Obstetrician and Gynaecologist, Dr B

A Report by the
Deputy Health and Disability Commissioner

(Case 22HDC00810)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns informed consent regarding the use of surgical mesh and the standard of care provided by an obstetrician and gynaecologist.

2. On 19 April 2017, a woman met with the obstetrician and gynaecologist for treatment of her vaginal vault prolapse. There is nothing in the clinical records to indicate that the woman had stress urinary incontinence or urge urinary incontinence at that point.

3. The woman signed a consent form to undergo surgery for an anterior and posterior vaginal repair, a suburethral sling, and a sacrospinous colpopexy. The suburethral sling was made of mesh material.

4. The woman and the obstetrician and gynaecologist have differing recollections of what was discussed with the woman in relation to the use of mesh and the risks involved. The obstetrician and gynaecologist said that the woman was informed that the suburethral sling was made of mesh, and that he provided her with copies of the RANZCOG information sheets on pelvic organ prolapse and urinary incontinence. The woman denied that this was the case and said that there was no discussion about the use of a mesh sling or about the mesh-related risks or complications. The woman said that she informed the obstetrician and gynaecologist that she did not want any mesh used in her surgery, and he confirmed that he would not be using any mesh.

5. There is no record in the clinical notes of what was discussed with the woman in relation to the use of mesh (that the suburethral sling was made of mesh material), or the mesh-related risks and complications.

6. On 28 July 2017, the obstetrician and gynaecologist performed the surgery for an anterior and posterior repair, a suburethral sling, and a sacrospinous colpopexy. The operation note does not include any detail of the sling placement, such as anatomical entry and exit points.

7. Following the surgery, the woman experienced a number of profound life-changing complications, including ongoing chronic pain and other issues that have had a significant impact on the normal functioning of several organs in the pelvic region. She has since undergone several further treatments and procedures.

8. On 29 September 2021, the woman had surgery to remove the mesh. The findings were noted to be 'really quite abnormal', and the mesh was discovered in a 'very unusual location'.

Findings

9. The Deputy Commissioner found that the obstetrician and gynaecologist breached Right 6(1)(b) of the Code as the continence procedure (the suburethral sling) was not discussed and documented in detail, and the woman did not consent to the use of mesh and specifically instructed that mesh was not to be used. It follows that, without this information, the woman was not able to make an informed choice and give informed

consent to the surgery on 28 July 2017. The Deputy Commissioner therefore also found that the obstetrician and gynaecologist breached Right 7(1) of the Code.

10. In the absence of documentation confirming where the sling was placed, and based on the findings of the mesh removal surgery, the Deputy Commissioner considered it more likely than not that the mesh had been placed incorrectly. The Deputy Commissioner found that by placing the sling incorrectly, the obstetrician and gynaecologist failed to provide services with reasonable care and skill, in breach of Right 4(1) of the Code.

11. The Deputy Commissioner also found that the obstetrician and gynaecologist's documentation was not up to the standard required by the Medical Council of New Zealand, in breach of Right 4(2) of the Code.

Recommendations

12. Taking into account the apology provided, the changes that have been made by the obstetrician and gynaecologist since the events, and the systemic measures introduced to reduce the risk of harm associated with mesh, the Deputy Commissioner recommended that the obstetrician and gynaecologist undertake further education/training on the informed consent process and documentation, and refresher training on the Code of Health and Disability Services Consumers' Rights.

Complaint and investigation

13. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her friend, Mrs F, by Dr B, an obstetrician and gynaecologist. Mrs F consulted with Dr B at a private hospital.[1]

14. The complaint concerns informed consent regarding the use of surgical mesh, and the standard of care Dr B provided to Mrs F. Following the surgery performed by Dr B in April 2017, Mrs F has had ongoing pain, and profound bladder and bowel dysfunction.

15. The following issues were identified for investigation:

- *Whether Dr B provided Mrs F with an appropriate standard of care between April 2017 and October 2017 (inclusive).*
- *Whether Dr B provided appropriate information about, and obtained Mrs F's informed consent to insert a suburethral sling made from surgical mesh.*

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

[1] Dr B was accredited to, but not employed by, the private hospital.

17. Due to the ongoing trauma and emotional harm Mrs F has experienced over the seven years post the surgery, Mrs F was not directly involved in the investigation but has confirmed that she supports the investigation and has provided a response to the provisional opinion.

18. The parties directly involved in the investigation were:

Ms A	Complainant
Dr B	Provider/obstetrician and gynaecologist

19. Further information was received from:

Private hospital	Provider
Dr C	Provider/urologist
Dr D	Provider/urologist
Dr E	Provider/orthopaedic surgeon
Mrs F	Consumer
Mr F	Husband of consumer
Accident Compensation Corporation (ACC)	

20. Also mentioned in this report:

Dr G	Gynaecologist
Dr H	Obstetrician and gynaecologist

21. Independent advice was obtained from gynaecologist and obstetrician Dr John Short (Appendix A).

Information gathered during investigation

Referral to Dr B

22. On 30 March 2017, Mrs F was referred to Dr B by her general practitioner (GP) for treatment of her vaginal vault prolapse.[2] Mrs F was known to Dr B as he had delivered her children and previously had performed a vaginal hysterectomy[3] on Mrs F (in 2003). Mrs F's husband said that this meant that 'there was a level of trust that had been established'.

23. The referral to Dr B stated:

> 'Over the past month, [Mrs F] has become aware of a vaginal vault prolapse. This is not associated with any stress [incontinence][4] or urge incontinence.[5] She does not have any

[2] The movement of pelvic organs from their normal position into the vagina.
[3] A procedure where the uterus is removed via the vagina without the need for an abdominal incision.
[4] When physical movement or activity, such as coughing, laughing, sneezing, running, or heavy lifting, puts pressure/stress on the bladder, causing leakage of urine.
[5] A sudden urgent need to urinate.

> problems with defaecating. Her main symptom is that of discomfort due to the sensation of a prolapsed "lump" which is uncomfortable when sitting or even when simply wearing trousers. She has a moderate degree of anterior vaginal vault prolapse [and] a minor degree of [posterior vaginal] prolapse. No incontinence on coughing.'

Consultation on 19 April 2017

24. On 19 April 2017, Mrs F met with Dr B in relation to the prolapse. Ms A advised HDC that Mr F was also present at this consultation.

25. In a clinic letter to Mrs F's GP dated 19 April 2017, Dr B confirmed that Mrs F had a prolapse. Dr B noted that most of the prolapse was anterior,[6] with some rotation of the urethra, a lesser degree of posterior wall prolapse,[7] and some descent of the vaginal vault. Dr B documented that Mrs F required an 'Anterior Vaginal Repair,[8] [suburethral sling[9]], a small Posterior Vaginal Repair[10] and a Sacrospinous Colpopexy[11]'.

26. Dr B advised the GP that Mrs F was going to 'sort out how to fit things in around her work and then contact us'.

27. Notwithstanding that there is nothing in the clinical records for the consultation on 19 April 2017 to indicate that Mrs F had stress urinary incontinence or urge urinary incontinence, Dr B stated in his clinical letter that Mrs F required a suburethral sling.

28. Dr B told HDC:

> '[Suburethral] sling procedures were the standard procedure for stress urinary incontinence in my practice from 2006. The tape was the only [non-absorbable] material I have ever used in surgery for pelvic organ prolapse. No mesh was used to repair the pelvic organ prolapse as instructed by [Mrs F] and confirmed by me[12].'

29. Dr B said that no mesh was used for the posterior vaginal repair and sacrospinous colpopexy, and that a suburethral sling was used to provide support for the urethra to improve symptoms of stress urinary incontinence.

