- Diagnosis of hip joint arthritis
- Bilateral hip replacement — right hip 10 ten years ago, left hip February 2017
- Stress urinary incontinence

- Gout
- Hypertension
- Gastro-oesophageal reflux
- Vaginal hysterectomy with vaginal wall repair, TVT 2013
- History of renal calculi requiring multiple treatment procedures with recurring urinary tract infections.
- Chronic pelvic pain, the aetiology of which has proven difficult to identify
- Mesh erosion with removal of the TVT

1. A document dated 31.10.12 had identified as 'referral to gynaecological surgical waiting list'. [Ms A] has been referred to the waiting list by [an O & G Fellow] with a view to surgery.

2. 19.11.12: Letter from [doctor] written to [the O & G Fellow] indicating that as a result of urodynamic evaluation undertaken by himself he has diagnosed [Ms A] with genuine urinary stress incontinence in the presence of a stable bladder. He concludes that [Ms A] would be suitable for a suburethral sling, in addition to, or part of, any surgical procedure to be undertaken by [the O & G Fellow].

3. 27.3.13: A referral to the gynaecological surgical waiting list by [Dr B] (Consultant O & G). The diagnosis made by [Dr B] is one of prolapse, postcoital bleeding, SM fibroid (assumed to be submucosal fibroid) and stress urinary incontinence. He formulates a surgical plan for total vaginal hysterectomy, pelvic floor repair (AP repair and sacrospinous ligament fixation), TOT and cystoscopy.

4. There are documents contained within the sequence of material from [the DHB] which purport to be from an outpatient assessment of [Ms A]. There is a presenting problem with symptoms and duration along with a history of presenting problems and a second sheet indicating past history hospital admissions. These documents are not signed or dated and it is an assumption by myself that these may purport to be outpatient assessments, although not confirmed.

5. 12.6.13: Ms A is admitted to [the DHB] for surgery to be performed that same day. The 'surgical safety check' is documented as: presenting problem — vaginal prolapse, menorrhagia, SUI (although there is no date on the document).

6. The 'operating room record' of the same date above indicates the surgery listed as 'vaginal hysterectomy, uterosacral fixation, posterior colporrhaphy, cystoscopy, insertion tension free vaginal tape — Monarc, perineorrhaphy'.

7. The consent documentation is available for the above surgery and describes the surgery to be undertaken. The potential complications of the surgery are organ injury, bleeding, infection, thromboembolism (no specific comment on TVT complications). An operation note in handwriting has been identified and dated 12.6.13 1605 hours. There is a pre operative diagnosis, a note re 'procedure' is TVH, uterosacral ligament suspension — high/bilateral, posterior repair, perineorrhaphy,

TOT, cystoscopy. A comment is also made regarding the EBL (estimated blood loss) 150cc. Anaesthetist and surgery are identified and post op plan regarding the removal of packing and indwelling catheter is noted. In addition the material used during the TOT has been appended to the top left corner of the clinical notes and identifies the material as Monarc® subfascial Hammock with the Lot number and expiry number.

8. Contained within the cohort of notes from [the DHB] is a document identified on 'Clinical Note paper with an asterisk "Written in retrospect" on 13.6.13 original notes on normal note paper'. This document then goes on to say that the admission date is 12.6.12 and appears to be an admission note written by the staff of ICU following surgery regarding the admission of [Ms A] to their service for immediate post op care.

9. There is post op documentation identifying that [Ms A] was transferred from the recovery unit to the ICU (due to a bed shortage). There are clinical notes written by the ICU team and then continued by the gynaecology team covering the recovery interval through to discharge on 17 June 2013. The documentation is of a satisfactory standard and is dated and timed with a clear plan prior to discharge.

10. 19.6.13: Post operative bleeding requiring admission via the emergency department. [Ms A] is identified as having a small right vaginal wall haematoma. She is seen by [Dr B] and investigations undertaken including both ultrasound and clinical assessment. Documentation is satisfactory and a clear plan is documented with follow up arranged. During the immediate post operative recovery phase (while an in-patient) trial voids of urine following removal of the catheter have not proven successful and a decision is made to discharge [Ms A] home with an indwelling catheter in place, to be removed by the District Nurse after an interval of one week. Appropriate gynaecology outpatient department follow up is put in place.

