Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02281)

Introduction

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

2. The report discusses the care provided to Ms A by obstetrician and gynaecologist Dr B, and the former Taranaki District Health Board, now Te Whatu Ora|Health New Zealand Taranaki (Te Whatu Ora).[1] The report concerns the adequacy of the information provided to Ms A prior to undergoing a mid-urethral mesh tape sling procedure, and the appropriateness of her postoperative care when she experienced complications.

3. The report also serves to highlight issues with both the timeliness of Ms A's subsequent remedial treatment as a result of the harm she had experienced, and the less than effective systems in place for referring patients between regional and tertiary centres for mesh revision surgery at this time.

[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 Taranaki District Health Board now refer to Te Whatu Ora.

Names have been removed (except Te Whatu Ora Taranaki, Taranaki Base Hospital and the advisor) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

4. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care in 2015 and 2016.*
- *Whether Taranaki District Health Board provided Ms A with an appropriate standard of care during 2015 to 2021 (inclusive).*

5. At the outset, I acknowledge that the difficulties Ms A experienced following her procedure were significant, and unfortunately, she endured these complications over an extended close to five-year period before revision surgery was eventually performed, and a more significant attempt was made to remedy her situation and alleviate the adverse symptoms she had been reporting. The nature of her complications and the ongoing profound imposition they have had on her day-to-day life over this extended period cannot be overstated. It is evident that this was, and still is, a very challenging situation for her, and it is understandable that she would seek an independent review into the care provided.

Background

6. In 2012, Ms A began attending a public gynaecology clinic to address endometriosis, period issues, and stress incontinence. Between 2012 and 2015 she was seen by Te Whatu Ora's gynaecology and urology services for incontinence. Dr C, an obstetrician and gynaecologist, was responsible for her care during this time, and diagnosed urinary stress incontinence following urodynamic studies.

7. On 15 April 2015, Ms A was seen by Dr D, a visiting urologist at Taranaki Base Hospital. In a clinic letter, Dr D advised Dr C:

> 'I saw [Ms A] today. She is somewhat upset that she has not heard from your Service yet regarding a possible date for surgery. She clearly needs a sling and this could be the transobturator or suprapubic, but I think a transobturator would probably be best for her. I think you indicated you would be happy to do this in one of your previous letters and I think she would get good benefit from it. She is well informed regarding the risks and consequences of the procedure and is very happy to have this done as soon as possible. She is a little bit financially constrained at present, in terms of coming up to [the city], and if you did want to see her, then she would be very happy to see you in [the town] if you thought this was advisable.'

8. Dr D advised Dr C that he had discharged Ms A from further urology follow-up.

9. In mid-2015, Dr C transferred Ms A's care to obstetrician and gynaecologist Dr B.

Part 1 — Dr B's care

Relevant facts

First consultation — 7 July 2015

10. On 7 July 2015, Ms A first met Dr B to discuss a vaginal mesh tape sling procedure (a TVT-O (transvaginal tension-free vaginal tape obturator procedure)).

11. Dr B told HDC that he discussed the procedure with Ms A and explained the surgical risks of bleeding, infection, groin pain, voiding difficulty, and a need for intermittent self-catheterisation. He said that he also provided her with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) patient information leaflet (RANZCOG leaflet) on Urinary Incontinence, which contains detailed information on the TVT-O procedure, including all the possible complications. It also details 'effective treatments for urinary incontinence' and lists those as being pelvic floor muscle exercises, bladder training, electrical stimulation, medication, devices (such as pessaries), and surgery, specifically mesh surgery.

12. The RANZCOG leaflet states:

> 'Erosion of tape through the vaginal wall is the most reported mesh-specific complication. At one year after surgery, the occurrence of erosion is about two patients in 100. Some cases of erosion are treated easily but in others, the tape has to be surgically removed. This is usually straightforward, but some cases can be difficult.'

13. Dr B said that he explained to Ms A that it was important she read the RANZCOG leaflet and raise any concerns with him for further discussion.

14. Dr B said that although it is his usual practice to do so, he acknowledges that he did not specifically discuss the complication of tape erosion or exposure with TVT-O with Ms A, and the possible consequences, including the possible need for further surgery and the negative impact on quality of life. He acknowledged that this was an 'error of omission', and he has apologised to Ms A.

15. There is no evidence from Dr B's contemporaneous notes that he discussed alternatives to the TVT-O procedure with Ms A. However, Dr B said that by the time he first met with Ms A, she had already gone through much of the consent process with two other clinicians, Dr C and Dr D, who had both recommended the TVT-O procedure over other options. Dr B said that he considered that Ms A had previously been 'fully counselled' on alternative options by Dr C and Dr D on separate occasions. Dr B said that based on this, he did not discuss all the alternative options with Ms A again, but he clearly recalls discussing the option of not performing the surgery. Dr B said that in other cases, where the option of a TVT-O procedure has not already been selected by the patient in consultation with other colleagues, his usual practice is to discuss alternative treatment options, which include referral to physiotherapy for pelvic floor muscle exercises, bladder training, electrical stimulation, medication, and medical devices (such as pessaries).

16. Dr B said that despite Ms A's previous discussions with Dr C and Dr D, he considered that it was still important that he obtained Ms A's informed consent directly.

17. Dr B said that consent is a process, and that it is important for patients to have time to reflect on procedures, including the risks and benefits, so that they do not rush into any decisions.

18. Dr B's reporting letter to Ms A's GP, which mirrors the handwritten notes from the consultation, states: 'I counselled her regarding TVT-O with a risk of infection, voiding

difficulties. The latter might result in the need for self-catheterisation. She is keen to proceed.'

Second consultation — 21 October 2015

19. Ms A attended a second consultation with Dr B on 21 October 2015 at his gynaecology clinic. During this consultation, they discussed a concern Ms A had after reading the RANZCOG information leaflet to do with the risk of developing voiding difficulty and resultant infections. Dr B also gave advice on weight loss and smoking cessation.

20. Dr B's reporting letter to Ms A's GP reflects the above and also states: '[Ms A] is also aware she might choose to decline surgery.'

21. There was no mention of the complication of tape erosion or exposure, and consequences of that, at this consultation.