30. In relation to alternative treatment options, Dr B said that no non-surgical therapies were trialled prior to the surgery. Dr B said that Mrs F was offered a vaginal pessary trial prior to

[6] A bulge in the front wall of the vagina.
[7] A bulge in the back wall of the vagina.
[8] A surgical procedure to repair or reinforce tissue between the bladder and the vagina.
[9] A surgical procedure to lift and support the urethra. Also referred to as a mid-urethral sling.
[10] A surgical procedure to repair or reinforce the tissue between the rectum and the vagina.
[11] A surgical procedure to repair vaginal vault prolapse through an abdominal incision.
[12] Dr B told HDC that initially when he said that no mesh was used, he was referring to the posterior vaginal repair and sacrospinous colpopexy, where no mesh was used, and not the incontinence procedure, where mesh was used (the suburethral sling was made of mesh). Dr B explained that initially he believed that the complaint related to complications from the posterior vaginal repair and the sacrospinous colpopexy, where no mesh was used. Dr B said that it was not until he had reviewed the independent advice provided to HDC that he became aware that the complaint related to the sciatic nerve injury from the mesh that was used (the suburethral tape, which was made of mesh).

the surgery but this was declined. Dr B stated that in Mrs F's case, there were 'multiple failures in the pelvic wall musculature', which he did not believe would have been improved with physiotherapy.

31. There is no record of any discussions with Mrs F about alternative treatment options.

Mesh sling and information provided

32. Dr B and Mrs F and Mr F, who accompanied his wife to the consultation with Dr B on 19 April 2017, have differing recollections of what was discussed with Mrs F in relation to the use of mesh and the risks involved.

33. Dr B said that Mrs F was informed that the suburethral sling was made of mesh, and that it was his usual practice to inform patients of this. Dr B stated:

> 'I have in my office an anatomical model of a pelvis. In 2017 I had samples of the suburethral tape I used supplied by a company representative. I used these as helpful props to demonstrate both the tape and its placement in all consultations involving the discussion of placement of suburethral tapes. In the case of [Mrs F] I also used this to demonstrate the placement of sacrospinous sutures for apical vaginal support. Certainly there was discussion that this was mesh.'

34. Mrs F disagrees that Dr B used an anatomical model to explain the procedures to her, and that he showed her a sample of the suburethral tape. Mrs F stated: 'The only explanation provided by Dr B was of the prolapse repair via a picture he [hand-drew] on a blank piece of paper.'

35. Mrs F said that there was no discussion about the use of a mesh sling, or about the mesh-related risks or complications. Mrs F stated:

> 'I was terrified of having mesh in me after all the articles of mesh harm that had been in the media in 2016 and early 2017. I told [Dr B] that I did not want any mesh used in my surgery and he replied that he would not use any mesh. That was the only conversation we had concerning mesh. [Dr B] did not mention suburethral tape to me at all, nor was there any mention of its composition … I did not stipulate no mesh for prolapse but yes mesh for stress urinary incontinence. I did not have stress urinary incontinence so I was not expecting any repair for a problem I did not have. At no point did [Dr B] discuss what material slings were made from, or that he would be inserting a sling during my surgery.'

36. Mr F's recollection of their consultation with Dr B concurs with his wife's position. Mr F stated:

> 'During the consultations [Mrs F] was very clear to [Dr B] that mesh products were not to be used in the procedure as there had been a number of articles in the press about the danger of complications post-surgery, he advised that he was not going to be using any of these products so there was no cause for concern in that regard. Based partly on this assurance the surgery was booked to proceed.'

37. There is no record in the clinical notes of what was discussed with Mrs F in relation to the use of mesh (that the sling was made of mesh material), or the mesh-related risks and complications.

38. Dr B accepted that his documentation did not meet the required standard.

39. Dr B stated that copies of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) information sheets on pelvic organ prolapse and urinary incontinence were provided to Mrs F, and used during the consultation to illustrate the plan. Dr B said that the RANZCOG information brochure provided to Mrs F 'clearly stated the material to be used'.

40. The RANZCOG information brochure on urinary incontinence states:

> 'Synthetic mesh materials have been used in SUI[13] surgery to provide additional support for tissues that are weak or damaged, and slow to heal. These synthetic meshes are not absorbed by the body and remain as permanent implants to reinforce and strengthen the urethra and bladder neck. Mesh sling, or tape, procedures have been reported in the medical literature as effective treatments for SUI. However, as with all surgical procedures, they do have risks and limitations. As many cases of complications due to synthetic mesh have been reported, ask your surgeon whether it is an option in your case. An absorbable mesh may be an option. A decision has to be made whether to have SUI surgery with or without mesh sling. It is important that you understand the possible complications of synthetic mesh and mesh slings. Discuss this issue carefully with your surgeon.'

41. The RANZCOG information brochure on urinary incontinence states that the possible complications of urinary incontinence surgery include:

> '
> - Tape procedures have been linked to chronic pain in the pelvic area for some patients. In recent years, new procedures have had fewer reports of chronic pain.
> - Some types of synthetic surgical mesh and tapes (mesh slings) may cause pain, inflammation, infection, recurrent incontinence, bleeding, vaginal scarring or tissue erosion many months after surgery. Erosion of tape through the vaginal wall is the most reported mesh-specific complication. At one year after surgery, the occurrence of erosion is about two patients in 100. Some cases of erosion are treated easily but in others, the tape has to be surgically removed. This is usually straight-forward, but some cases can be difficult. Complications due to surgical mesh are not linked to one brand or type.'

42. Mrs F disagrees that Dr B provided her with the RANZCOG information brochure, or with any other documents or information sheets. Mrs F stated: 'No documents or information sheets were given to me by [Dr B], his nurse or any of his administration staff.'

[13] Stress urinary incontinence.

Pre-admission assessment on 16 June 2017

43. On 16 June 2017, almost two months following her consultation with Dr B, Mrs F underwent a pre-admission assessment at the private hospital for the planned surgery.

Surgery on 28 July 2017

Preoperative consent and consent form

44. Prior to the surgery, on 28 July 2017 Mrs F signed a consent form for 'Anterior & Posterior vaginal repair, suburethral sling & sacropsinous colpopexy'. The consent form states:

> 'I agree that I have received a reasonable explanation of intent, risks and likely outcome of the operation anterior [and] posterior vaginal repair, suburethral sling [and] sacrospinous colpopexy and an explanation of treatment options, and an approximation of treatment and associated costs e.g. laboratory tests.'

45. There are no risks listed on the consent form.

46. Dr B said that the consent form 'exactly matched' the preoperative discussion. He stated:

> 'I had no doubt that [Mrs F] was aware of the mesh material of the tape when the surgical consent form was signed which occurred after [Mrs F] had ample time to consider the written material provided.'

47. Dr B said that the private hospital had a mandatory preoperative procedure, which involved the surgeon meeting with the patient in an anteroom prior to the procedure to confirm the patient's identity and consent for the procedure(s) to be performed. Dr B said that following the meeting, patients were taken to the operating theatre for their identity to be checked again, and the patients were required to verbally confirm the procedure(s) to which they had consented. Dr B cannot recall the details of his discussions with Mrs F during the preoperative procedure but said that if any of the theatre staff had had concerns, these would have had to be resolved before anaesthesia could commence.

48. Mrs F stated that with the exception of Dr B's hand-drawn picture, no written information was provided to her prior to the surgery, and therefore she was not aware that mesh would be used during the surgery.

49. The private hospital said that its informed consent policy in place at the time of the events (in 2017) stated the following:

- Informed consent was the medical practitioner's responsibility.
- All consultants at the private hospital were to ensure that their patients underwent the informed consent process as outlined in the Code of Health and Disability Services Consumers' Rights (the Code).
- It was valuable to document a summary of the discussion in the patient's notes.
- A written summary of information may be made available to the patient.

Surgery

50. On 28 July 2017 (the same day on which the consent form was signed by Mrs F), Dr B performed the 'Anterior & posterior vaginal repair, suburethral sling & sacrospinous colpopexy' at the private hospital.

Operation note

51. A description of the surgical steps undertaken is detailed in the operation note. The operation note states that an incision was made in the posterior wall of the vagina, and that the sacrospinous sutures were placed into the vault of the vagina to support it. The posterior wall was also supported with sutures.

52. The operation note states that the suburethral sling was placed in the mid-urethral level and that the bladder was supported.