11. 2.7.13: Outpatient department. Seen by [Dr B] and a letter describes the surgery as 'vaginal hysterectomy, anterior/posterior colporrhaphy, uterosacral ligament fixation, mid urethral sling, cystoscopy, perineorrhaphy'. [Dr B] identifies that there has been a rectovaginal collection and voiding difficulty, the former having drained spontaneously and the latter appears now to have resolved as [Ms A] is now three days post catheter removal and passing normal volumes of urine with no concerns. Examination at the time of the outpatient attendance on 2.7.13 confirms that there is no mesh visible and all wounds appear to be healing well. A further outpatient appointment is scheduled.

12. 17.9.13: Outpatient department. [Ms A] is identified by [Dr B] as having healed well with no evidence of any clinical prolapse. [Ms A] is now discharged back to her general practitioner care.

13. 11.6.14: Attendance at the Emergency Department of [the DHB] with ? right renal colic and right pyelonephritis. Presentation is sudden onset suprapubic lower abdominal pain while at work. Increasing severity. Investigations at this time indicate a urine sample with increased red blood cells, increased white cells and moderate number of bacteria seen. Treatment is instigated and the patient expresses a preference to discharge home to be reviewed the following morning.

14. 17.7.17: A booking form has been completed with a view to 'a right ureteroscopy and a laser lithotripsy'. There is further annotation on this form to indicate the patient may have gone 'private'.

15. 15.12.17: A letter to the effect that an iron infusion is to be scheduled for approximately the 10th of January 2018.

16. 7.5.18: A urology booking form is completed with a request for 'flexible cystoscopy'. The indications are given as recurrent urinary tract infections. A comment is also made on this form to the effect that ? any mesh erosion and signed …

17. There are references throughout the documentation to procedures performed elsewhere such as … (lithotripsy) along with private urological procedures ? … Hospital. Apart from references to surgery, there is no documentation describing the surgery available within the body of these notes.

18. 26.9.18: Referral document to gynaecological surgical waiting list addressed to [Dr D] and signed by [Dr B]. The document is a request for the removal of TOT sling due to left groin pain and dyspareunia. There is reference to a cystoscopy under GA with a referral on 22.5.18 although I can find no evidence that such a procedure has been performed and there are no surgical notes to indicate that such a procedure took place.

19. 21.11.18: An anaesthetic assessment chart refers to a procedure of cystoscopy under GA. There are no surgical notes relating to this event. There is an operation room record, of the same date, noting surgical staff as [Dr D]/… This same document identifies a surgical procedure 'removal of transobturator tape and vaginal advancement flap repair'. There is a 'specimen' document of the same date identifying transobturator tape left side and transobturator tape right side. A photograph is enclosed within the body of the notes containing two black and white pictures identified as left side and right side and further identification as transobturator tape. A measuring device is contained within the photograph and identifies that the tape measures approximately 8cm on each side.

20. A consent form identified by the patient [Ms A] and signed by her on 21.11.18 describes the nature of the surgery adequately and also describes the risk and complications of the procedure. The document is signed by [Dr D].

21. A surgical report identified within the clinical notes is dated 21.11.20 and appears to be in the handwriting of [Dr D]. The operation is described as a total removal of

transobturator tape. The findings include the comment that on the left side the sling is exposed a length of approximately 5cm. There follows a description of the procedure identifying that approximately 19cm of tape has been removed. A post operative plan is identified on the document. Although the document is handwritten it is reasonably legible. No official typed report of the surgical procedure could be identified in any of the notes supplied.

22. 21.11.18: Transfer of Care document to the GP (typed) identifying the reason for admission as total removal of transobturator sling. Follow up arrangements and general advice to the patient are well documented. This document presumably is also given to the patient.