Procedure — 16 May 2016

22. Initially the TVT-O procedure was scheduled for 22 February 2016, but it was postponed because Ms A developed a urinary tract infection. The procedure eventually took place on 16 May 2016.

23. That day, Ms A signed a consent form that documented that the risks discussed were bleeding, infection, groin pain, voiding difficulties and self-catheterisation. Ms A is concerned that Dr B did not disclose the risks of displacement and/or erosion of the mesh and tape at the time she signed the consent form.

24. Dr B stated that the procedure was uncomplicated and performed step by step in line with the manufacturer's recommendation. He said that after the insertion of the mesh, he performed cystoscopy,[2] and no evidence of the tape was seen in either the bladder or the urethra, which meant that an immediate complication of urethra or bladder perforation was excluded. This statement is supported by his operation note.

25. Ms A was discharged from hospital the next day with planned follow-up.

Follow-up consultation — 24 June 2016

26. Ms A states that she began to experience adverse symptoms immediately following the surgery. These included pain, discomfort, haemorrhaging, physical and psychological pain, and pain during intimate relations.

27. On 24 June 2016, around six weeks after the surgery, Ms A attended a postoperative follow-up clinic at Taranaki Base Hospital with Dr B's registrar, Dr E. Dr B did not see Ms A in person.

28. Dr B said that at that time, he had a high workload in a busy clinic and had to share his patients with a registrar.

29. Dr E's reporting letter to Ms A's GP notes that Ms A had had minimal improvement of her symptoms since her surgery, including no improvement in her urinary stress incontinence.

[2] Examination of the bladder and urethra.

It further notes that Ms A described problems with an increased sensation to pass urine but she was passing only small volumes. She also described pain — with sitting, around the urethra, deep in the vagina, and severe pain during sexual intercourse. A vaginal examination was attempted but could not be completed because of pain. No dysuria[3] or haematuria[4] or offensive smell were reported.

30. Dr E discussed Ms A's care with Dr B. Dr B told HDC that there was no active vaginal bleeding or visualisation of a foreign body, and that he did not intend to re-examine Ms A himself given that she had not tolerated the previous attempt.

31. Dr B and Dr E discussed a plan to offer Ms A lignocaine gel and Ural sachets (for pain relief), and oxybutynin (to control bladder spasms), to help alleviate her symptoms, and to arrange an earlier follow-up visit in eight weeks' time rather than the usual six months, with safety-netting advice that Ms A should contact her GP if her symptoms worsened.

32. Ms A states that when she reported her adverse symptoms to Dr E, she felt she was not listened to, and the severity of her symptoms was not acknowledged. She said that she found it an insult that she was prescribed pain relief and sent home.

33. Dr B had no further involvement in Ms A's care after the 24 June 2016 follow-up consultation, as Ms A's care was transferred to Dr C. The reason for the transfer is unclear, but Dr C has speculated that this may have been because he and Dr B both provided specialist obstetrics and gynaecology services in the town and would cover for each other if one of them was unable to attend.

34. Dr B said that Dr C, who had originally referred Ms A to him for surgery, had taken over the assessment of Ms A without his knowledge and that this was outside his control. Dr B left employment at Te Whatu Ora Taranaki.

Response to provisional opinion

35. Ms A was given an opportunity to comment on relevant parts of my provisional opinion. She expressed how difficult it was to revisit this information because it brings back so much hurt and pain, and she explained the ongoing profound impact these events have had on her quality of life.

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

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

My opinion: Dr B — adverse comment

38. Having carefully considered the care Dr B provided to Ms A, I have two primary concerns — first, the information he provided to Ms A in relation to the risks prior to the TVT-O

[3] Difficulty voiding.
[4] Blood in the urine.

procedure on 16 May 2016; and secondly, the lack of recognition and response to her complications at her follow-up consultation six weeks later on 24 June 2016.

39. In reaching my findings below, I have relied on the clinical advice provided by obstetrician and gynaecologist Dr John Short, attached as Appendix A. With reference to Dr Short's advice, I recognise that Dr B had the qualifications and accepted experience to undertake this type of surgery in 2016.[5] I am unable to determine in hindsight whether the procedure was performed with reasonable care and skill and have focused my assessment on the information provided to Ms A as part of the consenting process, and the follow-up care.

Information provided

40. Informed consent is the cornerstone of the Code of Health and Disability Services Consumers' Rights (the Code). It is not a perfunctory tick-box exercise but involves a process of effective two-way communication of relevant information, and an informed choice to agree or refuse treatment.

41. Under Right 7(1) of the Code, services should not have been provided to Ms A unless she gave her informed consent. Right 6(1) of the Code gave Ms A the right to the information that a reasonable consumer in her circumstances would expect to receive, including an explanation of the options available and the expected risks, side effects and benefits of those options. Right 5(1) of the Code gave Ms A the right to have that information communicated to her effectively, in a way that enabled her to understand it. I have considered whether Dr B effectively communicated to Ms A appropriate information about the alternatives to TVT-O surgery, and the risks and benefits of each option.

42. Prior to meeting with Dr B on 7 July 2015, Ms A had already consulted two other specialists (Dr C and Dr D) and had indicated that she wished to proceed with the TVT-O surgery. In a letter to Dr C, Dr D advised that Ms A had been well informed about the risks and consequences of the procedure and that she was 'very happy to have this done as soon as possible.'

43. Dr Short advised that, in these circumstances, the decision to proceed with the TVT-O surgery had been largely made, and it was reasonable for Dr B not to pursue a conversation with Ms A about the non-surgical options on 7 July 2015.

44. Dr Short advised that the consent process described by Dr B and supported by the documented events is 'consistent with the highest standards', with the exception that some of the key risks were not discussed with Ms A prior to the surgery. Dr Short advised:

> '[Dr B's consent process] includes a multi-step process, supported by written information (in this case the RANZCOG leaflet), with repeat visits for further discussion and signing of the consent form deferred until after the patient's key concerns have been discussed. Unfortunately the verbal discussions do not appear to have specifically

[5] I note that in 2018 a formal requirement was introduced specifically for credentialling TVT-O and related procedures. Dr B advised HDC that he gave up performing TVT-O procedures in September 2018, because he was not performing enough cases each year to maintain his skill level.

highlighted some significant risks including the common risk of mesh exposure and the uncommon but potentially devastating risk of urethral injury.'

