District Health Board

A Report by the
Health and Disability Commissioner

(Case 18HDC01162)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a woman who underwent a tension-free vaginal tape (TVT) procedure in 2017 to treat stress urinary incontinence. TVT is a surgical mesh product. In this report, the Commissioner highlights the importance of providers having in place systems that provide an environment to support clinicians to ensure appropriate and effective communication and provision of information to consumers.

2. The woman signed a consent form five months prior to the TVT procedure. The consent form listed three risks: "Infection, bleeding, perforation of adjacent organ". At this time she received an International Urogynaecological Association (IUGA) patient information sheet, which gives more information about the procedure and the associated risks. The surgeon who co-signed the form with the woman was not the operating surgeon. On the day of the procedure, one hour before the woman went to theatre, the operating surgeon discussed the procedure in detail with the woman and updated the consent form to list risks not previously identified on the form.

3. Following the procedure, the woman had a complicated clinical course, including bacterial and fungal infections and pubic osteomyelitis (infection of the pubic bone). The TVT was removed. The woman was admitted to hospital a number of times to treat the infections, and underwent further surgery and received long-term intravenous antibiotics. Sadly, the woman died.

Findings

4. Although the Commissioner did not find that the woman was given inadequate information or did not give her informed consent to the procedure, the Commissioner was concerned that the DHB's processes gave rise to the possibility that consumers could have insufficient opportunity to consider information to which they are entitled, before they consent to a procedure. The Commissioner was also critical that the DHB clinicians did not specifically enquire as to potential causes of the woman's newly developed lowered potassium.

Recommendations

5. The Commissioner recommended that the DHB provide a written apology to the woman's whānau; consider amending its surgical informed consent process for all procedures involving surgical mesh to ensure that consumers, as far as reasonably practicable, meet with the operating surgeon at least a week before the surgery; and consider amending its "Bladder Care for Urogynaecological Surgery" guideline to include routine consideration of post-surgical urine tests for consumers who have certain risk factors.

6. The Commissioner also recommended that the Ministry of Health discuss the anonymised version of this report, and any learnings from the report, at the Ministry of Health's Surgical Mesh Roundtable and/or Surgical Mesh Education and Harm Prevention Programme Steering Group.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint about the services provided by a district health board (DHB) to Mrs A. The following issue was identified for investigation:

- *Whether the district health board provided Mrs A an appropriate standard of care between Month6[1] and Month10 2017 (inclusive).*

8. The parties directly involved in the investigation were:

Ms B	Complainant/consumer's daughter
District health board	Provider/DHB

9. Further information was received from:

Dr C	Consultant
Dr D	Consultant
Dr E	Consultant
Dr F	Consultant
General practitioner (GP)	
Medical centre	

10. Also mentioned in this report:

Dr G	Registrar

11. Independent expert advice was obtained from an obstetrician and gynaecologist, Dr John Short (Appendix A), and an infectious diseases physician, Dr Sarah Metcalf (Appendix B).

Information gathered during investigation

Introduction

12. This report relates to the care provided to Mrs A (in her sixties at the time of events) in relation to a tension-free vaginal tape (TVT) procedure she underwent in Month6 to treat her stress urinary incontinence. The procedure involved placing TVT under the tube that carries urine from the body (the urethra), like a sling, to provide support for the urethra.

13. The report discusses the following issues:

- The process for obtaining Mrs A's informed consent to the TVT procedure and the overall effectiveness of communication with Mrs A.

[1] Relevant months are referred to as Months 1–10 to protect privacy.

- The multiple infections that Mrs A developed following the TVT procedure.
- The appropriateness of Mrs A's clinical course.
- The appropriateness of the medication prescribed for Mrs A, and the effects that the medication had on her.

Surgical mesh in New Zealand

14. TVT is a surgical mesh product. The term "mesh" refers to a permanent implant, usually made from a non-absorbable plastic material. According to the Ministry of Health's website:

> "Surgical mesh is widely used for hernia repair. It is also used in urogynaecological surgery, including in the treatment of stress urinary incontinence (SUI). Surgical mesh was previously used for repair of pelvic organ prolapse (POP) but since regulatory action was taken … no surgical mesh products have been supplied for POP in New Zealand."

Background

Mrs A

15. In 2014, Mrs A was referred by her GP to the DHB's Pelvic Floor Physiotherapy Service for treatment of her urinary incontinence. Mrs A was given advice and education about diet, fluid, and exercise. At the time, her symptoms of urinary incontinence responded well to physiotherapy. Mrs A had several other chronic medical conditions, including Type 2 diabetes.[2]

Referral and booking for TVT procedure

16. In 2016, Mrs A was referred by her GP to the DHB's Gynaecology Service for review of worsening urinary incontinence. It was noted in the referral that Mrs A had trialled the treatments of topical medicine (oestrogen)[3] and pelvic floor exercises. The referral also noted that Mrs A had recurrent urinary tract infections (UTIs).

17. On 24 Month1 2017, Mrs A was seen by an obstetrics and gynaecology (O&G) consultant, Dr C,[4] in the DHB's Gynaecology Service Outpatient Clinic. Dr C documented that Mrs A's incontinence was initiated by a chronic cough and was a daily problem. Following an examination and ultrasound, he diagnosed her with urethral hypermobility (a condition where there is excessive movement of the urethra).[5]

18. Dr C told HDC that his practice is to review the notes of any previous visits for all patients he sees. He stated that he noted the complications of Mrs A's diabetes and the severity of these, as well as her repeated UTIs. He said that he reviewed her most recent urine test which was negative for infection and therefore required no further action.

[2] Her other medical conditions included hypertensive disease, hyperlipidaemia, diabetic retinopathy, and possible gout.
[3] Topical oestrogen is a medicine used to treat symptoms of menopause and urinary incontinence.
[4] Dr C was trained overseas; he was awarded the O&G vocational scope of practice in 2018.
[5] A condition of excessive movement of the female urethra owing to a weakened urogenital diaphragm.

19. Dr C documented the following treatment plan:

> "Our plan is to already start with some conservative therapy; abstain from pushing during voiding, motivate her to drink less coffee after 4pm; a strict control of her diabetes and motivate her to lose weight. We talked about physiotherapy but this was kindly declined by the patient. She was booked for a TVT procedure and cystoscopy [an investigative process to inspect the urethra and bladder]."

20. On the same day, Dr C and Mrs A signed a "Request for Treatment" form (the Consent Form). Dr C documented in the Consent Form that he discussed with Mrs A the following risks of the TVT and cystoscopy procedure: "Infection, bleeding, perforation of adjacent organ." Aside from the conservative therapy discussed (as noted in paragraph 19 above), Dr C did not document having discussed with Mrs A any non-surgical options, or surgical options not involving surgical mesh. In response to the provisional opinion, Ms B also questioned whether her mother should have been offered TVT surgery in light of her pre-existing conditions.

21. Dr C told HDC that he would have provided Mrs A with the International Urogynaecological Association (IUGA) patient information sheets on stress urinary incontinence and mid-urethral sling procedures, as is his usual practice. The IUGA patient sheet on mid-urethral sling procedures for stress incontinence also lists other risks, including difficulty passing urine, sling exposure,[6] urgency and urge incontinence,[7] and pain. Ms B confirmed to HDC that her mother did receive a copy of the IUGA information sheet.

22. The DHB told HDC that the process of exchanging information with Mrs A and obtaining her informed consent for treatment began when she was first seen in 2014, when various options for managing her incontinence were discussed with her and she elected to manage her symptoms conservatively with physiotherapy. The DHB said that when Mrs A was seen by Dr C in Month1, her options were discussed again and this time she opted to have the TVT procedure. The DHB considered that Mrs A was given "more than adequate" time to reflect upon her decision to progress with surgery, in light of her worsening incontinence, in the more than four months between her being booked (in Month1) and the procedure taking place (in Month6 — as set out below).

3 Month6 — Pre-admission Clinic review

23. On 3 Month6, Mrs A was reviewed in the Pre-admission Clinic by a house officer. An examination and other tests (including assessment of Mrs A's heart function) were performed. The house officer concluded that Mrs A was fit for surgery.

9 Month6 — initial hospital admission for TVT procedure

Discussion with Dr D

24. At 7am on 9 Month6, Mrs A was admitted for the TVT procedure.

[6] Whereby the sling appears in the wall of the vagina.
[7] Leakage of urine associated with the sensation of urgency.

25. At 7.45am, consultant Dr D[8] met with Mrs A to discuss the surgery. Dr D documented having discussed the following risks: infection/bleeding/injury to adjacent structures, altered (slowed) urinary flow, 80–90% cure rate, need for mesh revision, including mesh excision, ongoing or worsening urinary urge symptoms, and need for short-term indwelling catheter (IDC)[9] or intermittent self-catheterisation. Dr D also updated the Consent Form to reflect that they had discussed the following risks of the procedure: "Slowing urine flow, mesh erosion, chronic pain, need for catheter, intermittent self-catheterisation, permanency of mesh, worsening urgency, cutting tape."

26. Dr D documented that Mrs A was "happy with discussion of risks + benefits" and that they were to "proceed to [operating theatre]". Dr D told HDC that she recalls that Mrs A already had a good understanding of both the procedure and the associated risks, and Dr D was satisfied that Mrs A had provided informed consent. Dr D stated that if on the day of a procedure she has any doubts that a consumer is not fully informed or has any hesitation about proceeding, she will postpone the surgery and arrange for a clinic appointment to discuss it further.