23. 18.12.18: Admission to [the DHB] with right flank pain and vaginal discomfort thought to be due to the recent surgery and suturing of the vaginal wall.

24. 20.12.18: Acute admission with right renal pain. There is good documentation within the case notes regarding these admission events and discussion has taken place with [Dr D], gynaecology and urology resident medical staff. It is noted that there is a 6mm calculus in the right pelviureteric junction (of kidney). There is good documentation by all resident medical staff and nursing staff.

Expert Advice Requested

Item 1. The adequacy of the information provided to [Ms A] by [Dr B] preoperatively in 2013.

25. Documentation within the notes around 2013 is difficult to interpret, often handwritten and of relatively poor quality with a lack of detail.

26. There are no notes contained within the body of material presented from [the DHB] which identify outpatient preoperative attendances, a discussion of patient's symptoms and options regarding management.

    Whilst RANZCOG identifies transvaginal sling procedures (TVT) as being the treatment of choice for stress urinary incontinence, a discussion regarding alternative procedures such as Burch colposuspension should take place and should be documented. The risks/benefits of treatment options should be noted.

    Given that the bulk of the surgery to be undertaken was to take place vaginally (vaginal hysterectomy and repair of the vaginal wall) it is entirely reasonable to approach the stress urinary incontinence as a TVT or TOT procedure.

    What appears to be missing is clear documentation that a discussion has taken place.

27. The pre operative consent documentation describes the surgery adequately and identifies a number of factors that should be present regarding operative complications and risks in such a complex combined procedure. There is however

no documentation regarding mesh erosion. This was not a matter that was foreign to [Dr B] as he notes in his outpatient letter of 2.7.13 three weeks after the surgery has been completed 'There is no mesh erosion noted'.

Conclusion:

There is no evidence contained within these notes of an appropriate discussion with [Ms A] prior to surgery taking place on 12.6.13. The consent document is adequate but fails to document the significant risk of mesh erosion, which all surgeons undertaking this procedure were aware of in 2013. [Dr B] documents himself that at post operative assessment he did not see any evidence of mesh erosion.

The standard of care with respect to documentation and consenting is inadequate and does not meet an accepted standard of care. The departure from a standard of care is of a moderate degree given that we have no comprehension of what sort of pre operative information [Ms A] has been given. My peers would see this as inadequate performance.

The NZ Ministry of Health has already moved towards providing adequate documentation to patients undergoing transvaginal tape bladder neck surgery for stress urinary incontinence. All surgeons undertaking such procedures now require to be credentialled and credentialling documentation includes confirming ongoing education and satisfactory case numbers to maintain a degree of expertise within this field. Should [Dr B] be undertaking such surgical procedures at the time of writing this report then [the DHB] should confirm that he is appropriately credentialled according to the NZ Ministry of Health Guidelines for this procedure.

Item 2. Whether the TVH and mesh procedures performed in 2013 were clinically indicated in the circumstances.

28. From the information that we have been able to glean it appears that [Ms A] had significant prolapse and menorrhagia. As noted in Item 1. the documentation is poor.

29. Urodynamic evaluation was performed and a letter has been forwarded by the Consultant undertaking this procedure to indicate that 'A mid urethral sling mesh procedure along the lines of TVT, or similar, would be appropriate given the urodynamic findings'.

Conclusion: It was appropriate that TVH and mesh procedure were clinically indicated for [Ms A]. There is no deviation from an accepted standard of care.

Item 3. Whether it appears that the TVH and mesh procedure performed in 2013 were carried out with reasonable skill and care.

30. The operation note of 12.6.13 is a handwritten note and apart from identifying the date as 12.6.13 and the time 1605 hours the document goes on to identify pre

operative diagnosis, procedure and a post op note including estimated blood loss during surgery.

31. The procedure is described in terms of global procedure undertaken but offers no description regarding the surgical technique. There is no documentation regarding the detail of the procedure that one would normally expect within a surgical report. There is no identification as to the type of suture material used or any difficulties encountered during the course of the procedure. Even a note to the effect that the procedure was uncomplicated is absent from the surgical note. A typed identification regarding the type of material used including Lot number and expiry date have been appended to the clinical notes.