53. The operation note also states that inadvertently a 5mm hole was made in the bladder due to some adherence at an old vaginal hysterectomy scar, which was oversewn twice.

54. The clinical records note that a 'Pelvic Sling' and absorbable sutures were used during the surgery, and that the pelvic sling was a tension-free vaginal transobturator tape (TVT-O) made of surgical mesh.

Sling placement

55. The operation note (discussed above) does not include any detail of the sling placement, such as anatomical entry and exit points.

56. Dr B has since provided HDC with an explanation of the procedure and placement of the sling. He said that in order to avoid the obturator nerve,[14] an incision is made under the urethra and extended to the obturator membrane.[15] He explained that the tip of the device is placed with precision onto the obturator membrane to avoid the obturator nerve. Dr B said that with a TVT-O instrument, this step is 'more exact than it is for a tape applied from the outside in'.

57. Dr B stated that it would be impossible for the tape to have been placed in the sciatic notch[16] as the instrument used was not long enough to reach it. He said that nerve damage with transobturator tapes is 'well described', notably with regard to the obturator nerve,[17] but he could find no reference to damage of the sciatic nerve.[18]

58. Regarding the sacrospinous sutures, Dr B said that they were placed with an instrument that 'passed the suture material from one needle to another in a pincer manoeuvre that allows precise suture placement'. Dr B said that he believes it is anatomically impossible to impact

[14] A nerve in the inner thigh that helps to flex the hip and rotate the leg away from the body.
[15] A thin membrane located in the pelvis.
[16] A concave area on the border of the hip bone near the sciatic nerve.
[17] A large nerve located in the pelvis and inner thigh. This nerve helps to detect sensations like temperature and pain in the lower limbs and carries motor signals from the brain to the legs, which helps to move the hips and thighs.
[18] Sciatic nerves branch from the lower back through the hips and buttocks and down each leg.

the sciatic nerve using this instrument, and he believes that there was a failure of the suburethral sling anchoring mechanisms.

59. Dr B said that no bowel injury occurred during the surgery on 28 July 2017. He stated: 'In this procedure I performed these surgical steps in exactly the same manner as I had done perhaps 150 times before.'

60. Dr B accepted that his clinical records were inadequate.

Postoperative care under Dr B

During postoperative admission

61. Following her surgery on 28 July 2017, Mrs F remained in hospital until 4 August 2017. It is documented in the clinical records that Mrs F's pain levels fluctuated between a 9/10 to 'minimal discomfort' during her postoperative stay, but generally improved over time. Dr B documented on 29 July 2017 that the pain Mrs F was experiencing was from the sacrospinous colpopexy.

62. On 31 July 2017, Mrs F's catheter was removed to trial voiding (urinating), but she needed to be re-catheterised due to some urinary retention.

63. By 4 August 2017 (the day of discharge), Mrs F was noted to be mobilising well, her catheter had been removed, and the urinary retention issue had resolved. However, Mrs F was having some ongoing issues with bowel movements (constipation) and general pain.

64. Dr B said that moderate to severe pain from sacrospinous fixation is common during the first four to five days postoperatively, and that urinary retention is common after surgery for anterior vaginal prolapse.

After discharge

65. In the weeks following discharge, Mrs F kept in contact with nursing staff regarding pain and ongoing bowel and bladder issues. By 30 August 2017, Dr B suspected that the issue might be a pudendal nerve[19] injury. On 4 September 2017, Dr B attempted to resolve the issue with a pudendal nerve block.[20] Dr B also included some Marcaine[21] and steroid in the injection. Dr B said that this treatment improved things 'about 60%', but Mrs F was unable to wear tight-fitting trousers or sit comfortably.

66. Mrs F stated:

> 'I would also like to mention that post discharge, because of all the pain and ongoing bowel and bladder issues, I asked [Dr B] to confirm that he hadn't used mesh during the surgery and he did so. That is, he stated that he had not used mesh.'

[19] A nerve located in the pelvis that provides most of the movement and sensations in the pelvic region, including the ability to regulate urination and defecation.
[20] An injection of medication close to the pudendal nerve in the pelvic region to provide temporary pain relief.
[21] A brand name of bupivacaine, a medication used to decrease feeling in a specific area.

67. On 27 September 2017, Dr B noted that there had been no obvious postoperative issue. Due to the ongoing pain Mrs F was experiencing, Dr B ordered an MRI[22] to exclude haematoma[23] or sepsis.[24]

68. The MRI was completed on 17 October 2017 and no clear cause for the ongoing pain was identified.

69. On 18 October 2017 (three months following the surgery), Dr B saw Mrs F in his clinic, and on 19 October 2017 he wrote to Mrs F's GP and to gynaecologist Dr G. Dr B advised that Mrs F's bowels remained 'abnormal' with 'different sensation', and she needed to take laxatives. He noted that Mrs F also needed to urinate frequently. Dr B advised that Mrs F's 'major issue' was 'severe pain associated with the sacrospinous fixation', which had persisted more than he had seen previously. Dr B said that he thought that the sacrospinous sutures needed to be removed and advised that he would discuss this with Dr G to see whether the procedure could be expedited because he was unavailable until late November 2017.

70. On 23 October 2017, Dr B completed a further pudendal nerve block and subsequently referred Mrs F to Dr G for a second opinion from an 'experienced pelvic floor surgeon'.

Subsequent events

Further procedures and treatments

71. Following the referral to Dr G, due to the ongoing pain and other issues in the pelvic region, Mrs F underwent several further treatments and procedures. These are summarised as a timeline in Appendix B of this report. The examinations and procedures that have helped to inform decisions on the standard of care provided by Dr B are summarised below.

72. Mrs F met with Dr G on 31 October 2017. In a letter to Dr B, Dr G advised:

> '[Mrs F] has unfortunately suffered a major postoperative complication with pain which will relate to the suture placement on the sacrospinous ligaments causing nerve entrapment within these ligaments. There is some sacral nerve[25] involvement on the left side and possibly some pudendal nerve injury. At the present point, I believe the majority of her pain relates to secondary myofascial spasm pain[26] with sympathetic disruption of bowel emptying and bladder function.'

73. In a letter to the GP dated 14 November 2017, Dr G advised: 'The clinical assessment of the treatment injury is that there has been neurological injury involving the sciatic and sacral nerve complex by the sacrospinous suture.'

[22] Magnetic resonance imaging — a non-invasive medical imaging test.
[23] A mass of usually clotted blood that forms in a tissue, organ, or body space as a result of broken blood vessels.
[24] The body's extreme response to an infection. It is a life-threatening medical emergency.
[25] A nerve in the pelvic region that influences the bladder, urinary sphincter, anal sphincter, part of the colon, and pelvic floor muscles.
[26] A chronic pain disorder where pressure on sensitive points in muscles (trigger points) causes pain in the muscle and sometimes in seemingly unrelated parts of the body.

74. On 22 November 2017, Dr G and obstetrician and gynaecologist Dr H performed an examination under anaesthesia (EUA). The findings, as documented in the operation note, were:

> 'EUA performed noting normal genital hiatus … vault descent giving the appearances of a Grade 2 cystocoele,[27] scarred anterior vaginal wall after previous surgery and two fibrotic nodules sub-epithelially[28] at the points of a marked trigger point pain on the low posterior lateral vaginal wall particularly on the left where it was measured 4mm in size.'

75. Dr G and Dr H administered Botox and removed the fibrotic[29] nodules[30] by simple dissection. The sacrospinous fixation sutures were also removed. The procedure was noted to be routine and uncomplicated.

76. On 5 December 2017, Mrs F met with Dr G for a postoperative review. Dr G noted that Mrs F's pain was improving and that she was able to sit down for short periods. Mrs F had been able to reduce her pain medication, and she had had no concerning bowel or bladder symptoms following the procedure.