27. Ms B (Mrs A's daughter) told HDC that she was with her mother at the hospital that day, and was present for the discussion with Dr D. Ms B said that on that morning her mother was still hesitant and having doubts about the procedure. Ms B also noted that on the morning of the operation, Dr D told Mrs A that they could change the date of the procedure if she wasn't happy, but Mrs A said, "Well, we're here now." Ms B acknowledged that her mother had no questions at the time, but said that Mrs A had only an hour to think about the information given by Dr D.

Surgery

28. Dr D, assisted by registrar Dr G, performed the TVT procedure. The surgery began at 8.47am and finished at 9.18am. The DHB told HDC that the procedure was uncomplicated. Dr D documented in the operation note that after placement of the TVT sling, they checked and confirmed that there was no mesh or perforation into the bladder. She also documented that Mrs A was given intravenous (IV) antibiotics during the operation, and that postoperatively she was to be treated in accordance with the "TVT protocol until complete". Mrs A was transferred to the ward at 10.45am.

29. The DHB told HDC that "TVT protocol" refers to bladder care processes following this type of surgery. It provided HDC with copies of its "Bladder Care for Vaginal Surgery" (Bladder Care Protocol) and "Urogynaecology Patients TVT/TOT[10] Post-Operative" (TVT/TOT Care Protocol) guidelines in place at the time of events. The TVT/TOT Care Protocol provided that if after the procedure the patient was retaining more than 200ml of urine following two attempts at emptying the bladder, then a catheter was to be inserted to empty the bladder, and then the residual volume of urine left in the bladder was to be re-checked. The patient

[8] Dr D was awarded the O&G vocational scope of practice in 2011.
[9] An IDC is a tube inserted into the bladder to drain urine, with the tube held within the bladder by a small balloon that is filled with sterile water.
[10] TOT refers to transobturator tape, and is another surgical procedure involving mesh used for the treatment of stress urinary incontinence.

could return home once less than 200ml of residual urine was left in the bladder on two consecutive occasions.

Post-surgical care and discharge

30. On 10 Month6, Mrs A was reviewed by Dr G. Dr G noted that Mrs A was well and mobile, and eating and drinking, but had variable residual urine (0–420ml) in her bladder following urination. Dr G's plan was to keep Mrs A as an inpatient, insert a catheter, and send a urine sample to the laboratory for testing. At 9.50am, an IDC was reinserted by nursing staff. The urine sample obtained that day was reported at 11.58am on 12 Month6 as positive for a bacterial infection (*E. coli*[11]).

31. At 8.15am on 11 Month6, Mrs A was reviewed again by Dr G. Dr G noted that Mrs A was "doing well", was comfortable, her bowels were moving, and she had 12ml of residual urine after passing 300ml. Dr G's plan was to trial removal of the IDC, follow the TVT protocol, and then discharge Mrs A home once completed, with a follow-up review with Dr D in six weeks' time. Mrs A was discharged at 11.27am.

11 Month6 — second hospital admission

32. Later that evening at 6.50pm (11 Month6), Mrs A presented to the Emergency Department (ED). Since 5pm that day, Mrs A had been experiencing shakes, feeling hot and cold, was giddy on her feet, and had increased shortness of breath. While in ED, Mrs A had a period of confusion.

33. Mrs A was assessed by Dr D at 11.30pm. The clinical notes acknowledge the positive *E. coli* result from the catheter urine sample taken on 10 Month6, and that this had not been treated. Mrs A was admitted under the care of the acute Gynaecology team and began receiving IV antibiotics (cefuroxime).

34. At 5am on 12 Month6, tests confirmed that Mrs A had a bacterial blood infection.[12] At 11am, Mrs A was noted to be grimacing and moaning in pain, with an irregular heart rate, increased respiratory rate, and increased temperature. Following discussion with an infectious diseases consultant, her antibiotic medication was changed.[13] Subsequently, she was diagnosed with urosepsis (a condition caused by a bacterial infection of the urinary tract that spreads to the bloodstream).

35. Mrs A remained in hospital until 18 Month6. During that time, she had elevated markers in her blood indicating ongoing infection/inflammation, and she continued to receive IV antibiotics. On discharge, Mrs A was noted to be feeling much better, and the urosepsis appeared to have resolved. She was to be reviewed in the Gynaecology Clinic four to six weeks after discharge.

[11] *Escherichia coli* (*E. coli*), a gram-negative bacterium found in the digestive tract, is commonly responsible for urinary tract infections.
[12] Her blood cultures tested positive for Gram negative bacilli — a group of disease-producing bacteria.
[13] To meropenem, a broad-spectrum antibiotic.

24 Month6 — third hospital admission

36. At approximately 4.45pm on 24 Month6, Mrs A returned to the ED with pelvic pain and fevers, as well as newly developed bowel incontinence. Mrs A was admitted under the care of the Gynaecology team. Her blood tests were again abnormal. After consultation with the Infectious Diseases team it was recommended that imaging be undertaken to investigate whether any abscess or fluid collection had developed.

37. At 12.45pm on 25 Month6, a CT[14] scan showed a small 10mm fluid collection in Mrs A's pelvis. IV antibiotics (meropenem) were restarted later that afternoon. It was documented that if Mrs A's pain did not improve within 24 hours, she was to be reviewed by the Orthopaedics team for the possibility of a bone infection.[15]

38. On 27 Month6, Mrs A was reviewed by a registrar, who documented that Mrs A was miserable with ongoing pain, and had had drenching sweats overnight. The registrar discussed with Mrs A the possibility of an MRI scan, as recommended by the Orthopaedics team. The registrar noted that Mrs A had experienced severe anxiety and claustrophobia when she had undergone an MRI years earlier. The registrar documented: "Under no circumstances will [Mrs A] consent to an MRI even with sedation" (emphasis in original).

39. Dr D reviewed Mrs A on 28 Month6 and noted that while a bone infection was "very unlikely", that possibility needed to be excluded. Later that day, the Radiology team reviewed the CT scan and advised the O&G team that there was no obvious suggestion of a bone infection.

29 Month6 — discharge

40. On 29 Month6, Mrs A was reviewed by an infectious diseases consultant, who considered it likely that Mrs A had a soft tissue infection, and that bone/joint involvement was "less likely". The consultant's recommendation was that a PICC[16] line be placed, and that Mrs A be referred to the Outpatient Intravenous Antibiotic (OPIVA) team to receive ongoing IV antibiotics until 15 Month7. Mrs A was discharged home that afternoon, and received daily district nurse home visits from 30 Month6 until 19 Month7.

14 Month7 — Infectious Diseases Clinic review

41. On 14 Month7, Mrs A was seen in the Infectious Diseases Clinic by a registrar. Mrs A's inflammatory markers in her blood remained mildly high (though reduced from previous testing). In his clinic letter, the registrar noted that Mrs A's recovery had been slow since discharge, and accordingly her antibiotic treatment was extended for another week. No further Infectious Diseases Clinic follow-up was planned.

[14] Computerised tomography.
[15] Osteomyelitis — an infectious, usually painful, inflammatory disease of bone that is often of bacterial origin and may result in death of bone tissue.
[16] Peripherally inserted central catheter, which is used for a number of treatments, including long-term antibiotics.

19 Month7 — fourth hospital admission

42. On 19 Month7, Mrs A was visited by a district nurse. The nurse rang the Infectious Diseases team to discuss concerns that Mrs A had a temperature of 38.7°C with chills, increased pain in her abdomen and lower back, and an increase in her inflammatory markers. The Infectious Diseases team advised Mrs A to present to the public hospital. She was admitted that day under the care of the Gynaecology team.

43. On 20 Month7, with Mrs A's consent, it was decided that Mrs A would undergo an MRI scan under general anaesthetic. The MRI was performed the following day, and the reported findings included: "Appearances are in keeping with infected TVT mesh complicated by osteomyelitis [bone infection] of the pubic bones bilaterally …" The MRI also indicated stress fractures.[17] Dr D told HDC that after the MRI, Mrs A recalled having had a fall a few days before the TVT surgery, and having since experienced persistent pain in her pelvis. Orthopaedic surgeon Dr F told HDC that the stress fractures were most likely caused by a decrease in Mrs A's bone density (osteopenia).[18] He said that treatment for the stress fractures had to be delayed until the infection was under control.

44. On 22 Month7, Mrs A was reviewed by the Orthopaedics team, which suggested that very strong consideration be given to the removal of the TVT. Mrs A was noted to be "very happy" to have the TVT removed. Dr D met with Mrs A at 4pm that day, and they discussed the risks of surgical removal of the TVT.

23 Month7 — removal of TVT

45. Dr D removed the TVT on 23 Month7.

28 Month7 — discharge

46. Mrs A remained in hospital until 28 Month7. Her inflammatory markers tested on 25 and 26 Month7 remained elevated. The discharge plan was for Mrs A to receive a further six weeks of IV antibiotics, combined with six weeks of oral antibiotics.[19]

47. Mrs A received daily district nurse home visits from 29 Month7 to 18 Month8. Blood tests were performed on 3 Month8, 5 Month8, 10 Month8, and 17 Month8. On 4 Month8, Mrs A was symptomatic of low iron (anaemia). She was treated with blood and iron transfusions in the Gynaecology Clinic.

18 Month8 — fifth hospital admission

48. On 18 Month8, Mrs A returned to the public hospital ED. She reported having lower back pain, decreased appetite, and dizziness. On 20 Month8, a CT scan showed further infection in the pelvis and progression of the infection in her bone.

