Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 19HDC01125)

Introduction

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

2. This report discusses the care provided at a public hospital to Ms A by Dr B,[1] Dr C,[2] and a District Health Board (DHB) (now Te Whatu Ora[3]).

3. On 16 April 2013, Ms A, aged in her fifties at the time of events, underwent anterior repair surgery[4] performed by obstetrics and gynaecology consultant Dr B and obstetrics and gynaecology consultant Dr C. The repair used surgical mesh.[5]

[1] Dr B retired from practice at the end of 2019.
[2] Dr C is no longer employed by the DHB.
[3] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to the DHB now refer to Te Whatu Ora.
[4] Anterior repair is used to tighten the front (anterior) wall of the vagina when the bladder has shifted from its normal position and bulges into the front of the vagina, causing the front wall of the vagina to sag. This condition is known as an anterior wall prolapse, cystocele, or dropped bladder.
[5] Surgical mesh is woven material used to provide additional support to weakened or damaged tissue.

4. A few weeks after the surgery, Ms A experienced pain and dyspareunia.[6] In the years following her surgery, Ms A's symptoms persisted and she continued to experience severe dyspareunia and vaginal pain. Since the mesh had been inserted, Ms A had also reported urge incontinence[7] and blood in her urine.

5. Ms A was examined by Dr B on 16 July 2015, and in 2017 Ms A was examined by Dr C for ongoing issues following the surgery. On examination, Dr C noted that Ms A was tender over the whole area of the mesh repair. Subsequently, the mesh was removed by urologist Dr D on 16 April 2019. Dr D documented that the mesh had been placed improperly. Dr D stated that the mesh was "extremely tight", and that it had been placed under tension. Dr D believed that this had caused Ms A's pain and the ongoing inflammatory response.

6. Ms A raised concerns about the care provided to her by Dr B and Dr C. Ms A stated that she was not informed clearly about the risks of mesh, and that when she raised concerns prior to the surgery, she was advised that the mesh she was to receive was not the type causing issues at the time. She also stated that she was not advised of alternative treatment options, such as native tissue repair.[8] Ms A also raised concerns about the care provided by Dr B after the anterior repair surgery, and stated that Dr B "discounted" her concerns during a follow-up visit.

7. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care between April 2013 and July 2015 (inclusive).*
- *Whether Dr C provided Ms A with an appropriate standard of care in April 2013.*
- *Whether Te Whatu Ora provided Ms A with an appropriate standard of care in April 2013.*

8. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Obstetrics and gynaecology consultant
Dr C	Obstetrics and gynaecology consultant

9. Urologist Dr D is also mentioned in the report.

Information gathered during investigation

Anterior repair surgery

10. In November 2009, Ms A underwent a vaginal hysterectomy[9] and posterior repair.[10] Following these procedures, Ms A started to experience symptoms of prolapse,[11] which

[6] Persistent or recurrent genital pain that occurs just before, during or after sexual intercourse.
[7] The involuntary loss of urine associated with urgency (a sudden need to urinate).
[8] Repair that involves the use of the patient's own tissue, rather than surgical mesh.
[9] Surgery to remove the uterus and cervix through the vagina.
[10] Surgery to repair or reinforce the fascial support layer between the rectum and the vagina.
[11] Slipping of a body part from its usual position.

caused pain in her lower pelvis. On examination, it was found that Ms A had a moderate anterior vaginal prolapse (cystocele).

11. On 16 April 2013, Dr B met with Ms A and obtained her consent to treatment. On the same day, Ms A underwent surgery to correct the anterior vaginal prolapse.

12. It was documented in the clinical records that the surgery was performed by Dr C, assisted by Dr B. However, Dr C told HDC that Dr B was responsible for supervising the procedure, and Dr C never performed mesh insertion without Dr B's assistance and supervision.

13. Ms A was admitted under Dr B's name, Dr B performed the ward rounds, and Ms A was discharged by Dr B's house surgeon. Dr C stated that "there is no question that [Ms A] was [Dr B's] patient, and [Dr B] took full responsibility for her care". Dr C said:

> "Irrespective of who was listed as surgeon as opposed to assistant in the surgical records, I would have considered [Dr B] to be in charge of the case and take the lead where required as [Dr B] was significantly more senior in the Department and a much more experienced pelvic floor surgeon."

14. The surgery performed by Dr B and Dr C was Ms A's first operation on the anterior vaginal wall.

15. Dr C noted that mesh was used "in the front wall because of the short time since [Ms A's] prior prolapse surgery".

16. A new form of mesh was used for the repair (Mesh Type B). As Mesh Type B was a new form of mesh, Ms A had consented to the representative of Mesh Type B and two other gynaecologists from the DHB being present in the operating theatre during the surgery.

17. Dr B stated that prior to this, Mesh Type A had been used by the public hospital. Dr B explained that Mesh Type A was larger than Mesh Type B.

18. Dr B stated that the new Mesh Type B required insertion of the mesh arms through a pelvic ligament[12] on each side. Dr B said that this technique was much simpler and safer than the technique that was required for inserting Mesh Type A.

19. Dr B and Dr C have different recollections as to whether this was the first time that Mesh Type B had been used by them.

20. Dr B stated: "[T]his was the first insertion of [Mesh Type B] and hence why we had asked the Representative to be present with [Ms A's] consent."

21. Dr C is unable to recall the details of Ms A's surgery due to the passage of time, but believes that this was not the first time that Mesh Type B was used at the public hospital because no visiting surgeon (other than the surgeons from the DHB) were present during the surgery.

[12] The sacrospinous ligament.

22. Dr C believes that based on the above, Ms A's surgery likely occurred within the first 18 months from when Mesh Type B was first used at the public hospital.

23. While Dr B and Dr C have different recollections as to whether or not this was the first time Mesh Type B was used, both state that they were familiar with the surgical technique.

24. Dr B stated that the technique for inserting Mesh Type B was similar to another procedure Dr B had performed on numerous occasions. Dr B explained:

> "[T]he [Mesh Type B] was a simpler procedure placing the mesh arms through the uterosacral ligaments[13] and I had been very familiar with a similar procedure called a uterosacral fixation which involved using the [Mesh Type B] device[14] to place sutures through the uterosacral ligament. I had done many of those procedures and was therefore comfortable about placement of [Mesh Type B] arms."

25. Similarly, Dr C stated:

> "I have used the [Mesh Type B] device for many years to insert sacrospinous sutures for vault prolapse and hysteropexy which uses exactly the same instrument and technique … Prior to the [Mesh Type B], I used the [Mesh Type A] endosuture to place sutures in the sacrospinous ligament which were also placed 2cm medial to the ischial spine.[15] I had performed these sutures for many years prior to the index case … Because the piece of mesh in [Mesh Type B] was much smaller than the older type of mesh, we believed that it was much less likely to shrink causing discomfort compared to the older meshes. The main difference in insertion as far as I remember was using the [Mesh Type B] device which, as stated, was not new to either [Dr B] or myself."

26. The clinical records note that the procedure was uncomplicated and that Ms A made a good recovery. She was discharged on 18 April 2013, and was to have a follow-up appointment with Dr B in eight weeks' time.

Events following anterior repair surgery

27. After the anterior repair surgery and prior to Ms A's follow-up appointment with Dr B, Ms A presented to her general practitioner (GP) on two occasions (on 7 May 2013 and 28 May 2013), as she was unsure of her healing.

28. On 17 June 2013, Ms A attended her follow-up appointment with Dr B. No early postoperative complications were detected, and Dr B noted that the anterior wall had "healed very nicely".

[13] A thick, supportive band of tissue that connects the lower part of the uterus to the base of the spine. It is part of the network of ligaments and muscles that support the pelvic organs.
[14] A device used in general suturing applications during surgery to assist in the placement of suture material in tissues at the operative site.
[15] Part of the posterior border of the body of the ischium bone of the pelvis.

29. On 5 July 2013, Ms A saw her GP with symptoms of a urinary tract infection. The clinical records note that she also had some lower pelvic pain.

30. On 3 September 2013, Ms A presented to her GP again with "stinging" in the anterior vaginal wall, and a "feeling of fullness". Ms A had no concerns about pain during sexual intercourse at that time. She was referred to a physiotherapist for review and pelvic floor exercises, and was to be reviewed by her GP in 12 months' time if her symptoms did not settle.

31. On 26 June 2015, Ms A presented to her GP as her prolapse symptoms had returned. She had symptoms of fullness, lower back ache, and dyspareunia. Ms A's GP sent a referral letter to Dr B requesting that Ms A be reviewed.

32. Ms A was seen by Dr B on 16 July 2015 with symptoms of dyspareunia and slight bladder urgency. Dr B noted that Ms A was "tender on introduction of a speculum,[16] almost certainly due to oestrogen[17] deficiency changes". Dr B found no significant prolapse. Dr B stated that no clear explanation could be found for Ms A's symptoms. Dr B advised Ms A to try to relieve the dyspareunia with a vaginal lubricant, as Dr B was reluctant to prescribe oestrogen following Ms A's diagnosis with breast cancer. At this point, Dr B did not consider mesh-related complications to be the cause of Ms A's symptoms.

