Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 20HDC00999)

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. The report discusses the care provided to Ms A by gynaecologists and obstetricians Dr B and Dr C at Whanganui Hospital, Te Whatu Ora Whanganui (formerly known as Whanganui District Health Board) (WDHB).[1]

3. In 2016, Ms A underwent two surgeries for vaginal prolapse[2] and urinary incontinence.[3] Surgical mesh slings[4] were implanted during both surgeries.

4. Following the first surgery (performed by Dr B), Ms A's incontinence recurred. Following the second surgery (performed by Dr C), Ms A developed large volume "random" incontinence,

[1] 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 WDHB now refer to Te Whatu Ora Whanganui.
[2] Protrusion of the bladder into the vagina.
[3] Involuntary passage of urine.
[4] Synthetic material used to treat pelvic organ prolapse and stress incontinence (involuntary loss of urine on exertion or on sneezing or coughing).

which she described to HDC as "a gush[5]". In 2019, she underwent surgery to remove the mesh.

5. Ms A raised concerns about the surgical care provided by Dr B and Dr C. She also raised concerns about a lack of communication from Dr C and the gynaecology service at WDHB.

6. The following issues were identified for investigation:

- *Whether Te Whatu Ora Whanganui (formerly known as Whanganui District Health Board) provided Ms A with an appropriate standard of care between November 2015 and October 2018 (inclusive).*
- *Whether Dr B provided Ms A with an appropriate standard of care between November 2015 and February 2016 (inclusive).*
- *Whether Dr C provided Ms A with an appropriate standard of care between June 2016 and October 2018 (inclusive).*

7. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Gynaecologist
Dr C	Gynaecologist

8. Also mentioned in this report:

Dr D	Gynaecology registrar
Dr E	Urologist
Dr F	Gynaecologist
Dr G	Gynaecologist
Dr H	Urologist
Dr I	Urologist

How matter arose

Posterior repair surgery and MiniArc sling

9. On 24 November 2015, Ms A (aged in her fifties at the time of events) presented to Dr B, a consultant gynaecologist at the gynaecology clinic at Whanganui Hospital, for assessment of urinary incontinence. She had been experiencing both stress incontinence and urge incontinence[6] for 12 months.

[5] A rapid and plentiful stream.
[6] Involuntary urine leakage accompanied by an urgent need to urinate.

10. Dr B noted that Ms A had a large cystocele (an anterior vaginal prolapse[7]), "although this was a little hard to evaluate", but no significant rectocele (posterior vaginal prolapse[8]).

11. In a clinic letter to Ms A's general practitioner (GP), Dr B advised that Ms A had been referred for physiotherapy and pelvic floor exercise, but that this was not successful.

12. Dr B considered that Ms A would likely need a mid-urethral sling[9] and an anterior vaginal repair with surgical mesh,[10] but because of the complex nature of her symptoms, he arranged for further investigations prior to making a decision on the surgery. The investigations included a bladder diary[11] and urodynamic studies.[12]

13. On 19 January 2016, Dr B advised Ms A's GP that the investigations confirmed stress urinary incontinence. He discussed with Ms A possible surgical options, including the potential complications, such as an infection, pain, and failure of the procedure.

14. Dr B recommended anterior vaginal repair surgery with surgical mesh to correct the vaginal prolapse, as well as the insertion of a MiniArc sling.[13]

15. In response to the provisional opinion, Dr B stated that Ms A was not re-examined at the clinic visit on 19 January 2016, but that the treatment options were discussed with her. Dr B said that he discussed with Ms A the failure of the conservative treatment options, the surgical treatment to be carried out, and the associated complications.

16. Dr B stated that he also gave Ms A written information provided by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) on pelvic floor repair, and the manufacturer of the MiniArc sling.

17. The RANZCOG written information states that the conservative treatments available are general lifestyle changes,[14] physiotherapy to assist with pelvic floor exercises, and a vaginal pessary.[15] The risks associated with surgery (both anterior and posterior repair) listed in the

[7] A dropped or prolapsed bladder that pushes on the front wall of the vagina.
[8] A weakening of the tissue between the rectum and the vagina, which causes the rectum to push into the back wall of the vagina.
[9] A piece of surgical tape to support the urethra.
[10] Synthetic material used to provide additional support when repairing weakened or damaged tissue.
[11] A record of how much liquid a person drinks, how often the person urinates, and when urine leakage is experienced.
[12] Studies that focus on how well parts of the lower urinary tract (the bladder, sphincters and urethra) work to store and release urine.
[13] A medical device used to correct stress urinary incontinence. A small piece of mesh is placed under the urethra. The sling cradles the urethra in a position that mimics normal anatomy to give it more support and prevent accidental urine leakage.
[14] Including maintaining a healthy weight, reducing or quitting smoking, avoiding constipation, avoiding heavy lifting, and high impact exercise.
[15] A soft, removable device that is inserted into the vagina to support areas that are affected by pelvic organ prolapse.

RANZCOG written information are anaesthetic risks, recurrent pelvic organ prolapse, injury to other organs, bladder function,[16] infection, bleeding, and pain.

18. The written information provided by the manufacturer of the MiniArc sling states that "some of the most common risks include urinary tract infections, symptoms of urgency and difficulty with urination". It also states:

> "Some potential adverse reactions to surgical procedures to correct urinary incontinence include: Pain/Discomfort/Irritation, Inflammation (redness, heat, pain, or swelling resulting from surgery), Infection, Mesh erosion (presence of suture or mesh material within the organs surrounding the vagina), Mesh extrusion (presence of suture or mesh material within the vagina), Fistula formation (a hole/passage that develops between organs or anatomic structures that is repaired by surgery), Foreign body (allergic) reaction to mesh implant, Adhesion formation (scar tissue), Urinary incontinence (involuntary leaking of urine), Urinary retention/obstruction (involuntary storage of urine/blockage or urine flow), Voiding dysfunction (difficulty with urination or bowel movements), Contracture (mesh shortening due to scar tissue), Wound dehiscence (opening of the incision after surgery), Nerve damage, Perforation (or tearing) of vessels, nerves, bladder, ureter, colon, and other pelvic floor structures, Hematoma (pooling of blood beneath the skin), Dyspareunia (pain during intercourse)."

19. Dr B told HDC that as conservative management had been unsuccessful previously, and as Ms A "felt she was unable to keep going on as she was, she was very keen to proceed to surgery".

20. The clinical records note that Ms A had been referred for physiotherapy and pelvic floor exercises, but there is no record in the clinical notes regarding whether any other conservative measures were tried (such as vaginal support pessaries), and what treatment options were discussed.

21. A consent form signed by Ms A on 19 January 2016 described the procedure as "anterior [and] vault vaginal repair (including mesh), [sub-urethral] sling". The risks discussed with Ms A were listed on the form as: "[Risks of a general anaesthetic,] bleeding, infection, DVT,[17] damage [to] pubic organs, mesh exposure, pain, [and] failure of procedure/recurrence." Ms A also agreed that "if during treatment/procedure(s) there [was] an unexpected finding or event, additional procedures deemed to be essential might be carried out".

22. The surgery was performed by Dr B on 29 February 2016, but instead of an anterior vaginal repair (correction of the front wall of the vagina) (as Dr B had recommended and as was noted on the consent form), a posterior vaginal repair (correction of the back wall of the vagina) was performed using native tissue. A MiniArc sling was also inserted. Dr B considered that anterior vaginal repair surgery was not necessary as the anterior vaginal wall was reasonably well supported.

[16] Difficulty passing urine and incontinence.
[17] Deep vein thrombosis (a blood clot that forms in a deep vein of the body (usually in the legs)).

23. In response to the provisional opinion, Dr B stated that his clinical assessment prior to Ms A's surgery (on 24 November 2015) had been "somewhat difficult". He said that while the indication was that a mid-urethral sling and anterior vaginal repair with surgical mesh was warranted, the prolapse was difficult to examine in a clinical setting.

24. Dr B explained that while he was carrying out the surgical procedure, he was privy to a clearer picture of Ms A's medical requirements. He noted that contrary to preoperative findings, during the procedure he found that an anterior repair was not indicated, and so he did not carry out that procedure. He said that what he discovered was a symptomatic prolapse of the posterior compartment, which needed repair, and he made the decision to carry out the repair, "noting that the potential surgical risks discussed with [Ms A] remained unchanged with the alternate repair".

25. Dr B told HDC that he believes he acted in Ms A's best interests, and that her surgical risks were no greater than those to which she had consented originally. Dr B stated:

> "I very much doubt that [Ms A] would have been happy about returning for a second procedure, especially as there was consent for an additional procedure under certain circumstances."

26. Dr B said that in his view, it was entirely reasonable for the procedure to be varied from what had been planned initially, as "the operative finding was unexpected, [Ms A] obviously needed a repair procedure, and any potential surgical risk was essentially unchanged from the risks previously discussed with her".

27. The consent form signed by Ms A did not include the possibility that posterior vaginal repair surgery would be required, and there is no documented evidence that Dr B discussed this possibility with Ms A ahead of the procedure.

28. The operation note stated:

> "Findings:
>
> The vaginal vault was actually well supported and the symptomatic prolapse was the posterior vaginal wall with descent beyond the introitus[18] … The perineum[19] was reasonably well supported with the genital hiatus[20] satisfactory. The anterior vaginal wall was likewise reasonably well supported and no anterior repair was considered necessary …

[18] An entrance into a canal or hollow organ such as the vagina.
[19] The area between the anus and vaginal opening.
[20] A measurement from the urethra to the vagina.

> Procedure:
>
> Initial assessment under anaesthesia confirmed that no vault support was indicated and therefore there was no requirement for a vaginal mesh repair … A Mini[A]rc sling was placed in the left obturator internus[21] muscle as per protocol … A snug fit was ensured.
>
> Cystoscopy[22] at this point confirmed the absence of any damage to bladder or urethra … Patient's condition satisfactory throughout."

29. Dr B met with Ms A on 22 March 2016 (one month later) for a postoperative review. Ms A had less urinary frequency and no stress urinary leakage, but if she overfilled her bladder, she would have some slight urge urinary leakage. Dr B advised her that it was important not to overfill her bladder.

30. On examination, Dr B noted that the pelvic tissues were "healing nicely" and that the pelvic floor supports looked "very good". Dr B found Ms A's postoperative result to be satisfactory. He did not consider it necessary to see Ms A again, and he discharged her into the care of her GP.

31. Dr B provided no further care to Ms A.

Follow-up after posterior repair surgery and MiniArc sling

32. Ms A was without urinary incontinence for two months following her surgery. Her stress urinary incontinence then recurred, and she sought the opinion of gynaecologist Dr C.

33. On 16 June 2016, Ms A met with Dr C and a gynaecology registrar, Dr D. On examination, Dr C and Dr D found that Ms A had a grade 2 (moderate) anterior prolapse and urethral hypermobility,[23] but there was no posterior prolapse. They found that the MiniArc sling inserted by Dr B was "virtually not supporting the urethra at all".

34. Dr C and Dr D apologised to Ms A for the earlier unsuccessful surgery. They advised that the options were to trial a pessary or to undergo "repeat" surgery (anterior repair surgery and a sub-urethral sling). They also advised Ms A that there was a risk of up to 40% of the anterior prolapse recurring "in the long term".