49. On 21 Month8, the infected collection in Mrs A's pelvis was drained. Laboratory tests indicated that the cause of the infection was a different bacteria from that found by the

[17] Insufficiency fractures are a particular type of stress fracture that predominantly occur in patients with decreased bone quality.
[18] Osteopenia is a common ageing process.
[19] An antibiotic medication.

previous tests. As a result, Mrs A was commenced on a different IV antibiotic.[20] Her care was then transferred to the Orthopaedics team.

30 Month8 — surgical debridement and resection

50. On 30 Month8, Dr F operated on Mrs A and removed the infected fluid, soft tissue, and bone, and took bone samples for later testing. He documented finding a significantly infected joint (between the two pelvic bones) and removing some very soft bone. Dr F also placed a device[21] in the pelvis to treat the ongoing infection and to make future operations easier. He recorded in his operation note that in the future Mrs A would most likely need reconstruction of her pelvic joint. Dr F told HDC that the surgery was "a large operation that had a large amount of blood loss".

51. During surgery, it was noted that Mrs A had an abnormal heart rhythm. On 3 Month9, in accordance with a recommendation from the Cardiology team, an ECG (heart monitor test) was performed and was reported as showing no significant abnormalities of Mrs A's heart or its function.

52. Tissue samples taken during the surgery subsequently tested positive for a number of bacterial and fungal infections.[22] Accordingly, on 6 Month9, Mrs A's medication was again changed to cover those infections.

53. On 7 Month9, Mrs A was reviewed by Infectious Diseases consultant Dr E. Dr E noted that Mrs A would need ongoing blood tests to monitor her infection and maintain consistent levels of medication in her system.

10 Month9 — discharge

54. Mrs A was discharged on 10 Month9, with a plan for GP review in two weeks' time, orthopaedic review in six weeks' time, and a heart function test. She received daily district nurse home visits from 11 Month9 to 16 Month10, and had blood tests twice a week.

55. On 27 Month9, Mrs A's potassium level was slightly below the normal range,[23] although it had returned to the normal range on 30 Month9. However, on 4 Month10, her potassium level was again noted to be low,[24] and she was prescribed potassium replacement by the Infectious Diseases team. Mrs A's potassium levels were tested on 7 and 11 Month10, and were closer to the normal range.[25]

[20] An antibiotic medication.
[21] An antibiotic-loaded cement spacer — a device used to provide support to preserve joint function and to enable local antibiotic delivery to prevent post-surgical infection.
[22] Extended spectrum beta-lactamase *E. coli*, *Enterococcus faecalis*, *Staphylococcus lugdunenerosis*, *Staphylococcus epidermidis*, Corynebacterium (a genus of usually gram-positive bacteria), and Candida (a genus of parasitic fungi).
[23] 3.3mmol/L — the normal range is 3.5–5.2mmol/L.
[24] 2.9mmol/L.
[25] 3.2mmol/L and 3.4mmol/L respectively.

8 Month10 — Orthopaedic Clinic review

56. On 8 Month10, Mrs A was seen in the Orthopaedic Clinic by Dr F. Dr F noted that her inflammatory markers had reduced but were still elevated. His plan was to give Mrs A a break after she completed her antibiotic treatment, and then to undertake further surgery (to remove infected tissue), with the goal of performing a reconstruction in the future.

14 Month10 — Infectious Diseases Clinic review

57. On 14 Month10, Mrs A was seen in the Infectious Diseases Clinic by a registrar, who noted that Mrs A reported being well, and able to mobilise with her walker. She was no longer taking any pain relief, and did not have ongoing pelvic pain. Dr E also reviewed Mrs A, and changed her medication to a three-month course of oral antibiotics,[26] along with the antifungal medication.[27]

16 Month10 — collapse and return to hospital

58. On 16 Month10, Mrs A was visited by a district nurse and noted to have a fever. Later that day, she collapsed while in the bathroom. An ambulance was called and she was taken to the public hospital. Her potassium level was low (2.6mmol/L) and she had multiple episodes of an abnormally rapid heart rhythm.

59. Mrs A was admitted to the Intensive Care Unit and required intubation and ventilation. However, she made poor progress and her neurological prognosis was considered to be poor. Following a discussion with Mrs A's whānau, the decision was made to provide comfort cares only. Sadly, Mrs A passed away at 5pm on 18 Month10.

60. In relation to the cause of Mrs A's death, the DHB told HDC that her cardiac arrest was thought to be related to her low potassium level, secondary to the prolonged use of an anti-fungal medication for the treatment of her severe pelvic infections following her TVT surgery.

61. Dr E told HDC that following Mrs A's death, he and another specialist met with two of Mrs A's daughters. He expressed his sorrow and offered his condolences for Mrs A's death. He stated:

> "I acknowledged that [Mrs A's] antifungal and antibacterial treatment may have contributed to causing ventricular tachycardia [abnormal heart rhythm], along with low potassium, as well as other potential contributors including the possibility of a heart attack. I explained the rationale for the choice of fluconazole and ciprofloxacin which was required to treat her severe bone infection … [Mrs A's] daughters informed me that [Mrs A] had complained of some diarrhoea prior to her collapse, which I explained may have contributed to her low potassium."

[26] Augmentin and ciprofloxacin.
[27] Fluconazole.

Further information

Ms B

62. Ms B told HDC that her mother was a very strong lady, and she wanted to know where it all went wrong. Ms B said that on the day of the surgery, her mother had doubts, but in the end she was convinced because she thought it would stop all the problems she was having. Ms B stated: "[T]o me the cause of all this was the first op TVT then all the ongoing different infections and drugs."

DHB

63. The DHB expressed its sincere condolences to Mrs A's family, and said that all staff have expressed their sadness at the tragic and unexpected passing of Mrs A. It further stated: "All specialties involved in the care and treatment of Mrs A have discussed this very rare and tragic outcome and reflected on how it might have been avoided."

64. Mrs A's case was discussed at the Department of Orthopaedic Surgery's meeting held on 12 February 2018, and as part of the Infectious Diseases team's morbidity and mortality review on 6 March 2018.

Responses to provisional opinion

65. Ms B and the DHB were both given the opportunity to respond to relevant sections of my provisional opinion. Where appropriate, their responses have been incorporated into this report.

66. In addition, Ms B told HDC that she was happy to hear that changes had been made at the DHB following these events, but she wished that those changes had already been in place when her mother was alive. She added that the doctors who were involved in the family meeting following her mother's death, including Dr E, were really good.

67. The DHB told HDC that its view is that Mrs A was afforded her rights to be fully informed and to receive effective communication. The DHB stated that at no stage over the course of Mrs A's interaction with the Women's Health service was there any concern that Mrs A did not understand the nature of the information being provided to her, or that the form, language, or manner of the information provided was such that she did not understand the options open to her (and the associated risks) for treatment of her incontinence.

68. The DHB reiterated that on the day of surgery, as Dr D explained, Mrs A seemed to have a good understanding of the procedure and the associated risks. The DHB further noted that although Mrs A had doubts that day, it is not uncommon for patients to express doubts on the day of surgery, and Mrs A's doubt was indicative of both Mrs A's understanding of the information, as well as an environment that enabled Mrs A to communicate openly, honestly, and effectively.

69. Lastly, the DHB noted that since the time of Mrs A's surgery, concerns have been raised internationally around the use of surgical mesh. The Ministry of Health, in response to these concerns, led a process to hear directly from New Zealanders affected by surgical mesh and, in 2019, it released a decision-making support document called "Considering Surgical Mesh

to Treat Stress Urinary Incontinence?". The DHB stated that it adopted this immediately as part of its standard consent process for women considering surgical management of their stress incontinence.

Opinion: District health board — adverse comment

Introduction

70. Mrs A's clinical course was tragic and unexpected. As noted by both my clinical advisors, obstetrician and gynaecologist Dr John Short, and infectious diseases physician Dr Sarah Metcalf, it is extremely rare to develop osteomyelitis (bone infection) following a TVT procedure. I also acknowledge the complexities that the DHB faced in treating the aggressive multiple infections that Mrs A developed following the TVT procedure.

71. However, and as discussed in more detail below, I am concerned that the DHB's systems did not support its clinicians appropriately to discuss with Mrs A information about the TVT procedure, including the risks and alternative treatment. I also discuss below the management of Mrs A's infections.

Gynaecology care — TVT procedure

Effectiveness of communication and informed consent process — adverse comment

72. Mrs A was booked for the TVT procedure by Dr C in Month1. The Consent Form shows that the only documented risks discussed were "[i]nfection, bleeding, [and] perforation of adjacent organ". Dr C told HDC that it was his usual practice to discuss these risks verbally in more detail. He also provided IUGA patient information sheets, which give more information about the procedure and the associated risks, but this was not documented. Ms B confirmed that Mrs A received a copy of the IUGA information sheet.

73. Mrs A was seen at a pre-admission clinic on 3 Month6, although there is no evidence that the TVT procedure was discussed further at that time.

74. On 9 Month6, approximately one hour before the TVT procedure, Dr D spoke with Mrs A. Dr D documented her discussion with Mrs A, including a number of risks and complications, and updated the Consent Form accordingly. Dr D told HDC that she felt that Mrs A had a good understanding of both the procedure and the associated risks. Dr D said that she was satisfied that Mrs A had provided informed consent.