77. Dr G noted that on internal examination, some tenderness persisted 'over the trigger point on the left obturator where the inflammatory nodule was excised', but that the right side was not tender. Dr G advised Mrs F's GP:

> 'At this stage we can remain optimistic that she will continue to improve and the process that she has had with the Botox etc would indicate that it was a combination of muscular spams and a neuralgia. Hopefully the ACC will support her. Histology has confirmed a mast cell foreign body reaction to the two points of fibrous tissue that were removed.'

78. Over the next few years, Mrs F was seen regularly by Dr G, Dr H, a colorectal surgeon, and an obstetrician and gynaecologist for several pudendal nerve blocks, Botox to the pelvic floor, and sacral nerve stimulation (SNS).[31]

79. On 8 July 2020, Mrs F was seen by a chronic pain consultant, who documented that Mrs F had obtained a copy of her clinical records and discovered that mesh may have been used in her surgery on 28 July 2017. The pain consultant noted that Mrs F was very unhappy about this and concerned that the mesh might be contributing to her ongoing issues. The pain consultant recorded that Mrs F was 'keen to explore getting mesh removed (if it was used in the initial surgery) before any other interventions'.

[27] Anterior vaginal prolapse.
[28] A thin layer of cells that line hollow organs and glands.
[29] Thickening or scarring of tissue.
[30] Abnormal tissue growth.
[31] A procedure in which a small wire is used to stimulate the sacral nerves. The wire is connected to a small surgically implanted device that generates the mild electrical impulses that stimulate the sacral nerve. This is mainly performed to help patients with bladder and bowel or faecal incontinence.

80. In an email to her GP on 12 July 2020, Mrs F wrote:

> 'I found out on Tuesday that I have a TVT Obturator mesh implant. This is despite stating to [Dr B] before surgery that I absolutely did not want any mesh, and then checking after surgery (when all my problems had started) and being assured he had not used mesh. As you can imagine I am shocked and furious to discover this now.'

Removal of mesh

81. On 8 September 2020, Dr H's registrar referred Mrs F to urologist Dr D, to review Mrs F regarding the potential removal of the mesh.

82. On 17 May 2021, Mrs F had a 3D transperineal ultrasound, and on 18 May 2021, urologist Dr C (who works with Dr D) wrote to Dr H stating that she had discussed mesh removal with Mrs F. Dr C noted that the ultrasound showed that the mid-urethral sling was not visible in the suburethral region, but that there was a 'linear mildly shadowing focus' which was suspicious for mesh within the adductor musculature.[32] However, this was not definitive as it could not be traced medially towards the obturator foramen.[33] Dr C also noted that Mrs F had had a recurrence of her anterior prolapse due to the removal of the sacrospinous sutures, but as she preferred not to have any more mesh material in her body, she could be offered a fascial sacrocolpopexy.[34]

83. Surgery to remove the mesh was approved by ACC on 19 July 2021.

84. On 29 September 2021, Mrs F had surgery to remove the mesh, as well as a fascial sacrocolpopexy and an anterior repair. The surgery was performed by Dr C, Dr D, and orthopaedic surgeon Dr E. The findings from the mesh removal surgery included:

> '1. No mesh material around a short urethra
>
> 2. Amputated mesh segment found in pelvis on left obturator internus muscle[35] which was very aberrant in its trajectory into left sciatic nerve …
>
> 3. A small fragment of mesh found on the right side of urethra retropubically[36] with no evidence of extension into groin/obturator [foramen].'

85. Following the mesh removal surgery, Dr E wrote to Dr D stating that the findings were 'really quite abnormal'. Dr E noted that no mesh had been seen on a preoperative ultrasound, or on initial exploration through 'both groins and the vagina', but that on a subsequent approach through the pelvis using 'the robot', mesh was located on the left side at the 'deep surface of the obturator internus muscle'. Dr E advised that this was then 'followed down' and discovered in a 'very unusual location'. Dr E advised:

[32] The group of muscles that go from the pelvic bone down to the inner thigh and knee.
[33] A large opening in the lower part of the pelvis.
[34] A sacrocolpopexy using the patient's own tissue instead of synthetic sutures.
[35] A deep muscle of the hip joint, which is part of the side wall of the pelvis.
[36] Behind the pubic bone.

> 'The mesh appears to have been placed in an angle that takes the limb down towards the ischium[37] and around the region of the sciatic nerve. The mesh did not come through the obturator foramen at any stage as the usual surgical technique would usually take … Rather than the limb coming out through the obturator foramen as designed the mesh limb has come out on the lateral aspect of the ischium in the region of the sciatic nerve …'

86. Dr B denies that the mesh was placed in the sciatic notch. He stated:

> 'The design of the instrument makes it physically impossible to approximate the [s]ciatic nerve and pierce to skin of the Vulva. The mesh is placed as one self anchoring tape. I note that when the mesh was removed the mesh was found in pieces. Neither end situated where they were placed. At some point the mesh has divided which was not at the primary surgery. While it is impossible to be absolute it is likely that at the division of the mesh it has migrated to encroach on the sciatic nerve. There is ample literature, and I can attest from my own experience of mesh removal, that when mesh loses its primary anchor points it can migrate into areas that would not be expected.'

ACC

Treatment injury claim for sacrospinous colpopexy

87. On 27 September 2017, Dr B lodged a treatment injury claim with ACC for Mrs F's ongoing pain related to the sacrospinous colpopexy.

88. On 3 November 2017, ACC requested further information about the injury, to which Dr B responded on 30 November 2017, stating:

> 'I am not sure that I can absolutely state the physical injury which is causing [Mrs F's] ongoing pain … There is no doubt that there was no pain prior to the treatment and the pain was associated with the treatment. Inflammatory changes close to nerves certainly can cause ongoing severe pain … The pain is not an ongoing ordinary consequence to the treatment. Certainly pain postoperatively associated with Pelvic Floor Repair is not inconsiderable but the general time course is that it lasts 4–5 weeks with gradually diminishing pain relief requirement, so that by six weeks patients are comfortable. We are now nearly four months down the track and [Mrs F] is still disabled by the pain.'

89. ACC accepted the claim for 'sciatic and sacral nerve injury following the sacrospinous suture placement'.

Further information

Impact on Mrs F

90. Ms A told HDC that Mrs F is 'mentally and physically exhausted' following the complications from her surgery on 28 July 2017. Ms A said that the complications Mrs F has experienced since the surgery on 28 July 2017 include 'unbearable pain' that has not abated, difficulty sitting, standing and walking, faecal and urinary incontinence, the insertion of two sacral

[37] A bone of the pelvis that forms the lower and back part of the hip bone.

neuromodulators due to loss of bladder and bowel function, and multiple nerve blocks every five months. Ms A also noted that Mrs F requires the use of a wheelchair and is unable to drive. Ms A said that Mrs F is due to undergo a full colon removal.

Dr B

91. Dr B stated: 'I am deeply saddened that my surgery has caused [Mrs F] so much morbidity and can only wish her recovery and extend my sincere apology.'

Responses to provisional opinion

Mrs F

92. Mrs F was given an opportunity to respond to the provisional opinion. Her comments have been incorporated into this opinion where relevant and appropriate.

93. In response to the changes that have been made by Dr B since the events (discussed under the 'Changes made since events' section below), and Dr B's statement that he now telephones all patients on the night before the surgery to ensure that there are no unanswered questions, Mrs F said that she does not believe that this meets the criteria of informed consent or that it adds any value to the informed consent process. Mrs F said:

> 'This is because patients will not know what questions to ask. For example, in my case, in my initial consultation and before surgery, I had made my preferences and concerns known and had asked all the questions I had based on the information [Dr B] shared with me. I believed I knew what was going to happen in surgery. However, I had not been given all the information regarding both the surgery and the risks, therefore I did not know to ask more questions. If [Dr B] had rung me the night before I would have been satisfied because, as patients, we don't know what we don't know or understand complex medical terms/names. We are totally dependent on the surgeon having informative and honest conversations with us and a phone call the night before does not guarantee this. These conversations should be happening well before the decision is made to proceed with surgery. Patients could still be harmed by his limited "explaining" and lack of informed consent. [Dr B's] version of events in my case, illustrates this point very clearly.'