35. Dr C and Dr D noted that Ms A was "very keen" to go ahead with the surgery, and that she also wanted to trial the pessary.

36. Dr D went through the consent process with Ms A, and a consent form for the surgery was signed by her on 16 June 2016. The risks discussed with Ms A were listed on the form as "urinary retention, recurrence, bladder perforation".

[21] A hip muscle that originates deep within the pelvis, wraps out and inserts on the posterior aspect of the head of the femur (thigh bone).
[22] A procedure to look inside the bladder using a thin camera called a cystoscope.
[23] The normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping away when any downward pressure is applied, resulting in involuntary urine leakage.

37. There is no reference in the clinical records to indicate whether or not Ms A was provided with any brochures or other written material prior to the surgery. Dr C told HDC that it was his practice at that time to give patients undergoing a sub-urethral sling procedure a copy of the manufacturer's pamphlets regarding the procedure.

38. There is no reference in the clinical records to urodynamic studies being completed by Dr C prior to the surgery.

Anterior repair surgery and TVT sling

39. On 12 August 2016, Dr C performed the anterior repair surgery and inserted a sub-urethral sling using tension-free transvaginal tape (a TVT sling[24]). He was assisted by Dr D.

40. Dr C documented in the operation note: "[The TVT] was inserted according to protocol under cystoscopic control. No bladder injury was noted." Ms A was discharged on 15 August 2016 and was to be seen for a follow-up appointment within six to eight weeks.

Follow-up after anterior repair surgery and TVT sling

41. Six weeks later, on 29 September 2016, Ms A attended a follow-up appointment with Dr D. Dr D noted that Ms A was very pleased with the result of her surgery, and she was not leaking urine. On examination, Dr D noted that the area had "healed very well" and the anterior vaginal wall was well supported.

42. The plan was for Ms A to be discharged from the clinic, but as her earlier surgery in February 2016 had been unsuccessful, a further follow-up appointment was scheduled for March 2017 (seven months postoperatively). Ms A was advised that she could cancel this appointment if she had no concerns.

Presentation to ED — urethral catheter

43. On 2 February 2017, Ms A was referred to the Emergency Department (ED) at Whanganui Hospital by her GP as she was continually leaking urine. On the same day, a urethral catheter[25] was inserted for symptomatic relief of her incontinence.

44. Ms A was due to be followed up by the gynaecology service on 23 February 2017.

Urology referral to another DHB (DHB2)

45. On 23 February 2017, Ms A was reviewed by Dr C. On examination, Dr C noted that Ms A's vaginal tissues were healthy, her urethral support was "good", and there had been no recurrence of her anterior vaginal prolapse. Dr C wrote to Ms A's GP on the same day, advising that there was nothing further he could offer Ms A surgically.

[24] A minimally invasive operation that involves the placement of a small piece of mesh (tape) around the pubic bones underneath the urethra.
[25] A tube that carries urine out of the bladder.

46. On the same day, Dr C referred Ms A to the urodynamic clinic at Hospital 2 (Te Whatu Ora 2) (formerly DHB2) for detailed urodynamic studies, including urethral pressure studies,[26] to see whether a clear diagnosis could be made as to why she was leaking urine.

47. On 25 May 2017, Ms A attended Hospital 2's urodynamic clinic and was seen by a urologist, Dr E. However, Dr E noted that Ms A's appointment had been made "[s]omewhat in error" as Hospital 2 was unable to perform the urethral pressure studies, which Dr C had specifically requested, as the hospital did not have the required equipment.

48. Although Dr E was unable to perform the urethral pressure studies, he performed a urodynamic study but was unable to determine why Ms A was leaking urine. Dr E advised Dr C that he had been unable to perform the urethral pressure studies in Hospital 2, and that he had not made any follow-up arrangements for Ms A.

Suprapubic catheter

49. On 30 June 2017, Ms A was seen by a locum[27] obstetrician and gynaecologist at Whanganui Hospital's gynaecology service. Ms A reported that she had an indwelling catheter,[28] but that the tubing would become kinked, and she had been experiencing overflow urinary incontinence and discomfort.

50. The locum discussed with Ms A the option of having a suprapubic catheter[29] inserted. Ms A agreed, and this procedure was performed by Dr E at Hospital 2 on 11 September 2017.

Urogynaecology referral to DHB3 and cystoscopy

51. On 17 September 2017, Dr F, a gynaecologist at Whanganui Hospital, referred Ms A to a urogynaecologist at Hospital 3, Te Whatu Ora 3 (formerly DHB3).

52. On 27 October 2017, Ms A was seen by gynaecologist Dr G at Hospital 3. At this point, notwithstanding the suprapubic catheter in situ, Ms A's urine leakage was occurring at any time without warning, sometimes with urgency but often with no urgency. She also had urine leakage with minor coughing, laughing, lifting, or standing up after having been seated.

53. Dr G noted that Ms A had had two operations for stress urinary incontinence, the first a MiniArc procedure, "which did not last", and then a further TVT procedure. He said that the TVT procedure seemed to work better, but there were still symptoms of urinary leakage.

54. Dr G explained to Ms A that the situation was "quite tricky". He referred her to a urologist, Dr H, for videourodynamics[30] with pressure profile studies of the bladder to determine why the urine leakage was occurring and, depending on the results, whether further surgery could be arranged.

[26] Studies to measure the balance of pressure at each point along the urethra.
[27] A doctor who temporarily fulfils the duties of another.
[28] A catheter that is left in place.
[29] A drainage tube inserted directly into the bladder through the abdomen.
[30] The study of pressure and flow in the lower urinary tract when it is filling and emptying.

55. Dr H performed the urodynamic studies on 19 January 2018. He reported: "A voiding study showed narrow bladder neck with a dilated mid urethra, and narrow distal urethra." He concluded:

> "[Ms A] has developed overactive bladder following her [MiniArc] sling. The subsequent TVT has not improved her continence. The video today suggests that the [MiniArc] sling is situated underneath the bladder neck while the TVT is under the distal urethra which explains the hourglass shape urethra and bladder."

56. Dr H recommended a cystoscopy and examination of Ms A's anterior vaginal wall. He advised that if the mesh was found to have eroded, this would need to be removed and the area repaired.

57. On 13 April 2018, Dr H performed a cystoscopy and documented his findings as:

> "Normal appearance to the urethra with support of the bladder neck … There was no significant anterior prolapse with a normal position of the ureters … On vaginal examination there appeared to be a small erosion of the TVT mesh on the left side however this had healed with film over the top and only 2mm of blue tape could be seen through mucosa."

58. Dr H injected 100 units of Botox[31] throughout the bladder. He advised Ms A that she should notice a "significant improvement in her urinary incontinence within the next week".

59. On 20 April 2018, Dr H wrote to Dr F asking if he would see Ms A at Whanganui Hospital's gynaecology clinic and arrange for Ms A to have a repeat cystoscopy either at Whanganui Hospital or Hospital 2. Dr H advised that he had not arranged any further follow-up with Ms A.

Follow-up

60. On 8 May 2018, Ms A had an outpatient home visit from a clinical nurse specialist (CNS), who documented: "[Ms A] believes the Botox has not worked and she has been discharged from the Urologist in [Hospital 3]. Will discuss with Urology CNS."

61. Ms A told HDC that subsequently, WDHB advised her that on 8 May 2018, DHB3 had referred her to Dr E at DHB2, but that this referral had been declined. She said that WDHB advised her that the referral had not been sent to WDHB to follow up. However, Ms A told HDC that in a subsequent telephone call, the WDHB Clinical Nurse Manager advised her that the referral letter from DHB3 had been found "in the wrong part of [Ms A's] file", and she apologised for the lost referral.

62. On 5 July 2018, Dr C saw Ms A "for a catch-up on her situation". On the same day, he sent a clinic letter to Ms A's GP advising:

[31] Botox can be injected into the bladder to treat urge incontinence or an overactive bladder. It helps the muscles to relax.

> "[Ms A] has apparently been diagnosed as having a non-functional bladder, possibly neurogenic. She does want some sort of a permanent solution, possibly some sort of urine diversion. We are awaiting a letter from the urologists in [Hospital 3]. Once I have seen that letter I will liaise with my urology colleagues to see if we can work out some sort of a plan for [Ms A]."

63. On 25 July 2018, a registered nurse documented in the clinical records:

> "[Patient] visited clinic today to enquire about status of issues. I spoke to [Dr C] who advised he is working on this. I rang [patient] to advise of outcome, and left [message] on answerphone."

64. Ms A told HDC that following her cystoscopy with Dr H, she received no follow-up from WDHB. She said that between May and October 2018, she made numerous attempts to contact Dr C to obtain information about "referrals and appointments", and left messages for Dr C, but he never contacted her. Ms A told HDC that she felt that the lack of communication was disrespectful and jeopardised the continuity of her care.

65. Dr C said that he did not contact Ms A as "he felt there was nothing further his clinic could do for [her]". Dr C has apologised to Ms A for not contacting her.

66. WDHB has apologised to Ms A for the poor communication between WDHB and DHB2, which resulted in the delay in treatment.

Mesh removal

67. Ms A relocated to another region early in 2019. On 20 February 2019, she was seen by a urologist, Dr I, at the urology service at Hospital 4. Dr I performed a cystoscopy and found the bladder to be normal, with no evidence of erosion. Dr I arranged for urodynamic studies to be performed to "get a better idea of the functional profile of [Ms A's] bladder".

68. On 2 May 2019, Dr I performed urodynamic studies and found that Ms A had a "painful unstable contraction that emptied her bladder in the supine position[32]". Dr I's initial plan was to provide Botox treatment. As the 100 units of Botox administered by Dr H had not helped Ms A, Dr I planned to use 300 units.

69. On 26 June 2019, Dr I advised Ms A's GP:

> "[Ms A] also has marked vaginal pain and seems very keen to have a removal of all mesh. We have no evidence of erosion. There was a question of a tiny erosion on an operation note from [Hospital 3] in [2018]. Certainly on today's cystoscopy I saw no evidence of this. Neither today did I see any significant prolapse."

[32] Lying on her back.

70. Dr I inserted 300 units of Botox into Ms A's bladder. Dr I advised Ms A that if the Botox treatment was successful and the capacity of her bladder improved, a Flip-Flo[33] valve could be attached to the suprapubic catheter.

71. On 16 August 2019, Ms A met with a urologist at Hospital 4's urology service. The urologist arranged further urodynamic studies to see if the Botox had had any effect and to plan further treatment. The urologist noted that Ms A had mesh erosion[34] and was "keen to get all the mesh removed". The urologist advised Ms A that both the MiniArc sling and the TVT sling would need to be removed.

72. In December 2019, Ms A underwent surgery to remove the mesh.

Responses to provisional opinion

Ms A

73. Ms A was given an opportunity to respond to the "Introduction" and "How matter arose" sections of the provisional opinion. Her comments have been incorporated into this opinion where relevant and appropriate.

74. Ms A told HDC that she has been in chronic pain since the events, and she has lost her bladder as a result of the events. Ms A believes that the TVT sling was the primary cause of her issues, and that in light of her complexities, she should have been managed more closely.