33. Dr B performed surgery on Ms A for an unrelated matter on 28 July 2015. Dr B stated that at that point, "no obvious problems" with the mesh were noted.

34. On 4 April 2017, Ms A presented to her GP again with ongoing symptoms of dyspareunia and severe pain in the vaginal wall. She had also experienced some urge incontinence. The GP referred Ms A to Dr C for review.

35. On examination, Dr C noted that Ms A had good anterior vaginal support with no signs of erosion.[18] Dr C noted that Ms A was "clearly tender over the whole anterior mesh, but especially the left upper mesh arm when any tension was placed over it". Dr C submitted a treatment injury claim to the Accident Compensation Corporation (ACC) for "mesh causing dyspareunia" so that the mesh could be removed privately.

36. On 9 August 2018, Ms A was examined by Dr D and an obstetrics and gynaecology registrar. The registrar reported that on examination, the left mesh arm was "exquisitely tender to touch", and was considered to be the predominant cause of Ms A's symptoms.

Mesh removal surgery

37. On 16 April 2019, Dr D performed surgery on Ms A to remove the mesh. Following the surgery, Dr D documented that the mesh had been placed improperly, with the "left very close to the pudendal nerves[19]". Dr D also stated that the mesh was "extremely tight", and

[16] An instrument used to dilate an orifice or canal in the body to allow inspection.
[17] A female hormone.
[18] Erosion is a common complication following the use of surgical mesh devices to repair pelvic organ prolapse. The mesh can break down or wear away over time.
[19] Major nerves in the pelvic region that send movement and sensation information from the genital area.

that it had been placed under tension, which is what Dr D believed had caused Ms A's pain and the ongoing inflammatory response.

38. Dr D told HDC:

> "[T]here were significant [radiological] abnormalities with [Mesh Type B] which correlated with [Ms A's] clinical symptoms of pelvic pain and dyspareunia. [Ms A] was seen by [an obstetrics and gynaecology registrar] in 2018 who found significant abnormalities on vaginal examination suggestive of complications of mesh insertion … There was suspicion for vaginal erosion, as the mesh was very close to the probe in place …
>
> This highlights the importance of not placing a suture or a mesh too close to the ischial spine[20] as has occurred in this case. It would be reasonable to expect that the pudendal nerve is entrapped or affected by this placement too close to the ischial spine and that this significantly contributed to [Ms A's] pelvic pain, which has significantly improved since removal of that arm …
>
> Taken together the pelvic floor [ultrasound] and MRI[21] show significant abnormalities of the anterior vaginal mesh and explain [Ms A's] pain. The arm placement particularly represents a significant technical issue as the placement should have been carefully scrutinised and identified as being too close to the ischial spine."

39. Dr B disagreed with Dr D's observations that the mesh had been placed improperly. Dr B stated that it cannot be claimed clearly that the arm placement represented a significant technical issue, and Dr B questioned whether that was really the cause of Ms A's pain. Dr B stated that there had been no mention of any postoperative pain during Ms A's hospital stay immediately after the anterior repair surgery, nor had there been any mention of pain at her follow-up visit in June 2013. Dr B said that for these reasons, it was difficult to believe that there had been a direct neurological injury[22] due to a surgical error.

40. Dr B also stated that Dr B was well aware of "the need to try and stay at least 2cm medial to the ischial spine to avoid any nerve injuries", and that Dr B was confident at the end of the procedure that the mesh had been placed correctly.

41. Dr C considers it "very unlikely" that the mesh had been placed too close to the pudendal nerves. Dr C said:

> "[Dr B] and I were very aware that anything passed through the sacrospinous ligament needed to be 2cm medial to the ischial spine to be well clear of the pudendal nerves … I believe that all of us in the Department were aware that any mesh needed to be inserted loosely, without tension. This applies to all mesh products, not just [Mesh Type B] so again this would have been checked by [Dr B] and myself and possibly by [the

[20] Part of the posterior border of the body of the ischium bone of the pelvis.
[21] Magnetic resonance imaging — a technique used in radiology to form pictures of parts of the body.
[22] Injury to the brain, spinal cord or nerves.

other doctors from the Department] as well. As such, I think it unlikely that the mesh was placed under tension."

Provision of information

42. Ms A raised concern that she was not advised about all of the risk factors of mesh, and that she was advised that Mesh Type B was not the type causing issues at the time. She told HDC that "the risk factors of mesh erosion and mesh issues were not clearly represented to [her]". She also raised concern that she was not advised of any alternative treatment options, such as native tissue repair.

43. Dr B was responsible for the consent process. Dr B does not believe Ms A was given inappropriate information about her surgery.

44. Dr B met with Ms A on 8 February 2013, prior to her surgery. In Dr B's correspondence to Ms A's GP, Dr B advised:

> "Given that this is a recurrent prolapse it would be best to do her next repair with mesh. I have explained to [Ms A] our concerns about the possibility of mesh erosion which hopefully would be minimised with regular use of Ovestin cream so I have started her on that now."

45. Dr B told HDC that when mesh technology for vaginal prolapse was introduced, "it appeared to be the answer for what was a known, significant issue, namely women being at risk of prolapse recurrence when native tissue repairs were performed". Dr B said that both Dr B and the Gynaecology Department took a very conservative approach to the use of mesh, avoiding its use in young women, and restricting its use to women with recurrent prolapse.

46. Dr C was not present when the decision was made to use mesh for Ms A's anterior repair. Dr C stated:

> "[Dr B's] approach differed from the rest of the Department who only placed mesh in the same compartment as previous surgery had failed i.e. we would not have recommended anterior mesh repair for this patient. However, as [Dr B] had far more experience in pelvic floor surgery and mesh than myself I did not question [Dr B's] selection criteria. My other colleagues similarly accepted [Dr B's] management decisions in this area."

47. A consent form signed by Ms A on 16 April 2013 stated that Dr B had explained the reasons for, and the possible risks of, the procedure relating to Ms A's clinical history and condition. The risks of bleeding, infection and mesh erosion were listed on the consent form. The consent form also noted that the representative for Mesh Type B and Dr B's colleagues would be present in the operating theatre. The consent form does not contain any information about any alternative treatment options that were discussed.

48. Dr B does not have clear documentation about what was discussed with Ms A about Dr B's training, skills, and experience using Mesh Type B. Dr B stated:

> "… I am certain that I would have explained that we had used mesh on several occasions over recent years and [Ms A] would have been informed that this was the first occasion we were using [Mesh Type B] and hence the desire to have the Representative present."

Further information

Dr B

49. Dr B apologised for not appreciating that it could have been the mesh that was causing Ms A's dyspareunia when Ms A was seen in 2015, as Dr B "was unable to identify any obvious clinical problem and [Dr B] thought [Ms A's] discomfort was far more likely related to oestrogen deficiency". Dr B unreservedly apologised for Ms A's longstanding problems, and that she has had to undergo corrective surgery. Dr B stated that the intention was not to cause Ms A any harm, and Dr B wanted only the best outcome for her.

Dr C

50. Dr C told HDC that "small town surgery" had its own challenges, one being that no one in the region was performing sacrocolpopexy[23] operations for prolapse surgery. Dr C said:

> "There simply was not an effective referral pathway for non-malignant surgery in the public system. As such, this meant that women with recurrent prolapse in [the region] did not have this surgical option available to them that they would have had if they had lived in [larger centres]. Dr B provided an alternative with pelvic floor [mesh] which, at the time, seemed appropriate."

Ms A

51. Ms A stated that at the time of her anterior repair surgery in 2013, mesh technology and mesh safety were being queried worldwide. She said that the prolapse she was experiencing was only moderate, and she was in her early fifties at the time, and was still sexually active.

52. Ms A stated that the mesh complications have affected her partner, and will continue to affect her for the rest of her life. She said that this includes her inability to have sexual intercourse (as well as the associated emotional trauma), nerve damage to her groin and left leg, and ongoing bladder issues.

53. Ms A said that she appreciated Dr B's apology.

ACC

54. Dr C assisted Ms A with an ACC treatment injury claim. In support of the claim, Dr C advised ACC that Ms A's severe pain with intercourse dated back to the mesh placement in April 2013. Dr C advised:

[23] A surgical procedure that treats pelvic organ prolapse by lifting the vagina or uterus back into its normal position by attaching a piece of synthetic mesh between the top of the vagina and a bone in the lower part of the spine.

"Vaginal mesh is not supposed to be pulled tight but sit without tension … The mesh has shrunk causing tension across the anterior wall of the vagina and especially across the left upper arm."

55. ACC obtained clinical advice from an obstetrician and gynaecologist.

56. The ACC advisor advised that Ms A's physical injury appeared to be due to shrinkage or contraction of the mesh. ACC's advisor noted that a study found that 1.2% of women experienced mesh complications within the first year of their surgery, but that this increased to 3.3% within ten years of their surgery. ACC's advisor said that this illustrated that "late complications" were more common, which was likely due to the long-term effects of mesh contraction on surrounding tissues.

57. ACC's advisor considered that the evidence strongly supported that mesh contracture was responsible for Ms A's symptoms.