<u>Clinical advice</u>

75. My advisor, Dr Short, noted that according to what Dr C documented during his consultation with Mrs A, "no other surgical options (e.g. those not requiring surgical mesh) were discussed. Nor was there any discussion about the impact of Mrs A's co-morbidities on her risk profile, which would have been significantly increased for surgery compared with non-surgical management." Dr Short further advised:

> "The risks documented on the consent form are limited to 'infection, bleeding, perforation of adjacent organ', which falls far short of covering the full spectrum of risks relating to that particular surgery. I would expect a consent process to also cover a discussion of the risks of bladder emptying issues, development of an overactive bladder, the possibility of treatment failure, together with the risks of mesh-related complications such a mesh exposure, pelvic pain and painful intercourse.
>
> … Based on the available documentation (i.e. what is written on the consent form, as this is all that was documented) [Dr C] did not provide sufficient information to [Mrs A] regarding the risks of surgery. However, one must consider that, as he was not the operating surgeon, technically this is not his ultimate responsibility."

76. Dr Short advised that it was the responsibility of Dr D, as the operating surgeon, to ensure that Mrs A had given her informed consent to the TVT procedure. I note that Dr Short considered that Dr D provided appropriate information and "did her very best" to ensure that Mrs A's consent was obtained adequately on the day of the TVT procedure. However, Dr Short noted that the information was provided by Dr D "barely one hour prior to the actual surgery being performed (i.e. too close to allow [Mrs A] to reflect upon on any new information provided)".

77. Dr Short commented:

> "[The DHB] should have better systems in place to support specialists in discharging this responsibility, especially if they are to be expected to operate on patients whom they have not previously met. Ideally, this would involve meeting the patient prior to the day of surgery to have further discussions and confirm the consent."

78. Dr Short also noted:

> "[U]nder the process followed at [the DHB], it appears the consent form is signed at the same time as written information is given. This makes it virtually impossible for the patient to read the information leaflet prior to signing the consent form. An ideal consent process would entail the patient having time to read the information prior to further discussion about the surgery and a later signing of the consent form."

79. In Dr Short's view, the DHB did not provide the appropriate environment/systems for its surgeons to obtain appropriate consent. Dr Short considered that this represented a moderate departure from accepted standards.

Discussion

80. I accept the DHB's submission that consent is an ongoing process. I also acknowledge, as pointed out by the DHB, that in addition to the discussion with Dr C in 2017 (in which no other surgical options (eg, those not requiring surgical mesh) were discussed), non-surgical and other treatment options for urinary incontinence were discussed with Mrs A previously in 2014.

81. However, I also agree with Dr Short that, based purely on what was documented in Month1, there is concern about the adequacy of information given to Mrs A about the surgical procedure. The clinical notes refer only minimally to some risks, do not reference other risks that should have been discussed, and do not indicate that Mrs A was provided any additional information such as the information sheet. This put Dr D, the operating surgeon, in a difficult position on the day of the procedure. She was required to address what would have appeared to be deficiencies in information provided to Mrs A by fully discussing the risks and potential complications of the TVT procedure only one hour before the operation, having not met with Mrs A previously. This meant that the consent form was added to, notwithstanding it having been signed months earlier.

82. In this latter respect, I note that the Medical Council of New Zealand statement on "Information, choice of treatment, and informed consent"[28] states: "The patient must have the opportunity to consider and discuss the relevant information with the treating doctor."

83. The question is whether new and salient information was given to Mrs A only an hour before her surgery in an environment that did not give Mrs A enough opportunity to reflect on and consider that new information.

84. Dr Short's criticisms are based on the written record, and his understanding that significant information was given to Mrs A "for the first time" on the day of the procedure. He also said that ideally patients should have the opportunity to reflect on written information provided to them.

85. We now know that Mrs A did receive the information sheet in Month1, which contains detailed information about the procedure and its risks. However, we do not know whether she read it. Ms B has expressed her genuine concern that her mother did not have adequate time to reflect on the day of the operation.

86. Dr D's evidence is that she spent considerable time with Mrs A on the day of the procedure, and she recalls Mrs A having a good understanding of the surgery and it associated risks. Dr D was satisfied that Mrs A had provided informed consent, commenting that if Mrs A had had any doubts, the surgery would have been postponed.

87. Regrettably, given Mrs A's death, it is not possible to determine exactly what Mrs A understood at the time about the TVT procedure, including the risks, possible complications, and alternative treatment options. I do, however, accept that she was given relevant information prior to the day of surgery in the form of the information sheet, and that Dr D proceeded in the belief that informed consent had been given properly.

88. I nevertheless have residual concerns about the DHB's informed consent processes, which permit consumers to sign consent forms on the same day as receipt of detailed written information, and that potentially the process allows new, significant information to be provided to patients on the day of their procedure by a clinician whom the consumer has never met previously. In both situations, the consumer does not have adequate opportunity

[28] March 2011.

to fully consider information given to them, and their right to give informed consent is at risk.

89. In making these comments, I am not finding that Mrs A was not given sufficient information or that she did not give her informed consent to the TVT procedure. Rather, my concern is that the DHB's processes give rise to the possibility that consumers will have insufficient opportunity to consider information to which they are entitled, before they consent to a procedure.

90. It is important to acknowledge Dr Short's further comments:

> "[I]t must also be clearly understood that an alternative consent process would be unlikely to have altered the final outcome of this case. [Mrs A] appeared motivated towards surgical treatment and osteomyelitis is extremely rare in this situation, so would not have been specifically referenced in any discussion. Also, although there was no apparent discussion of other surgical options, I would agree that the best surgical treatment for [Mrs A] was indeed a TVT, particularly in view of her co-morbidities (obesity, diabetes etc) and the fact that this procedure is associated with reduced peri-operative morbidity compared to other incontinence surgeries. Other incontinence surgeries would also have the potential to lead to osteomyelitis."

91. In addition, I acknowledge that the DHB has since adopted the Ministry of Health's document "Considering Surgical Mesh to Treat Stress Urinary Incontinence?". In my view, this will help to support clinicians to communicate effectively with consumers and to ensure that consumers have been adequately informed with respect to surgical mesh procedures for urinary incontinence. I make further recommendations below as to how the consenting process could be improved.

Discharging Mrs A on 11 Month6 — other comment

92. Following the TVT procedure, Mrs A was discharged home on 11 Month6 before the results from the catheter urine sample taken on 10 Month6 were available.

93. I note Dr Short's advice:

> "The decision to discharge [Mrs A] on 11 [Month6] was very reasonable, based on the information available. She was voiding, observations were normal and no problems or concerns were reported."

94. I accept this advice. However, in retrospect and with the knowledge that Mrs A did in fact develop an infection that resulted in her readmission to the public hospital later that day, I note that it would have been ideal to have had the results of the catheter urine sample before the decision was made about discharge. Nonetheless, in the circumstances, and in particular that Mrs A was asymptomatic at the time of discharge, I am not critical that Mrs A was discharged before the test results became available.

Infectious Diseases care

Management of Mrs A's infections — adverse comment

95. Infection was a known risk of the TVT procedure and, unfortunately, Mrs A developed multiple infections following the TVT procedure. My clinical advisor, Dr Metcalf, summarised Mrs A's post-surgical clinical course as follows:

> "[Mrs A] suffered an extremely rare and complex complication of her TVT surgery with initial urosepsis as well as infection of the TVT tape/mesh and secondary pelvic osteomyelitis/myositis/pelvic collection. This infection was made even more complex by the multiple pathogenic bacterial and candida species isolated [multiple bacterial and fungal causes of the infection], all of which have to be presumed to be involved in her infection due to isolation from usually sterile sites such as blood cultures, bone biopsies, urine and aspirates from abscesses. Many of these bacterial organisms had limited anti-bacterial susceptibility. The result of this is that multiple different anti-bacterials were required to adequately treat her infection."

96. Following Mrs A's collapse on 16 Month10, she was found to have a very low level of potassium in her blood (2.6mmol/L). A few weeks before her death, in late Month9, her potassium level had been noted to be low. On 4 Month10, she was prescribed potassium replacement by the Infectious Diseases team. Subsequent blood tests showed that her potassium level was increasing and closer to normal.

97. Dr Metcalf advised:

> "Overall the Infectious Diseases team provided very good care to [Mrs A] throughout the course of her multiple admissions with timely input, appropriate management plans and follow up."

98. Dr Metcalf also considered that by providing a prescription for potassium replacement on 5 Month10, the Infectious Diseases team responded to Mrs A's low potassium on 4 Month10 appropriately. However, Dr Metcalf also commented:

> "Prior to [late Month9], [Mrs A] had consistently had normal serum potassium levels, therefore a change in serum potassium should have triggered an enquiry as to the potential cause (eg. addition of medication such as furosemide, vomiting or diarrhoea). [Mrs A] didn't volunteer any 'side effects from her current antibiotics' during her last consultation on 14 [Month10], although it is unclear whether specific enquiry was made regarding gastrointestinal symptoms or new medications."

99. I accept Dr Metcalf's advice that, overall, the care provided to Mrs A by the Infectious Diseases team was of an appropriate standard. However, I agree with Dr Metcalf that the Infectious Diseases team should have specifically enquired as to potential causes of the newly developed lowered potassium (hypokalaemia) in late Month9. I note that it is not possible to determine whether such enquiry would have changed Mrs A's clinical course. I also acknowledge and commend the changes made to the OPIVA guidelines, which

specifically highlight the need for consumers to report diarrhoea (because of its link with low potassium).