Dr B

75. Dr B was given an opportunity to respond to the sections of the provisional opinion that relate to the care he provided. Dr B's comments have been incorporated into this opinion where relevant and appropriate.

76. Dr B acknowledged that there were some deficiencies in the care he provided to Ms A (failing to advise Ms A of potential voiding difficulties and an overactive bladder, and failing to use terminology that highlighted the potential of a possible unexpected operative finding, and the need to change the surgical plan to accommodate this). However, Dr B considers that these were minor failings and that they did not amount to a breach of the Code of Health and Disability Services Consumers' Rights (the Code).

77. Dr B acknowledged the considerable difficulties Ms A had experienced with respect to her urinary function since the surgery he carried out in February 2016. He stated that he is deeply sorry for the distress Ms A has faced.

78. Dr B told HDC that he left Whanganui Hospital a short time after the surgery and that any follow-up care would have been the responsibility of other health professionals.

[33] A tap-like device that fits into the end of a catheter (urethral or suprapubic). It offers an alternative to using urinary drainage bags. The bladder then continues to store urine and can be emptied intermittently by releasing the Flip-Flo.

[34] Dr I said that there was no mesh erosion, but both Dr H and the urologist found that there was mesh erosion.

Dr C

79. Dr C was given an opportunity to respond to the sections of the provisional opinion that relate to the care he provided. Dr C had no further comment.

80. Dr C said that he hopes Ms A has managed to get the help she needs to resolve her problems, and apologised for the part he may have played in creating those problems.

WDHB

81. WDHB was given an opportunity to respond to the provisional opinion. WDHB accepted the recommendations made in the provisional opinion.

82. WDHB apologised to Ms A for her experience.

83. WDHB told HDC that as recommended in the provisional opinion, it has made changes to its referral system to ensure that patients are informed of referrals and plans for follow-up.

84. WDHB now has an electronic referral management system (ERMS), which "went live" at Whanganui Hospital in October 2022. WDHB provided HDC with copies of its new processes for its ERMS, secondary referrals, emailed referrals, and bariatric referrals.

85. WDHB told HDC that it also has an audit trail in its Patient Management System for electronic referral information, and that this system is "working well".

Opinion

Introduction

86. First, I acknowledge the significant difficulties Ms A experienced following the two surgeries performed on her in 2016. It is evident that the complications Ms A developed had a significant impact on the quality of her life on a day-to-day basis. Following her surgeries with Dr B and Dr C, Ms A experienced ongoing symptoms of urinary incontinence, resulting in further surgery to remove the mesh in 2019.

87. The events surrounding this case occurred at a time when there was an increasing body of knowledge 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. Regulatory action was being taken across a number of international jurisdictions in response to the harm caused to consumers. New Zealand clinicians were not, and should not have been, oblivious to this.

88. To determine whether Ms A was provided with the required information and services with reasonable care and skill, in accordance with the Code, I have considered the advice of an independent obstetrician and gynaecologist, Dr Jackie Smalldridge, and an independent urologist, Dr Hazel Ecclestone.

89. In determining whether Dr B and Dr C met the standard of care, it is important to assess their care against accepted practice, based on the opinion of a reasonable peer — which in this case is an obstetrician and gynaecologist. For the avoidance of doubt, I confirm that

primarily I have relied on Dr Smalldridge's advice in assessing Dr B's and Dr C's care given that she is their peer. However, there is overlap between urology and gynaecology in the area of surgical mesh and the management and treatment of urinary incontinence, and, as such, the perspective of a urologist on this kind of surgery is relevant in determining the standard of care and identifying systemic issues and sector-wide recommendations. In any case, it appears that both Dr Smalldridge and Dr Ecclestone are, for the most part, in agreement about what represented accepted practice at the time and where departures from accepted practice occurred in this case.

Dr B — breach

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

Provision of information and informed consent — breach

Consent to procedure

91. As noted on the consent form, Ms A consented to an "anterior [and] vault vaginal repair (including mesh), [and a sub-urethral] sling", and to additional procedures deemed to be essential in the event of an unexpected finding or event during the treatment/procedure.

92. On 29 February 2016, Dr B performed posterior repair surgery, and not anterior repair surgery, which was the procedure to which Ms A had consented. The findings at the time of surgery showed a well-supported vaginal vault, and therefore it was determined that anterior repair surgery was not required.

93. In response to the provisional opinion, Dr B submitted that he obtained Ms A's informed consent because the consent form provided for additional procedures to be performed in the event of an unexpected finding during the procedure.

94. Both my independent advisors identified that aspects of the consent process for the procedure should have been better. However, they had differing views as to whether those aspects amounted to a departure from accepted practice.

95. Dr Ecclestone advised:

> "The rationale for proceeding with an operation that wasn't consented for was not clearly documented in the operation note. There is no clear consent in the note for a posterior repair. The consent regarding the 'mesh insertion' aspect is adequate however … The patient appears to have undergone an operation she was not consented for (either in clinic or on the handwritten consent form) the risks of a posterior repair are very different to that of an anterior repair and vaginal vault repair. I consider this a severe departure from accepted practice and indeed goes directly against [the Code]. There would be no body of surgeons who would accept performing a non life saving operation, without the patient's prior consent, to ever be acceptable."

96. On the other hand, Dr Smalldridge advised:

> "Sometimes in a clinic setting it is difficult to fully assess the extent of a prolapse and the extent only becomes apparent [on the] operating table with a general anaesthetic and the good access. [Dr B] performed a posterior repair with native tissue because he felt this was the most appropriate treatment at the time. He did not perform the mesh repair because it was not indicated. This is not a departure from practice, and I think all gynaecologists would have had this experience where the findings in clinic are different from what we see on the operating table and we usually counsel the patients about this …
>
> We as gynaecologists always strive to make the correct diagnosis preoperatively but it is sometimes difficult to do a full assessment on the patient in the clinic and therefore as I have stated above, the extent and degree of prolapse does sometimes vary from the findings in clinic when the patient is on the operating table and it is best to perform the surgery that is necessary …
>
> In retrospect it would have been better if he had put '+/- anterior +/- posterior repair' or 'pelvic floor repair'. This is what my colleagues and I would do to mitigate this problem. He did the correct repair based on what he found at the time, and it would have not been a good idea to perform his initial surgery namely vaginal mesh repair if it was not indicated. This is not a departure from the accepted standard of care."

97. As a peer of Dr B, I accept Dr Smalldridge's advice that the extent and degree of prolapse in clinic can vary from the intraoperative findings, and I accept on the basis of her advice that Dr B performed the procedure with reasonable care and skill. However, my primary concern lies with the information that was provided to Ms A before the surgery.

98. With reference to the clinical advice I have received, I acknowledge that at times, situations can arise during surgery that necessitate a change of plan. Dr Smalldridge advised that all gynaecologists would have experienced findings in clinic being different from intraoperative findings. This supports the need for the surgeon to have a fulsome discussion on the proposed treatment and all possible alternatives with the patient prior to surgery as part of the informed consent process. This is essential so that the patient has had involvement where it is reasonably foreseeable that a decision may need to be made intraoperatively, based on the surgical findings, and there can be no unexpected outcomes. With reference to Dr Smalldridge's advice, in this instance this could take the form of noting the possible alternatives that could eventuate, indicated by the notation "+/-".

99. If Dr B was not certain of the extent and degree of prolapse and the procedure that would need to be performed (whether to perform an anterior or posterior repair), I would have expected him to communicate that uncertainty to Ms A, as well as the likely alternatives that could eventuate (eg, "+/- anterior +/- posterior repair"). I consider this to be information that a reasonable consumer in Ms A's circumstances would expect to receive. I would have also expected Dr B to communicate the risks associated with the planned procedure and all possible alternatives to ensure Ms A was fully informed (discussed further

below). Any such discussion should also have been reflected accurately in the documentation.

100. Although I acknowledge that the consent form generally allowed for the possibility of additional, essential procedures in the event of an unexpected finding, I am concerned that there is no documented evidence that the reasonably foreseeable possibility of a posterior repair was discussed with Ms A prior to the procedure, or that her consent was obtained for this alternative surgery. In my view, this was not an emergency situation and, given the unique set of risks associated with posterior repair (discussed further below), Ms A should have been advised of this possible outcome prior to surgery.

101. Dr B accepts that recording the procedure as "+/- anterior +/- posterior repair" or "pelvic floor repair" and discussing the potential need for an intraoperative decision to be made would have alleviated concerns and meant that Ms A was armed with additional information about the procedure.

Risks

102. On 19 January 2016, Dr B documented that he discussed with Ms A the potential surgical complications, such as infection, pain, and failure of the procedure. The risks discussed with Ms A were listed on the consent form as: "[Risks of a general anaesthetic], bleeding, infection, DVT, damage [to] pubic organs, mesh exposure, pain, [and] failure of procedure/recurrence." The consent form was signed by Ms A on 19 January 2016.

103. Dr B also provided Ms A with written information by RANZCOG and the manufacturer of the MiniArc sling. The risks associated with both anterior and posterior repair listed in these leaflets included anaesthetic risks, recurrent pelvic organ prolapse, injury to other organs, bladder function, infection, bleeding, and pain.

104. Dr Ecclestone advised that owing to the brevity of the clinical records, it was not possible for her to assess what risks and benefits were explained to Ms A.

105. Dr Smalldridge advised that the risks listed on the consent form were the standard risks outlined by gynaecologists when performing procedures such as Ms A's, but that many gynaecologists would also include the risks of "voiding difficulties" and an "overactive bladder". Dr Smalldridge considered the failure to mention these risks to be a minor departure from the accepted standard of care.

106. I accept Dr Smalldridge's advice. The risks were outlined in the written information provided by RANZCOG and the manufacturer of the MiniArc sling, which was provided to Ms A. However, I am not satisfied that Ms A was informed by Dr B about the risks of voiding difficulties and an overactive bladder. Although I acknowledge that Dr Smalldridge considers this to be a mild departure from accepted practice, in my view, this was information that Ms A needed to receive before giving consent to proceed with the proposed surgery.

107. Dr B accepts that it would have been advisable to include the risks of voiding difficulties and an overactive bladder in his discussion with Ms A, and regrets that this was not discussed.

108. In addition, I am not satisfied that Ms A was informed by Dr B about all of the risks associated with a posterior repair. This would include the risks of a rectal injury and dyspareunia. This was information that Ms A was entitled to receive before Dr B proceeded to perform a posterior repair.

Conclusion

109. Right 6(1) 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.

110. Right 7(1) of the Code states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.[35]

111. In my view, a reasonable consumer in Ms A's circumstances would have expected to be informed of the risks of voiding difficulties and an overactive bladder. I also consider that a reasonable consumer in Ms A's circumstances would have expected to be informed that sometimes, it is not possible to tell the nature and extent of the prolapse, and that while a surgeon may have anticipated performing an anterior repair based on the information available, it is possible that once a patient is on the operating table and the surgeon has further information, it may become clear that a different type of repair (eg, a posterior repair) is required. A reasonable consumer in Ms A's circumstances would have expected to be informed of the risks of the planned repair, as well as the risks of the alternative type of repair (eg, the risks of rectal injury and dyspareunia for a posterior repair).