58. ACC declined the treatment injury claim on two occasions before eventually it was accepted.

Mesh

Recommendations

59. In July 2007, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) developed its guideline "Polypropylene vaginal mesh implants for vaginal prolapse" (RANZCOG guidelines). The objective of this guideline was to provide advice on the use of mesh for the treatment of vaginal prolapse.

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

"
- The patient should be informed that very limited robust data is available on the efficacy and safety of many of the transvaginal mesh products available in Australasia …
- Alternatives to surgical management, including non-surgical options such as pelvic floor muscle training and vaginal support pessaries[24] …
- Other alternative surgical treatments such as conventional native tissue repair …
- Complications discussed of transvaginal mesh must include mesh exposure/erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or pelvic pain which may require additional intervention and may not be completely resolved even with mesh removal. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest should be discussed."

61. Also in March 2013, RANZCOG provided a summary of recommendations made by the International Urogynaecological Association (IUGA). The IUGA recommended that caution

[24] A device inserted into the vagina to support the uterus.

be exercised in transvaginal mesh implants in primary prolapse cases, and in cases of lesser grades of prolapse.

Medsafe

62. The New Zealand Medicines and Medical Devices Safety Authority, Medsafe, has been monitoring adverse event reports associated with surgical mesh implantations, and has provided information and guidance.

63. Medsafe conducted its first review of the use and adverse events associated with the use of mesh in 2008. On 7 May 2009, Medsafe wrote to the chief executive officers of hospitals known to be using surgical mesh, outlining the key points from the 2008 Medsafe review, and supporting the guidance provided by RANZCOG. At that time (2009), Medsafe concluded that when used in accordance with the manufacturer's directions for use by appropriately trained surgeons, the devices did not present an unreasonable safety risk to patients. It recommended that surgeons follow the manufacturer's directions for use and the guidance published by RANZCOG in July 2007. Medsafe took further action on mesh in 2017 (see the changes made since the events section below).

Food and Drug Administration (FDA)

64. My independent advisor, consultant urologist Dr Hazel Ecclestone, made reference to the FDA in the United States. While the FDA contains recommendations relevant to mesh, I have relied on New Zealand rather than overseas guidance when making my findings.

Responses to provisional opinion

Ms A

65. Ms A was given an opportunity to respond to the "information gathered during investigation" section of the provisional opinion.

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

67. Ms A told HDC that she appreciates and accepts Dr B's apology in relation to the pain and suffering she has experienced.

68. Ms A said that Dr B appears to believe that oestrogen deficiency and inflammation were the cause of her pain. She said that Dr B has not acknowledged any culpability for the possibility of erroneous placement and implantation of the device, causing injury. Ms A said that oestrogen deficiency and inflammation certainly played a role in her symptoms, but she believes that it was the deep placement and tension of the mesh across her pelvis that caused the significant pain and permanent nerve damage that she lives with to this day.

69. Ms A told HDC:

> "The years since mesh was implanted in my body have been difficult, and I would like to reiterate that I am more than just a body, I am a human, and a woman, whose life has been hugely impacted by this procedure. The process to eventually gain ACC coverage was extremely distressing for both myself and my partner, and my family. My quality of life has been severely impacted, and it has affected my family life. The mesh

> injury has significantly damaged my relationship, sexual intercourse is not possible. The emotional trauma of that loss is immense. My work was also impacted, I was no longer fit to work full-time, and had to pick up part-time and casual employment instead, and often turn down employment due to the pain I was in. I am no longer able to exercise without pain, or urinary issues, and I am still suffering despite it being 10 years since the implantation surgery, and four years since its removal. In those years, I have had major family milestone events, and have become a grandmother, and the pain caused by the surgery has marred each of those events with me being unable to participate or be as involved as I wish due to the discomfort I still suffer."

Dr B

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

71. Dr B's comments have been incorporated into this opinion where relevant and appropriate.

72. Dr B accepts that there were aspects of Ms A's care "where different decisions might well have led to a better outcome". Dr B said that overall, the decision made was the one felt would give Ms A the best outcome, and Dr B is "genuinely sorry that things have turned out as they did for her".

73. Dr B told HDC:

> "I am sorry that this case did cause [Ms A] such distress. I do not believe the mesh was incorrectly inserted and feel strongly that her pain symptoms are due to the recognised inflammatory properties that mesh is known to cause … I regret not having made a definite follow up appointment with [Ms A] after a three month trial of topical treatment but … I was able to see her very quickly after the initial referral to me in 2015 and I would have been very happy to see her without delay had I known that her symptoms were ongoing."

Dr C

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

75. Dr C's comments have been incorporated into this opinion where relevant and appropriate.

76. Dr C unreservedly apologised to Ms A for any part in the surgery that caused Ms A's pain. Dr C expressed regret for the difficulties that Ms A has been contending with.

DHB

77. The DHB was given an opportunity to respond to the provisional opinion.

78. The DHB's comments have been incorporated into this opinion where relevant and appropriate.

Opinion: Dr B — breach

79. First, I acknowledge that the difficulties Ms A experienced following the insertion of surgical mesh were significant. The nature of her complications and the impact they have had on her day-to-day life over an extended period of time cannot be over stated. Following her anterior repair surgery in 2013, Ms A experienced ongoing symptoms of pain and dyspareunia, which eventually resulted in further surgery to remove the mesh in 2019. It is evident that this was, and still is, a very challenging situation for Ms A. I am mindful of Ms A's statement that the complications will continue to affect her for the rest of her life.

80. To determine whether Ms A was provided with the required information and services with reasonable care and skill, I have considered the independent advice of a specialist obstetrician and gynaecologist, Dr John Short, and a consultant urologist, Dr Hazel Ecclestone.

81. Dr Short expressed some unease about HDC seeking advice from a urologist when examining the care provided by an obstetrician and gynaecologist. He noted that while there is some overlap between the two specialties, they are distinctly different in terms of training and scope of practice.

82. I acknowledge Dr Short's comments and agree that when determining whether Dr B met the recognised standard of care, it was important to assess Dr B's actions objectively against accepted practice, based on the opinion of a reasonable peer — which in this particular case is an obstetrician and gynaecologist.

83. For the avoidance of doubt, I confirm that primarily I have relied on Dr Short's advice in reaching my position on the standard of Dr B's care. However, because there is an overlap between urology and gynaecology in relation to this patient population (on account of the position in the pelvis of the urinary tract and female sex organs), I am aware that it is not uncommon for obstetrician/gynaecologists and urologists to work collaboratively to address a patient's needs. For this reason, I consider it is relevant to have the perspective of a urologist to hand as I determine the reasonableness of the options considered, and the standard of care provided. The additional advice has contributed to the identification of systemic issues and the formulation of sector-wide recommendations. In any event, I note that both Dr Short and Dr Ecclestone reached similar conclusions about Dr B's care, albeit with different emphasis and reliance on different professional guidance and standards.

84. Dr Short opined that the overall care provided by Dr B to Ms A was not reasonable on the basis of the following factors:

- Insufficient information was provided to Ms A about the risks of transvaginal mesh surgery for vaginal prolapse;
- The option of native-tissue/non-mesh surgery was not discussed with Ms A; and
- Insufficient effort was made to explore the possibility that Ms A's pain was a complication of the mesh surgery.

85. I have undertaken a thorough assessment of the information gathered in light of Ms A's concerns, and I consider that Dr B breached Right 6(1)(b),[25] Right 7(1),[26] and Right 4(1)[27] of the Code of Health and Disability Services Consumers' Rights (the Code). The reasons for my decision are set out below.

Information provided

Risks

86. Right 6(1)(b) of the Code states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option.

87. Dr Short advised:

> "The consent process should include discussion of risks common to most surgeries, which include bleeding, infection, visceral injury and thrombosis, together with risks specific to the particular procedure. In this case that would include the risks associated with transvaginal mesh such as mesh exposure/erosion, vaginal scarring, fistula, dyspareunia and persistent pelvic pain (which may be unprovoked). The possibility of surgery being unsuccessful (i.e. not treating the prolapse symptoms) should also be included."

88. Dr Short said that in addition to the above-mentioned risks, there are risks of injury to the pudendal nerve and vessels, which are known risks or complications specific to Mesh Type B. He advised:

> "This is due to the placement of the mesh arms in the sacrospinous ligament, close to these structures. For that reason the mesh arms would be placed 2–3cm away from the ischial spine, although this would not completely remove the risk of injury. Pudendal nerve injury would cause persistent pain."

89. Dr Short opined that on the basis of the documentation, insufficient information was provided to Ms A about the risks of transvaginal mesh surgery for vaginal prolapse.

90. I accept Dr Short's advice. The consent form shows that the only documented risks discussed were "bleeding", "infection", and "mesh erosion". There is no reference to any of the other risks (visceral injury and thrombosis, and the risks specific to the particular procedure, which included the risks associated with mesh such as vaginal scarring, fistula formation, dyspareunia and persistent pelvic pain (which may be unprovoked)).

[25] Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option.
[26] Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of the Code provides otherwise.
[27] Every consumer has the right to have services provided with reasonable care and skill.