Dr B

94. Dr B was given an opportunity to respond to the provisional opinion.

95. Dr B disagrees with the conclusions reached in the provisional opinion. He disagrees that there was no detailed discussion with Mrs F prior to the surgery, and that the mesh was placed incorrectly and is the cause of Mrs F's morbidity.

96. Dr B said that while he disagrees with the provisional opinion, what is undisputed is that Mrs F has suffered catastrophic morbidity from the surgery. Dr B stated that in the interest of concluding the matter for Mrs F, he accepts the findings and will comply with the recommendations.

97. Dr B has provided Mrs F with a formal written apology (Appendix C), as recommended in the provisional decision. He said that he is truly sorry for the consequences of the surgery

and offered his sincere apology to Mrs F. Dr B said that it was not until he had received all the information from the HDC investigation that he understood the catastrophic complications Mrs F had suffered from the surgery performed in 2017.

Opinion: Dr B — breach

98. First, I acknowledge the substantial life-changing complications Mrs F experienced following her surgery in 2017. She has suffered chronic pain over an extended period, has experienced urinary and faecal incontinence, and has required several corrective interventions to manage her ongoing symptoms. Understandably, these events have had a profound impact on Mrs F's quality of life, and the psychological impact of this experience should not be underestimated.

99. The events surrounding this case occurred at a time when an increasing body of knowledge was emerging about the difficulties experienced by some consumers following the insertion of particular surgical mesh products. There was an increasing awareness of the need for greater control and oversight of its use, and a recognition that it was essential that consumers were fully informed about selected mesh products utilised in certain circumstances, and the possible complications, prior to consenting to their use. Regulatory action was being taken across several international jurisdictions in response to the harm caused to consumers. New Zealand clinicians were not, and should not have been, oblivious to this.

100. I have undertaken a thorough assessment of the information gathered in light of this complaint, and I consider that Dr B breached Rights 6(1)(b), 7(1), 4(1), and 4(2) of the Code. The reasons for my decision are set out below.

Provision of information and informed consent

101. The principle of informed consent is at the heart of the Code. Under Right 6(1)(b) of the Code, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. This includes an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option. Under Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.[38]

102. Due to her ongoing trauma and emotional harm, Mrs F elected at the outset not to be directly involved in this investigation. However, Mrs F was offered the opportunity to comment on the provisional opinion, and the information she provided has been incorporated into this report where appropriate. In carrying out my investigation, I have drawn on all relevant information, as well as the clinical documentation available. I have taken into account statements made by Mrs F, and I have also considered the recollections

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

of Mrs F's husband, when he accompanied Mrs F to the consultation with Dr B on 19 April 2017 and was party to the discussions that occurred. I have considered each piece of evidence objectively on its merits, with due consideration to the perspective of each party. In so doing, I must also acknowledge the significant passage of time since the events described in this complaint occurred, and the difficulties this presents in terms of assessing the recollections of the discussions held. In weighing up the information available, I have therefore placed great reliance on the contemporaneous clinical documentation.

Suburethral sling

103. Dr B stated that a suburethral sling was used in Mrs F's surgery on 28 July 2017 to provide support for the urethra to improve 'the symptoms of stress urinary incontinence'. However, the referral from Mrs F's GP to Dr B stated that Mrs F's prolapse was 'not associated with any stress or urge incontinence', and there is no indication in the clinical records that Mrs F experienced stress urinary incontinence prior to the surgery on 28 July 2017. Mrs F herself stated in her response to the provisional opinion that she did not have stress urinary incontinence, a point that is documented by both her GP and Dr B, so she was not expecting any repair of a problem she did not have.

104. To assist in my assessment of the care provided to Mrs F, I obtained independent advice from obstetrician and gynaecologist Dr John Short.

105. Dr Short advised that surgery for the treatment of the vaginal prolapse was appropriate, which includes the anterior and posterior repair procedures and the sacrospinous fixation. Dr Short said that these procedures were appropriate for the physical findings described, but the procedure involving the suburethral sling to treat urinary incontinence is unclear. Dr Short advised:

> 'I note that urinary incontinence was not one of the symptoms described in the letter describing the initial consultation (on 19 April 2017). Therefore the indication for performing a surgical procedure for urinary incontinence is unclear; it is possible that he was placing the sling prophylactically to prevent so-called "occult stress incontinence" — a phenomena whereby women begin to suffer stress urinary incontinence following surgery due to changes in the anatomical relationship between the bladder and urethra. Many surgeons would "routinely" perform a continence procedure at the time of prolapse surgery to prevent this. However, if this were the case, one would expect this to be discussed with the patient and for it to be clearly documented.'

106. Dr Short considers that the performance of the suburethral sling surgery in terms of the lack of surgical indication is a severe departure from the accepted standard of care.

107. I accept Dr Short's advice. While it may have been appropriate to perform a continence procedure (the suburethral sling) to prevent any stress urinary incontinence that may have occurred following the surgery, I would have expected this option to have been discussed with the patient prior to the surgery being performed, and for this to have been documented in detail. I am extremely critical that this did not occur.

Risks

108. Dr B and Mr F, who accompanied his wife to the consultation with Dr B on 19 April 2017, have differing recollections of what was discussed with Mrs F in relation to the use of mesh and the risks involved.

109. Mrs F stated that her instructions to Dr B were that no mesh was to be used. Mr F also stated that Mrs F was 'very clear' that mesh products were not to be used in her surgery. Dr B was aware of this and stated that '[n]o mesh was used to repair the pelvic organ prolapse as instructed by Mrs F and confirmed by me'.

110. Dr B stated that Mrs F was aware that the suburethral sling was made of mesh, and that the RANZCOG information brochure that was provided to Mrs F and used to provide her with an explanation of the surgery 'clearly stated the material to be used'. Conversely, Mrs F has stated that no documents or information sheets were given to her by Dr B, his nurse, or any of his administration staff.

111. On 28 July 2017, Mrs F signed a consent form for an 'Anterior & Posterior vaginal repair, suburethral sling & sacropsinous colpopexy'. The consent form states:

> 'I agree that I have received a reasonable explanation of intent, risks and likely outcome of the operation anterior [and] posterior vaginal repair, suburethral sling [and] sacrospinous colpopexy and an explanation of treatment options, and an approximation of treatment and associated costs e.g. laboratory tests.'

112. The consent form does not list any risks in relation to the surgery generally, or any risks in relation to the mesh procedure (such as chronic pelvic pain, recurrent incontinence, or mesh erosion).

113. On 12 July 2020, almost three years following the surgery, Mrs F advised her GP that she had been 'shocked and furious' to discover that mesh had been used in her surgery on 28 July 2017, when she had informed Dr B that mesh was not to be used.

114. There is no record in Dr B's documentation of what was discussed with Mrs F in relation to the use of mesh, or the mesh-related risks and complications.

115. Dr Short advised:

> 'It is documented that [Mrs F] was given RANZCOG information leaflets and there is a consent form, signed on the day of surgery (3 months after the initial consultation). However, this only contains the name of the procedures to be performed and does not detail any of the surgical risks which were disclosed. It is noted on a pre-operative checklist that [Mrs F] understood the operation/procedure she was having. However, it is not clear what steps were taken by staff to assess how much she "understood" — an answer of "yes" could mean she thought she was having a prolapse operation or could simply name the procedures being performed … Overall I am limited in my ability to comment on the adequacy of the informed consent process by the lack of detail included in [Dr B's] documentation. Ultimately, consent is concerned with what was

> said to the patient rather than is documented in the records. The fact that nothing is documented does not necessarily mean that nothing occurred. However, it certainly does mean that I cannot confirm that the informed consent process was adequate.'

116. I acknowledge that the consent form is only a small part of the consenting process, with the bulk of the consenting process occurring in the verbal discussion between doctor and patient in the lead-up to the signing of the consent form. However, in my view, it is reasonable to expect that the risks listed on the consent form reflect the content of the accompanying verbal discussion.