    Conclusion: The documentation is inadequate for a surgical procedure of this complexity. There are essentially three aspects to this procedure;

    1. Vaginal Hysterectomy
    2. Pelvic Floor Repair with Ligament Suspension
    3. Transobturator Tape with Cystoscopy

    The standard of care and the degree of skill with which the procedure has been carried out is unable to be commented on as there is no documentation to judge the adequacy of surgery.

    The anaesthetic notes identify that this was a lengthy procedure of a significant timeframe. (2½ hours by anaesthetic record).

    The documentation falls well below an appropriate standard of care and leaves my peers uncertain as to what was undertaken and how the procedure progressed. This is a moderate degree of deviation from an accepted practice.

    A recommendation for the future would be that all operation notes should be dictated and typed at the time of the procedure having been completed. The dictation should take place before the next patient arrives in theatre for surgery. Typing facilities are available as evidenced by the outpatient letters of 2.7.13, three weeks after surgery and again on 17.9.13. Not only should the surgical note be typed but documentation regarding how the procedure progressed giving the observer some insight to any difficulties that might have been experienced during the course of the surgery is a minimum standard.

Item 4. The adequacy of the post-operative care provided to [Ms A] following the 2013 procedures. In particular, I note that [Dr B] states that [Ms A] had a *'poor post op recovery period'* with repeat Trial Removals of Catheter (TROC) because of urinary retention and with readmissions for pain, retention and a vaginal cuff haematoma, and that the plan was to review [Ms A] in several weeks and if still with retention to loosen the sling. Please advise whether the sling should have been loosened following the second TROC.

32. [Ms A] had a complex surgical procedure performed including the three elements which I have already identified.

33. I note that [Dr B] has stated that [Ms A] had 'a poor post recovery period'. In hindsight this comment is not synonymous with an unsatisfactory recovery. It is meant to indicate that following the removal of the catheter there was difficulty with voiding, a term often referred to by those surgeons undertaking bladder neck surgery as 'bladder dysfunction'.

34. It is very common to have an element of bladder dysfunction following such surgery. The majority of modern surgical hospitals undertaking this type of surgery will have bladder scan facilities available as one progresses through the 'trial removal of catheter (TOC)'. It may take several weeks (up to six to eight weeks) for urine flow to be well established with small residual urines. This may extend to the patient having intermittent self catheterisation at home in some circumstances.

    Invariably almost all of these situations resolve and do not require surgery to release the sling. This would be a last resort and one would not embark upon surgery under six weeks. There is still significant post operative recovery to take place and a further surgical procedure within six weeks could be a difficult procedure.

    There has been no deviation from an accepted standard of care relating to the post operative recovery phase.

Item 5. The adequacy of the gynaecology care provided to [Ms A] from 2014 until the removal of her mesh in November 2018.

35. [Ms A] was discharged from the gynaecology service on the 17th of September 2013.

36. She reattended the Emergency Department with predominantly pain symptoms and the Urology Department played quite an important role in what was largely deemed to be referred renal pain due to renal stones and recurring bladder infections. There are references through 2017 and 2018 to these admissions including a private hospital admission to … Hospitals. These latter attendances we have no information on.

    Throughout 2017 and 2018 [Ms A] has been cared for with well documented admissions and empathy on the part of the various departments (Emergency Department and Urology, and on occasion Gynaecology). The attendances are well documented and care plans with a referral back to the general practitioner for further follow up have been put in place. Good documentation has been identified.

    An accepted standard of care has been demonstrated through the 2017/2018 interval.

Item 6. Whether the removal of the mesh in 2018 was clinically indicated.

37. Referral to [Dr D] has been based on symptoms elicited by [Dr B] late in 2018. [Ms A] is identified as having a dyspareunia and left groin pain. From the documentation I have reviewed there was concern that these pain symptoms may be due to the

mesh material and a concern that there may be mesh erosion vaginally. There is reference to cystoscopy under GA (general anaesthetic) with a referral dated 22.5.18. I am unable to find amongst the evidence from [DHB] documentation that any such procedure took place. This would be an appropriate procedure to undertake along with pelvic EUA (examination under anaesthesia).