91. Dr Ecclestone similarly advised that although Dr B discussed some of the risks of mesh with Ms A, Dr B failed to identify all of the risks, including dyspareunia, which was significant to Ms A. Dr Ecclestone advised that she would also have expected Dr B to have been aware of the FDA's warning that was released in July 2011, stating that serious complications with mesh were not rare (as was thought to be the case in 2008), but there was no evidence that this had been discussed with Ms A. Dr Ecclestone said that given the international guidance and literature that was available in 2013 about the reservations of using mesh, she considers the failure to discuss all of these risks to be a moderate departure from accepted practice.

92. While I acknowledge Dr Ecclestone's comments and accept that more information was coming to light about issues with mesh technology and the safety of certain mesh products, I do not hold New Zealand providers to the standards of overseas jurisdictions unless those standards are adopted nationally or represent current accepted practice in New Zealand.

93. Of relevance to this case, in March 2013 RANZCOG recommended that the mesh-related risks (mentioned above) should be discussed with patients as part of the consent process prior to surgery. Acknowledging that the RANZCOG guidelines were published only a month prior to the surgery, as advised by Dr Short, the content of these guidelines was not new information as of March 2013, and should have been "common knowledge" to all practitioners using transvaginal mesh at that time.

94. Also, the DHB's policy on informed consent states that "there is a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments".

95. As commented on by Dr Short, I appreciate that the consent process is "more nuanced" than merely what is written on the consent form, and that the most important aspect is the verbal discussion that occurs between the surgeon and patient. I agree with this sentiment. Informed consent is an ongoing process where there are multiple opportunities for the consumer to receive information and ask questions of the healthcare provider concerned. To help a consumer decide whether they agree to a particular treatment or procedure, the healthcare provider must give the consumer all the information they need in an understandable format to enable them to make up their mind and make an informed decision.

96. However, Ms A told HDC that "the risk factors of mesh erosion and mesh issues were not clearly represented to [her] in terms of informed consent". She said that when she "queried the reputation of surgical mesh [she] was told the type [she] was offered was not the type causing issues at the time". Dr B does not believe Ms A was given inappropriate information about her surgery.

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

98. Based on the available documentation (being what was documented on the consent form), Dr B did not provide sufficient information to Ms A about the risks and complications of using mesh (including the risks specific to Mesh Type B) to allow an informed choice. This was also contrary to the DHB's policy on informed consent.

Alternative treatment options

99. Dr Short advised that alternative treatment options should have been discussed with Ms A, which in this case would have included no treatment, non-surgical treatment such as pessaries or physiotherapy, and native tissue/non-mesh surgery such as anterior repair. He stated:

> "The role of mesh in surgery for vaginal prolapse was primarily for recurrent prolapse, where prior surgery had been unsuccessful. However, at that time many surgeons did use mesh in primary surgeries, on the basis that the rate of failure would be lower and consequently there would be less risk of needing further surgery in future. In this case the prolapse was predominantly affecting the bladder (a cystocele). [Ms A] had not had surgery for this problem previously and therefore it was not a recurrent prolapse (although [Dr B] states this, her previous surgery was actually for uterine prolapse and rectocele, not cystocele). Therefore, she should have at least been offered a native-tissue/non-mesh anterior repair. On the basis that this was not apparently offered and the limited apparent discussion of risks associated with the use of mesh, I would conclude that it was not appropriate to use [Mesh Type B] in [Ms A's] procedure."

100. Dr Ecclestone advised that in light of the international guidance and literature available at that time, the failure to fully discuss the risks and benefits of native tissue repair versus mesh repair was a moderate departure from accepted practice.

101. I accept the advice of both my advisors that alternative treatment options should have been discussed with Ms A.

102. The RANZCOG guidelines in 2013 referred to the FDA's 2011 update and an accompanying literature search that concluded that most cases of pelvic organ prolapse could be treated successfully without mesh. The RANZCOG guidelines (which Dr Short advised reflected accepted practice at that time) stated:

> "The consent process should be wide ranging and cover issues such as … alternatives to surgical management, including non surgical options such as pelvic floor muscle training and vaginal support pessaries … other alternative surgical treatments such as conventional native tissue repair, as well as abdominal sacrocolpopexy (open or laparoscopic)."

103. Ms A said that she was not offered native tissue repair as an option. There is no evidence to suggest that Dr B discussed alternative treatment options such as native tissue repair with her prior to the use of mesh.

104. In March 2013, the IUGA recommended that caution be exercised in transvaginal mesh implants in primary prolapse cases, and in cases of lesser grades of prolapse.

105. Ms A had a moderate primary prolapse. It was not severe or recurring, and, as advised by both Dr Short and Dr Ecclestone, native tissue repair was "certainly an option" to treat Ms A's primary prolapse. The clinical records also indicated that previously Ms A had had a successful posterior native tissue repair in 2009. Because this option was not discussed with Ms A, the eventual clinical decision to proceed with the use of mesh was inappropriate. As advised by my independent advisors, in this case, Ms A should at least have been offered a native tissue/non-mesh anterior repair.

Conclusion

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

Services provided

Care provided after anterior repair surgery

107. On 26 June 2015, Ms A presented to her GP as her prolapse symptoms had returned. She had symptoms of fullness, lower back ache, and dyspareunia. Ms A's GP sent a referral letter to Dr B requesting that Ms A be reviewed.

108. When Ms A saw Dr B on 16 July 2015, she presented with symptoms of dyspareunia and slight bladder urgency. Dr B could not find a clear explanation for her symptoms. Dr B noted that Ms A was "tender on introduction of a speculum", and stated that this was "almost certainly due to oestrogen deficiency changes".

109. Dr Short advised that "fullness" and "lower back ache" are non-specific symptoms that could each have a number of causes, and that it was reasonable for Dr B not to immediately equate these to a complication of the mesh surgery. However, Dr Short advised that "reports of painful intercourse from someone with a background of any vaginal surgery, and mesh surgery in particular, should have prompted consideration of a causal link between the two".

110. Dr Short advised that Dr B should certainly have considered that Ms A's symptoms post-surgery were a complication of the mesh implant, especially in light of Dr B's examination findings of vaginal tenderness. Dr Short said that while it may have been reasonable for Dr B to prescribe a short course of vaginal lubrication, follow-up should have been arranged to ascertain whether this had been successful. Had Dr B done so, Dr B may have been prompted to explore further, which may have resulted in earlier diagnosis and treatment.

111. Dr Ecclestone similarly advised that Dr B's failure to identify the mesh complications in July 2015, particularly in light of the international discussions around mesh at that time, would be considered a moderate departure from accepted practice.

112. I accept Dr Short's and Dr Ecclestone's advice, and agree that Dr B should have considered and excluded the possibility of mesh-related complications when Ms A was seen on 16 July

2015. At that time, a number of reports had been published by the FDA and RANZCOG, and the potential complications that can be caused by mesh were well known.

113. While I acknowledge that some time had passed from when Ms A had her surgery (2013) until she saw Dr B (2015), late complications with mesh were not uncommon. As commented on by ACC's clinical advisor, the incidence or manifestation of mesh complications increases over time. This is information that Dr B should have been aware of.

114. Given the information available at that time, I am critical that Dr B did not consider mesh complications as a possible cause of Ms A's symptoms. In my view, Dr B's failure to recognise the mesh complications resulted in a missed opportunity for Ms A to be diagnosed and treated earlier.

Conclusion

115. In my view, Dr B breached Right 4(1) of the Code by failing to recognise the mesh-related complications when Dr B examined Ms A in July 2015.

Documentation — adverse comment

116. In March 2013, RANZCOG made the following recommendations in relation to surgical training:

> "Transvaginal placement of surgical mesh for pelvic organ prolapse should only be performed by surgeons who have requisite knowledge, surgical skills, and experience in pelvic reconstructive surgery. When intending to introduce the use of a new mesh technique into their practice, individual surgeons should keep a clear record of all relevant training and experience. This knowledge and experience should be objectively demonstrable either by completion of the CU fellowship or by attendance and close involvement at surgical workshops, conferences, and peer to peer training. It is essential that such training should be 'hands on' training on multiple occasions. Simple observation of theatre cases is insufficient to demonstrate adequate expertise in performing these surgical procedures.
>
> Specific knowledge for a particular procedure should be obtained. Different mesh kits demand different skills and specific training. It is essential that surgeons should keep themselves up to date with reported results and complications of particular procedures that they use."

117. Dr B and Dr C presented differing accounts as to whether Ms A's surgery was one of the first surgeries that they had performed with Mesh Type B.

118. Dr B stated that Ms A's surgery was "the first insertion of [Mesh Type B]", whereas Dr C cannot recall the details, but assumed that Ms A's surgery was not the first they had performed with Mesh Type B.

119. Dr Ecclestone commented that the Mesh Type B representative was present in the operating theatre presumably because the operating surgeons were less familiar with the new insertion technique. She advised that if this was one of the first times the technique had

been utilised, she would have expected this to have been documented in the clinical records. Dr Ecclestone opined that the failure to disclose to Ms A that this was a new technique would be considered a mild departure from accepted practice.