45. Dr Short advised that the following risks should be discussed with a consumer when contemplating a TVT-O procedure: bleeding, infection, injury to the bladder or urethra, voiding difficulties, overactive bladder, mesh exposure, and persistent pain (provoked or unprovoked), including groin pain. He said that when discussing the complication of tape erosion or exposure, clinicians should include information about the possible need for further surgery to treat those, and the potential for some complications to have a negative impact on the consumer's quality of life.

46. Dr B stated that he explained the surgical risks of bleeding, infection, groin pain, voiding difficulty, and intermittent self-catheterisation, and this is supported by his contemporaneous documentation. However, he acknowledged that contrary to his usual practice, he did not specifically discuss the complication of tape erosion or exposure with TVT-O, the possible consequences, the possible need for further surgery, and the possible negative impact on quality of life.

47. Although Dr B did not discuss the above risks verbally, the risks of tape erosion and possible requirement for further surgery are mentioned in the RANZCOG leaflet that Dr B provided to Ms A.

48. I acknowledge that providing written information to consumers about their procedure is helpful; as Dr Short notes, verbal discussions are supported by written information. The RANZCOG leaflet was a useful tool to assist in the informed consent process, as it contains detailed information about the procedure and associated risks and benefits, and the patient can then refer back to this information independently of the consultation. There is evidence that Ms A read the leaflet, as subsequently she made an appointment to discuss concerns she had after doing so. Consequently, I accept that relevant information was provided to Ms A.

49. However, as advised by Dr Short, common and significant risks should also be discussed verbally with the patient. In a previous decision, I expressed my view that the provision of information leaflets is not a substitute for a full discussion of the risks.[6] As advised by Dr Short, the purpose of information leaflets is to serve as an adjunct to verbal discussions and should not be used as a substitute for ascertaining whether a person understands the nature of, and risks involved in, the procedure or treatment.

50. The RANZCOG leaflet outlines that the erosion of tape through the vaginal wall is the most reported mesh-specific complication. In my view, given that this was a substantial risk, it warranted a verbal discussion with Ms A, explicitly drawing it to her attention and highlighting its significance, and allowing her the opportunity to discuss the resulting complications in more detail. This would have better enabled her to understand that she needed to be aware of this important risk before agreeing to the procedure.

[6] 19HDC02166.

51. Dr Short advised that considering the overall context of the consent process, the lack of discussion of the significant risks is a mild departure from the accepted standard of care.

52. I accept Dr Short's advice. In my view, a reasonable consumer in Ms A's circumstances would expect to be informed of the known risks of the TVT-O procedure, including mesh erosion and injury to the urethra. While I am critical that these complications were not discussed with Ms A prior to the surgery, considering Dr B's role in the overall consent process, which involved two other doctors, and that he did provide written information about these risks, I consider that Dr B did not breach the Code.

Follow-up care

53. At her follow-up consultation with Dr B's registrar on 24 June 2016, Ms A had had minimal improvement of her symptoms since her surgery, including no improvement in her urinary stress incontinence. She also described an increased sensation to pass urine, and pain with sitting, around the urethra and deep in the vagina, and severe pain during sexual intercourse. A vaginal examination could not be completed because of her pain. Dr B's registrar reported the symptoms to Dr B, who did not review Ms A in person.

54. Dr Short advised that Ms A's symptoms were strongly indicative of significant complications of the TVT-O procedure, and that by six weeks after the surgery, a patient should be able to tolerate a clinical examination. Dr Short advised that the signs and symptoms described at that point were 'significant and very much outside what could be considered normal'.

55. Dr Short advised that while it would have been ideal for Dr B to review Ms A personally, it is not uncommon for junior doctors to assess patients on behalf of a specialist. Dr Short advised that he considers the lack of personal review by Dr B to be a mild departure from the accepted standard of care.

56. I accept Dr Short's advice. I consider that it would have been desirable for Dr B, as the senior clinician responsible for Ms A's recovery following her surgery, to have reviewed Ms A personally on 24 June 2016 after being alerted to her symptoms. However, I acknowledge that this is not an absolute requirement and that it may not always be practicable for the postoperative care of a patient to be managed by one practitioner alone, for instance in a busy clinical setting where senior clinicians are carrying high workloads.

57. I also acknowledge the steps taken by Dr B as soon as he became aware of Ms A's complications. Dr B made a follow-up plan to see Ms A within eight weeks' time, rather than the usual period of six months, and provided her with safety-netting advice to contact her GP if her symptoms worsened.

Part 2 — Subsequent management by Te Whatu Ora Taranaki

Relevant facts

58. Ms A experienced significant ongoing issues postoperatively. On 6 July 2016, Ms A presented to Taranaki Base Hospital Emergency Department, on referral from her GP, due to ongoing pain. She was reviewed by a consultant, who noted her worsening pain and stress incontinence, and that there was 'nil erosion evident'. The consultant formed the

impression that her pain was secondary to the TVT-O procedure and aggravated by a possible urinary tract infection and coughing. Ultrasound scans confirmed that there was no infection, and Ms A was discharged home with pain relief and a plan to attend the arranged follow-up (see paragraph 31), and to undergo an MRI if the pain was ongoing.

59. On 22 July 2016, Ms A was admitted to Taranaki Hospital again with ongoing pain, and an MRI was undertaken. The MRI reported a normal-appearing vagina with no obvious fluid collections. However, it noted that the mesh was not 'imaged', that is, able to be seen. The plan was for pain relief, a referral to physiotherapy, and a bone scan to investigate osteomyelitis, and Ms A was discharged on 24 July 2016 to await the planned follow-up. The physiotherapy referral occurred on 28 July 2016, and the bone scan was undertaken on 10 August 2016.[7] Ms A is concerned that no follow-up of the postoperative scan that failed to visualise the mesh tape was arranged, nor a pelvic probe ultrasound scan.