Appropriateness and effects of medication — other comment

100. Shortly before Mrs A's collapse on 16 Month10, her medication regimen had changed from IV to oral antibiotics. She was also taking antifungal medications. Following her collapse, Mrs A was noted to have multiple episodes of abnormal heart rhythm. Dr E acknowledged that the antifungal and antibacterial treatment may have contributed to Mrs A developing the abnormal heart rhythm.

101. Dr Metcalf considered that the decision to change Mrs A to oral medications was "reasonable and appropriate", and that the medication prescribed was "the only oral antimicrobial to treat all pathogens".

102. Dr Metcalf also discussed whether Mrs A's medications caused abnormal heart rhythms. Dr Metcalf noted that, broadly, the types of oral antifungal and antibacterial medications that Mrs A was taking are associated with abnormal heart rhythms. However, she also noted that the specific antibiotic that Mrs A was taking at the time of her death is thought to have the "weakest" effect on the heart rhythm. Dr Metcalf also noted two studies undertaken in respect of combining the relevant types of oral antifungal and antibacterial medications, which reached differing conclusions on whether such medications do in fact cause clinically significant changes in heart rhythms.[29] Ultimately, in Dr Metcalf's view, the most significant contributor to Mrs A developing an abnormal heart function prior to her death was not the medications, but rather the low level of potassium in her blood (discussed in further detail above).

103. I accept Dr Metcalf's advice. I acknowledge the difficulty faced by the Infectious Diseases team in balancing treatment of Mrs A's infections with antifungals and antibiotics, against the effects of those medications on heart function. The medication that Mrs A was taking at the time of her death may have had an impact on her heart function. In any case, the medication was necessary and appropriate to treat the complex infections that, unfortunately, Mrs A had developed.

Changes made

104. The DHB told HDC that since these events it has made the following changes:

- The women's health services introduced a process whereby each surgical booking will be assessed to determine whether the procedure is being done by the consenting/clinic doctor and, if required, will arrange a clinic appointment with the operating surgeon.

[29] Dr Metcalf discussed the following two papers: Zeuli et al. AAC; 2013; 57: 1121–27; and Berger et al. BJCP 2018; 84: 369–78.

- It now provides all women considering surgical mesh as treatment for stress incontinence with a copy of the Ministry of Health's document "Considering surgical mesh to treat stress urinary incontinence?" (released August 2019).
- The Bladder Care Protocol and the TVT/TOT Care Protocol have been revised and incorporated into one document entitled "Bladder Care for Urogynaecological Surgery".
- The OPIVA patient information booklet has been updated to highlight the need to call an ambulance if a patient collapses or faints, and advice to contact the OPIVA team in the event of diarrhoea (which may cause low potassium).
- The orientation material for new Infectious Diseases registrars has been updated to emphasise the importance of supporting the OPIVA service, and to add information about the effects on heart function (specifically, the QT prolonging[30] effects) of some antimicrobial drugs, and routine performance of ECGs prior to and following initiation of such medications.
- The OPIVA programme document will be updated to include information about daily weekday review of blood test results, communication of any abnormal results to the Infectious Diseases team, and expected outcomes for concerning results such as low or high potassium.
- An Infectious Diseases Department education meeting was held to discuss the issues of antibacterial and antifungal medications that prolong the QT interval.

Recommendations

105. Bearing in mind the above changes already made by the DHB, I recommend that the DHB:

a) Provide a written apology to Mrs A's whānau for the issues identified in this report. The apology is to be provided to HDC within three weeks of the date of this report.

b) Consider amending its surgical informed consent process for all procedures involving surgical mesh to ensure that consumers, as far as reasonably practicable, meet with the operating surgeon before the day of the scheduled surgery to discuss the surgery and finalise the informed consent documentation. The DHB is to report back to HDC on the results of its consideration, and details of any changes made or to be made, within six months of the date of this report.

c) Consider amending its "Bladder Care for Urogynaecological Surgery" guideline to include routine consideration of post-surgical urine tests for consumers who have a history of recurrent UTIs and other risk factors such as diabetes and catheterisation. The DHB is to report back to HDC on the results of its consideration, and provide a copy of the updated guideline, if relevant, within three months of the date of this report.

[30] QT prolongation is a measure of delayed ventricular repolarisation, which means that the heart muscle takes longer than normal to recharge between beats.

106. I also recommend that the Ministry of Health discuss the anonymised version of this report, and any learnings from the report, at the Ministry of Health's Surgical Mesh Roundtable and/or Surgical Mesh Education and Harm Prevention Programme Steering Group.

Follow-up actions

107. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Ministry of Health, the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), the Health Quality & Safety Commission, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

108. A copy of this report will be sent to the Coroner.

Appendix A: Independent clinical advice to the Commissioner

The following expert advice was obtained from obstetrician and gynaecologist Dr John Short:

"I have been asked to provide advice in this case (18HDC01162). 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. Pertinent to this case I have extensive experience in urogynaecology and the TVT procedure in particular. I am also the current Chairperson of the Urogynaecology Society of Australasia (UGSA).

I have been provided with relevant documents, including extensive hospital records and reports from the coroner and DHB. I have been asked to comment specifically on the following:

1. the appropriateness of the information provided to [Mrs A] about the TVT procedure, including the risks and alternative treatment options
2. the adequacy of the TVT procedure carried out on 9th [Month6]
3. the adequacy of post-operative care provided to [Mrs A] including reasonableness of the decision to discharge [Mrs A] on 11 [Month6]
4. the appropriateness of the care provided to [Mrs A] by the gynaecology service after she developed multi-resistant bacterial infections following the TVT procedure
5. the adequacy of the removal of the TVT carried out on 22nd [Month7]
6. any other matters in this case that you consider warrant comment

Background
[Mrs A] was seen in [the DHB] Pelvic floor Clinic, by O&G specialist [Dr C], on 24 [Month1]. Her complaint was stress urinary incontinence, occurring on a daily basis. [Dr C] also elicited a history of increased urinary frequency (10 voids per day) and possible urinary voiding difficulties ('she mentions pushing during voiding'). He also identified that she suffered a chronic cough, diabetes, weighed 105 kg and was an ex-smoker. He does not comment on her complications of diabetes, including retinopathy (eye disease) or nephropathy (kidney disease), which are markers of the severity of her condition, nor does he comment on her history of recurrent urinary tract infection (this is mentioned in later correspondence from the infectious diseases team and it is noted later (in case report notes) that there were past growths of ESBL e coli and 1 month prior to her surgery there was a mixed growth of organisms in the urine).

A thorough pelvic examination was carried out, including ultrasound. The diagnosis of stress urinary incontinence due to urethral hypermobility was made. Some conservative therapy options were discussed, including 'abstain from pushing during voiding, motivate her to drink less coffee after 4pm, a strict control of her diabetes and motivate her to lose weight', although no actual plan to achieve these appears to have been made (eg, referral to continence nurse, referral to dietician, correspondence with diabetes team). Referral to physiotherapy was apparently discussed but declined by [Mrs A]. It is noted that she had previously seen a pelvic floor physiotherapist in 2014, which appears to have been successful in controlling her symptoms at that time.

The final outcome of this consultation was to book [Mrs A] for surgery in the form of a Tension Free Vaginal Tape (a 'mesh' sling procedure) and cystoscopy. Other than stating that this procedure is to be booked, there is no record of any discussion about this procedure or any alternative surgical treatments or the provision of any written information. A consent form appears to have been signed by both [Mrs A] and [Dr C]. This states the abbreviated name of the procedure (TVT) and specifies the risks of 'infection, bleeding, perforation of adjacent organ'. It is noteworthy that additional risks were added to the consent form at a later date (see later). It is also unclear as to the level of detail to which these risks were discussed by [Dr C] at that time.

[Mrs A] attended for her surgery on 9th [Month6]. This was performed by another O&G specialist, [Dr D]. [Dr D] met with [Mrs A] that morning and discussed the surgery. The documentation of this discussion states at the end 'happy with discussion of risks and benefits'. At this time some changes were made to the consent form (see earlier), particularly the addition of the following risks — 'slowing urine flow, mesh erosion, chronic pain, need for catheter, intermittent self-catheterisation, [something I can't decipher, but relating to mesh], cutting tape'. The full name of the procedure was also added at this time.

The operation itself appears to have been straightforward and carried out in an appropriate manner, including the administration of prophylactic antibiotics. Postoperative recovery was complicated initially by difficulty voiding, requiring a catheter to be inserted the morning after surgery (10th [Month6]). The plan was for this to remain until the following day, after which a repeat trial of void would be undertaken. This subsequent trial of void the next day (11th [Month6]) appears to have been successful. There appear to have been no other concerns, clinical observations had been normal and [Mrs A] was discharged home later that day.

[Mrs A] was readmitted to hospital later that day, feeling unwell with 'shakes, feeling hot and cold … increasing SOB [shortness of breath]'. Her temperature was 38 degrees (increased). The diagnosis was urinary tract infection with associated delirium and appropriate treatment with antibiotics was commenced. (The organism e.coli was identified from her urine 2 days previously). The following day a resistant organism, ESBL positive e.coli, was identified in the urine and treatment was modified accordingly, in consultation with the infectious diseases team. She remained unwell, spiking high

temperatures and her recovery was quite slow. However she did begin to improve after a few days and was discharged from hospital again on 18th [Month6].