120. I accept Dr Ecclestone's advice. While I acknowledge that Dr B and Dr C were both familiar with the surgical technique for inserting Mesh Type B, given that it was a new mesh requiring specific training, I would have expected a discussion about this to have been documented in detail.

121. I am critical that Dr B, as the person responsible for the informed consent process, did not document what had been discussed with Ms A about Dr B's surgical skills and experience with Mesh Type B.

Opinion: Dr B and Dr C — other comment

Mesh placement

122. Following the mesh removal surgery, Dr D reported that the mesh had been improperly placed, with the "left very close to the pudendal nerves". Dr D also stated that the mesh was "extremely tight", and that it was placed under tension. Dr D believed that this was the cause of Ms A's pain and the ongoing inflammatory response.

123. Dr B and Dr C both disagreed with Dr D's observations that the mesh had been placed improperly. At the end of the procedure, Dr B was confident that the mesh had been placed correctly. Similarly, Dr C considers that it was "very unlikely" that the mesh had been placed too close to the pudendal nerves. Dr Ecclestone advised that without prior imaging and more detailed sequential examination findings, it was not possible to determine whether the mesh had been inserted "under tension". She advised that the proximity of the mesh to the pudendal nerve on the left (as evidenced by the MRI and intra-operatively, and by Dr C's examination findings on 4 April 2017) was more likely to represent a technical error of insertion. Dr Ecclestone stated:

> "[T]he arms are unlikely to migrate to lie next to the nerves, more likely were placed there at the time of surgery using the [Mesh Type B] device. Although the operating surgeons were apparently aware of the need to stay lateral to the ischial spine, they have not achieved this. The surgeon's relative unfamiliarity with this insertion technique may well have contributed to this technical error. This would be considered a mild deviation from accepted practice."

124. Dr Short advised that he was unable to comment with certainty whether the mesh had been placed improperly. He said that while it was possible that the mesh had been placed too tightly at the time of surgery, which would explain Dr D's surgical findings, it may also have contracted over the subsequent years. Therefore, one cannot assume from Dr D's operation note or report that the mesh had been placed inappropriately. Dr Short also advised "extreme caution when deciding whether findings at surgery in [2019] indicate unsatisfactory performance of surgery in 2013".

125. I accept Dr Ecclestone's and Dr Short's advice. It is possible that the proximity of the mesh to the pudendal nerve represented a technical error of insertion. However, as commented on by Dr Ecclestone, without prior imaging and more detailed sequential examination findings, it is not possible to determine whether the mesh had been inserted "under tension".

126. While the overall tension across the mesh, as noted by Dr D, could have been present immediately postoperatively, Dr Short advised that it could also have occurred sometime after the surgery as a result of mesh contracture. This is supported by the fact that Ms A had no symptoms suggestive of pudendal injury/irritation at her initial follow-up with Dr B.

127. There is an innate difficulty in retrospectively reviewing the standard of care in surgical mesh cases where questions are raised about the appropriateness of the mesh placement at the time the surgery was performed. Due to the passage of time (from the mesh insertion in 2013 until the mesh removal in 2019), and the unavailability of any prior imaging, it is not possible for me to determine whether or not the mesh was inserted correctly.

Opinion: District Health Board — no breach

128. As a healthcare provider, the DHB was responsible for providing services in accordance with the Code.

129. In this case, I consider that the deficiencies in the care provided to Ms A related to Dr B and Dr C individually, and did not indicate broader systems or organisational issues at the DHB. Accordingly, I do not consider that the DHB breached the Code.

Changes made since events

Dr B

130. Dr B has retired from medical practice, and Dr B's practising certificate has expired.

Dr C

131. Since 2013, Dr C has been operating a private practice.

132. In October 2014, Dr C attended a conference on "New Insights into Prolapse Surgery", which discussed vaginal and laparoscopic options, with an emphasis on issues relating to mesh shrinkage and the pain caused where mesh had been used. Since attending the conference, Dr C has not used posterior mesh, and has used only "minimal" vaginal mesh. Since leaving the public hospital in 2018, Dr C has not used mesh for pelvic floor prolapse, in private or public practice.

133. Dr C has applied to ACC for all women who presented with pain that was likely to be mesh related, and Ms A is one of a number of women referred by Dr C for mesh removal.

134. Dr C undertook a careful self-audit for complications following all surgeries performed by Dr C, and recently provided data to the national credentialling body for incontinence tapes and sacrospinous fixations. Dr C also decided to stop providing incontinence tapes "due to

insufficient numbers meaning that there is … a lack of opportunity for the maintenance of surgical skills".

135. Dr C stated:

> "Because of the effect on so many women's lives from mesh and other causes of pelvic pain, I spent a significant portion of my sabbatical [in 2018] [focusing on] treatment of chronic pelvic pain including from [mesh]. I have advocated for individuals repeatedly through ACC and made referrals to centres better equipped to manage their complex surgical needs as well as worked to provide a more comprehensive chronic pelvic pain service locally including co-ordinating multi-disciplinary chronic pelvic pain meetings in [the region]."

136. Dr C has regular updates on surgical techniques and complications, and in 2021 undertook a skills update with a urogynaecologist.

DHB

137. The DHB told HDC that the mesh product used in Ms A's procedure has been withdrawn from the market and is no longer an option for women experiencing vaginal prolapse.

138. The DHB also told HDC that its obstetrics and gynaecology consultant has been training to be credentialled for procedures involving surgical mesh, under supervision, by a credentialled surgeon. The DHB said that currently it is awaiting the formal review process for credentialling Tier 2 hospitals by Manatū Hauora|Ministry of Health, which the Ministry plans to undertake later in 2023/2024. The DHB said that in the interim, its policy for credentialling senior medical practitioners applies to ensure that its consultants are appropriately qualified and competent.

139. The DHB said that it has also implemented the Ministry of Health's recommended practices to support fully informed consent by consumers to procedures involving the use of surgical mesh, including:

- Adopting the Ministry of Health's guidance "Considering surgical mesh to treat Stress Urinary Incontinence?" as a resource to support patients during the consent process;
- Connecting its Obstetrics and Gynaecology consultant with another hospital-based urogynaecology multi-disciplinary meeting for support in planning care for patients who have been referred for a procedure using surgical mesh; and
- Implementing preoperative health quality questionnaires and counselling to ensure that risks associated with the procedure are identified and addressed in the care plan.

140. The DHB told HDC that it is the view of its obstetrics and gynaecology clinicians that the awareness of risks in the use of surgical mesh has changed significantly since Ms A had her surgery in 2013, as has current clinical practice around the consent process, including documenting discussions of specific risks and alternative options for treatment.

141. The DHB stated that its obstetrics and gynaecology consultants endorse the guidance issued by RANZCOG in 2019 on "Consent and provision of information to patients in New Zealand regarding proposed treatment", and ensure that these standards are reflected in clinical practice.

Changes in medical practice

142. Due to the high risk of complications associated with mesh, a number of changes have been made since the events.

143. 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.

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

145. Currently, the Ministry is working on a process to credential surgeons who undertake pelvic floor procedures. This means that a committee of experts will check that surgeons have the right skills, experience and education to be performing complex surgeries such as those using surgical mesh. The Ministry of Health 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.

146. HDC, as a member of the Surgical Mesh Roundtable,[28] alongside representation from a number of other agencies including the Health Quality & Safety Commission (HQSC), is overseeing and monitoring the surgical mesh work programme led by the Ministry of Health. The work programme includes the actions and recommendations arising from the Health Committee and Restorative Justice reports.[29]

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

[28] https://www.health.govt.nz/system/files/documents/pages/terms_of_reference_surgical_mesh_roundtable_updated_march_2021.pdf.

[29] In 2014, Carmel Berry and Charlotte Korte petitioned Parliament for an inquiry into the use of surgical mesh in New Zealand. The Health Committee's report on this petition, with seven recommendations, was presented to the House in 2016. In December 2019, the Ministry released a report prepared by the Diana Unwin Chair of Restorative Justice at Victoria University, "Hearing and Responding to the Stories of Survivors of Surgical Mesh". The report included 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.

Recommendations

148. I have taken into account the changes that have been made, and are continuing to be made, by the Ministry of Health (in leading the surgical mesh work programme with oversight and monitoring by the Surgical Mesh Roundtable), Medsafe, and RANZCOG, which should go some way in reducing harm in the future.

149. As recommended in the provisional decision, Dr B provided a formal written apology to Ms A. Taking into account that Dr B has retired from medical practice, I do not consider that any other recommendations are necessary.

150. Dr C has provided details of the actions undertaken to address some of the shortcomings, and to improve surgical skills. I take this opportunity to recognise the efforts made by Dr C to improve the outcome for women who have suffered harm because of mesh surgery.

Follow-up actions

151. A copy of this decision with details identifying the parties removed, except the advisors on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's and Dr C's names in the cover letters.

152. A copy of this decision with details identifying the parties removed, except the advisors on this case, will be sent to Dr Joseph Bourne, CMO of Manatū Hauora and Chair of the Surgical Mesh Roundtable, Margie Apa, the Chief Executive of Te Whatu Ora National Office, the Accident Compensation Corporation, and Te Tāhū Hauora 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 my final decision at the next meeting of the Surgical Mesh Roundtable.