112. I find that Dr B breached Right 6(1) of the Code for failing to provide Ms A with information that a reasonable consumer in her circumstances would expect to receive. It follows that by not providing such information, Dr B also breached Right 7(1) for failing to obtain Ms A's informed consent for the posterior repair procedure.

Alternative treatment options — other comment

113. In March 2013, RANZCOG provided recommendations for the consent process in relation to surgical mesh. These guidelines (RANZCOG guidelines), which I accept reflected accepted practice at that time, state:

> "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)."

114. On 24 November 2015, Dr B noted that Ms A had been referred for physiotherapy and pelvic floor exercises, but this had not been successful.

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

115. On 19 January 2016, Dr B advised Ms A's GP that he had discussed with her the "possible surgical options", but there is no record in the clinical notes of what these options were.

116. Dr Ecclestone advised that while the surgery was a reasonable treatment option, there was a lack of discussion around alternative treatment options (which in this case would include non-surgical options such as pelvic floor muscle training and vaginal support pessaries). She said that when consenting a patient for any procedure, it would be prudent to discuss alternative treatment options, including "doing nothing". Dr Ecclestone considered the lack of discussion to be a moderate departure from accepted practice.

117. Dr Smalldridge advised that the surgical treatment option was reasonable, and that Ms A had received conservative management with pelvic floor physiotherapy.

118. I accept both my independent advisors' advice that the surgical option offered to Ms A was reasonable. In addition, having reviewed Dr B's clinic letters, I am satisfied that alternative treatment options were discussed, and that Ms A was offered alternative treatment options prior to surgery.

Surgical technique — other comment

119. Following the posterior repair surgery and MiniArc sling placement on 29 February 2016, Ms A was without urinary incontinence for two months.

120. On 16 June 2016, Dr C and Dr D found that the MiniArc sling inserted by Dr B was "virtually not supporting the urethra at all", and they apologised to Ms A for the unsuccessful surgery.

121. Dr Ecclestone advised that Dr H's report (noting that "[a] voiding study showed narrow bladder neck with a dilated mid urethra, and narrow distal urethra") seemed to confirm that the MiniArc sling had been inserted "too proximally (sitting at the bladder neck rather than the mid-urethra)".

122. Dr Ecclestone said that it was also possible that the MiniArc sling was obstructing the bladder neck, given that Ms A had postoperative urinary retention, the videourodynamics showed a narrowed bladder neck, and subsequently she had developed detrusor overactivity.[36] Dr Ecclestone advised that this may be an indication of a deficient insertion technique, which she considered to be "at least a mild deviation from accepted practice". However, she noted that it appears that at that time Ms A was not followed up directly by Dr B, who may have been able to identify any technical error had he reviewed her.

123. Dr Smalldridge advised that based on the operation records, as far as she could tell, the procedure was done correctly. She noted that Dr B stated that he made his incision over the mid-urethra and inserted the MiniArc, as per the standard technique.

124. I have considered both Dr Ecclestone's and Dr Smalldridge's advice. It is possible that the narrowed bladder neck with a dilated mid-urethra represented a technical error of insertion.

[36] Increased or involuntary contractions of the detrusor muscle in the bladder (which contracts during urination to push the urine out of the bladder and into the urethra).

It is also possible that Dr B was unaware of this error at the time, which would explain why no error of insertion or complications were noted in the operation record. However, while an error could have been present immediately postoperatively, it could also have occurred sometime after the surgery as a result of mesh erosion. As advised by Dr Smalldridge, mesh erosion from a mid-urethral sling procedure is a well-known complication of the procedure and happens in 1–3% of cases. This possibility was also noted on the consent form.

125. In light of the above, and due to the passage of time (from the procedure in February 2016 until the urodynamic studies performed by Dr H in 2019), it is not possible for me to determine with certainty whether or not the MiniArc sling was inserted correctly.

Dr C — breach

126. I have undertaken a thorough assessment of the information gathered in light of Ms A's concerns. I find Dr C in breach of Right 4(1), Right 6(1)(b)[37] and Right 7(1)[38] of the Code. The reasons for my decision are set out below.

Preoperative tests — breach

127. On 12 August 2016, Dr C performed Ms A's anterior repair surgery and inserted a TVT sling. Urodynamic studies were completed by Dr B prior to Ms A's surgery on 29 February 2016, but there is no evidence that urodynamic studies were repeated by Dr C prior to Ms A's surgery on 12 August 2016.

128. Dr Ecclestone advised:

> "[T]here are no positive findings from the history and examination to suggest that a second mesh sling [was] appropriate. The diagnostic workup is hugely inadequate and national and international guidance and surgeons would suggest that at a minimum multichannel urodynamcis are mandated prior to surgery (ideally video urodynamics).
>
> From the clinical history it is very likely [Ms A] [had] developed detrusor overactivity (potentially as a consequence of an overtight initial sling). This does not appear to have been picked up by [Dr C] and this indicates an underlying lack of understanding of normal bladder function and the consequences of a malpositioned mid urethral sling.
>
> The failure to perform adequate diagnostic tests prior to proceeding with irreversible surgery, in direct contravention of national and international guidelines, is a severe departure from expected practice. In addition, [Dr C's] actions in inserting a further, potentially unnecessary sling have led to irreversible injury to [Ms A]."

[37] 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.
[38] 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.

129. Dr Smalldridge similarly advised:

> "Usually, to make a diagnosis we use history and examination findings sometime[s] backed up by diagnostic tests. With regard to the history and examination findings [these] would be consistent with stress incontinence however it would have been prudent to repeat the urodynamics [because] of the previous surgery to see if there were any other factors that were causing her incontinence, and this would be the usual practice. This is a moderate departure from standard practice."

130. I accept both my advisors' advice that Dr C should have arranged further urodynamic studies prior to performing further surgery. The Best Practice Advocacy Centre New Zealand (bpac[nz]) guidelines published in May 2016 offered best practice advice on the care of women with urinary incontinence. The guidelines state:

> "Women whose primary surgical procedure for SUI[39] has failed (including women whose symptoms have returned) should be referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT,[40] or offered advice as described in recommendation 1.6.9[41] if the woman does not want continued invasive SUI procedures."

131. The guidelines also state:

> "After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry[42] before surgery in women who have:
>
> - symptoms of OAB[43] leading to a clinical suspicion of detrusor overactivity, or
> - symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or
> - had previous surgery for stress incontinence."

132. I consider that Dr C should have been aware of the bpac[nz] guidelines, and I accept that these represented appropriate practice at the time. I am critical that Dr C did not follow the guidelines. The guidelines stated: "Healthcare professionals are expected to take [the bpac[nz] guidelines] fully into account when exercising their clinical judgement."

133. Further, as advised by Dr Ecclestone, the bpac[nz] guidelines also stated that invasive therapy for overactive bladder and/or recurrent post-surgical and complex cases of stress urinary

[39] Stress urinary incontinence.
[40] The multidisciplinary team.
[41] Recommendation 1.6.9 of the bpac[nz] guidelines states: "If a woman chooses not to have further treatment for urinary incontinence: offer her advice about managing urinary symptoms, and explain that if she changes her mind at a later date she can book a review appointment to discuss past tests and interventions and reconsider her treatment options."
[42] A test to look for problems with the filling and emptying of the bladder.
[43] Overactive bladder.

incontinence should be offered only after an MDT review. There is no evidence that this occurred.

134. In conclusion, I find that Dr C failed to provide services to Ms A with reasonable care and skill, in breach of Right 4(1) of the Code, for failing to perform urodynamic studies and complete an MDT review prior to performing further surgery. This was contrary to the bpac^{nz} guidelines and accepted practice.

Provision of information and informed consent — breach

135. On 16 June 2016, Dr D went through the consent process with Ms A for the anterior repair surgery and TVT sling. The risks that were discussed with Ms A were listed on the consent form as urinary retention, recurrence, and bladder perforation.

136. Dr Ecclestone advised:

> "Concerningly the risks listed on this consent form are minimal and don't include some of the most common complications, including voiding dysfunction, dyspareunia[44] and mesh exposure. Although the consent form only forms part of the overall process of consent, it is part of the written documentation of this process. The failure to mention any of these potentially debilitating complications either in the pre-operative letter or consent form is a moderate deviation from accepted practice."

137. Similarly, Dr Smalldridge advised that there are some complications "missing" from the consent form, namely pain, mesh extrusion, and bladder overactivity. She advised that in circumstances where the consent process is delegated to a registrar, it is prudent for the operating surgeon to "double check" that all of the relevant complications have been documented, as a registrar may not be aware of all the complications of each procedure. She considered this to be a departure from the accepted standard of care.

138. I accept the advice of both my advisors. As commented on by Dr Ecclestone, I acknowledge that the consent form is only a part of the informed consent process, and that an integral aspect of the process is the verbal discussion that occurs between the surgeon and patient where options are discussed and information is shared.

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

140. Based on the available documentation (ie, the consent form), I consider that Ms A was not provided with sufficient information about the risks of the procedure to allow an informed choice.

141. I acknowledge that Dr Smalldridge considers this to be a mild departure from accepted practice. However, I consider that knowledge of those risks was information that a

[44] Pain in the genital area or within the pelvis during sexual intercourse.

reasonable consumer in Ms A's circumstances would expect to receive, and needed to receive to give informed consent. While the consent process was delegated to Dr D, and with reference to Dr Smalldridge's advice, ultimate responsibility to discuss the risks and obtain informed consent rested with Dr C as the consultant responsible for the surgery. Accordingly, I find that Dr C breached Right 6(1) of the Code. By not providing such information, Dr C also breached Right 7(1) for failing to obtain Ms A's informed consent.

Postoperative management — adverse comment

142. On 2 February 2017, following Ms A's anterior repair surgery and TVT sling, she presented to the ED as she was experiencing urinary frequency with urgency and urge incontinence. A urethral catheter was inserted on the same day.

143. Dr C reviewed Ms A on 23 February 2017 and advised her GP that there was nothing further he could offer her surgically. Dr C referred Ms A to DHB2 for detailed urodynamic studies, including urethral pressure studies, to determine why she was leaking urine.

144. Dr Ecclestone advised that Dr C's failure to diagnose an overactive bladder on 23 February 2017 reflected poor clinical acumen, and that Dr C's postoperative management of Ms A "severely departed from accepted practice". Dr Ecclestone advised that Ms A "was not referred to an appropriate team to manage her early enough in the process which contributed to many more months of suffering than she might ordinarily have endured".

145. I acknowledge Dr Ecclestone's advice and her perspective as a urologist, but again note that in these circumstances I must give more weight to the advice of Dr Smalldridge, as Dr C's peer. Dr Smalldridge noted that at Ms A's initial postoperative check her symptoms had resolved, and it took some time for her new symptoms to present and for her to be referred. Dr Smalldridge advised that given the complexity of the situation, Ms A's "puzzling and persistent symptoms", and the lack of expertise locally, referral to a tertiary centre was the most appropriate course of action.

146. Dr Smalldridge advised that Dr C made the correct decision by referring Ms A to Dr H, as an expert in mesh complications, for further investigation and management. Dr Smalldridge said that as Dr E at DHB2 is a general urologist, he was "perhaps not the correct person" for Ms A to be referred to, given the complexity and the specific expertise in Hospital 3 in this area.