117. The absence on the consent form of any risks, particularly any mesh-related risks, is concerning. I would expect that when a discussion of risks takes place during a preoperative consultation, the content of this discussion, listing the risks discussed, would be documented in the clinical records.

118. There is no evidence that a discussion of the mesh-related risks and complications occurred. This is particularly concerning considering that there was sufficient information coming to light at that time to indicate the risk to consumers of selected mesh products utilised in certain circumstances. As such, it is reasonable to assume that surgeons proposing to undertake procedures involving mesh products had a heightened awareness of the importance of the consenting process.

119. Based on the information available (Dr B's preoperative consultation notes and the consent form), I am not satisfied that Dr B informed Mrs F of the mesh-related risks and complications, including those of chronic pelvic pain, recurrent incontinence, and mesh erosion.

120. While I am very much aware that Mrs F is adamant that she was not given information sheets preoperatively, Dr B has said that he provided Mrs F with the RANZCOG information brochures. Irrespective of whether or not the RANZCOG brochures were supplied, I consider that provision of such brochures is not a substitute for a full discussion of the risks, and I am not satisfied that this occurred.

Conclusion

121. In my view, there are two issues in relation to Dr B's consent process. First, the continence procedure (the suburethral sling) was not discussed and documented in detail. I am critical that this did not occur, particularly because the referral stated that Mrs F's prolapse was not associated with any stress or urge incontinence, and there was no indication in the clinical records that Mrs F experienced stress urinary incontinence prior to the surgery on 28 July 2017.

122. A reasonable consumer in Mrs F's circumstances would expect to be informed of a procedure (the suburethral sling procedure) that was to be performed to prevent stress urinary incontinence following the surgery, and the known risks of the procedure, including chronic pelvic pain, recurrent incontinence, and mesh erosion, and any such discussions should have been reflected in the documentation.

123. Secondly, Mrs F did not consent to the use of mesh and specifically instructed that mesh was not to be used.

124. Accordingly, I find that by failing to provide Mrs F with information that a reasonable consumer in her circumstances would expect to receive, Dr B breached Right 6(1) of the Code. It follows that, without this information, Mrs F was not able to make an informed choice and give informed consent to the surgery on 28 July 2017. I therefore also find that Dr B breached Right 7(1) of the Code.

Surgical technique

125. Determining whether Dr B provided Mrs F with an appropriate standard of care when he performed the 'Anterior & posterior vaginal repair, suburethral sling & sacrospinous colpopexy' on 28 July 2017, and whether failings in his care met the threshold for a breach of the Code has not been straightforward. In reaching my decision I have taken careful note of all the information I have available to me.

126. Dr B's operation note does not include any detail of the sling placement, such as the anatomical entry and exit points.

127. On 29 September 2021, Mrs F had surgery for the mesh to be removed. The findings of the mesh removal surgery included: 'Amputated mesh segment found in pelvis on left obturator internus muscle which was very aberrant in its trajectory into left sciatic nerve …'

128. Dr Short advised that Dr B's clinical records are 'extremely brief' and contain minimal detail of how the procedure was performed. Dr Short said that because of the brevity and lack of detail contained in Dr B's operation note, he is unable to advise whether the sling was placed correctly, but later records from the sling removal surgery suggest that the sling was 'lying in an extremely abnormal position'. Dr Short advised:

> 'The only possible explanation for this is that the sling was incorrectly inserted on 28 July 2017, passing more widely than intended, possibly missing the obturator membrane/foramen altogether and encroaching on the sciatic nerve, presumably in the region of the sciatic notch. Therefore, I have to conclude that the care provided during surgery was inadequate.'

129. Dr Short considers the incorrect placement of the sling to be a severe departure from the accepted standard of care.

130. I accept Dr Short's advice and agree that if the sling was placed incorrectly, this would be a severe departure from the accepted standard of care. Dr B maintains that the sling was placed correctly. He believes that it was anatomically impossible to impact the sciatic nerve by the instrument that was used during the surgery, and that there was a failure of the suburethral sling anchoring mechanisms.

131. I acknowledge Dr B's strong disagreement with Dr Short's advice. I have considered whether it is possible that changes to the sling placement could have occurred during Mrs F's further surgery on 22 November 2017. I have also considered the time that had passed (more than

four years) from the time of the insertion of the sling (July 2017) until the removal of the sling (September 2021).

132. In my view, it is unlikely that the subsequent surgery in November 2017, which was described as 'routine and uncomplicated', would have caused the sling to change or move to such an extent for it to have been found in an extremely abnormal position during the mesh removal surgery. As noted by Dr Short, the 2017 operation note does not contain any detail to confirm the positioning of the sling.

133. In the absence of documentation confirming where the sling was placed and based on the findings at the mesh removal surgery, I consider it more likely than not that the mesh was placed incorrectly. Accordingly, I find that Dr B failed to provide services to Mrs F with reasonable care and skill by placing the sling incorrectly, in breach of Right 4(1) of the Code.

Documentation

134. As discussed above, there is no record of what was discussed with Mrs F in relation to the use of mesh products, or the mesh-related risks and complications, and there is a lack of detail in the operation note of the surgery on 28 July 2017.

135. Regarding Dr B's documentation, Dr Short advised:

> 'This is extremely brief and lacking in detail, particularly with the operation note which fails to mention crucial information. I would rate the level of departure as severe. Unfortunately, the level of documentation has hindered my ability to adequately comment on some matters of this case.'

136. I accept Dr Short's advice. The Medical Council of New Zealand (MCNZ) publication 'Managing Patient Records' states that doctors should maintain clear and accurate patient records, including information regarding relevant clinical findings; information given to and options discussed with patients; decisions made and reasons for them; consent given; and requests or concerns discussed during the consultation. This publication also states that it is good practice to record information that may be relevant during the patient's healthcare journey.

137. The MCNZ publication 'Informed Consent: Helping patients make informed decisions about their care' states that doctors must keep clear and accurate patient records that note the information that was discussed; any specific risks that were highlighted; any request or concerns expressed; and any decisions made and the reasons for them. The guideline also states that doctors should check that what they record is enough to guide another doctor or health practitioner if they need to follow up with the patient, and any pamphlets, brochures, or leaflets given to the patient should be noted in the patient's records.

138. I consider that Dr B's documentation was not up to the standard required by the MCNZ, in breach of Right 4(2) of the Code.

139. Dr B accepts that his documentation was not up to standard.

Changes made since events

Dr B

140. Dr B has made several changes to his practice since the events.

141. Dr B resigned from his general gynaecology appointment. He stated:

> 'At that time I made a calculation of the prospective volume of a number of procedures I would likely perform from that date. When the number of cases fell below a number that I regarded as essential for maintaining practice I ceased performing those surgeries. This was one of those.'

142. Dr B said that he has reduced the number of surgical procedures he undertakes, and he now telephones all patients on the night before the surgery to ensure that there are no unanswered questions.

Changes in medical practice regarding use of surgical mesh

143. HDC, as a member of the Surgical Mesh Roundtable[39] (the MRT) alongside representation from several other agencies, including Te Tāhū Hauora | Health Quality & Safety Commission (HQSC), is overseeing and monitoring the surgical mesh work programme led by the Ministry. The work programme includes the actions and recommendations arising from the Health Committee and Restorative Justice reports.[40] The more notable actions are described below.

144. In August 2023, the Director-General of Health supported a time-limited pause on the use of surgical mesh for stress urinary incontinence. The use of surgical mesh to treat stress urinary incontinence has been paused until the following four specified conditions have been met to minimise harm linked to the procedure for women:

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

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

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

145. A 'high vigilance' process is being implemented to monitor the use of alternative procedures for the management of stress urinary incontinence during this time-limited pause.

146. The New Zealand Female Pelvic Mesh Service has been established to treat complications related to pelvic surgical mesh.

Recommendations

147. As recommended in the provisional opinion, Dr B has provided Mrs F with a formal written apology for the deficiencies in the care provided, as outlined in this decision. Taking into account the apology provided and the changes made by Dr B since the events, and noting the systemic measures introduced to reduce the risk of harm associated with surgical mesh, I recommend that Dr B undertake further education/training on:

a) The informed consent process;

b) Documentation; and

c) Refresher training on the Code of Health and Disability Services Consumers' Rights.