153. A copy of this decision 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.

Independent clinical advice to Commissioner

Dr John Short

"**Complaint: [Ms A]/[Dr B]**

Your ref: C19HDC01125

I have been asked to provide advice in this case … regarding the care provided to [Ms A] by [Dr B] in 2013 and 2015. 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 relevant documents, including the consumer complaint, hospital records, clinician reports and documents from [the DHB]. I understand expert advice has already been received for this case, so my report will focus on the specific questions I have been asked.

Care provided in 2013

1. In April 2013, when consenting a patient, such as [Ms A], for anterior repair surgery using surgical mesh, what risks, complications, and alternative treatment options should have been discussed?

The consent process should include discussion of risks common to most surgeries, which include bleeding, infection, visceral injury and thrombosis, together with risks specific to the particular procedure. In this case that would include the risks associated with transvaginal mesh such as mesh exposure/erosion, vaginal scarring, fistula, dyspareunia and persistent pelvic pain (which may be unprovoked). The possibility of surgery being unsuccessful (ie not treating the prolapse symptoms) should also be included.

Discussions should also include treatment alternatives. In this case that would include no treatment, non-surgical treatment such as pessaries or physiotherapy and native-tissue/ non-mesh surgery such as anterior repair.

2. Please consider the consent form dated 16 April 2013 and advise on the adequacy of the risks and complications that were documented. If there are any outstanding risks and complications, what would they be?

The consent form only refers to 'bleeding, infection and mesh erosion'. The other risks mentioned above are not mentioned on the consent form.

One must of course understand that the process on consent is more nuanced than merely what is written on the form and the most important aspect is the verbal discussion between

surgeon and patient. Unfortunately, we have no way of knowing exactly what information was given in such discussions. However, it is (in most cases) reasonable to assume that the items written on the form at least summarise the content of discussions.

3. Whether gynaecologists and obstetricians should have been aware of the RANZCOG guidelines of March 2013 and whether these guidelines should have been adhered to at the time of events (April 2013)?

The RANZCOG document had only just been published at the time of surgery. Therefore, a gynaecologist may not have specifically been aware of the guideline at that time. However, the content of the guideline was not new information as of March 2013 and the points made should have been common knowledge to all practitioners using transvaginal mesh at that time.

4. Given the published literature that was available in 2013 about the risks and reservations of using mesh, was it appropriate to use [Mesh Type B] in [Ms A's] procedure?

The specifics of surgical plans are ultimately a result of discussions between the doctor and patient and would be dependent upon the information provided. Therefore, for an appropriately informed patient, this may have been an appropriate decision. The role of mesh in surgery for vaginal prolapse was primarily for recurrent prolapse, where prior surgery had been unsuccessful. However, at that time many surgeons did use mesh in primary surgeries, on the basis that the rate of failure would be lower and consequently there would be less risk of needing further surgery in future.

In this case the prolapse was predominantly affecting the bladder (a cystocoele). [Ms A] had not had surgery for this problem previously and therefore it was not a recurrent prolapse (although [Dr B] states this, her previous surgery was actually for uterine prolapse and rectocoele, not cystocoele). Therefore, she should have at least been offered a native-tissue/non-mesh anterior repair.

On the basis that this was not apparently offered and the limited apparent discussion of risks associated with the use of mesh, I would conclude that it was not appropriate to use [Mesh Type B] in [Ms A's] procedure.

5. Were there any known risks or complications specific to [Mesh Type B] in April 2013?

In addition to those mentioned in response to question 1, there are risks of injury to the pudendal nerve and vessels. This is due to the placement of the mesh arms in the sacrospinous ligament, close to these structures. For that reason the mesh arms would be placed 2–3 cm away from the ischial spine, although this would not completely remove the risk of injury. Pudendal nerve injury would cause persistent pain.

6. Considering [Dr D's] operation note and report, is it possible to comment on the appropriateness of the mesh placement and whether the surgery was performed with reasonable care and skill?

Unfortunately, I cannot comment with certainty on this.

I do not have a copy of the operation note describing the placement of the mesh, although this is unlikely to specifically document inappropriate mesh placement. [Dr D's] operation note describes the mesh being 'tightly banded across the vaginal vault. Palpable in left fornix. Mesh under tension'. [Dr D's] report also states that the mesh was too close to the ischial spine and pudendal structures on the left side. This is based on a MRI report and is not described in [Dr D's] operation note. I would generally consider the operation note to be a more reliable descriptor than a MRI.

In [Dr B's] report, [Dr B] states [Dr B's] awareness that the mesh should be placed more than 2cm away from the ischial spine. Given that [Dr D's] report makes no mention of the mesh being too close I must, on balance, conclude that the mesh placement in relation to the ischial spine/pudendal structures was probably correct at the time of placement although I cannot be certain. This is supported by the fact that [Ms A] had no symptoms suggestive of pudendal injury/irritation at her initial follow up with [Dr B].

Whilst it is possible that the mesh was placed too tightly at the time of surgery, which would explain [Dr D's] surgical findings, it may also have contracted over the subsequent years. Therefore, one cannot assume from [Dr D's] notes or report that the mesh was placed inappropriately.

Care provided in 2015 — adequacy of follow-up treatment by [Dr B]

7. When [Dr B] examined [Ms A] on 16 July 2015 and she was presenting with symptoms of fullness, painful intercourse and lower back ache, what causes for her symptoms should have been considered by [Dr B] and what follow-up investigations and management should [Dr B] have undertaken?

'Fullness' and 'lower back ache' are non-specific symptoms that could each have a number of causes. It was reasonable not to immediately equate these to a complication of the mesh surgery. However, reports of painful intercourse from someone with a background of any vaginal surgery, and mesh surgery in particular, should have prompted consideration of a causal link between the two. Most information would usually be obtained from a clinical examination. [Dr B] did perform a clinical examination, with a finding of significant tenderness and assumed atrophic changes were the cause. [Dr B] prescribed vaginal lubricants but did not arrange follow up to see if this was successful. Had this been arranged the feedback may have alerted [Dr B] to the need for further investigation such as MRI scan or examination under anaesthetic. [Dr B] does state that when [Ms A] underwent a laparoscopic BSO on 28/7/15 that 'no obvious problems with the intravaginal mesh were noted'. As I do not have a copy of that operation note or findings report I cannot comment on the reliability of that statement or the thoroughness of the assessment.

8. Whether [Dr B] should have recognised the symptoms post-surgery were a complication of the mesh implant?

This should certainly have been considered, especially in light of [Dr B's] examination findings of vaginal tenderness. Whilst it may have been reasonable to prescribe a short course of vaginal lubrication, follow-up should have been arranged to ascertain if this had been successful. Had [Dr B] done this [Dr B] may have been prompted to explore further to thus result in an earlier diagnosis.

9. Any other issues you wish to raise?

I'd like to take this opportunity to express some unease with the process of commissioning this report. It is my understanding that my advice has been sought as a secondary expert. I understand the primary advice was from a urologist, despite the practitioner in the complaint being an obstetrician and gynaecologist. Whilst there is some overlap between the two specialties, they are distinctly different in terms of training, scope of practice and, most importantly, recognition by the medical council. Therefore, it seems highly unusual and somewhat concerning that the HDC should, in the first instance, seek advice from a urologist when the complaint is about a gynaecologist.

Conclusion

Based on the information provided, I have formed the opinion that the overall care provided by [Dr B] to [Ms A] was not reasonable, on the basis of these factors:

- Insufficient information was provided about the risks of transvaginal mesh surgery for vaginal prolapse.
- The option of native-tissue/non-mesh surgery was not discussed.
- Insufficient effort was made to explore the possibility that [Ms A's] pain was a complication of the mesh surgery.

I am unable to comment on whether the surgery was performed appropriately and I would advise extreme caution when deciding whether findings at surgery in 2021 indicate unsatisfactory performance of surgery in 2013.

I hope you find this report helpful and please contact me if require further information.

Yours Sincerely,

John Short"

Dr Hazel Ecclestone

"**Advice provided by: Hazel Ecclestone. MBChB MSc FRCS(Urol) Consultant Urologist TDHB**

RE: Ref C20HDC01125

Care provided by [Dr B] and [Dr C] to [Ms A]

I provide this opinion based on my training as a consultant Urologist, which I undertook in the UK. I completed a fellowship in female functional and reconstructive urology including mesh complications at University College Hospital London. I have previously worked in the largest pelvic floor MDT in Europe, which included cross speciality working with colorectal surgeons and gynaecologists. I have been credentialed to perform operations for female incontinence both in the UK and in New Zealand. I have also published widely in this field.