147. Having considered both Dr Ecclestone's and Dr Smalldridge's advice, I accept that Ms A's condition was complex, and that Dr C provided appropriate care by referring her to a urologist for further investigation and management. However, with the benefit of hindsight, I agree with both my advisors that Ms A's postoperative management may have been improved if she had been referred to Dr H earlier, given his expertise in dealing with mesh complications. In the interim, the complications Ms A was experiencing were having a significant impact on the quality of her life on a daily basis. I am also concerned that Dr C did not refer Ms A for videourodynamics when he saw her on 23 February 2017. When videourodynamic studies were eventually performed, Ms A was diagnosed with an

overactive bladder. I agree with Dr Ecclestone that this was a missed opportunity for earlier diagnosis and treatment.

148. Given the complexity of Ms A's condition, and as Dr C appropriately referred her for further investigation and management, I conclude that the lapses in Dr C's postoperative management did not amount to a breach of the Code.

Surgical technique — other comment

149. Dr C documented in the operation note: "[The TVT] was inserted according to protocol under cystoscopic control. No bladder injury was noted." No complications were noted during the procedure, and Ms A was discharged on 15 August 2016. By 2 February 2017, Ms A had developed urinary frequency and incontinence.

150. Dr Ecclestone advised that due to a lack of information in the operation note, it was not possible for her to assess the operative technique. Similarly, Dr Smalldridge advised that without being present during the time of surgery, she was unable to comment on whether the surgery was performed with reasonable care and skill.

151. I accept the advice of both my independent advisors. Due to the passage of time and a lack of evidence, it is not possible for me to determine whether the surgery was performed with reasonable care and skill.

WDHB — breach

Follow-up and communication

152. On 20 April 2018, Dr H at DHB3 wrote to Dr F asking for Ms A to be seen at Whanganui Hospital's gynaecology clinic and to have a repeat cystoscopy, either at Whanganui Hospital or Hospital 2. Dr H advised WDHB that he had not arranged any further follow-up.

153. Ms A said that after her appointment with Dr H, she contacted Dr C's clinic on numerous occasions between May and October 2018, leaving messages and seeking information, but she was never contacted.

154. WDHB advised Ms A that on 8 May 2018, DHB3 had referred her to Dr E at DHB2, but this referral had been declined and it had not been sent to WDHB to follow up. However, Ms A told HDC that in a subsequent telephone call, the Clinical Nurse Manager advised her that the referral letter from DHB3 had been found "in the wrong part of [Ms A's] file", and she apologised for the lost referral.

155. On 5 July 2018, Dr C met with Ms A and advised her GP that WDHB was awaiting a letter from the urologists in Hospital 3, and that once received, he would liaise with his urology colleagues to see if they could work out a plan for her. It appears from the clinical records that following this appointment, Ms A received no further communication or follow-up from WDHB.

156. I am critical that Ms A received no further communication or follow-up from WDHB. It is concerning that she attempted to contact WDHB on numerous occasions and that her

requests for further information about the follow-up care were disregarded. This lack of engagement would have been very understandably distressing and stressful for Ms A.

157. I reject Dr C's explanation that he did not contact Ms A as there was nothing further his clinic could do for her. If that were the case, he should have communicated this information to Ms A and referred her to the appropriate service for further follow-up and treatment. This was poor communication and resulted in delayed treatment.

158. In a previous decision by HDC,[45] a district health board was found in breach of Right 4(1) of the Code when its staff did not arrange a follow-up appointment for a patient. In that case, the Deputy Commissioner found:

> "It is the responsibility of healthcare providers, such as [the district health board], to ensure that there are robust systems in place to minimise the risk of errors in arranging important follow-up care."

159. Through no fault of her own and despite her best efforts to seek assistance, Ms A's care was uncoordinated and disjointed. Her complications were not addressed in a timely manner. As a consequence, Ms A was subject to prolonged and unnecessary suffering that would have significantly impacted the quality of her life on a day-to-day basis. Her circumstances could have been managed far more effectively had care been coordinated and had there been an effective patient referral management system between secondary and tertiary care (and back again).

160. In circumstances where a health service is not provided to consumers within their local area of domicile, the consumers are reliant on effective patient referral systems operating between districts to ensure there is continuity of care and equitable access to care and treatment. This is one of the foundations of our new health system[46] — "supporting good health and wellbeing for all New Zealanders, no matter who you are and where you live … Health equity matters for everyone", irrespective of a person's area of residence.

161. I am critical that no further follow-up care was arranged for Ms A. I have considered whether any individuals should be held to account but conclude that because this was a service delivery failure, responsibility more appropriately rests with WDHB. Accordingly, I find that by failing to communicate with Ms A and by failing to refer her to the appropriate service for further follow-up and treatment, WDHB breached Right 4(1) of the Code.

162. I acknowledge that WDHB has apologised to Ms A for the poor communication between WDHB and DHB2, and that Dr C has apologised to Ms A for not contacting her.

[45] 20HDC01960.
[46] https://www.tewhatuora.govt.nz/whats-happening/what-to-expect/nz-health-plan/.

Changes in medical practice since events

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

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

165. 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.

166. Currently, the Ministry of Health 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.

167. Te Whatu Ora has also very recently established specialist service centres for the treatment of women experiencing significant mesh complications.

168. HDC, as a member of the Surgical Mesh Roundtable,[47] alongside representation from a number of other agencies, including Te Tāhū Hauora Health Quality & Safety Commission (HQSC), is overseeing and monitoring the surgical mesh work programme led by Manatū Hauora|Ministry of Health, with input from Te Whatu Ora. The work programme includes the actions and recommendations arising from the Health Committee and Restorative Justice reports.[48]

Recommendations

Dr B

169. I recommend that Dr B provide a formal written apology to Ms A for the deficiencies in the care provided, as outlined in this report. The apology should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this decision.

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

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

Dr C

170. I recommend that Dr C provide a formal written apology to Ms A for the deficiencies in the care provided, as outlined in this report. The apology should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this decision.

Te Whatu Ora Whanganui

171. In light of the apology already provided to Ms A, and the changes made by Te Whatu Ora Whanganui to its referral system to ensure that patients are informed of referrals and plans for follow-up, I do not consider that any recommendations are necessary.

Follow-up actions

172. I will take the following follow-up actions:

1. A copy of this decision with details identifying the parties removed, except Te Whatu Ora Whanganui, Whanganui Hospital, and 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.
2. A copy of this decision with details identifying the parties removed, except Te Whatu Ora Whanganui, Whanganui Hospital, and the advisors on this case, will be sent to Dr Joe Bourne, Chief Medical Officer of Manatū Hauora|Ministry of Health and Chair of the Surgical Mesh Roundtable, Te Tāhū Hauora Health Quality & Safety Commission, the Accident Compensation Corporation, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, to highlight systemic learnings that can be taken from this case. Dr Bourne will be asked to table a copy of this decision at the next meeting of the Surgical Mesh Roundtable.
3. A copy of this decision with details identifying the parties removed, except Te Whatu Ora Whanganui, Whanganui Hospital, and the advisors on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Independent advice

Dr Smalldridge

Complaint Ref: 20HDC00999

My name is Dr Jacqueline Smalldridge MBBS, FRCOG ,FRANZCOG . I am a practising gynaecologist with a special interest in urogynaecology and have been practising for nearly 30 years. I am well acquainted with the types of surgery that I have been asked to comment on. I have read all the written information provided to me. I have no conflict of interest.

Dr

Q 1
The appropriateness of Dr decision in February 2016 to place the mesh sling secured by Miniarc tape. In particular consider whether bladder testing suggested this was inadvisable and whether Ms urinary symptoms were attributable to an alternative cause.

You did not provide me with the outpatient clinic preoperative letter or the copy of the urodynamic findings, however in a letter dated 17 September 2017, Dr wrote to Dr in refers to these findings.

"A pelvic examination at the time noted a large cystocoele and vault descensus. Urodynamics confirmed marked stress incontinence with a stable bladder" The findings of stress incontinence with a stable bladder would be an indicator that the proposed surgical intervention would likely be successful. It is usual practice prior to performing a continence procedure to have urodynamics performed as a preoperative test and this was the case with Ms I cannot comment on the urodynamic traces since you did not provide them to me, but I am assuming their conclusions were correct. This is standard practice. His choice of product the Miniarc in 2016 was appropriate. At that time, it was used as a minimally invasive procedure for stress incontinence which was thought to be equivalent in efficacy to transobturator slings. It was subsequently found to be inferior (1) and withdrawn from clinical use in 2018 in NZ (2)

Q2
Whether there was appropriate diagnostic evidence to support the need for surgical mesh and sling

Ms has 2 issues that needed to be addressed, the urinary incontinence and the prolapse From the information you have given me preoperative urodynamics would be the appropriate diagnostic evidence to support the need for a sling procedure for stress incontinence.

Although Ms was consented for a mesh repair for prolapse this did not happen because the

findings at the time of the operation showed a well-supported vaginal vault and so this was not required. Sometimes in a clinic setting it is difficult to fully assess the extent of a prolapse and the extent only becomes apparent on the on the operating table with a general anaesthetic and the good access. Dr performed a posterior repair with native tissue because he felt this was the most appropriate treatment at the time. He did not perform the mesh repair because it was not indicated. This is not a departure from practice, and I think all gynaecologists would have had this experience where the findings in clinic are different from what we see on the operating table and we usually counsel the patients about this.

Q3
In February 2016 when consenting the patient such as Mrs , what risks complications and alternative treatment options should have been discussed prior to the procedure and was the information provided to her adequate?

Because I do not have the clinic notes from Dr preoperative assessment, I am unable to comment as to whether she was offered at that time any other alternative treatments such as pelvic floor physiotherapy or the use of a ring pessary.

Q4
Please consider the consent form dated 19 January 2016 and advise on the adequacy of the risks and complications that were documented if there are any outstanding recent complications what these?

On the consent form I note that he did discuss the complications with her. " General anaesthetic, bleeding, infection, DVT, damage to pelvic organs, mesh exposure, pain, failure or recurrence" on the consent form which she signed. These are the standard risks outlined by gynaecologists performing these procedures. Many of us would also include "Voiding difficulties and overactive bladder". This is a minor departure from the accepted standard of care.

Q5
Whether it is appropriate for Dr to perform posterior repair surgery on 29 February 2016 when anterior repair was recommended and documented on the consent form.

We as gynaecologist always strive to make the correct diagnosis preoperatively but it is sometimes difficult to do a full assessment on the patient in the clinic and therefore as I have stated above, that the extent and degree of prolapse does sometimes vary from the findings in clinic when the patient is on the operating table and it is best to perform the surgery that is necessary.

His operation findings he states that "there was no requirement for a vaginal mesh repair because of a well-supported vaginal vault" and the main prolapse was in the posterior compartment and so he did have a repair of this using native tissue. Then he performed the Miniarc for the stress incontinence as planned. In retrospect it would have been better if he had put " +/- anterior +/- posterior repair" or "pelvic floor repair". This is what my colleagues and I would do to mitigate this problem. He did the correct repair based on what he found at the time, and it would have not been a good idea to perform his initial surgery namely vaginal mesh repair if it was not indicated. This is not a departure from the accepted standard of care.