[Mrs A] was once again readmitted to hospital, on 24th [Month6], with ongoing suprapubic pain and chills. Due to these persisting symptoms despite appropriate treatment, a CT scan of the pelvis was performed. This identified a small fluid collection in the retropubic space. Due to the possibility of this being infected, antibiotics were restarted. Around this time the possibility of osteomyelitis was raised. This was discussed with the orthopaedic team who recommended a MRI if there were ongoing concerns. Unfortunately [Mrs A] had previously had a MRI scan and found the experience distressing to the point that she refused to have one without a general anaesthetic. In view of this the management continued as previously. She appears to have been discharged on approximately 29th [Month6] with a plan for intravenous antibiotics to be administered in the community for 3 weeks, for a presumptive diagnosis 'soft-tissue infection'.

Following a further readmission on 19th [Month7], with symptoms of increasing pain, a MRI scan was arranged. This was done on 21st [Month7]. Reported findings were 'infected TVT mesh, osteomyelitis of pubic bones bilaterally, myositis on medial aspect of abductor compartment …'. (Also, sacral insufficiency fractures were noted, although the significance of these is unclear). Subsequently an orthopaedic opinion was sought, which recommended removal of the TVT device. Surgery to remove the device took place the following day. This was performed by [Dr D] and [another gynaecology specialist]. This surgery appears to have been relatively straightforward. There was no evidence of pelvic inflammation or pus. Notably, some bony tissue/periosteum was biopsied at this time and sent for both microbiology and histology. Histology showed 'minimal chronic inflammation'. Histology of the TVT mesh showed mild inflammation only. Apparently, microbiology showed colonies of bacteria, specifically Staphylococcus and Propionibacterium species (this is surmised from other comments in the records — I cannot find a specific microbiology report). Following this surgery, her condition improved reasonably quickly and she was discharged on 28th [Month7] (in consultation with the infectious diseases team) with a plan for ongoing outpatient antibiotics. There was minimal Gynaecology input following this.

Subsequently there was a further admission on 19th [Month8], following a deterioration in [Mrs A's] condition. Imaging at this time demonstrated a pelvic collection, which was subsequently drained under ultrasound guidance (with minimal fluid drained) and progression of the osteomyelitis. Further surgery took place on 30th [Month8], performed by [Dr F] (orthopaedic surgeon) and [a general surgeon]. A pelvic collection was drained ([Dr F] suggests this was not infected whilst [the general surgeon] suggests it was) and a large amount of infected bone was debrided.

Unfortunately, [Mrs A] continued to require antibiotic treatment. She later developed cardiac complications from this, suffered a cardiac arrest and died on 18th [Month10]. The coronial autopsy recorded the cause of death as hypoxic encephalopathy due to resuscitated cardiac arrhythmias due to chronic infective complications with long-term

antibiotic therapy due to TVT procedure for stress urinary incontinence, with contributing conditions of Diabetes Mellitus and Hypertension.

Comments

This is an extremely complicated case with a particularly sad outcome. I have been asked to comment on the care provided by the gynaecology team involved. There was considerable involvement of other specialist teams in [Mrs A's] care, including infectious diseases and orthopaedics. The most significant diagnosis was osteomyelitis, a condition about which I have limited knowledge and no expertise. It is extremely rare for this to occur following gynaecological surgery and I have never heard of this occurring following a TVT procedure.

[Mrs A] had significant co-morbidity including Diabetes with evidence of microvascular disease (retinopathy and nephropathy). This would likely have increased her susceptibility to infection and her body's ability to fight it. Ultimately this is likely to have contributed to the development of osteomyelitis and the difficulties treating it.

In response to the commissioner's questions:

1. **the appropriateness of the information provided to [Mrs A] about the TVT procedure, including the risks and alternative treatment options**

I can find limited record of any information given to [Mrs A] about the TVT procedure during her initial consultation with [Dr C] in [Month1]. The consent form signed at that time (approximately 5 months prior to surgery) only stated the risks of 'infection, bleeding, perforation of adjacent organ'. There is minimal record of what discussion took place to elaborate upon these risks in either the handwritten or typed record of this consultation. There is no record of what written information was provided. Non-surgical management was offered (i.e. physiotherapy) but no other surgical options (eg those not requiring surgical mesh) were discussed. Nor was there any discussion about the impact of [Mrs A's] co-morbidities on her risk profile, which would have been significantly increased for surgery compared with non-surgical management.

On the day of surgery there is a detailed record of the conversation between [Mrs A] and [Dr D] (the actual surgeon). Modifications to the consent form were made to reflect this. The content of the discussion and modifications to the consent were appropriate. However, as this was the day of surgery and barely 1 hour before the procedure commenced it is highly debatable as to whether this can be considered 'informed consent', despite [Mrs A] indicating she was happy with the information provided. This is not to criticise [Dr D], whose efforts in the circumstances are in fact laudable. However, I suspect it is indicative of systems issues within [the DHB] whereby a surgeon operates on patients they have not consulted with previously and does not have an opportunity to meet said patients prior to the day of surgery. As the operating surgeon it was [Dr D's] responsibility to ensure the patient was appropriately consented (MCNZ guidelines). However, it appears that there was no opportunity for her to do this prior to the day of surgery, which suggests inadequate DHB systems.

An ideal consent process would involve the surgeon describing details of the proposed surgery, the benefits, risks and alternatives and providing written information to the patient at the time of consultation. A further consultation would take place at a later date to discuss the proposed surgery again and allow the patient to ask questions arising from their readings and previous discussions. This also affords the opportunity for a 'cooling off' period for the patient to thoroughly consider the treatment and other options. Once both patient and surgeon are satisfied that all issues have been addressed, then written consent can be taken. This is particularly important for complex or controversial surgery.

Unfortunately, based on the information provided, I can only conclude that [Dr C] fell below acceptable standards in terms of the information provided to [Mrs A] at the initial consultation. It is possible that systems within [the DHB] prevented an appropriate consent process from taking place. Obviously, if further information can be provided to support an alternative view I would be happy to revise my opinion.

In saying that, it must also be clearly understood that an alternative consent process would be unlikely to have altered the final outcome of this case. [Mrs A] appeared motivated towards surgical treatment and osteomyelitis is extremely rare in this situation, so would not have been specifically referenced in any discussion. Also, although there was no apparent discussion of other surgical options, I would agree that the best surgical treatment for [Mrs A] was indeed a TVT, particularly in view of her co-morbidities (obesity, diabetes etc) and the fact that this procedure is associated with reduced peri-operative morbidity compared to other incontinence surgeries. Other incontinence surgeries would also have the potential to lead to osteomyelitis.

2. the adequacy of the TVT procedure carried out on 9th [Month6]

Based on the information provided, the surgery was performed in an appropriate manner and to an appropriate standard.

3. the adequacy of post-operative care provided to [Mrs A] including reasonableness of the decision to discharge [Mrs A] on 11 [Month6]

I am satisfied that an appropriate standard of post-operative care was provided to [Mrs A]. The decision to discharge her on 11th [Month6] was very reasonable, based on the information available. She was voiding, observations were normal and no problems or concerns were reported.

4. the appropriateness of the care provided to [Mrs A] by the gynaecology service after she developed multi-resistant bacterial infections following the TVT procedure

Overall I am satisfied that the gynaecology team provided an acceptable standard of care to [Mrs A] following her re-admissions. She was a complex patient prior to surgery, with her diabetes putting her at risk of infections developing and being difficult to treat. One could make a case for earlier diagnostic imaging but it would be overly harsh to criticise the gynaecology team for not doing this in the circumstances, or indeed for not

removing the TVT earlier. Findings at the time of removal surgery, supported by histology, suggest any infection was still relatively mild at this point.

5. the adequacy of the removal of the TVT carried out on 22nd [Month7]

The procedure to remove the TVT appears to have been adequate. In particular, the device appears to have been removed in its entirety and specimens were sent for both microbiology and histology. Unfortunately this surgery appears to have been complicated by the development of a pelvic haematoma/collection (a recognised complication). It is possible that this became infected which may have contributed to the subsequent significant deterioration in the osteomyelitis. The removal of the TVT certainly appears to have been a catalyst for significant progression of the osteomyelitis, despite being performed appropriately.

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

One other area particularly worthy of comment is the initial decision to perform surgery. Based on the documentation of the initial consultation in [Month1], which is limited, there does not appear to have been much discussion around the relative risk and benefits of surgery compared to non-surgical management. Physiotherapy was offered but once declined appears to have dropped from the conversation altogether. However, because [Mrs A] had previously benefitted from physiotherapy and was at increased risk of complications from surgery, it would have been reasonable to discuss this option further in that context, although it does remain possible that surgery would have gone ahead anyway and the outcome would be unchanged.

Another area worthy of comment, more as a possible learning point rather than a criticism, is the history of bacteruria, particularly with ESBL e-coli. It is unclear if either [Dr C] or [Dr D] were aware of this prior to surgery. Had they been aware they might have considered discussion with an infectious diseases specialist preoperatively and considered alternative antibiotic prophylaxis, particularly in a patient with complicated diabetes. I understand that a specimen one month prior to surgery was negative which may have provided reassurance, albeit falsely with hindsight.

Finally, any criticism of [Dr C] needs to be considered in light of the fact that he was new to practice in New Zealand at that time. According to the Medical Council online register he only obtained general registration to practise in New Zealand in [2017] and presumably was still practising under routine supervision when he saw [Mrs A]. Therefore, the Commissioner may wish to clarify whether he had been fully oriented (by his employer) to practise in New Zealand, including the requirements for informed consent under the code of rights.