In particular, please comment on:

1. The appropriateness of the decision to perform an anterior [Mesh Type B] repair to treat [Ms A's] symptoms of prolapse and moderate cystocele and rectocele

Letter from [Dr B] to HDC 16.8.19 '[Ms A] was admitted to [the public hospital] on 17/11/2009 and a vaginal hysterectomy and posterior repair was performed … I next met [Ms A] on 8/2/13 and in my correspondence with her general practitioner I noted 'it is disappointing that [Ms A] has developed symptoms of a recurrent prolapse after only four years … given that this is a recurrent prolapse it would be best to do her next repair with mesh'. [Dr B] also stated:

> 'When mesh technology for vaginal prolapse was introduced it appeared to be the answer for what was a known significant issue namely women being at risk of prolapse recurrence when native tissue repairs were performed however as an individual, and as a gynae department we took a very conservative approach to the use of mesh, restricting its use to women with recurrent prolapse and avoiding its use in young women.'

It seems that the anterior compartment prolapse (cystocoele) is not actually a 'recurrent' prolapse, but a primary (as previously only mid and posterior compartment prolapse dealt with). In addition, intraoperatively it was noted 'mod cystocele with only slight vault laxity. No significant post wall prolapse other than prominent fold of mucosa just within hymen' indicating previous native tissue repair had been successful in both posterior and middle compartments.

In addition the FDA in 2008 had released a statement saying : 'In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia' and recommended:

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.

- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labelling from the surgical mesh manufacturer, if available.

Little regard to the consequence of using mesh appears to have been considered pre-operatively. There is also little information as to how much training and experience the operating surgeons had with using [Mesh Type B]. This case also appears to have gone against 'departmental policy' of reserving mesh for recurrent prolapse only. The decision to use mesh in this case seemingly goes against departmental policy (of only using mesh in recurrent prolapse) and also does not take into account the potential severe complications that were known to be caused by mesh and would be considered by my peers as a moderate deviation from accepted practice in 2013.

2. Whether appropriate testing and diagnostics were undertaken, and whether they indicated surgery was appropriate

There seems no question that [Ms A] had symptomatic pelvic organ prolapse. The pre-operative letter discussing examination and surgical options does not appear to have been included in the case file. This makes it difficult to fully establish whether adequate diagnostics were undertaken. The diagnosis of prolapse however is usually a clinical one, and there is clear evidence from [Dr B's] letter to the HDC that [Dr B] did perform a clinical examination, and felt surgery was indicated. The decision to perform the repair with mesh is however more contentious (see comments in point one). As regards the pre-operative evaluation however I am unable to find deviation from accepted practice.

3. Whether other treatment options should have been discussed with [Ms A] in 2013. If so please describe them.

I do not have access to prior notes to see if conservative management (such as pelvic floor exercises) or a pessary was tried. The risks of doing nothing are also not clearly explained in the case file. If the patient had been offered or failed these conservative measures, then surgical treatment would have been an alternative option.

Native tissue repair was certainly an option to treat this primary prolapse, I am unsure whether this was discussed due to lack of pre-operative assessment included in the file. I do note however in [Dr B's] response to the HDC that due to the presence of a recurrent rectocoele as well as a cystocoele that 'it would be best to do her next repair with mesh'. There is no further documentation regarding what enabled [Dr B] to come to this conclusion,

or indeed if this was joint decision making with the patient, or a unilateral decision on the part of the surgeon. Either way it does not meet the recommendations made by the HDC in 2008 and it is unlikely that true informed consent was sought.

I would consider the deviation both from the FDA recommendation and indeed [Dr B's] self-identified local policy (of only using mesh for recurrent prolapse) to be a moderate departure from expected practice.

4. Whether it was appropriate to use [Mesh Type B] in [Ms A's] procedure, noting that prior to this, the clinicians had used [Mesh Type A].

As outlined above, the FDA clearly suggest that 'Obtain specialized training for each mesh placement technique, and be aware of its risks'. It is not clear that [Dr B] and [Dr C] had indeed had specialised training in this new mesh, and their decision to change from [Mesh Type A] was based on '[the DHB] changing supplier for surgical mesh' the reason for the change of supplier was explained as '[Mesh Type B] requires insertion of the mesh through the sacrospinous ligament on each side, using a [Mesh Type B] device — a much simpler and safer technique. This plus the smaller mesh size is why we changed products.'

I note the consent form states that the [Mesh Type B] representative was in theatre. This is presumably because the operating surgeons had changed to an alternative mesh recently and were therefore less familiar with insertion technique of the newer mesh. It is not documented in the notes how many [Mesh Type B] the operating surgeons had previously inserted prior to [Ms A's] case, but I would expect there to be documented candour if this was one of the first times this technique had been utilised by these surgeons and the failure to disclose to the patient the fact that this was a new technique to them would be considered a mild departure from standard practice.

5. The risks and benefits of mesh procedure, and [Mesh Type B], that should have been discussed with [Ms A].

In addition to the FDA statement of 2008 (as above) a further update from the FDA was released on 13/7/11 which stated that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare.** Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. In addition it states '*mesh contraction (*shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh … Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain … mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse.'

I would expect the operating surgeons to be aware of this FDA warning, but there is no evidence that this was communicated to the patient, despite this FDA alert being in the public domain and easily accessible online. The failure of the surgeons to have fully discussed the risks and benefits of mesh vs native tissue repair in light of the international guidance and literature would be considered a moderate departure from accepted practice.

I have not however seen the pre-operative letter directly, just quotes from it in [Dr B's] reply to the HDC.

6. The adequacy of the information given to her as part of the informed consent process. The adequacy of the signed consent form — in particular did the signed consent form appropriately describe the risks [Ms A] should have been fully aware of prior to consenting to the surgery at this time

Consent form 16.4 — 'Anterior mesh repair "[Mesh Type B] posterior repair (mesh repair or sacrospinous fixation' Risks documented 'Rep/colleagues in theatre. Risks — bleeding, infection, mesh erosion'.

RANZCOG released a statement regarding consent for pelvic mesh, initially in 2007, the latest version of which reads:

> 'Complications of transvaginal mesh must include mesh exposure/erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or unprovoked pelvic pain at rest. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest that can be difficult to treat should be discussed. That these complications may occur some years after implantation and can be difficult to treat should be discussed.'

Although some of these risks were indeed discussed, the consent form fails to identify all risks, including ones that may be significant to the patient (eg dyspareunia). Given the current international guidance and literature available in 2013 about the reservations of using mesh, I would consider this a moderate departure from accepted practice.

7. Whether the mesh surgery performed by [Dr B] and [Dr C] was performed with reasonable skill and care. Was their surgical technique correct? In particular, consider the subsequent pain and dyspareunia, and any relevant findings by [Dr D] in the subsequent surgical mesh removal surgery undertaken in April 2019.

Operation record 16.4.13 p349 — surgeon [Dr C], assistant [Dr B]. Findings 'mod cystocele with only slight vault laxity. No significant post wall prolapse other than prominent fold of mucosa just within hymen' … 'midline anterior insertion. — wide dissection of fascia out to each spine + sacrospinous ligs. No plication needed. Mesh in gentamicin, Mesh arms placed through lateral aspect of each SS ligament then 3 x 3/0 PDS sutures to fix both proximal and postal edge of the mesh to vagina. 1 PDS plicating suture above distal edge of mesh to vagina.

Clinic letter 9.9.17 [Dr C] … on examination … she was clearly tender over the whole anterior mesh, but especially the left upper mesh arm when any tension was placed over it'.

[Dr B] reply to HDC 2.7.21 — 'we were well aware of the need to try and stay at least 2cm medial to the ischial spine to avoid any nerve injuries and we were confident at the end of [Ms A's] operation that the mesh had been correctly placed'.

I note [Dr D's] post operative letter 29.05.19 stating 'the mesh was improperly placed with the left very close to the pudendal nerves and also over all the mesh was extremely tight i.e.

the mesh was placed under tension and I believe that was causing ongoing inflammation and traction.'

The description of the operative technique in the operation note is good. It does not however directly comment on the distance from the ischial spine despite [Dr B's] insistence in 2021 that [Dr B] was confident that the mesh had been correctly placed. The overall increased tension across the mesh, noted by [Dr D] may have been present from immediately post operatively, but may also be the result of mesh contracture and without prior imaging and more detailed sequential examination findings it is not possible to say whether the mesh was indeed inserted 'under tension'. The proximity of the mesh to the pudendal nerve on the left (as evidenced both on MRI and intraoperatively, and the findings on examination in 2017) is more likely to represent a technical error of insertion, and the arms are unlikely to migrate to lie next to the nerves, more likely were placed there, at the time of surgery, using the [Mesh Type B] device. Although the operating surgeons were apparently aware of the need to stay lateral to the ischial spine, they have not achieved this. The surgeon's relative unfamiliarity with this insertion technique may well have contributed to this technical error.

This would be considered a mild deviation from accepted practice.

8. The management of symptoms after [Ms A's] surgery, including the adequacy of care provided by nursing staff, [Dr B] and [Dr C]

Post op ward notes — seen by [Dr B] D1, D2 post op. Bladder scan performed following catheter removal. Residual 88ml. Daily nursing notes in file post operatively, including pain scores.

17.6.13 p526 [Dr B] OPD — 'S/B GP x2 as difficult inserting ovestin' … 'bladder fine, no incontinence. O/E excellent result. 1 tiny bleb of granulation on ant wall'.