60. On 5 October 2016, Dr C saw Ms A in a gynaecology clinic. Dr C's reporting letter to Ms A's GP states that the TVT-O had 'cured her random passing of urine' but that she still had urge incontinence. The plan was for Ms A to have physiotherapy for bladder training, and for follow-up in six months' time.

61. On 10 August 2017, Dr C saw Ms A again in a gynaecology clinic. His reporting letter outlines that Ms A described continued and worsening stress incontinence, poor flow (dribbling), and that she was only partially emptying her bladder. Clinical examination revealed that she was 'exquisitely tender' over the tape and external urethral meatus.[8] Dr C noted that he could not feel any exposure, but he was not able to explore the area completely.

62. Dr C recorded that he thought the hospital should ask ACC if it would support Ms A with the 'incontinence things'. He also commented that the vaginal portion of the tape would probably need to be removed and another TVT procedure undertaken, and that because of the complexity of the procedure it might need to be done by a urogynaecologist, for which ACC assistance would be helpful. He referred Ms A for a midstream urine test and noted that a cystoscopy and an examination under anaesthesia to remove the tape would be likely.

63. On 27 December 2017, Ms A's GP wrote to Te Whatu Ora Taranaki enquiring about the timing of further follow-up, as no appointment had been received. The referral was acknowledged on 15 January 2018 and prioritised as being semi-urgent.

64. On 5 April 2018, Ms A was seen by a consultant obstetrician and gynaecologist in a gynaecology clinic. The notes record that Ms A had developed chronic vulvar pain after the TVT-O, was still having stress incontinence, and reported bleeding from her vagina. A midstream urine test was taken, and an ultrasound was organised to exclude a uterine cause of the bleeding. It is noted that Ms A was happy to be reviewed by Dr C in six months' time.

65. On 11 April 2018, an ultrasound scan showed no obvious pelvic abnormalities.

[7] The results of the scan did not suggest osteomyelitis.
[8] The opening of the urethra.

66. Ms A was next seen by Dr C in clinic on 24 September 2018. In his reporting letter, actioned on 4 October 2018, Dr C commented on the extreme pain Ms A was experiencing, and noted his opinion that it was being caused by the TVT being 'very close to the urethral meatus'. He requested review by a urogynaecologist in another region, in relation to the removal of the mesh (noting that they were not in a position to do so at Taranaki Hospital), and also noted that Ms A had yet to be registered for ACC (to enable funding for further treatment). Dr C mentioned that there had been a six-month hiatus in Ms A's care.

67. Dr C completed ACC treatment injury paperwork on 19 November 2018, which was lodged by Taranaki Hospital support staff on 3 December 2018. ACC accepted the claim in February 2019, on the basis that there had been 'displacement of the mid-urethra sling to the proximal area of the urethral meatus'. ACC sought advice from an obstetrician and gynaecologist, who noted that the timing and severity of pain indicated that a physical injury had occurred either during surgery or in the immediate postoperative period. The ACC advisor considered that the position of the mid-urethral sling appeared to have been misplaced, or displaced after postoperative coughing, and it was noted to be in a position just proximal to the urethral meatus, and not supporting the mid-urethra.

68. Ms A saw Dr C again in clinic on 1 April 2019. He asked the urogynaecologist to see Ms A.

69. On 14 May 2019, Dr C initiated a further referral for Ms A, for post-menopausal bleeding. Subsequently, Ms A underwent an examination under anaesthesia on 15 August 2019, performed by Dr C and his team. The examination revealed no evidence of tape erosion or a breach in the anterior vaginal mucosa.

70. Ms A was seen by a urogynaecologist on 21 August 2019. The plan was for urodynamic studies, an ultrasound scan to assess the position of the tape, and consideration of a further examination under anaesthesia and tape removal in the future. A cystoscopy in November 2019 revealed a blue string (tape) within the urethra.

71. Ms A underwent surgery in another region on 10 February 2021 to remove the urethral portion of the TVT-O tape. She continues to have ongoing issues with incontinence and pain and receives ongoing gynaecological care.

Response to provisional opinion

72. Te Whatu Ora was given an opportunity to respond to the provisional opinion. Te Whatu Ora confirmed that it agreed with the opinion and recommendations in respect of Te Whatu Ora Taranaki.

My opinion: Te Whatu Ora | Health New Zealand

Communication around change of specialist — adverse comment

73. Ms A has concerns about her postoperative care being inexplicably changed from Dr B back to Dr C. Generally, I am not critical of specialists changing, as I appreciate that there can be several reasons for this, and I acknowledge that Dr C and Dr B shared care of their patients. However, if providers change, it is helpful for patients to be told why, and for provision to be made for continuity of care. I have no reason to believe that continuity of Ms A's care

was impacted significantly by the change from Dr B to Dr C postoperatively, but I am concerned that no one has provided me with a definite explanation of why this occurred in Ms A's case, and why no explanation was given to her. Dr B described it as outside his control. I encourage Te Whatu Ora to reflect on the poor communication, and the impact for the consumer on this occasion, and to ensure as far as reasonably possible, that consumers of its services are kept informed about changes in their care.

Postoperative management — breach

74. The focus of my review of this part of Ms A's care has concentrated on the timeliness of Ms A's review, investigations, diagnosis, and treatment of her postoperative complications.

75. In August 2017, Dr C identified potential concerns about Ms A's clinical picture that he felt warranted further investigation. However, it was not until October 2018 that Ms A was referred to urogynaecology services in a main centre for further review. This was the first delay. Ms A was then not seen in the main centre until August 2019. This was the second delay.

76. Dr Short advised that the care provided by Te Whatu Ora was somewhat haphazard, chaotic, and unnecessarily slow, and that the interval of greater than one year to follow up on the proposed pathways to expedite care represented a moderate departure from accepted standards of care. Dr Short referred to Dr C's written plan after Ms A's 10 August 2017 clinic appointment, to request urogynaecology review and apply for ACC funding. Dr Short noted that had a specialist with experience in TVT-O procedures been responsible for follow-up, the need for appropriate investigations may have been recognised earlier. Dr Short stated:

> 'Had [Dr C] followed up on his own suggestion to refer to ACC and a urogynaecologist in August 2017, it is easy to see that an earlier diagnosis and treatment could have been achieved.'