Conclusion

This is a case of an extremely rare complication following a tension free vaginal tape procedure, ultimately resulting in the death of a [woman in her sixties]. For the most part I am satisfied that the care provided was of an appropriate standard. However, it is my opinion that the consent process was below acceptable standards, although it must be emphasised that this is unlikely to have contributed to the final outcome. From

the records it appears that insufficient information was given to the patient prior to booking the procedure and taking her consent. There was no 'cooling-off' period between booking the procedure and confirming the consent. The specialist performing the surgery did not have the opportunity to meet the patient until the day of surgery. The only documented discussion regarding the surgery was less than one hour prior to the surgery and significant changes to the consent form were made at this time. Whilst this information was appropriate in itself, it was too close to the actual surgery to allow the patient to give it full consideration. [Dr D] appears to have done her best to ensure the patient was appropriately informed, however [the DHB] should have provided her with an opportunity to do this prior to the day of surgery. The DHB also had a responsibility to ensure that [Dr C], as a specialist new to practice in New Zealand, was fully aware of his responsibilities to patients under the code of rights and was able to act accordingly.

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

Yours Sincerely,

John Short"

The following further advice was obtained from Dr Short:

"Overall, I think that [Dr D], as the treating surgeon ultimately responsible for obtaining adequate consent, has done her very best in the circumstances to achieve this. However [the DHB] appears to have a system whereby surgeons operate on patients they have not previously met until that day and therefore have not provided the appropriate environment/systems for their surgeons to obtain appropriate consent. Therefore it is primarily [the DHB] that has departed from acceptable standards, to a moderate level."

The following further advice was obtained from Dr Short:

"**Addendum to report 25/9/2020**
I have been asked to provide further comment on this case following the responses of [the DHB] and Drs [Dr C] and [Dr D]. As per my original report I remain satisfied that the overall standard of care provided meets acceptable standards, except in the area of providing informed consent. I must again emphasise that, in my view, this almost certainly did not impact upon the final outcome of the surgery. The decision to perform surgery was appropriate, the specific procedure and prosthesis chosen were appropriate, the procedure was performed appropriately and the aftercare was appropriate.

My concerns are with the process of obtaining consent. [Mrs A] was seen by [Dr C] in gynaecology outpatients on 24 [Month1]. A consent form for the surgery was signed at this time. The only record of the discussion about the surgery is what is written on the consent form. There is no other contemporaneous record of the risks or details explained by [Dr C] or what written information was provided. We are reliant upon [Dr C's] assertion that he '… would have …' provided the appropriate information.

The risks documented on the consent form are limited to 'infection, bleeding, perforation of adjacent organ', which falls far short of covering the full spectrum of risks relating to that particular surgery. I would expect a consent process to also cover a discussion of the risks of bladder emptying issues, development of an overactive bladder, the possibility of treatment failure, together with the risks of mesh-related complications such a mesh exposure, pelvic pain and painful intercourse. I think my peers would agree. I would not expect the risks of osteomyelitis or death to be included.

Another point worthy of mention is that, under the process followed at [the DHB], it appears the consent form is signed at the same time as written information is given. This makes it virtually impossible for the patient to read the information leaflet prior to signing the consent form. An ideal consent process would entail the patient having time to read the information prior to further discussion about the surgery and a later signing of the consent form.

As it happens the surgery was performed by another specialist, [Dr D], who had not met the patient prior to the day of surgery. Significant modifications to the consent form were made at this time, with the addition of more risks. [Dr D] has also thoroughly documented her discussion. At this point, the concern is not the adequacy of information provided, but the timing of this in relation to the surgery. Discussion of significant information pertaining to surgery for the first time less than one hour before surgery, as occurred in this case, is not consistent with accepted standards of care.

In her response [Dr D] states that she felt [Mrs A] was adequately informed prior to her surgery. Unfortunately, we are not able to confirm this. However, in my opinion, the sequence of events in this case and with the systems in place at [the DHB] to support the consent process mean that there is a significantly increased risk that a patient would not be adequately informed prior to undergoing surgery.

As the operating surgeon, it was the responsibility of [Dr D] to ensure consent was adequate. As previously stated, I do believe that she did her very best to achieve this. I also believe however that [the DHB] should have better systems in place to support specialists in discharging this responsibility, especially if they are to be expected to operate on patients whom they have not previously met. Ideally, this would involve meeting the patient prior to the day of surgery to have further discussions and confirm the consent.

To summarise:

- Based on the available documentation (i.e. what is written on the consent form, as this is all that was documented) [Dr C] did not provide sufficient information to [Mrs A] regarding the risks of surgery. However, one must consider that, as he was not the operating surgeon, technically this is not his ultimate responsibility.

- The consent form was signed the same day as written information was apparently given to [Mrs A], meaning she would not have had the opportunity to read it prior to signing the consent.

- Appropriate information was eventually documented as being given to [Mrs A] by [Dr D], but barely one hour prior to the actual surgery being performed (i.e. too close to allow her to reflect upon on any new information provided).

- There do not appear to be adequate systems within [the DHB] to allow operating surgeons the opportunity to discuss and confirm informed consent at an appropriate time prior to surgery.

In conclusion, the view stated in my original report is unchanged. I sympathise with [Dr D] and acknowledge her efforts to ensure [Mrs A] was appropriately informed prior to the surgery. However, I remain concerned that [the DHB's] systems do not adequately support operating surgeons to fulfil their responsibilities to ensure informed consent. I would strongly recommend that they cease the practice of signing a consent form at the time of booking surgery, except for possibly minor or low-risk procedures, and introduce a system whereby surgeons can meet with patients at a time prior to the day of surgery to discuss and confirm consent, such as when the patient attends the pre-admission clinic."

Appendix B: Independent clinical advice to the Commissioner

The following expert advice was obtained from infectious diseases physician Dr Sarah Metcalf:

"I have been asked by the Health and Disability Commissioner to provide expert advice with respect to the care provided by the district health board to [Mrs A] between 24 [Month1] and 18 [Month10].

I am a specialist in Infectious Diseases and General Medicine and hold vocational registration with the Medical Council of New Zealand. I have no personal or professional conflict in this case.

I have read the HDC's Guidelines for Independent Advisors.

I have received and read the clinical records from [the DHB] covering the period from 9 [Month6] to 18 [Month10], the Coroner's referral letter, [the DHB's] response dated 29 November 2018 including the individual responses from involved clinicians.

Clinical Summary
[Mrs A] was a [woman in her sixties] with a background of longstanding type 2 diabetes with complications including diabetic retinopathy and nephropathy, hypertension, hyperlipidaemia on atorvastatin, gastro-oesophageal reflux disease (GORD) and urinary stress incontinence.

On 09 [Month6] she underwent an elective Tension-free Vaginal Tape (TVT) and cystoscopy procedure for management of her stress incontinence.

Admission 11 [Month6] to 18 [Month6]
She was readmitted on the day of discharge and diagnosed with urosepsis with E. coli bacteraemia (blood and urine cultures were positive for the same organism). The E. coli was an extended spectrum beta-lactamase (ESBL) producing strain and was reported as being sensitive to cefoxitin, gentamicin, ciprofloxacin and ertapenem and resistant to amoxicillin, cotrimoxazole, aztreonam, ceftazidime, ceftriaxone and cefuroxime.

An Infectious Diseases (ID) opinion was sought and provided by phone advice on the 14 [Month6] and subsequent face-to-face consultation on the 15 [Month6]. The management recommendation was to continue management with intravenous (IV) meropenem for approximately 5 days until afebrile and improving clinically. [Mrs A] was discharged home on 18 [Month6], having become afebrile and feeling and looking improved. CRP which is an inflammatory marker was trending down to 115, from a peak of 226.

Admission 24 [Month6] to 29 [Month6]
[Mrs A] was readmitted with supra-pubic pain. A CT scan revealed a 10mm fluid collection in the retropubic space. She was recommenced on IV meropenem. There was concern over possible pubic symphysis osteomyelitis. A MRI was considered but not

performed due to [Mrs A] declining this secondary to severe anxiety from a previous MRI. Following ID advice, she completed 3 weeks of intravenous antibacterial therapy with IV ertapenem as an outpatient for a presumed soft tissue infection via a peripherally inserted central catheter (PICC) line.

[Mrs A] was reviewed in Infectious Diseases Outpatients on 14 [Month7] and was felt to be making slow progress, however she had a persistently raised CRP. Her intravenous ertapenem was prolonged for a further week. There was no plan for further follow up as it was felt she would either get better, or present back to hospital acutely.

Admission 19 [Month7] to 28 [Month7]
[Mrs A] represented with worsening suprapubic pain, dysuria and fever. A MRI was performed under general anaesthesia which demonstrated infected TVT mesh, osteomyelitis of pubic bones bilaterally and adductor myositis. Incidental sacral insufficiency fractures were also noted, which were thought to be due to a fall prior to TVT surgery. The TVT tape was removed surgically on 23 [Month7]. Microbiology from the TVT tape cultures was positive for Staph lugdenensis and Staph epidermidis (one colony, no sensitivities reported) and Propionibacterium acnes. The Staph lugdenensis was sensitive to flucloxacillin, erythromycin and cotrimoxazole. The Propionibacterium acnes was sensitive to ertapenem. ID recommended discharge on IV ertapenem and PO cotrimoxazole for 6 weeks to treat prior ESBL E. coli and currently cultured organisms.

Admission 18 [Month8] to 10 [Month9]
[Mrs A] was readmitted with worsening low back pain, feeling unwell and feverish. A repeat CT demonstrated a 10 x 6.5 x 7.2 cm collection in the right pelvis which tracked into the retropubic space and changes of progressive osteomyelitis of the pubic bones. Percutaneous drainage via radiology guidance was undertaken on 21 [Month8]. An aspirate from this collection cultured E. faecalis sensitive to amoxicillin. IV amoxicillin was commenced.