38. Although there is no good documentation prior to the surgical procedure of 21.11.18 there is adequate documentation within the surgical note of that same date to indicate that 'mesh erosion into the vaginal wall' has taken place and the surgical procedure of mesh removal is clinically indicated.

An accepted standard of care has been delivered with respect to a decision to remove the mesh in 2018.

Item 7. Whether it appears that the removal of the mesh was carried out with reasonable skill and care.

39. The surgical note of 21.11.18 has been reviewed. It is handwritten by [Dr D] and contains sufficient detail regarding the surgery undertaken. The surgical notes include a photograph taken of the two segments of mesh, together with a ruler, for measurement purposes.

It would appear that a reasonable standard of care has been exercised with respect to the removal of the mesh in 2018.

Item 8. The adequacy of the gynaecology care provided to [Ms A] following the removal of the mesh.

40. Following removal of the mesh the patient remained in hospital and was discharged on 22.11.18, the following day. Prior to her discharge she was seen by the consultant surgeon, [Dr D].

41. Subsequently [Ms A] attended the Emergency Department on 18.12.18 with a right flank pain and again on 20.12.18 with right renal pain.

42. There is evidence to suggest that there is a persisting right renal calculus of some 6mm size in the right pelviureteric junction of the kidney, which may well be contributing to her symptom profile. She has been well monitored and is likely to remain under the care of the urology services for [the DHB].

A satisfactory standard of care has been delivered following the removal of the mesh.

Item 9. Any other matters in this case that you consider warrant comment or amount to a departure from the standard of care or accepted practice.

43. There are no other matters related to this case that warrant further comment. All issues have been covered in Items 1–8 above."

Appendix B: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr John Short, a gynaecologist:

"**Complaint: [Ms A]/[Dr B]**
Your ref: C19HDC02166

I have been asked to provide advice in this case (19HDC02166), regarding the surgical care provided to [Ms A] by [Dr B] in 2013. I have read and agree to follow the Commissioner's guidelines for independent advisors. I can confirm there is no conflict of interest.

I am a specialist Obstetrician and Gynaecologist, vocationally registered in New Zealand since 2007. I have worked as a senior medical officer in Obstetrics and Gynaecology at Christchurch Women's Hospital since 2006. Relevant to this case, I am experienced in Urogynaecological surgery. I am a past president of the Urogynaecological Society of Australasia and current Advisory Board Member for Continence New Zealand and the International Urogynaecological Association.

I have been provided with clinical documents relating to surgeries performed on [Ms A] in 2013 and 2018. I have been asked the following specific questions:

1. *Considering the operation note from the surgery on 12 June 2013 performed by [Dr B's] and [Dr D's] findings in the surgery on 21 November 2018, whether it appears that the surgery on 12 June 2013 was carried out with reasonable care and skill, and in particular, whether it appears that the mid-urethral mesh sling was placed in the correct position and with an appropriate level of tension.*

   The operation note from 2013 contains only limited information and few specifics. Based on this note alone I am not able to say whether the surgery was performed with reasonable skill or if it was placed in the correct position and with correct tension. There is brief mention of the repair of a vaginal perforation but no description of where or how this occurred. Overall, the operation note is of a poor standard. It should also be noted that the surgery was performed (and presumably the note written by) the registrar working under [Dr B's] supervision.

2. *In particular, is it possible to comment on the appropriateness of the mesh placement and whether the June 2013 surgery was performed with reasonable care and skill based on [Dr D's] findings in the 21 November 2018 surgery?*

   The findings of the 2018 [surgery] do suggest that the surgery in 2013 was not performed appropriately. However, one must be mindful of the 5 year interval when interpreting this information.