77. Dr Short could see no explanation for the second delay and considers that had ACC referral and funding been arranged earlier, Ms A may well have been seen earlier.

78. I agree that the delays in Ms A receiving appropriate investigations, diagnosis and treatment are unacceptable and meant that she was unnecessarily subjected to the adverse symptoms for an extended period. Dr C has acknowledged that the actioning of his plan of 10 August 2017 was delayed because he left medical practice temporarily, and this contributed to the 'hiatus' in Ms A's care. For this reason, I consider that the issue lies with Te Whatu Ora at a systemic level. If Dr C had left medical practice temporarily, Te Whatu Ora needed to ensure that appropriate systems were in place to transfer Ms A's care to another specialist to action any plans in a timely manner. Instead, it was not until Dr C returned to practice and saw Ms A again in September 2018 that the failure to action the plan was identified.

79. I am unable to determine the cause of the second delay. I can appreciate that inter-hospital referrals may be complicated to co-ordinate. However, I agree with Dr Short that more timely actioning of the August 2017 plan may have mitigated the subsequent delays that occurred, including the delay in Ms A being seen by urogynaecology services in the main centre.

80. Previously this Office has raised concern about failures by public health services to action referrals and manage follow-up in a timely manner.[9] As stated in those cases, it is the responsibility of healthcare organisations to ensure that robust systems are in place to minimise the risk of errors occurring in the referral process and in arranging important follow-up.

81. I accept Dr Short's advice that the ongoing care and follow-up provided by Te Whatu Ora Taranaki was inadequate, and consequently I find that Te Whatu Ora failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Changes made since events

82. Te Whatu Ora stated that there is a now a combined monthly multi-disciplinary meeting between the Urology and Gynaecology teams, to discuss and review all women referred with urinary incontinence issues. The aim of the meeting is to develop the most appropriate plan in terms of clinical assessment, investigation, and management — surgical or otherwise — for each individual. A letter about each patient is sent to their GP, and the doctor who chairs and coordinates the meeting maintains a spreadsheet of each patient and the decisions made. Te Whatu Ora stated that this system ensures that follow-up is consistent and that if there are surgical complications, the team will review, give advice, and make recommendations about the best response. If there is a change of consultant for whatever reason, then the plan of care and decisions made will be documented and communicated clearly.

83. Te Whatu Ora has also recently established the New Zealand Female Pelvic Mesh service for women harmed by mesh, which has been established to support and care for women such as Ms A who have suffered injury from pelvic surgical mesh.

84. Dr B stated that he has learned from this experience and has since ensured that in addition to the written information he provides to patients, he always provides verbal advice on all the matters covered by the written material, so that he can be assured that the patient has had the relevant information brought to their attention before making an informed choice about treatment.

85. Dr B noted that he ceased performing TVT-O procedures in September 2018 because he had not performed enough cases each year as was required to maintain his skill level.

86. Dr B further noted that in 2017 he underwent a Performance Assessment Committee review of his practice, which determined that he was practising at the required standard. In 2018, he voluntarily underwent a RANZCOG peer review of his practice, and the outcome was favourable. In 2019, he satisfactorily performed a recertification programme with the Medical Council of New Zealand. In 2023, Dr B attended an 'Advanced Communication Skills for Healthcare Professionals' course and currently is undertaking the Māori Indigenous Health Initiative course.

[9] See Opinion 19HDC02393, 30 June 2021 and Opinion 20HDC01960, 27 June 2022.

Recommendations

87. I have taken into account the changes that have been made by the providers in this case, and changes that are continuing to be made by Manatū Hauora (in leading the surgical mesh work programme with oversight and monitoring by the Surgical Mesh Roundtable), Medsafe, and RANZCOG, which should go some way in reducing harm from surgical mesh in the future.

88. I recommend that Dr B provide a formal written apology to Ms A for the deficiencies in his care 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.

89. In the provisional opinion, I recommended that Te Whatu Ora provide a formal written apology to Ms A for the deficiencies in care as outlined in this report. This apology has been provided and forwarded to Ms A.

Follow-up actions

90. A copy of this report with details identifying the parties removed, except Te Whatu Ora Taranaki, Taranaki Base Hospital, and the advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name in covering correspondence.

91. A copy of this report with details identifying the parties removed, except Te Whatu Ora Taranaki, Taranaki Base Hospital, and the advisor 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, the Accident Compensation Corporation, Te Tāhū Hauora|Health Quality & Safety Commission, Te Whatu Ora, and RANZCOG to highlight systemic learnings that can be taken from this case. Dr Bourne will be asked to table this report at the next meeting of the Surgical Mesh Roundtable.

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

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr John Short, an obstetrician and gynaecologist:

'12th October 2022

Dear Ms McDowell

Complaint: [Dr B]/Te Whatu Ora — Taranaki District
Your ref: C21HDC02281

I have been asked to provide advice in this case (21HDC02281), regarding the care provided to [Ms A] by [Dr B] and Taranaki District Health Board from 2015 onwards. I have read and agree to follow the Commissioner's guidelines for independent advisors. I can confirm there is no conflict of interest.

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

I have been provided with clinical documents relating to care provided to [Ms A] from 2015 onwards. I have been asked the following specific questions:

Please comment on whether the following aspects of [Dr B's] care were in line with accepted practice, with reasons and references as appropriate.

1. The information provided to [Ms A] preoperatively. In particular:

1.1. What information is usually provided to consumers in [Ms A's] circumstances, prior to undergoing a procedure such as this? If appropriate, please advise what accepted practice was at the relevant time (2015 and 2016), and what accepted practice is currently.

1.2. In [Ms A's] circumstances, is it accepted practice for the clinician to discuss the possible complication of tape erosion or exposure with TFVT, the possible consequences, and the possible need for further surgery and negative impact on quality of life?

1.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

2. The surgical procedure. In particular:

2.1. In your opinion, did [Dr B] perform the procedure on 16 May 2016 with reasonable care and skill?

2.2. Whether the immediate post-operative care was adequate/appropriate, including the adequacy of relevant checks, visualisations and investigations.