Q6
With the mesh surgery performed by Dr was performed with reasonable skill and care. With reference to the clinical documentation available to you was a surgical technique correct? In particular considering the subsequent erosion of mesh into the bladder and in the pain are worsening bladder symptoms.

I have had access to the typed operation note and the handwritten note. As far as I can tell the procedure was done correctly. He says that he made his incision over the mid urethra and inserted the Miniarc as per the standard technique. In your question above, you incorrectly state that there was an erosion of mesh into the bladder. There was an erosion of mesh into the vagina only, not into the bladder. Erosion of the mesh in the vagina can cause symptoms of dyspareunia and bleeding and not usually associated with bladder pain per se. Mesh erosion from a mid-urethral sling procedure is a well-known complication of the procedure and happens in 1 to 3% of cases. This possibility was noted on her consent form. If it does not settle using oestrogen cream, it is sometimes excised which is a minor vaginal procedure which usually resolves it.

Q7

And the other matters in this case that you consider warrant comment.

no

Dr

Q1

The appropriateness of Dr decision in August 2016 to place a mesh sling secured by a tension free vaginal tape. In particular with Dr appropriately considered the possible involvement of Mrs previous procedure in her worsening symptoms?

Unfortunately, I have not had access to the outpatient letters from Dr reassessing exactly what her symptoms were, however in the letter dated 17/9/ 2017 from Dr to Dr makes reference to clinic visit in 6/2016. "Examination reveals a grade 2 anterior compartment prolapse, urethral hypermobility. The vaginal vault was well supported as was the posterior compartment ". The findings of urethral hypermobility with a history of stress incontinence may indicate that the previous procedure had not corrected the hypermobility, and this was why she still had her symptoms. However, given the findings of hypermobility and the fact that the second procedure (TVT Exact) did correct her stress incontinence would confirm that his clinical impression was correct. It is standard practice in the case of repeat incontinence surgery to repeat the urodynamic test. This is a moderate departure from standard practice.

Q2

Whether there was appropriate diagnostic evidence to support the need for a second mesh procedure

Usually, to make a diagnosis we use history and examination findings sometime backed up by diagnostic tests. With regard to the history and examination findings would be consistent with stress incontinence however it would have been prudent to repeat the urodynamics in case it because of the previous surgery to see if there were any other factors that were causing her incontinence, and this would be the usual practice. This is a moderate departure from standard practice.

Q3

In August 2016, when consenting the patient such as Ms what risks complications and alternative treatment options should have been discussed prior to the procedure and was the information provided to her adequate?

It appeared that Ms was offered alternative options other than repeat surgery. A ring pessary with knob to help correct the stress incontinence was inserted but she did not wish to proceed with this because it was uncomfortable. It was stated in the letter from outpatients that she wanted further surgery. There was mention of written material given to the patient by Dr which I am assuming was a TVT Exact leaflet from the company which provides information about the procedure and the complications. At that time, my colleagues and I would also have given the patient this information leaflet.

Q4

Please consider the consent form dated 16 August 2016 and advise on the adequacy of the risks and complications that were documented. If there are any outstanding risks and complications what these?

I note the consent was done by the registrar Dr . The complications listed "urinary retention, recurrence, and bladder perforation "only. There are some complications missing namely pain, mesh extrusion, bladder overactivity as mentioned previously. This is a departure from standard practice but understand that it is not always possible for the senior operating surgeon to consent all the patients under his care. The registrar is often delegated to do this. They may not be aware depending on their seniority of all the complications of each procedure. It is prudent for the operating surgeon to double check that all the relevant complications have been documented. This is minor departure from standard care.

Q5

Whether the mesh surgery performed by Dr was performed with reasonable skill and care. With reference to the clinical documentation available to you was his surgical technique correct in particular consider the subsequent erosion of mesh into the bladder and the pain and worsening bladder symptoms?

I have read the handwritten and the typed operation note. Dr describes the operation as per the protocol which is the standard technique that we all use for insertion of TVTs. I do not have any other comment to make on this since I was not there and have never seen him operate. As I have said before the subsequent erosion of the mesh was not into the bladder but into the vagina. This is of completely different significance as I have stated already. From the information I have, it would appear that there has been no departure from standard care.

Q6

The adequacy of follow-up care by Dr , for that period following her surgery in 2016 until she was referred to Dr in 2018. In particular whether Dr should her recognise that Ms pelvic pain and worsening bladder symptoms post-surgery were a complication of 1 or both mesh implants. If so what follow-up investigations and management should Dr have undertaken?

At her initial post-operative check her symptoms had resolved. It took some time for her new symptoms to present and to be referred to outpatients to be seen. Given the complexity of the situation and the lack of expertise locally, referral to a tertiary centre was most appropriate course of action given her some puzzling and persistent symptoms. This was complicated by the fact that she had a initial indwelling catheter and then a suprapubic catheter inserted locally. The appropriate investigations need to be performed by experts and this was not available locally. She initially saw Dr , Gynaecologist in who then referred her to Dr for video urodynamics. She would also need an examination under anaesthetic and cystoscopy by an expert such as Dr to accurately assess her situation and help with ongoing management. I see that she moved and I have seen this subsequent correspondence that you have sent me. Her problem is complex and difficult. I think her made the correct decision to refer her to for further investigation and management.

Q7

Any other matters that warrant comment.

I think it was correct that Dr referred the patient to the urologist he is an expert in mesh complications . Dr urologist in is a general Urologist and

was perhaps not the correct person given the complexity of the problem and the specific expertise in in this area.

With the development of credentialling for urogynaecological procedures currently being introduced by the Ministry of Health, it will be clear to practitioners when they should refer their patients to Tier 2 or Tier 3 colleagues.
Patients presenting with recurrent stress incontinence are best dealt with by colleagues with Tier 2/3 expertise and would perform the necessary pre-operative investigations such as urodynamics before determining a plan.
The practitioners will have to demonstrate appropriate skills in the operations they do and can be mentored if necessary to increase their skills to achieve the Tier level status they want.
There is always a tension between patients wanting to have their care locally and the availability of the most appropriate practitioners. The development of a mesh service in NZ in long overdue and would give better outcomes for patients, even though they will need to travel to access it.

References
1-Single incision sling operations for urinary incontinence in women. cochrane review 26/7/17
2. Medsafe surgical mesh implants Jan 2018

Kind Regards

5/10/22

Dr Jackie Smalldridge
MBBS FRCOG FRANZCOG
Specialising in Urogynaecology, Urodynamics, Gynaecology

Dr Ecclestone

Expert advice requested

Advice provided by : Hazel Ecclestone. MBChB MSc FRCS(Urol) Consultant Urologist TDHB
RE: Ref C20HDC00999
Care provided by Dr and Dr to November 2015-Jan2018

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.

Please review the enclosed documentation and advise whether you would consider the care provided to Ms by Dr and Dr was reasonable in the circumstances, and why.

In Particular, please comment on:

Dr

1. The appropriateness of Dr decision in February 2016 to place a mesh sling secured by a MiniArc tape. In particular, consider whether bladder testing suggested this was inadvisable and whether Ms urinary symptoms were attributable to an alternative cause

   It is very difficult to assess the appropriateness of this decision as the information in the file does not contain

   a) pre operative urodynamic reports or tracings or
   b) pre operative clinic letters.

   The only written documentation is a 10 line handwritten entry as detailed in (2). The patient does seem to have urinary incontinence, some of the handwritten entry is illegible. In 2016 a miniArc was an acceptable surgical treatment option for stress incontinence. The RANZCOG position statement 2014 states 'non-surgical, conservative measures such as pelvic floor muscle training... are first line treatment options for SUI' It is not clear from the file whether these were completed. A group of peers would all suggest that these should be completed prior to considering irreversible surgery. This would constitute a mild departure from standard practice if they were not completed prior.

   It is also worth noting that MiniArc is a 'single incision sling' in that it is anchored to the obturator muscle and fascia without external incisions. In 2016 this remained a technique still under scrutiny regarding its effectiveness and there was no evidence within the literature to suggest it was more, less or equivalently successful compared to 'standard' midurethral slings (Nambiar et al 2014)

   To prevent a similar occurrence it is imperative that all primary stress incontinence surgeries are discussed at an MDT by appropriately staffed and credentialled professionals. Pelvic floor exercises must have been tried and failed before the MDT will agree that a surgical option is appropriate.

2. Whether there was appropriate diagnostic evidence to support the need for surgical mesh and sling

P199 hand written clinic note Dr : 'Diaries and UDS confirm (illegible) SUI.' 'pressure normal through filling stage. Continually wet throughout the day. Surgery discussed incl potential complications eg infection pain failure. Can't go on as she is. Rec – Ant vag repair +/- mesh. SUI miniArc info tick W/L tick'

The diagnostic tests that the surgical decision making was made upon are not included in the case file (namely the urodynamic studies and diaries). There is also no documentation regarding what conservative measures were tried (if any) and what other options were discussed. It is not clear exactly what 'info' was provided from the case file.
I note that Ms did undergo urodynamics (although the report is not available to me) however the BPAC guidelines in 2016 (published after her MiniArc sling surgery) would have suggested urodynamics were not necessarily required provided 'pure SUI is diagnosed based on a detailed clinical history and examination'. I am unsure whether she did indeed try (and fail) pelvic floor retraining, but on balance she does appear to have had adequate diagnostic work up according to the guidance at the time (in 2016). No deviation from accepted practice noted.

3. Whether other treatment options should have been discussed with Ms

The RANZCOG statement in 2014 states 'MUS (midurethral sling) surgery is a recommended surgical procedure for SUI in routine cases. It also adds 'there are different risks and long-term outcomes from different surgical approaches which need to be discussed and tailored to each individual woman'

Urinary incontinence guidelines in the UK were published by NICE in 2006 that stated 'the best available data support the use of retropubic mid urethral tape procedures, colposuspension and autologous fascial sling…. Retropubic mid-urethral tape procedures using a 'bottom up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Open colposuspension and autologous fascial sling are the recommended alternatives when clinically appropriate….Synthetic slings using a ..transobturator foramen approach are recommended as an alternative treatment options for stress UI…provided that women are made aware of the lack of long term outcome data'.

The BPAC guidelines (national NZ guidance on SUI) were not published until May 2016 detailing appropriate options for primary stress incontinence. It would however be prudent as when consenting for any procedure to discuss risks, benefits and alternatives (including doing nothing). Without this, true informed consent has not been sought.

I note no other surgical options were discussed, which likely reflects the surgeons inability to offer any alternative option. This would not be considered acceptable by a group of my peers. Although the surgical option Ms underwent is a reasonable one, the lack of discussion around alternatives is not reasonable and there was no evidence of tailoring of surgical procedures to the individual. I would consider this a moderate departure from

accepted practice, especially given that international guidance had been available on this subject for almost a decade.

To prevent such occurrences in future surgeons should be credentialled to perform stress incontinence procedures as part of an MDT that can offer all surgical options. All cases must go through a formal MDT discussion and all suitable options must be discussed with the patient. The model needs to be shared decision making, not a paternalistic situation whereby the surgeon decides what operation is best for the patient based on the surgeons skill set. Individualized care should be the mainstay of stress incontinence surgery and if the preferred surgical option can not be offered by that individual surgeon, there must be a process whereby consumers can be referred to an appropriately skilled surgeon.