3. *The possible reason(s) why [Ms A's] mid-urethral sling was found in the 21 November 2018 surgery to be:*

a. *Exposed in the vagina of 5mm.*

This probably relates to the vaginal perforation mentioned in the original operation note.

b. *Indent in the urethra and causing obstruction of the urethra.*

This suggests that by 2018, the sling was too tight. However, it is unclear whether this was due to incorrect tensioning at the time of original surgery or because it had tightened over time, eg due to scarring.

c. *Lying too distal, too close to the external urethral meatus and very distal within the vagina.*

This suggests that the sling was place incorrectly.

d. *Running very horizontally in the vaginal area.*

A monarc sling should run in a slight curve, with the lowest point at the mid-urethral level and the uppermost points where the sling exits the obturator fossa. A horizontally running sling suggests incorrect placement.

e. *With a low exit site of the adductor region on the left, 5cm below adductor longus (at least 3cm lower than would be expected) and similarly on the right.*

This suggests incorrect placement and would be consistent with the sling lying horizontally. Lower exit points would mean the sling is not placed in the normal curve. It would also increase the risk of vaginal perforation.

f. *Attached to a soft tissue entity, possibly a small nerve.*

The exact nature of the soft tissue entity is not definitively established so I cannot comment.

4. *The consumer has raised concerns that at the time of her surgery in June 2013 the type of mesh used in her surgery, Monarc® Subfascial Hammock, had begun to be recalled due to safety concerns. Please advise whether you are aware that there were any such concerns in June 2013, and whether this product is still in use in New Zealand today.*

Safety concerns had been expressed about all surgical mesh products before 2013. The Monarc device became unavailable in New Zealand in about 2016. This was a decision by the manufacturer and not due to any regulatory issues. The monarc was a brand of mid-urethral sling (MUS), made from polypropylene mesh. The two subtypes of these are 'retropubic' and 'transobturator', depending on the method of placement. The monarc is in the latter subtype. Use of these types of MUS is now discouraged due the higher complication rates and they are now used very rarely. Retropubic MUS are still used.

5. *Any other matters in this case that you consider warrant comment.*

   I suspect the vaginal perforation mentioned at the end of the 2013 operation note was not managed correctly. This would be most likely to have occurred in the left anterior vaginal sulcus at the time of trochar passage. If so, it would require more than simple suturing to correct. However, one cannot be completely sure due to the limited information in the records.

Conclusion

The findings of the 2018 surgery do strongly suggest that the sling was incorrectly placed in 2013. The operation note from 2013 contains insufficient information to confirm correct placement of the sling. I would therefore conclude that the sling was probably not placed correctly in 2013. As the accepted standard of care would be to place the sling correctly and it IS likely that multiple steps were incorrectly performed (incorrect exit points in obturator foramen, placement in relation to urethral meatus, vaginal perforation and possibly incorrect tension) then this constitutes a moderate departure from accepted standards.

The Monarc sling is no longer available in New Zealand. Transobturator slings are rarely performed nowadays. Surgeons performing Midurethral slings are now required (since 2018) to undergo regular credentialling. This and other initiatives already being undertaken by the NZ Ministry of Health should reduce future harm from mesh surgeries. Therefore I have no other recommendations to make in relation to this case.

I hope you find this report helpful. Please don't hesitate to contact me if you need more information.

Yours Sincerely,

John Short"

Appendix C: Summary of presentations 2014 to 2018 (inclusive)

2014	
January	Attendance at [the medical centre] with UTI symptoms. Antibiotics prescribed.
June	Presentation to [the public hospital's] emergency department (ED) with renal colic[1] and urosepsis.[2] Ultrasound showed a non-obstructing 9mm right renal calculus (kidney stone).
July	Attendance at [the medical centre] with right kidney pain, thought to be due to known right renal calculus. Urinalysis results normal.[3] Pain medication prescribed.
2015	
No reference to complaint of, or treatment for, recurrent UTIs or renal symptoms.	
2016	
January	Two attendances at [the medical centre] with UTI Prescribed short course antibiotics.
February	One attendance at [the medical centre] with UTI symptoms. One month course of prophylactic antibiotics prescribed.
July	Three attendances at [the medical centre] with UTI symptoms. Prescribed short course antibiotics. Referral to [the public hospital's] urology service and for ultrasound scan for investigation of loin pain/renal colic. [The public hospital's] urology service recommended three month course of prophylactic antibiotics (prescribed), then re-referral if symptoms persist.
September	Ultrasound (ordered by [the medical centre]) showed non-obstructing kidney stones in both renal tracts.