2.3. If there has been a departure from accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

2.4. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

3. [Ms A's] post-operative care at [Dr B's] clinic on 24 June 2016, noting:

- [Ms A's] reported symptoms;
- That [Dr B] did not personally examine [Ms A];
- The lack of an MRI (or other scan);
- The prescription of oxybutynin, ural sachets, and lignocaine gel; and
- The timing (8 weeks) of the arranged further follow-up.

3.1. In your opinion, were the decisions, investigations, information provided and treatment plan reached at the 24 June 2016 post-operative clinic in line with accepted practice? Please explain why/why not.

3.2. If there has been a departure from accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

3.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

4. Please comment on [Dr B's] qualifications to perform TVT-O surgery, more information about which can be found in his response to Advocacy, and Taranaki DHB's response to HDC.

5. More generally, please advise on the qualification requirements obstetricians and gynaecologists must meet in order to perform TVT-O surgery.

6. Are there any other matters in respect of [Dr B's] care that warrant comment?

Taranaki DHB

1. Please comment on the approach taken by clinicians who examined [Ms A] since the TVT-O procedure. In particular:

1.1. The management and transfer of [Ms A's] care between consultants.

1.2. The follow up of referrals to [the second] DHB.

1.3. The assessments and investigations undertaken. In particular, the timeliness of a scan to check the positioning of the mesh.

2. For each question, please advise:

2.1. What is accepted practice?

2.2. If there has been a departure from accepted practice, how significant a departure do you consider this to be (mild, moderate or severe)?

2.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

3. Are there any other matters in respect of Taranaki DHB's care that warrant comment?

Background

[Ms A] first met [Dr B] on 7/7/2015, to discuss a TVT-O procedure (a vaginal mesh procedure) to treat urinary incontinence. She had previously seen [Dr C], gynaecologist, and [Dr D], Urologist, who had recommended the procedure. At their first meeting, [Dr B] discussed the procedure and some of the risks including infection and voiding difficulties. She was placed on the waiting list for surgery. They met again for a pre-operative discussion on 21/10/2015. A consent form was signed, with the risks of "bleeding, infection, groin pain and voiding difficulties" documented, indicating that they had been discussed.

On that occasion the surgery was postponed due to a urinary tract infection being detected. Surgery eventually took place on 16/5/2016. Based on the operation record and subsequent notes, the surgery and immediate recovery appear to have been uncomplicated. A cystoscopy was performed as part of the procedure, which documented no bladder injury being identified.

[Ms A] returned for a follow-up appointment on 24/6/16. She was seen by a junior registrar, not [Dr B]. She reported no improvement in symptoms and problems with an increased sensation to void, associated with passing small volumes. She also described pain, with sitting, around the urethra, deep in the vagina and severe pain during sexual intercourse. Physical examination was not able to be completed due to pain. The case was discussed with [Dr B] who advised some simple treatments but did not see [Ms A].

Over the coming months [Ms A] was seen several times by gynaecologists and physiotherapists. The symptoms reported include vaginal pain, ongoing incontinence, groin pain and urethral pain. Pelvic ultrasound and MRI were performed but no specific complication was seen, although the mesh was not visualised. Simple treatment measures were undertaken during this time.

On 10/8/17, [Ms A] was seen by [Dr C]. His examination found there to be exquisite tenderness at the urethra and the TVT-O was extremely close to the meatus. Mention is made of making an ACC claim and referral to a urogynaecologist. However, these steps do not appear to have been taken at this time and didn't happen for quite some time. Indeed, the ACC claim was only made in November 2018 and referral to the Urogynaecology team at [the second DHB] was only made in April 2019.

Following review by the Urogynaecology fellow at [the second DHB] in August 2018, recommendations were made for urodynamic studies and transperineal ultrasound to assess the position of the TVT-O. To minimise travel, she was referred to the Taranaki urologists for urodynamics. They also performed a cystoscopy, 12/11/2019, which identified mesh in the urethra. She underwent removal of the mesh on 10/2/2021 at [the second] DHB.

Comment

[Ms A] underwent a TVT-O procedure on 16/5/16. Symptoms suggesting complications were reported at review 6 weeks later, yet these took several years and multiple reviews to be fully addressed. Even after [Dr C's] assessment on 10/8/17, there were inexplicable delays in completing ACC paperwork and onward referral for definitive treatment.

In response to specific questions:

Please comment on whether the following aspects of **[Dr B's] care** were in line with accepted practice, with reasons and references as appropriate.

1. The information provided to [Ms A] preoperatively. In particular:

1.1. What information is usually provided to consumers in [Ms A's] circumstances, prior to undergoing a procedure such as this? If appropriate, please advise what accepted practice was at the relevant time (2015 and 2016), and what accepted practice is currently.

I would expect the following risks to be discussed with a consumer contemplating a TVT-O: Bleeding, infection, injury to bladder or urethra, voiding difficulties, overactive bladder, mesh exposure and persistent pain (provoked or unprovoked) including groin pain. Other treatment options, such as physiotherapy, should be discussed as should the option of not having any treatment. Verbal discussions should be supported by written information. The essence of this has not changed since 2015.

The decision to perform surgery appears to have been made before [Dr B] saw [Ms A], although it is notable that not having surgery was discussed. However, it would appear that he did not provide all the above information to [Ms A], in particular the risks of surgery.

1.2. In [Ms A's] circumstances, is it accepted practice for the clinician to discuss the possible complication of tape erosion or exposure with TFVT, the possible consequences, and the possible need for further surgery and negative impact on quality of life?

Yes, it is accepted practice to discuss complications of tape erosion or exposure. When discussing complications the possible need for further surgery to treat these should be included. The potential for some complications to have a negative impact on quality of life should be discussed.

1.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

I do not have any specific recommendations. Since 2018 surgeons are required to undergo specific credentialling to perform mesh procedures for urinary incontinence. This process includes assessment of consent processes. Therefore, no additional recommendations are made in this area.

It should also be noted that [Dr B] voluntarily ceased performing TVT procedures in 2018. Also, the TVT-O device is rarely used in current practice.