148. Evidence of attendance (eg, a certificate) and a written reflection on the learnings and how these will be applied in practice are to be provided to HDC within three months of the date of this decision.

Follow-up actions

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

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

Appendix A: Independent clinical advice to Commissioner

The following advice was obtained from Dr John Short:

'12th June 2023

Dear Ms McDowell

Re: Complaint: [Mrs F]. Your ref: 22HDC00810

I have been asked to provide advice in this case (21HDC00810), regarding the care provided to [Mrs F] by [Dr B] in 2017. 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 have a special interest in urogynaecology; I am a past Chairperson of the Urogynaecological Society of Australasia (UGSA) and current board member of Continence New Zealand (CNZ) and the International Urogynecological Association (IUGA).

A large amount of documentation has been provided; including copies of the consumer complaint, [Dr B's] medical notes and records from other health professionals subsequently involved in [Mrs F's] care, together with subsequent responses from [Dr B].

In particular, I have been asked to comment on the following:

1. The adequacy of the informed consent process prior to surgery on 28 July 2017, particularly with regard to the mesh sub urethral sling.

2. The adequacy of the documentation of the informed consent discussions.

3. Whether surgical intervention was appropriate at the time, and whether the procedures undertaken were correct.

4. The adequacy of the care provided during surgery on 28 July 2017.

5. The adequacy of the care provided post-operatively, from 28 July 2017 to 30 November 2017.

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

Background

On 19 April 2017, [Mrs F] presented to [Dr B] with prolapse. A plan was made for "Anterior & Posterior vaginal repair, suburethral sling & sacropsinous colpopexy," which was completed on 28 July 2017. There is no mention of any symptoms of urinary incontinence. The "suburethral sling" was actually a TVT-O, a type of transobturator midurethral sling used to treat stress urinary incontinence. This is placed "in-out", meaning a trochar was

used to place the mesh, passing from under the urethra outwards and through the obturator membrane and foramen on each side.

[Mrs F] has experienced substantial complications following this surgery, including pain which has not abated, and urinal and faecal incontinence. She has undergone pudendal nerve blocks, sacral nerve stimulation, and further surgeries to remove the sacrospinous sutures, remove the mesh, and for an ileostomy.

The surgery on 29 September 2021, to remove the mesh, found that there was no mesh around the short urethra, but an amputated mesh segment was found in the pelvis on the left obturator internus muscle, which was "very aberrant in its trajectory into the left sciatic nerve". Further, a small mesh fragment was found on the right side of the urethra retropubically, with no evidence of extension into the groin/obturator fossa. Adhesions of the omentum to the anterior abdominal wall and adhesions of the right colon and caecum to the pelvic side wall were also found.

An ultrasound on 5 November 2021 did not show any obvious mesh retention, but did show evidence of "fusiform thickening of the sciatic nerve from the level of the tuberosity down more distally."

Comment

1. The adequacy of the informed consent process prior to surgery on 28 July 2017, particularly with regard to the mesh sub urethral sling.

Unfortunately there is limited documentation of the informed consent process. It is documented that [Mrs F] was given RANZCOG information leaflets and there is a consent form, signed on the day of surgery (3 months after the initial consultation). However, this only contains the name of the procedures to be performed and does not detail any of the surgical risks which were disclosed. It is noted on a pre-operative checklist that [Mrs F] understood the operation/procedure she was having. However, it is not clear what steps were taken by staff to assess how much she "understood" — an answer of "yes" could mean she thought she was having a prolapse operation or could simply name the procedures being performed.

Overall I am limited in my ability to comment on the adequacy of the informed consent process by the lack of detail included in [Dr B's] documentation. Ultimately, consent is concerned with what was said to the patient rather than is documented in the records. The fact that nothing is documented does not necessarily mean that nothing occurred. However, it certainly does mean that I cannot confirm that the informed consent process was adequate.

2. The adequacy of the documentation of the informed consent discussions.

There is no documentation of the informed consent discussions, therefore I can only conclude that this was inadequate.

3. Whether surgical intervention was appropriate at the time, and whether the procedures undertaken were correct.

Surgery for the treatment of the vaginal prolapse was appropriate. This covers the procedures of anterior and posterior repairs and sacrospinous fixation, which were the correct procedures for the physical findings described. The indication for a 'suburethral sling', a procedure to treat urinary incontinence, is unclear.

I note that urinary incontinence was not one of the symptoms described in the letter describing the initial consultation (on 19 April 2017). Therefore the indication for performing a surgical procedure for urinary incontinence is unclear; it is possible that he was placing the sling prophylactically to prevent so-called "occult stress incontinence" — a phenomena whereby women begin to suffer stress urinary incontinence following surgery due to changes in the anatomical relationship between the bladder and urethra. Many surgeons would "routinely" perform a continence procedure at the time of prolapse surgery to prevent this. However, if this were the case, one would expect this to be discussed with the patient and for it to be clearly documented. Also, it is noteworthy that, in his response to the HDC, [Dr B] states that the indication for the sling was stress incontinence, which is not consistent with his contemporaneous records.

As [Dr B] does not specify an indication for including this addition procedure, therefore I can only conclude that the "suburethral sling" was not an appropriate or correct procedure to undertake at that time.

4. The adequacy of the care provided during surgery on 28 July 2017.

Again, the notes are extremely brief and contain minimal detail of how the procedure was performed. In particular [Dr B] does not state the type of sling used or include any detail of the sling placement, such as the anatomical entry and exit points. Therefore I am unable to confirm if the sling placement was correct. Later records, from the sling removal surgery, suggest the sling was lying in an extremely abnormal position. The only possible explanation for this is that the sling was incorrectly inserted on 28 July 2017, passing more widely than intended, possibly missing the obturator membrane/foramen altogether and encroaching on the sciatic nerve, presumably in the region of the sciatic notch. Therefore, I have to conclude that the care provided during surgery was inadequate.

5. The adequacy of the care provided post-operatively, from 28 July 2017 to 30 November 2017.

Overall, I am satisfied that the care provided post-operatively was adequate. The hospital stay was longer than would normally be expected but bladder emptying problems and pain appear to have been managed adequately. [Mrs F's] complaint of persistent pain following discharge appears to have been taken seriously and appropriate actions were taken by [Dr B], including ACC paperwork and consultation with colleagues. The initial assumption was that the sacrospinous fixation was the cause of the pain and therapeutic attention was focused on this. Whilst later events would suggest that this was not necessarily a correct assumption, I think it was reasonable in the circumstances as persistent postoperative pain following this procedure is very well described.

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

In writing this report I have been mindful of the fact that it occurred some years ago. A great deal of change has occurred in this space following events between 2016–18. This

was prompted by the health select committee report on the use of surgical mesh (June 2016), the Medsafe alerts of 2017/18 and MOH requirements for surgeon credentialing (October 2018). This has led to improvements in overall standards of care by surgeons, particularly in relation to consent and documentation. Nonetheless, even taking this into account, there are areas of concern relating to this case.

Conclusion

In my opinion, [Dr B] has failed to provide an appropriate standard of care on the following items:

Documentation. This is extremely brief and lacking in detail, particularly with the operation note which fails to mention crucial information. I would rate the level of departure as severe.

Unfortunately, the level of documentation has hindered my ability to adequately comment on some matters of this case.

Performance of midurethral sling surgery, both in terms of the lack of surgical indication and incorrect placement. I would rate the level of departure as severe.

Regarding informed consent, I am extremely limited in my ability to comment by the lack of documentation. However, I cannot confirm that the informed consent process was consistent with the accepted standards in 2017.

The care provided postoperatively by [Dr B] was satisfactory.