4. The risks and benefits of mesh procedures that should have been discussed with Ms

The FDA in 2008 (Schultz) suggested the following discussion should take place pertaining specifically to the use of vaginal mesh
Physicians should:

- ***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. (Schultz 2008)***

The brevity of the clinical notes preoperatively limit my assessment of the extent of the discussion of risks with Ms . I note the handwritten assessment states information was handed out. It is not possible to assess what risks and benefits were explained in this document.

Not possible to assess deviation from accepted practice due to insufficient information. Going forward it would be helpful if surgeons used a universal 'consent booklet' which contained risks, benefits and alternatives.

5. The adequacy of the information given to her as part of the informed consent process. Please comment on the adequacy of the signed consent form – in particular did the signed consent form appropriately describe the risks Ms should have been fully aware of prior to consenting to the surgery?

Consent form dated 19.1.16 signed by Dr and Ms [p77]. Consent is for – 'Anterior and vault vaginal repair (including mesh) suburethral sling' Particular risks discussed 'GA, bleeding, infection, DVT, damage pelvic organs, mesh exposure, pain, failure of procedure/recurrence'. I note the consent form was for an ANTERIOR repair but what was actually performed was a posterior repair as per the operation note on p39. The rationale for proceeding with an operation that wasn't consented for was not clearly documented in the operation note. There is no clear consent in the note for a posterior repair. The consent regarding the 'mesh insertion' aspect is adequate however...

The patient appears to have undergone an operation she was not consented for (either in clinic or on the handwritten consent form) the risks of a posterior repair are very different to that of an anterior repair and vaginal vault repair. I consider this a severe departure from accepted practice and indeed goes directly against the HDC code of health and disability consumer rights. There would be no body of surgeons who would accept performing a non life saving operation, without the patients prior consent, to ever be acceptable.

6. Whether the mesh surgery performed by Dr was performed with reasonable skill and care. With reference to the clinical documentation available to you, was his surgical technique correct? In particular, consider the subsequent erosion of mesh into the bladder and the pain and worsening bladder symptoms.

Discharge summary dated 1.3.2016 – Elective admission for post vaginal repair and sub-urethral sling reports 'Some urinary retention on catheter removal so IDC put back in. Removed again 3/3/16 and urine residuals post voiding were 50ml.' Bladder scan on 2/3/16 shows residual >999ml. Catheter inserted with 1400ml residual. Residuals on 3/3/16 were 198ml and 596ml. Consultant ward round 4/3/16 'difficult to interpret residual volumes on chart'
The fluid balance sheet from 4/3 shows a bladder scan residual of 53ml
Operation note (handwritten) [p39] 29.2.16- POSTERIOR VAGINAL REPAIR SUBURETHRAL SLING (MiniArc) ' for symptomatic vaginal prolapse UD proven stress incontinence. findings- bladder essent N. ... linear incision over midurethra. Paraurethral tunnels created, sling placed, incision closed'. The brevity of this operation note makes it impossible to comment on technical aspects of insertion. There is no mention of a cystoscopy (either in the procedure title or findings) so it is not possible to ascertain whether this was infact completed from the operation note, or what the findings were. The nursing notes however do note a cystoscopy was performed. It doesn't state whether this was done before or after the sling was inserted. The anaesthetic chart details that the anaesthetic started around 1515 and anaesthesia concluded at 1615.
Dr urodynamic report19.1.18 reported 'A voiding study showed narrowed bladder neck with a dilated mid urethra and narrow distal urethra'. This seems to confirm that the first sling (MiniArc) was inserted too proximally (sitting at the bladder neck rather than the mid-urethra), it is also very possible that it is obstructing the bladder neck (given that 1. She had post operative urinary retention 2. The video urodynamics show a narrowed bladder neck and 3. She developed de-novo detrusor overactivity subsequently) this may indicate a deficient insertion technique.

I would consider this to be at least a mild deviation from accepted practice, although it also appears that the patient was not followed up directly by the operating surgeon who may have been able to identify any technical error if he had indeed reviewed her.

7. Any other matters in this case that you consider warrant comment.
It is difficult for two reasons to establish how severe the deviation from accepted practice is in the case of Dr – firstly the clinical notes are brief and incomplete, and consist only of one preoperative visit with a handwritten entry and the operation note. Secondly at the time of Ms first surgery national guidelines were not yet in existence in New Zealand (despite their use in the UK since 2006) . There was however significant emerging

evidence in the literature of some of the harms that were occurring due to mesh, as well as the FDA announcement in 2008. A current practitioner offering stress incontinence surgery in 2016 should have been aware of the controversies and communicated these risks and benefits to the patient. (as a comparison to international practice, mesh was banned in the UK in 2016 pending further review of its safety).

Dr

Of note the BPAC guidelines for stress urinary incontinence were published in May 2016 (between Ms 2 operations)

1. The appropriateness of Dr decision in August 2016 to place a mesh sling secured by tension-free vaginal tape. In particular, whether Dr appropriately considered the possible involvement of Ms previous procedure in her worsening symptoms

P200 – letter from Mr registrar 'the mini sling is virtually not supporting the urethra at all'. It is not clear what investigation Mr. and his registrar performed to conclude this. Presumably it was inferred from clinical examination. In addition this letter states
'She leaks about three times a day without any warning' and
'Cough test today was negative'

The decision to place a second sling is a contentious one – there was a vogue to do so in the early and mid-2000s but the literature suggests a second sling has a significantly lower cure rate than a primary sling, with an increased risk of de-novo overactivity (Stav et al 2010). None of these risks appear to have been considered or discussed when the patient was booked for surgery.

The history of leaking without warning is highly suggestive of urge incontinence, which may have been caused by the previous surgery. This does not appear to have been considered by Dr No conservative or medical options for treatment of this urge incontinence seem to have been discussed. The BPAC guidance states 'discuss with the patient the benefit of conservative management including OAB medicines before offering surgery' This was not complied with.

No information regarding Ms voiding function was enquired about before proceeding with further surgery.

No further evaluation of the patients reported leakage has been suggested by Dr despite the clinical examination failing to show stress leakage. The BPAC guidelines state 'After undertaking a detailed clinical history and examination, perform multi-channel filing and voiding cystometry before surgery in women who have:

- **Symptoms of OAB leading to a clinical suspicion of detrusor overactivity**
- **Symptoms suggestive of a voiding dysfunction or anterior compartment prolapse**
- **Had previous surgery for stress incontinence**

Clearly Ms fits into all three of these categories and should categorically have had urodynamics prior to further surgery. Every international guideline in the world would support this on the basis of failed previous surgery.

In addition the BPAC guidelines state 'offer invasive therapy for recurrent post surgical; and complex cases of SUI symptoms only after MDT review. There is no evidence that this was complied with

There is a separate section in the BPAC guidance regarding 'considerations following unsuccessful invasive SUI procedures or recurrence of symptoms' which state 'Women whose primary surgical procedure for SUI has failed should be:

- **Referred to tertiary care for assessment (such as repeat urodynamic testing…) and discussion of treatment options by the MDT OR**
- **Offered advice as described in recommendation 1.6.9 if the woman does not want continued invasive SUI procedures.**

The guidelines appear again to have been disregarded.

To book a patient for irreversible surgery without clear evidence of the correct diagnosis would be considered a severe departure from accepted practice and Mr has gone against not only the BPAC guidance published in May 2016 but all international guidance about the management of recurrent stress incontinence. Peers internationally would not support surgical management in this case without further investigation.

A pertinent comment in the BPAC guidelines is 'All MDTs should work within an established regional clinical network, and be funded to ensure all women are offered the appropriate treatment options and high quality care' whereas this was clearly not the case here, it is necessary that going forward that these networks are not only developed but also used regularly to ensure equitable and safe access to anti incontinences surgeries.

2. Whether there was appropriate diagnostic evidence to support the need for a second mesh procedure

Outpatient letter page 200 Dr. O+G registrar ' was seen today by Mr and me for recurrence of her urinary incontinence. For two months following the surgery she was very well without any incontinence but now the stress incontinence has recurred. She leaks about three times a day without any warning and this is socially very limiting for her'…'on clinical examination..the mini sling is virtually not supporting the urethra at all….cough test today was negative'

As outlined in question 1 – there are no positive findings from the history and examination to suggest that a second mesh sling is appropriate. The diagnostic workup is hugely inadequate and national and international guidance and surgeons would suggest that at a minimum multichannel urodynamics are mandated prior to surgery (ideally video urodynamics)

From the clinical history it is very likely Ms has developed detrusor overactivity (potentially as a consequence of an overtight initial sling) This does not appear to have

been picked up by Dr and this indicates an underlying lack of understanding of normal bladder function and the consequences of a malpositioned mid urethral sling.

The failure to perform adequate diagnostic tests prior to proceeding with irreversible surgery, in direct contravention of national and international guidelines, is a severe departure from expected practice. In addition, his actions in inserting a further, potentially unnecessary sling have led to irreversible injury to Ms .

3. Whether other treatment options should have been discussed with Ms prior to the August 2016 procedure. If so please describe them

P200 preoperative letter 'we have discussed with the diagnosis and apologized for the unsuccessful surgery. We have discussed the options which are 1. to trial a pessary and see whether the anterior support improves the symptoms. 2. Offer repeat surgery (anterior repair and suburethral sling)…. I have booked and consented her today for anterior repair and suburethral sling'

The BPAC guidelines are clear that 'when offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in the table' which compares retropubic (bottom up and top down) transobturator (inside out and outside in), open colposuspension and autologous rectus fascial sling. It is clear from the documentation that none of the above were discussed. And neither was the likelihood of success of any of the aforementioned.

I find the consent process grossly lacking, and that informed consent can not have been fully obtained as she has not been counselled regarding any alternatives (including conservative). There is no evidence of individualized care for Ms .

In addition, in Dr reply to the HDC 'Mrs was always most adamant that she wanted further surgery but before the insertion of her TVT she did have a trial of alternative treatment namely a vaginal pessary' seeks to blame the patient for being 'adamant' that she wanted operative intervention. I wish to express my disquiet about this terminology – surgical consent should be shared decision making, with a fully informed patient. Ms was clearly not fully counselled about any risks, benefits or alternatives and thus was not in a position to make an informed choice despite her apparent 'insistence'. In addition if the surgeon does not feel the surgery is advisable, but the patient is 'adamant' that they want that surgery, then the surgeon should not perform the surgery and refer the patient for a second opinion.

4. The risks and benefits that should have been discussed with Ms

As outlined above, the insertion of a second midurethral sling, after the initial failure of a first is a fairly unusual procedure, although being described with increasing regularity in the literature. The ameliorated success rate of such an experimental technique has not been explained to the patient. No other surgical risks have been explained either other than those detailed on the consent form (see question 5). This is despite the FDA warning in 2008 having been around for 8 years and stating:

Physicians should:

- ***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. (Schultz 2008)***

This is a moderate departure from accepted practice and implies an overall unfamiliarity with the current mesh literature internationally. It would not be considered acceptable by a group of peers to not fully discuss risks and benefits of all surgical options prior to proceeding with surgery

To prevent this occurring in future, clinicians must be credentialled to allow them to perform stress incontinence surgery. This must include a CPD requirement to ensure clinicians are up to date with current practice and literature, and particularly current concerns about new devices.