2. The surgical procedure. In particular:

2.1. In your opinion, did [Dr B] perform the procedure on 16 May 2016 with reasonable care and skill?

The operation note does not suggest otherwise. In particular, the surgical incision was made in an appropriate place and steps were taken to ensure the sling was not under too much tension. The most likely cause of the ongoing problems was an unrecognised injury to the urethra. Although a cystoscopy was performed, the records do not specifically state that the urethra itself was checked for injury (only the bladder). However, I cannot confirm if this is an actual omission or a documentation error. The latter would be most likely.

2.2. Whether the immediate post-operative care was adequate/appropriate, including the adequacy of relevant checks, visualisations and investigations.

It appears to have been adequate and appropriate.

2.3. If there has been a departure from accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

Based on the documentation provided, I can see no definite evidence of substandard surgery. Subsequent events suggest a urethral injury had occurred, which was unrecognised at the time of surgery. The question then becomes whether [Dr B] took appropriate steps to minimise the risk of injury and to identify if any such injury occurred. The operation note does not specifically address these questions and reads as a record of a straightforward uncomplicated procedure. I suspect, albeit with the benefit of hindsight, that there was injury to the urethral wall during the surgical dissection. This would be potentially difficult to recognise. This injury, in the presence of the mesh sling, likely progressed over time to reach the state identified in 2019.

Published literature estimates the incidence of urethral injury at TVT-O to be approximately 1% (Morton, BJOG 2009;116:1120–1126). The fact the injury occurred is not evidence of substandard care. As reasonable steps to avoid and/or identify such an injury are described in the operation note, then I cannot conclude there was a departure from accepted practice.

2.4. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

No. Since 2018 a number of measures have been initiated nationally.

3. [Ms A's] post-operative care at [Dr B's] clinic on 24 June 2016, noting:

- *[Ms A's] reported symptoms;*
- *That [Dr B] did not personally examine [Ms A];*
- *The lack of an MRI (or other scan);*
- *The prescription of oxybutynin, ural sachets, and lignocaine gel; and*
- *The timing (8 weeks) of the arranged further follow-up.*

3.1. In your opinion, were the decisions, investigations, information provided and treatment plan reached at the 24 June 2016 post-operative clinic in line with accepted practice? Please explain why/why not.

The symptoms reported by [Ms A] on 24/6/16 are strongly indicative of significant complications of the TVT-O. It was quite remiss of [Dr B] to not assess her himself after hearing of her ongoing problems. Certainly by the 6 week mark the patient should be able to tolerate a clinical examination. That alone should have alerted [Dr B] to the possibility of significant ongoing problems and he should have assessed her himself.

3.2. If there has been a departure from accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

In my opinion, [Dr B's] decision to not personally examine [Ms A] despite hearing of her symptoms at a time when she should be recovered from her surgery does amount to a departure from accepted practice, which I would rate as moderate.

3.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

No. The requirements for credentialling of surgeons to perform these procedures includes knowledge of the complications and how they should be managed.

4. Please comment on [Dr B's] qualifications to perform TVT-O surgery, more information about which can be found in his response to Advocacy, and Taranaki DHB's response to HDC.

This is difficult to answer as there are, generally speaking, no formal "qualifications" relating to the performance of most specific surgical procedures. The qualifications, experience and assessment/observation described by [Dr B] in his response would be compatible with the standards expected at that time.

5. More generally, please advise on the qualification requirements obstetricians and gynaecologists must meet in order to perform TVT-O surgery.

As alluded above, in 2016 there were not really any specific qualification requirements for surgeons to meet in order to perform TVT-O surgery, or indeed most other surgeries. Surgeons would generally require sign-off by the credentialling committees of the hospital in which they operate. Fine details of this process probably vary from place to place but would rarely (I suspect!) involve a level of detail to include every specific procedure.

This has changed since 2018 when a formal requirement for credentialling specifically for TVT-O and related procedures was introduced nationally.

6. Are there any other matters in respect of [Dr B's] care that warrant comment?

No.

Taranaki DHB

1. Please comment on the approach taken by clinicians who examined [Ms A] since the TVT-O procedure. In particular:

1.1. The management and transfer of [Ms A's] care between consultants.

1.2. The follow up of referrals to [the second DHB].

1.3. The assessments and investigations undertaken. In particular, the timeliness of a scan to check the positioning of the mesh.

2. For each question, please advise:

2.1. What is accepted practice?

2.2. If there has been a departure from accepted practice, how significant a departure do you consider this to be (mild, moderate or severe)?

2.3. Do you have any recommendations for improvement that may help to prevent a similar occurrence in future?

Overall, the care provided by Taranaki DHB appears to have been somewhat haphazard, chaotic and unnecessarily slow. Ideally [Ms A] would have continued under the care of [Dr B]. However, for reasons not apparent to me, she continued most of her follow-up with [Dr C]. When he saw her in October 2016 she did seem relatively settled. However, by August 2017 there were definite signs of significant problems. Strangely, despite identifying problems and making several suggestions about future pathways to pursue, nothing seems to have been arranged following this assessment. The final diagnosis was not made until a cystoscopy was performed in November 2019. Had [Dr C] followed up on his own suggestion to refer to ACC and a Urogynaecologist in August 2017, it is easy to see that an earlier diagnosis and treatment could have been achieved. Had a specialist with experience of these procedures (eg [Dr B] — I'm assuming that [Dr C] did NOT) been responsible for follow-up then the need for cystoscopy may also have been recognised earlier.

Referral to a Urogynaecologist in [the main centre] was made in October 2018. ACC paperwork was completed the following month. [Ms A] was not seen in [the main centre] until August 2019. This represents a further delay and is without explanation. The one point to make is that had ACC referral and funding been arranged sooner, then [Ms A] would have likely been seen sooner.

The inexplicable inaction of [Dr C] following the August 2017 consultation appears to have resulted in significant and wholly unnecessary delay in [Ms A's] care. In my opinion, the interval of greater than one year to follow up on the proposed pathways to expedite care does represent a departure from accepted standards of care. The significance of this departure is difficult to state. I suspect that [Dr C] was working outside of his comfort zone, having limited experience of the TVT-O procedure and its follow up … He also appears to have been a genuinely caring and thoughtful clinician. However, after careful consideration the significant delay in acting on his clinical findings represents a moderate departure from accepted standards of care.