[1] Sharp, intense pain usually caused by a kidney stone becoming stuck in the urinary tract.
[2] Sepsis caused by an infection originating in the urinary tract.
[3] Tests of urine to detect and manage disorders including UTIs, kidney diseases and diabetes.

2017	
January	One attendance at urgent care clinic and one attendance at [the medical centre] for UTI symptoms. Thought to be due to right kidney stone. Referral to [the public hospital's] urology service.
February	Surgery for left total hip joint replacement (THJR).
May	Review by [the public hospital's] urology service. X-ray showed right 11mm kidney stone. Waitlisted for extracorporeal shock wave lithotripsy (ESWL)[4] on right kidney stone.
June	Presentation to [the public hospital's] ED with increasing right flank pain. Admitted under the urology service. Known right kidney stone noted. Underwent cystoscopy[5] and inserted a stent in right ureter. Antibiotics prescribed and scheduled for ESWL in two weeks.
July	ESWL performed but not successful in breaking up kidney stone. A multi-drug resistant bacteria was noted on urine culture, limiting the range of antibiotics to which UTIs were likely to respond. Review by [the public hospital's] urology service for review of recurrent UTIs and management of kidney stones. Prescribed prophylactic antibiotics and waitlisted for surgery for ureteroscopy[6] and laser lithotripsy,[7] "in the hopes that this will prevent further infective episodes". Continued to experience suprapubic and abdominal discomfort and UTI symptoms.
August	Surgery in private sector for removal of ureteric stent.
October	Surgery in private sector for removal of kidney stone fragments. Attendance at [the medical centre] for UTI symptoms. Prescribed antibiotics.
November	Review by [the public hospital's] renal service. Noted long history of recurrent UTIs and kidney stones. Urine culture showed *E.coli*, prescribed longer course of antibiotics, followed by prophylactic

[4] A non-invasive procedure to break up stones inside the urinary tract, bile ducts or pancreatic duct with a series of shock waves generated by a machine called a lithotripter.
[5] A procedure to look inside the bladder using a small telescope called a cystoscope.
[6] A procedure to examine the interior of a ureter with a small telescope called a ureteroscope.
[7] A procedure that uses lasers to break apart kidney stones in the urinary tract.

	antibiotics. Encouraged higher fluid intake. Ultrasound of kidneys arranged. Attendance at [the medical centre]. [Ms A] reported a history of recent worsening left hip pain following her recent kidney surgery in October 2017. Pain was attributed to her positioning for the procedure and her recent left THJR in February 2017. Referral to [the public hospital's] orthopaedic service for review.
2018	
January–May	Three reviews with [the public hospital's] orthopaedic service for investigation of left hip pain. Orthopaedic service concluded that there was no clear orthopaedic cause of [Ms A's] pain. Noted that [Ms A] was on long course antibiotics for treatment of recurrent UTIs and that the attachment site of the mid urethral sling is very close to the hip. Referred [Dr B] for investigation and review.
February	Presentation to [the public hospital's] ED with lower abdomen and right kidney pain. Diagnosis: UTI.
May	Review by [the public hospital's] urology and renal services following referral by [the medical centre]. Renal service noted possibility of mesh sling and any anatomical urinary tract abnormalities contributing to recurrent UTIs.
September	Review with [Dr B] (gynaecology service). Vaginal examination showed mesh erosion on left side. Booked for surgery to remove mesh.
November	Review by [the public hospital's] urology service. Vaginal examination showed mesh exposed on left side and noted sling was "a little on the tight side". Surgery to remove mesh performed on 21 November 2018.