5. The adequacy of the information given to her as part of the informed consent process. Please comment on the adequacy of the signed consent form – in particular did the signed consent form appropriately describe the risks Ms should have been fully aware of prior to consenting to surgery (reference in (4) above)

Consent form p149 – 'pelvic floor repair (anterior repair) + TVT (suburethral sling) risks specific to surgery 'urinary retention, recurrence, bladder perforation' signed by registrar 16.5.16

Concerningly the risks listed on this consent form are minimal and don't include some of the most common complications, including voiding dysfunction, dyspareunia and mesh exposure. Although the consent form only forms part of the overall process of consent, it is part of the written documentation of this process. The failure to mention any of these potentially debilitating complications either in the pre-operative letter or consent form is a moderate deviation from accepted practice.

A standardized consent form may be one way of ensuring all patients get adequate written information regarding the risks and benefits and alternatives for stress incontinence surgery, but also ensure that risks specific to mesh are outlined.

6. Whether mesh surgery performed by Dr was performed with reasonable skill and care. With reference to the clinical documentation available to you, was his surgical technique correct? In particular, consider the subsequent erosion of mesh into the bladder and the pain and worsening bladder symptoms.

Operation note p129 12.8.16 'TVT (exact) Inserted according to protocol under cystoscopic control, no bladder injury, ureteric jets x2'

Again the relative lack of information in the written operation note makes it hard to assess exactly how and where the mesh sling was placed. The subsequent urodynamics however that show a dilated mid urethra suggest that this tape may be causing bladder outflow obstruction, and in addition a mesh exposure has been detected. Although these are not obviously causally linked to a defective technique, it is known that the greater the level of experience, the lower the complication rate for these procedures (Australian Commission on Safety and Quality in Health Care 2018).

The paucity of information on the operation note makes it impossible to assess whether there has been a deviation from accepted practice with regard to operative technique.

7. The adequacy of follow up treatment by Dr , for the period following her surgery in 2016 until she was referred to Dr in 2018. In particular, whether Dr should have recognized that Ms pelvic pain and worsening bladder symptoms post-surgery were a complication of one or both mesh implants. If so, what follow up investigations and management should Dr have undertaken?

14.8.16 p107 Mr – 'pt experiencing urinary leakage prior to removal.'
WR 15.8 – Day 3 post TVT – 'still c/o severe suprapubic pain and urgency. Passing urine no residual D/C'. It is quite clear from this description that she has an overactive bladder and urge incontinence despite the catheter. No one in the treating team seemed to pick up on this, pre or post operatively. I am concerned about the overall level of knowledge and understanding regarding bladder function as the history is very clear but not acknowledged or acted upon at any point.

P203 29.9.16 Dr O+G Registrar '. come today for follow up after repeat TVT and anterior repair. She is very pleased with the result, and she is not leaking urine. She is able to empty the bladder well. … I have today discussed with that as things are so good we can discharge her from the clinic but as the previous tape failed, she would be keen to have one more appointment'. I would personally be very reticent to discharge a patient with previous failed surgery after just one outpatient appointment. I personally think that outcomes should be gathered by treating surgeons regarding their procedures for at least 2, but ideally 5 years, and that these outcomes should form part of the credentialling framework. This is reinforced by the BPAC guidelines which state 'Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes'

P204 23.2.17 Dr 'I saw on 23 February 2017 complaining of incontinence of urine to the point that she needs to have an indwelling catheter. From the description of her incontinence it is difficult to describe the pathogenesis of this…. there is nothing further I can offer surgically. I am referring her to for detailed urodynamics…to see if we can make a clear diagnosis of why is leaking' Once again, the failure to diagnose an overactive bladder at this sitting reflects poor clinical acumen. In

addition, there is no reflection that a year old lady being left with an indwelling catheter after anti incontinence surgery is a catastrophically poor outcome.

P207 – urodynamic report from Mr 25.5.17 Urologist 'I attempted to perform a urodynamic study to try and determine whether main problem was detrusor overactivity or stress incontinence. On attempted filling she had complete leakage very early on. It was not possible to tell whether this was from detrusor overactivity or stress'. It is concerning that the tertiary center to whom she was referred were unable to come up with a urodynamic diagnosis. Especially given the very thorough urodynamic report produced 8 months later in It should have been possible to assess the lower urinary tract further than it was, and this calls into question the whole regional clinical network's expertise, especially at managing complex cases.

Dr video-urodynamics 19.1.18 'Thank you for your referral of who developed overactive bladder symptoms following her of mini sling for symptoms of stress incontinence…she had urodynamics prior to the procedure which had shown a stable bladder with stress incontinence. Following her surgery, she then developed urinary frequency with urgency and urge incontinence. She had an anterior repair with a TVT. This did not improve her symptoms….. filling commenced. She had an early unstable contraction at 30cc. Filling was continued up to 100 and she had a rise in the detrusor pressure leak point pressure of 50cmH20. A voiding study showed narrowed bladder neck with a dilated mid urethra and narrow distal urethra. There was no sign of leakage with Valsalva of 130cm H20…there appears to be a small tape erosion of the distal sling'.

I would like to comment that this is the first thorough assessment of urinary function since prior to her first surgery. The urodynamic report quality is extremely comprehensive.

25.3.21 - Mr reply to HDC to the question 'whether the option of no treatment was discussed with Ms prior to surgery… Mrs was always most adamant that she wanted further surgery but before the insertion of her TVT she did have a trial of alternative treatment, namely a vaginal pessary.'

I find Mr clinical acumen to be somewhat wanting, both pre and post operatively. There appears from the correspondence to be no responsibility assumed for the poor outcome and no candor regarding any relationship to previous surgery. I also am concerned about an underlying knowledge gap in terms of Mr understanding of bladder function. He had asked for 'urethral pressure studies' during the urodynamics, whereas international guidance would suggest these are experimental, and he should have been referring the patient for video urodynamics, which Ms eventually underwent and confirmed the likely diagnoses which appear to have been missed by Dr

I also note with concern that Ms is now headed down the line of a permanent urinary diversion, I am disappointed at the tone of the letter from Dr of 5.7.18 which fails to reflect the seriousness of this outcome. The inability to further reconstruct the urethra will have been contributed to by the second mid urethral sling, for which I have no evidence was clinically justified. The failure to acknowledge harm and distress is one of the

recurrent themes seen in the restorative justice project 'hearing and responding to the stories of the survivors of surgical mesh'.

I consider the post operative management of Ms severely departed from accepted practice. There is a lack of acceptance of culpability from the operating surgeon, and a failure to acknowledge the degree of harm that Ms has suffered. She was not referred to an appropriate team to manage her early enough in the process which contributed to many more months of suffering than she might ordinarily have endured.

It is of utmost importance that going forward all surgeons that perform SUI surgery are appropriately trained and credentialled to do so. Recurrent stress incontinence surgery should only be tasked to clinicians experienced in its management who have thorough training and understanding of bladder dysfunction and recurrent incontinence. Outcomes should be gathered and compared nationally and any 'outliers' in terms of outcomes should be more closely audited and mentored to ensure no excess harm is coming to patients.

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

Reply to HDC complaint from Whanganui DHB 25/03/2021 –

'Dr believes the sub-urethral slings were appropriately placed'….'Also notwithstanding Dr later comments, examination by practitioners following the insertion of the TVT have noted 'Her urethral support is good'…'there is a mention of mesh erosion …it has not been mentioned by any other practitioners who have examined Mrs . Dr opinion is that this is insignificant almost - exposure and certainly does not warrant removal of the mesh'

I have gross reservations about both the content and the wording of this reply to the HDC. Not only does it attempt to gaslight the urologist (Dr and imply that mesh erosion may not even be present (as it was not noted by other clinicians), it also attempts to reduce the significance of this complication to an 'insignificant event'. I am extremely concerned that if this is a formal reply to the HDC that patients with vaginal mesh exposure have been inadequately managed by Dr previously. Vaginal exposure of mesh is clearly an ACC defined treatment injury. In addition the FDA in 2008 stated clinicians should 'Be vigilant for potential adverse events from the mesh, especially erosion and infection.' 'The description by Dr that the mesh was 'placed rather superficially in that area' but also insistence that the sling was 'appropriately placed' is an oxymoron. Either the sling was incorrectly placed (too superficially) or it was intended to be placed too superficially and thus not correctly placed. Excision of an exposed piece of mesh is the mainstay of surgical management and this has been known about in the literature for many years (Zambon 2016 et al) and a more recent metanalysis has confirmed the correlation between excision of exposed mesh and symptom resolution (Bergersen 2019 et al). This implies a lack of familiarity with the current management of mesh complications, and I view this as a severe departure from the accepted practice.

To prevent a similar occurrence in the future, a credentialling system must be introduced in New Zealand, similar to that in the UK where clinicians who perform stress incontinence

(SUI) surgery are nationally credentialled to do so. Salvage SUI surgery is further increased in complexity and any patient who requires salvage surgery should at a minimum be discussed at an appropriately skilled MDT, and operated on by a clinician skilled and credentialled for recurrent stress incontinence operations. When complications arise such as vaginal exposure, if a clinician is not experienced in their management, they should be referred to a network that can manage such complications.

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?
c. How would it be viewed by your peers
d. Recommendations for improvement that may help to prevent a similar occurrence in future?

References

Australian Commission on Safety and Quality in Health Care (the Commission) Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Surgery for Pelvic Organ (Vaginal) Prolapse (2018) available from: **https://www.safetyandquality.gov.au/sites/default/files/migrated/Credentialing-of-Senior-Medical-Practitioners-to-Undertake-Transvaginal-Mesh-Implant-Surgery-for-Pelvic-Organ-Prolapse.pdf**

Bergersen A, Hinkel C, Funk J, Twiss CO. Management of vaginal mesh exposure: a systematic review. Arab Journal of Urology. 2019 Jan 2;17(1):40-8.

BPAC guidelines bpacnz Guidelines : Urinary incontinence in women: the management of urinary incontinence in women

Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008709. DOI: 10.1002/14651858.CD008709.pub2

NICE 2006 CG40 Urinary incontinence - NICE guideline (sauga.org.za)

Restorative justice Hearing and Responding to the Stories of Survivors of Surgical Mesh | Ministry of Health NZ

RANCOG Midurethral-Slings-(C-Gyn-32)-Board-approved-March-2022.pdf (ranzcog.edu.au) Position Statement on midurethral slings

Schultz 2008 FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issues Oct 2008 available from : http://www.amiform.com/web/documents-risques-op-coelio-vagi/fda-notification-about-vaginal-mesh.pdf

Stav K, Dwyer PL, Rosamilia A, Schierlitz L, Lim YN, Chao F, De Souza A, Thomas E, Murray C, Conway C, Lee J. Repeat synthetic mid urethral sling procedure for women with recurrent stress urinary incontinence. The Journal of urology. 2010 Jan;183(1):241-6.

Zambon JP, Badlani GH. Vaginal mesh exposure presentation, evaluation, and management. Current urology reports. 2016 Sep;17(9):1-8.

Signed 

Date 10.04.2022