3. Are there any other matters in respect of Taranaki DHB's care that warrant comment?

No.

Conclusion

[Dr B] failed to provide sufficient information to [Ms A] as part of the consent process prior to her surgery. He also failed to act appropriately by not assessing her personally at her follow-up appointment. Each of these represents a moderate departure from accepted standards of care. The ongoing care and follow-up provided by Taranaki DHB was inadequate and represents a moderate departure from accepted standards of care.

Most of the concerns raised by this case are reflected in current processes in place since 2018 or being introduced to ensure surgeons performing procedures for urinary incontinence are credentialled. Therefore, there are no further actions to recommend. Also, the TVT-O and similar transobturator slings are now rarely performed.

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

Yours Sincerely,

John Short

19 December 2023.

Addendum to report

In response to my report (above) the deputy commissioner has formed a provisional opinion. [Dr B] has responded to this and raised some points for me to consider. I should note that I do not have a copy of the provisional opinion.

Firstly, with regard to the consent process. My report states that "*[Dr B] failed to provide sufficient information to [Ms A] as part the consent process prior to her surgery*". This is based on the omission of key information such as injury to the bladder or urethra and discussion of alternative treatments.

It is noteworthy that [Dr B] was the 3rd specialist to see [Ms A] and by this time the decision to pursue Transobturator mesh surgery was more or less accepted. I also note that the consent process described by [Dr B], and supported by the documented events, is consistent with the highest standards. This includes a multi-step process, supported by written information (in this case the RANZCOG leaflet), with repeat visits for further discussion and signing of the consent form deferred until after the patient's key concerns have been discussed. Unfortunately the verbal discussions do not appear to have specifically highlighted some significant risks including the common risk of mesh exposure and the uncommon but potentially devastating risk of urethral injury.

[Dr B] and his advisors argue that his responsibilities in this area are covered by provision of the RANZCOG information leaflet. I disagree. Common and significant risks should be discussed verbally with the patient. The purpose of an information leaflet is to serve as an adjunct to these discussions. I attach a RANZCOG document in support of my viewpoint[10]. The following is a statement from the NHMRC (2004):

Pre-prepared material (translated where relevant) about a procedure or treatment may be useful if given to the patient as a means of stimulating discussion and for guiding the medical practitioner when informing the patient. However pre-prepared material should not be used as a substitute for ascertaining whether a person understands the nature of, and risks involved in, the procedure or treatment, as the provision of the pre-prepared material alone will not discharge the legal duty in most cases. The practitioner should assist the patient to understand the material and explain any information that the patient finds unclear. The practitioner must give the patient an opportunity to read the material and raise any specific issues of concern either at the time the information is given to the patient or subsequently.

However, after reflection and careful consideration I do believe that I was somewhat harsh in my initial comments about [Dr B] regarding the consent. As stated above, he was the third specialist to see [Ms A] and the decision to pursue surgery had already been made. Therefore, in these circumstances, it was reasonable to not pursue a conversation regarding non-surgical options. Also, again as stated above, the consent process utilised by [Dr B] is consistent with the highest standards. The only problem was the key risks he omitted to discuss were precisely those that the consumer fell victim to. Considering this in the overall context of the consent process employed, I still conclude there was a departure from accepted standards of care although I now consider this to be mild, NOT moderate.

[10] RANZCOG — Category: Clinical Guidance Statement — Position statement on midurethral slings (first endorsed by RANZCOG in March 2014 and current as at July 2020 (amended in March 2022).

The second matter for my consideration is the fact that [Dr B] did not personally review [Ms A] postoperatively on 24/6/2016. This was approximately 6 weeks post-operatively. She was seen by the registrar and a number of symptoms reported. Clinical examination was painful. This was discussed with [Dr B] who recommended some simple measures. Apparently a further review was planned after 8 weeks, with [Dr B], which never occurred as care was transferred to [Dr C]. [Dr B] and his advisors argue that there was no absolute requirement for him to see [Ms A] on that day. I do agree with this, and that it is commonplace for junior doctors to see patients on the specialist's behalf. However, the signs and symptoms described are significant and very much outside what could be considered normal at that stage. Therefore, it would certainly have been ideal for [Dr B] to review her after the registrar that day and I believe most of our peers would agree with me. However, one must acknowledge that other factors may have contributed to his decision not to and that he did he did not dismiss the problems outright but did bring the next review forward. That this review with him did not occur with him was outside his control.

Again, after reflection and careful consideration, I believe I was somewhat harsh in my report regarding the review on 24/6/16. Whilst I am still of the opinion that he should have personally reviewed [Ms A] that day, when reconsidering the bigger picture I now conclude this amounts to a mild, NOT moderate, departure from accepted standards of care.

One other matter on which I will comment is the performance of surgery. My report states that *"Based on the documentation provided, I can see no definite evidence of substandard surgery. Subsequent events suggest a urethral injury had occurred, which was unrecognised at the time of surgery. The question then becomes whether [Dr B] took appropriate steps to minimise the risk of injury and to identify if any such injury occurred. The operation note does not specifically address these questions and reads as a record of a straightforward uncomplicated procedure. I suspect, albeit with the benefit of hindsight, that there was injury to the urethral wall during the surgical dissection. This would be potentially difficult to recognise. This injury, in the presence of the mesh sling, likely progressed over time to reach the state identified in 2019. Published literature estimates the incidence of urethral injury at TVT-O to be approximately 1% (Morton, BJOG 2009;116:1120–1126). The fact the injury occurred is not evidence of substandard care. As reasonable steps to avoid and/or identify such an injury are described in the operation note, then I cannot conclude there was a departure from accepted practice".*

I wish to clarify that ultimately my comment regarding urethral injury amounts to a suspicion and that, even if such an injury had occurred, it cannot be taken as evidence of substandard care as reasonable steps were taken to avoid and identify such an injury.

To summarise, after reflection and careful consideration, I am of the opinion that my initial report was unreasonably harsh on [Dr B]. Therefore my re-assessment of the departures from accepted standards is that they were mild, NOT moderate.

I hope you find this addendum helpful. Please let me know if you require further comment.

Yours Sincerely,

John Short'