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

Yours Sincerely,

John Short'

Addendum to advice, dated 1 September 2023:

'Re: Complaint: [Mrs F]. Your ref: 22HDC00810

[Dr B] has responded to my original report. He accepts the conclusion that his record-keeping was inadequate. However, he maintains that he placed the "transoburator tape (TVT-O)" correctly. In relation to this, the relevant part of my report is quoted below:

4. The adequacy of the care provided during surgery on 28 July 2017.

Again, the notes are extremely brief and contain minimal detail of how the procedure was performed. In particular [Dr B] does not state the type of sling used or include any detail of the sling placement, such as the anatomical entry and exit points. Therefore I am unable to confirm if the sling placement was correct. Later records, from the sling removal surgery, suggest the sling was lying in an extremely abnormal position. The only possible explanation for this is that the sling was incorrectly inserted on 28 July 2017, passing more widely than intended, possibly missing the obturator membrane/foramen altogether and encroaching

on the sciatic nerve, presumably in the region of the sciatic notch. Therefore, I have to conclude that the care provided during surgery was inadequate.

In preparing my report, I am dependent upon the contemporaneous records provided. Of note these confirm 2 things — That [Dr B] placed a TVT-O on 28 July 2017 and that this was later found to be in a very abnormal position, during surgery on 29 September 2021. [Dr B] speculates that another surgery, performed sometime between placement and removal of the TVT-O, is responsible for the abnormal position. However, there is no record of any such surgery having taken place. As a result, as I cannot confirm that the device was properly inserted, I can only conclude that the abnormal position is the result of incorrect placement.

In accepting that his record-keeping was inadequate, [Dr B] must also accept the consequences of this. Therefore, my opinion is unchanged. Should further information become available, which indicates a further surgery had taken place, then I would be happy to review this conclusion. The only other thing to add is that, in the interests of fairness and integrity of the process, it would be reasonable for the HDC to make absolutely certain that no other surgeries had occurred.

I hope you find this helpful.

Yours Truly

John Short'

Appendix B: Timeline of subsequent care

31 Oct 2017	Appointment with Dr G, who documented that Mrs F was 'very compromised' as she was unable to sit, was constipated, and had urinary urgency, needing to empty her bladder at least hourly. On examination, Dr G noted that there was marked tenderness over the right sacrospinous ligament, with severe tenderness over the site where the sacrospinous fixation suture has slightly scarred the vaginal wall. There was also generalised obturator muscle tenderness on the left side. On the anterior wall, there was a recurrent anterior vaginal prolapse. Dr G noted that there was no mesh exposure and no tenderness over the mesh suture line. Dr G reported to Dr B: '[Mrs F] has unfortunately suffered a major postoperative complication with pain which will relate to the suture placement on the sacrospinous ligaments causing nerve entrapment within these ligaments. There is some sacral nerve involvement on the left side and possibly also some pudendal nerve injury. At the present point, I believe that the majority of her pain relates to secondary myofascial spasm pain with sympathetic disruption of bowel emptying and bladder function.' Dr G arranged for Mrs F to have urgent physiotherapy with a pelvic floor musculature massage. Dr G also prescribed muscle relaxants and advised Mrs F to continue taking laxatives for constipation. Dr G arranged to review Mrs F within two weeks' time with the option of having a Botox injection in the vicinity of the sacrospinous ligaments if there was no significant improvement.
15 Nov 2017	Dr G reviewed Mrs F again and noted that Mrs F continued 'to be dreadfully disabled by pain' and was unable to sit. Dr G's clinical assessment of the treatment injury was that there had been a neurological injury involving the sciatic and sacral nerve complex by the sacrospinous suture.
22 Nov 2017	Dr G documented that the indication was 'intractable sciatica and pudendal pain with pelvic floor hypertonus, that is not responding to simple analgesics, muscle relaxants or physiotherapy'. Dr G and Dr H completed an examination under anaesthetic, and administered Botox, Kenacort and a pudendal nerve block. They also

	excised two 'subepithelial fibrous nodules'[1] at trigger points associated with the sacrospinous fixation sutures. Dr G arranged for further follow-up within four weeks' time.
April 2018–Feb 2020	During this period, Mrs F received pelvic floor Botox and bilateral pudendal nerve blocks on a 4–5 monthly basis, as well as bilateral Sacral Nerve Stimulation (SNS), and a colonoscopy. Mrs F also had two sacral neuromodulators[2] inserted (on 5 February and 10 December 2019).
July 2020	On 8 July 2020, Mrs F was reviewed at a chronic pain clinic. The pain specialist advised Mrs F's GP: '[Mrs F] obtained medical notes and found yesterday that it looks like mesh was used in the initial surgical repair. She is very unhappy about this and is concerned about how much this mesh may be contributing to her ongoing pains.' The pain specialist noted that Mrs F was 'keen to explore getting mesh removed (if it was used in the initial surgery) before any other interventions'.
8 Sept 2020	Dr G's obstetrician and gynaecology registrar referred Mrs F to urologist Dr D, for Dr D to review Mrs F regarding potential removal of the TVT-O. The registrar advised that at the time of Mrs F's surgery, she suffered a pudendal nerve injury and resulting bladder and bowel dysfunction which was not relieved by removal of the sacrospinous fixation suture. The registrar advised that Mrs F had been receiving pelvic floor Botox and bilateral pudendal nerve blocks on a 4–5 monthly basis, and that she had had six of these procedures to date.
29 Oct 2020	Mrs F was seen by Dr H for further Botox to pelvic floor muscles and bilateral pudendal nerve blocks.
19 Mar 2021	Mrs F was seen by an obstetrician and gynaecologist for further Botox to pelvic floor muscles and bilateral pudendal nerve blocks.
17 May 2021	Mrs F had a 3D transperineal ultrasound which found that a mid-urethral sling was not visible in the suburethral region, but that there was a 'linear

[1] Abnormal tissue growths with a 'fibrous' appearance.
[2] A minimally invasive therapy to treat urinary incontinence, urinary retention, urgency, frequency, and faecal incontinence.

	mildly shadowing focus' which was suspicious for mesh within the adductor musculature. However, this was not definitive as it could not be traced medially towards the obturator foramen.
15 Jun 2021	Dr C discussed mesh removal surgery with Mrs F.
19 Jul 2021	ACC approved surgery for: 'Removal of transobturator mesh sling + bilateral groin dissections + robotic fascial sling and sacrocolpopexy + adhesiolysis + cystoscopy' under Dr C.
16 Sep 2021	Dr C had a preoperative appointment with Mrs F.
29 Sep 2021	Mesh removal surgery completed by Dr C, Dr D and Dr E. Mesh fragments located in an 'unusual location', in the region of the sciatic nerve. Unable to retrieve all mesh fragments.
18 Oct 2021	Dr H noted that further investigation was likely to see if any residual mesh was close to sacral nerves. Dr H noted that this would be an unusual place for it to end up, but could explain some of Mrs F's longstanding issues with bladder and bowel function.
5 Nov 2021	Mrs F was referred to a specialist pain medicine physician for comprehensive pain management, and a general and colorectal surgeon for colorectal management of ongoing atonic bowel.[3]
9 Mar 2022	Laparoscopic adhesiolysis and formation of loop ileostomy completed.
12 June 2023	Mrs F underwent surgery for replacement of the left and right sacral neuromodulator leads and batteries.
8 November 2023	Mrs F underwent surgery for removal of the large bowel and rectum and a peristomal hernia[4] repair.
14 February 2024	Mrs F underwent bilateral buttocks sacral nerve stimulation reposition surgery.

[3] Also known as lazy colon or colon stasis, it may result in chronic constipation. It occurs when there is a lack of normal muscle tone or strength in the colon.
[4] A common complication that affects people with stomas. It forms because of a weakness in the abdominal wall that allows the abdominal protrusion of an organ or part of an organ.

Appendix C: Dr B's apology to Mrs F

'Dear [Mrs F],

It was not until I rec[ei]ved all the information from the HDC enquiry that I understood the catastrophic complications you have suffered from the surgery performed in July 2017.

I am truly sorry for the consequences of the [surgery] and offer my sincere and profound apology.

I hope that, in time, your health can be somewha[t] restored.'