Typed letter p750 [Dr B] 17.6.13 — 'The anatomical result looks excellent … I have encouraged her to resume normal activity now and explained that it would probably be best to persevere with twice weekly ovestin cream, certainly for as long as she wishes to be sexually active'.

Pre-assessment for bilateral salpingo-oophrectomy — 'painful mesh site with sexual intercourse — will speak to [Dr B] about this at time of op' (28.5.15 p454).

The management in the hospital setting in the perioperative periods by wider members of the MDT is on the whole very good. Notes are extremely comprehensive and appropriate post operative investigations were completed (such as a bladder scan). Daily consultant ward rounds were also completed. I would also like to commend the pre-assessment nurse for enquiring and listening to [Ms A's] experiences of dyspareunia which she has encouraged the patient to speak with [Dr B] about.

No deviation from accepted practice noted in perioperative/MDT care.

9. The adequacy of follow up treatment by [Dr B], for the period following [Ms A's] surgery in 2013 until she obtained review from [Dr C] in 2017. In particular, whether [Dr B] should have recognised that [Ms A's] pelvic pain, urinary urgency and inability to have sexual intercourse post-surgery were a complication of the mesh implant. If so, what follow up investigations and management should [Dr B] have undertaken?

16.7.15 — clinical review [Dr B] — 'she now presents with symptoms the most important being discomfort with intercourse … And she notices slight bladder urgency' … 'She is tender on introduction of a speculum, almost certainly due to oestrogen deficiency' hand written clinic note p526 'now aware of some dyspareunia. Tender secondary to E3 low'.

9.9.17 p611 — Clinical review [Dr C] '[Ms A] requested to be seen by someone other than [Dr B] who has performed most of her previous surgery, not because she had any complaints about [Dr B], but that she was unhappy having to explain that there had been a problem following a surgical procedure' … 'Sadly [Ms A] reports that since she resumed sexual intercourse which was after her post operative check she has had severe pain in her vaginal wall. … on examination … she was clearly tender over the whole anterior mesh, but especially the left upper mesh arm when any tension was placed over it' … 'I have … placed an ACC request in for [Ms A] for mesh causing dyspareunia'.

[Dr B], although reporting [Ms A's] symptoms, does not consider mesh complications to be in the differential diagnosis. [Dr B] somewhat dismisses and minimises [Ms A's] symptoms being due to 'oestrogen deficiency'. The lack of acknowledgment of harm is part of the harm itself and the 'medical gaslighting' is well defined in the restorative justice report 2019. She was not then followed up after the appointment with [Dr B] to see if the oestrogen had indeed been effective. In addition RANZCOG had in 2007 released a statement regarding polypropylene vaginal mesh implants for vaginal prolapse, which is still updated regularly, which states

> 'Complications of transvaginal mesh must include mesh exposure/erosion, vaginal scarring/ stricture, fistula formation, dyspareunia, and/or unprovoked pelvic pain at rest. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest that can be difficult to treat should be discussed. That these complications may occur some years after implantation and can be difficult to treat should be discussed.'

I note [the] comment in [Dr B's] reply to the HDC 16.8.19 'I am sorry I did not appreciate that the mesh might be causing [Ms A's] dyspareunia when I saw her in 2015 as we were unable to identify any obvious clinical problem and I thought her discomfort was far more likely related to oestrogen deficiency. I am also sorry that she has had this longstanding problem and has had to have corrective surgery. I unreservedly apologise to [Ms A] for this problem but it was never our intention to cause her any harm and we only wanted the best outcome for her prior to her mesh operation'.

Although it is encouraging to hear the remorse for the outcome suffered, the failure to identify the mesh complication at the appointment in 2015, especially in light of the international discussions around mesh at that time would be considered a moderate departure from accepted practice.

I consider [Dr C's] review in 2017 is a more balanced assessment of the differential diagnoses, including a familiarity with potential mesh complications, and an appropriate referral to ACC for cover as a treatment injury. There is certainly no doubt about the temporal relationship of surgery and the development of symptoms. I do not identify any deviation from accepted practice in the follow up provided by [Dr C].

10. The appropriateness of [Dr B] declining to surgically investigate [Ms A's] symptoms when performing her bilateral oophrorectomy in 2015

P660 letter from GP to [Dr B] '[Ms A] is due for an elective bilateral oophorectomy this month under your care. [Ms A] has previously had an anterior repair and reports that in the last few months her symptoms of fullness, painful intercourse and lower back ache have returned … [Ms A] is very keen to know whether this can be addressed at the same time as her planned surgery' 26.6.15.

P657 16.7.15 [Dr B] letter to GP 'Thanks for your letter about [Ms A] asking if she needed to have any surgical attention to a prolapse at the time she has a laparoscopic oophorectomy … She is tender on introduction of a speculum, almost certainly due to oestrogen deficiency … we are just going to do her planned laparoscopic bilateral oophorectomy and I have suggested she try a vaginal lubricant'.

As outlined above, I certainly think [Dr B] should have considered the possibility of mesh related complications when [Dr B] saw [Ms A] prior to her salpingo-oophorectomy. It is clear from a multitude of sources (GP, pre assessment nurse, gynaecologist) that [Ms A] was extremely troubled by her symptoms, and the failure to establish resolution after initiating treatment would be considered a mild departure from accepted practice.

11. The appropriateness of [Dr B] advising continued use of Ovestin cream given its lack of effectiveness for [Ms A] and her breast cancer diagnosis.

16.7.15 letter from [Dr B] to GP 'Many thanks for your letter about [Ms A] asking if she needed to have any surgical attention to a prolapse at the time she has a laparoscopic oophorectomy' … 'she now presents with symptoms the most important being discomfort during intercourse' … 'she is tender on introduction of the speculum … we are just going to do her planned laparoscopic bilateral oophorectomy and I have suggested she try with a vaginal lubricant such as sylke but if that is not sufficient to ease her discomfort then she could go back onto Ovestin'.

As alluded to above, I do not think that the differential diagnosis of oestrogen deficiency is an unreasonable one, but given the degree of distress caused by the symptoms I would have expected a further clinical review to ensure the treatment had been effective. In addition the failure to consider mesh complications in the differential diagnosis would be a mild departure from accepted practice.

12. The adequacy of follow up treatment by [Dr C], for the period of 2017 onwards.

Referred to [Dr D] by [Dr C], urologist with expertise in mesh removal on 21.1.18 for consideration of mesh removal in public system owing to extreme dyspareunia.

ACC treatment injury form 8.9.17 completed by [Dr C]. 'Symptoms of severe pain with intercourse … rarely has intercourse with partner … mesh is known to cause dyspareunia in some women'.

9.9.17 letter from [Dr C] to [breast surgeon] '[Ms A] has seen me with severe dyspareunia which is no doubt in part due to her anterior mesh repair which was performed in 2013'.

[Dr C] has seemingly performed a thorough history and examination and appropriately considered the differential diagnosis of mesh complications. [Dr C] appropriately completed ACC treatment injury paperwork and referred on to a specialist with expertise in mesh complications and mesh removal. [Dr C] also advocated for the patient in correspondence with ACC.

I consider the care offered by [Dr C] from 2017 onward to be of a good standard with no deviation from accepted practice.

13. Any other issues you wish to raise.

Thankfully the use of mesh for pelvic organ prolapse is now used extremely rarely owing to the high risk of complications. RANZCOG recommend that transvaginal polypropylene mesh is not recommended as a first line treatment of any vaginal prolapse. In addition, when it is considered to be used, this should ideally be as part of a trial, with extensive discussion regarding other options and referral for a second opinion considered. This will hopefully go a long way to reducing harm from transvaginal mesh for POP. In addition, if POP mesh is going to be continued to be offered in New Zealand, there should only be a small number of credentialled surgeons working as part of an MDT implanting mesh, as part of a clinical trial with prospective data gathering and analysis. It is worth noting that internationally pelvic mesh kits for pelvic organ prolapse are no longer used in the UK, and in the USA following withdrawal of devices from the market as ordered by the FDA due to:

> 'On April 16, 2019, after reviewing their premarket approval (PMA) applications, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse [Mesh Type B] to stop selling and distributing their products immediately. The FDA determined that [the manufacturers] did not demonstrate reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to transvaginal mesh for pelvic organ prolapse since the agency reclassified them into class III (high risk) in 2016.'

In addition:

* There are currently no FDA-approved surgical mesh products for transvaginal repair of prolapse marketed in the United States.

To prevent similar harms, credentialled surgeons must be also be engaged in ongoing continued professional development to ensure that they remain abreast of the latest literature and developments in the field of pelvic organ prolapse and mesh.

For each question, please advise:

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

b. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be? With an accompanying explanation as to why you have formed this view.

c. How would it be viewed by your peers?

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

Where appropriate please reference relevant national and/or international literature on this topic.

FDA 2008 hIp://www.fda.gov/cdrh/safety/102008-surgicalmesh.html (amiform.com)

FDA 2011 hIps://wayback.archive-it.org/7993/20170111231226/hIp:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm

Hearing and Responding to the Stories of Survivors of Surgical Mesh | Ministry of Health NZ Polypropylene vaginal mesh implants for vaginal prolapse (ranzcog.edu.au)

Signed

Date 10.04.2022”