On 30 [Month8] [Mrs A] underwent surgical debridement of the infected pubic symphysis/pubic bones as well as multiple bone biopsies for culture. An antibiotic loaded cement spacer was inserted into the pubic symphysis space.

The bone biopsy cultures were positive for S. epidermidis, Finegoldia magna, E. faecalis, Anaerococcus sp., Actinomyces radinge, Corynebacterium tuberculostearicum and Candida parapsilosis (one colony).

Sensitivities were reported for the: S. epidermidis (sensitive to vancomycin, tetracycline and rifampicin only); Corynebacterium tuberculostearicum (sensitive to penicillin, erythromycin, rifampicin and vancomycin); E. faecalis (sensitive to amoxicillin and vancomycin); Candida parapsilosis (sensitive to fluconazole and voriconazole). The Finegoldia magna was reported as being expected to be sensitive to penicillin. No susceptibilities were reported for the Anaerrococcus sp. or Actinomyces radinge. These two organisms would be expected to be sensitive to penicillin.

The ID recommendations were to treat with IV ertapenem, vancomycin and PO fluconazole to cover all isolated organisms for a further 6 weeks. The fluconazole was recommended to continue for 6 months for candida osteomyelitis. Clear recommendations were made in the clinical notes as well as the rationale behind the recommendations, and monitoring instructions for antimicrobial toxicity and efficacy. [Mrs A] was discharged home on 10 [Month9].

Infectious Diseases Outpatient Review 14 [Month10]
[Mrs A] reported good compliance with her medications and reported no side effects from her antimicrobials. Her intravenous ertapenem and vancomycin were due to finish on 18 [Month10]. The PO fluconazole was due to continue for a total of 6 months. Her most recent CRP remained elevated at 48. Following subsequent review of prior microbiology [Dr E] recommended switching to oral ciprofloxacin and amoxicillin+clavulanic acid on completion of the intravenous anti-bacterials and a script was provided.

Blood test monitoring as an outpatient revealed that [Mrs A's] serum potassium was below the normal range from 27 [Month9] onwards with levels ranging from 2.9 to 3.6 with a normal range of 3.5 to 5.2 mmol/L. The laboratory commented on each specimen that the potassium may be falsely elevated due to the time delay in specimen separation, indicating that the serum potassium may have actually been lower than that measured. Prior to 27 [Month9] [Mrs A's] potassium was consistently normal. There is nothing documented to indicate that the low potassium was addressed prior to the admission on 16 [Month10].

Admission 16 [Month10] to 18 [Month10]
[Mrs A] collapsed at home at approximately 1400hrs on 16 [Month10] and was readmitted. In the Emergency Department she had multiple episodes of polymorphic ventricular tachycardia (torsades de pointe) requiring three DC shocks. She was admitted to the Intensive Care Unit (ICU). Cardiology review found her QTc interval difficult to assess on ECG, but felt that it was likely prolonged. She had a profoundly low serum potassium at 2.6 mmol/L. Potassium was replaced and QTc prolonging medications were withheld. Supportive care was provided.

On a subsequent ECG later on 16 [Month10] the QTc was calculated to have corrected to normal at 460ms, by my calculations it is mildly prolonged at 474ms. This is in spite of her still being hypokalemic (serum potassium 2.9 mmol/L) and it being too early for the effect of any QTc prolonging medications to have dissipated.

Unfortunately, over the ensuing 2 days there was no significant neurological recovery. She was transitioned on to an End of Life Care pathway and passed away shortly afterwards.

Opinion
[Mrs A] suffered an extremely rare and complex complication of her TVT surgery with initial urosepsis as well as infection of the TVT tape/mesh and secondary pelvic

osteomyelitis/myositis/pelvic collection. This infection was made even more complex by the multiple pathogenic bacterial and candida species isolated, all of which have to be presumed to be involved in her infection due to isolation from usually sterile sites such as blood cultures, bone biopsies, urine and aspirates from abscesses. Many of these bacterial organisms had limited anti-bacterial susceptibility. The result of this is that multiple different anti-bacterials were required to adequately treat her infection.

The infection was also made complex by anatomical structures as outlined in the report by [Dr F] (Orthopaedic Surgeon). Adequate control of the infection required aggressive debridement/excision of the pubic symphysis and pubic bones which would have destabilized her pelvic ring structure, which was also adversely affected by the sacral insufficiency structures. From a pelvic structural perspective, it was of the utmost importance to achieve effective treatment of the osteomyelitis as quickly as possible to allow subsequent pelvic reconstruction. The decision was made to treat all cultured organisms with active antimicrobial therapy to achieve clearance of infection.

Standard of care to treat bacterial osteomyelitis is a minimum of 6 weeks of active anti-bacterial therapy, most of which is usually administered intravenously. For chronic osteomyelitis or more complex cases longer treatment is required, typically 3 or more months. Given the aggressive nature of [Mrs A's] infection and the necessity to treat the osteomyelitis effectively to allow reconstruction, I agree with the Infectious Diseases team decision to continue active antibacterial therapy beyond the final 6 weeks of intravenous ertapenem and vancomycin. The CRP at the end of intravenous treatment had not yet normalized, which is also an indicator that her infection had not yet been adequately treated.

The options at the clinic review on 14 [Month10] were to continue with the intravenous anti-bacterials for a longer period of time (a further 6 weeks) or to switch to oral anti-bacterials.

Potential complications of continuing intravenous anti-bacterials include complications relating to the PICC line, especially PICC-associated sepsis or deep vein thrombosis and toxicity relating to the current anti-bacterials, especially acute kidney injury/ nephrotoxicity secondary to the vancomycin. [Mrs A] was a diabetic with mild diabetic nephropathy which would have placed her at increased risk of vancomycin associated nephrotoxicity. In addition, daily intravenous anti-bacterials require daily district nursing visits to administer, which most patients tire of after a period of time. The potential side effects and risks of switching to an oral antimicrobial combination would need to be balanced against the potential risks of continuing the intravenous antimicrobials.

Oral anti-bacterials with excellent oral bioavailability were an option for ongoing treatment of [Mrs A's] infection, however there were few anti-microbials available to treat each individual bacterial and fungal organism isolated. The combination of ciprofloxacin to treat the ESBL E. coli plus the amoxicillin+clavulanic acid to treat the Enterococcus, Finegoldia, Corynebacterium tuberculostearicum, Propionibacterium

acnes, Anaerococcus and the Actinomyces, plus the fluconazole to treat the Candida parapsilosis was a reasonable option for [Mrs A]. There was no oral option included to treat the Staph epidermidis. The only alternative to using oral ciprofloxacin would have been to continue [Mrs A] on the IV anti-bacterials (ertapenem plus vancomycin) for a further 6 weeks.

It was reasonable and appropriate to change [Mrs A's] antimicrobials to oral antimicrobials and given the number of organisms and likely/presumed/known susceptibilities for all organisms the combination of ciprofloxacin, amoxicillin+clavulanic acid and fluconazole was the only oral antimicrobial to treat all pathogens. Ciprofloxacin and fluconazole are commonly co-prescribed in settings such as ICU, haematology and general surgery.

Overall the Infectious Diseases team provided very good care to [Mrs A] throughout the course of her multiple admissions with timely input, appropriate management plans and follow up.

The initial recommendation during the first admission to treat the ESBL E. coli urosepsis with approximately 5 days of antibacterial therapy is a relatively short course and most Infectious Diseases physicians would treat a gram negative bacteraemia for 10–14 days, however this is unlikely to have made any significant difference in the remainder of the treatment course as the polymicrobial pelvic infection leading to osteomyelitis was already established.

At the outpatient review dated 14 [Month7] there was clearly concern about lack of improvement and that her infection would relapse. There had also been concern about the potential for pelvic osteomyelitis during the preceding admission and she had not had adequate imaging to assess for that. A 3–4 week course of antimicrobials would not adequately treat osteomyelitis. Follow up should have been arranged following this appointment, however again this would not have altered the clinical course as she represented before completing the current IV anti-bacterial course.

The only aspect of care which doesn't appear to have been adequately addressed was the development of hypokalemia in late [Month9]. Prior to this [Mrs A] had consistently had normal serum potassium levels, therefore a change in serum potassium should have triggered an enquiry as to the potential cause (eg. addition of medication such as furosemide, vomiting or diarrhea). [Mrs A] didn't volunteer any 'side effects from her current antibiotics' during her last consultation on 14 [Month10], although it is unclear whether specific enquiry was made regarding gastrointestinal symptoms or new medications. A prescription for potassium replacement should also have been provided in response to the low potassium over the interval from 27 [Month9] to 14 [Month10], especially for a potassium of 2.9 mmol/L on 04 [Month10].

Cause of Torsades de Pointe

Both the azole antifungals and fluoroquinolone anti-bacterials are associated with prolonging QTc and causing torsades de pointe. [Mrs A] was reported to have an ECG following commencement of the fluconazole demonstrating a normal QTc.

The fluoroquinolone antibiotics are recognized to cause QTc prolongation and therefore the risk of torsades de pointe. Ciprofloxacin is thought to be the quinolone with the weakest QTc prolonging effect, with very little evidence in the published literature associating ciprofloxacin with prolonged QTc or ventricular arrhythmias.

There are 2 papers assessing the risk of the combination of azole antifungals and fluoroquinolones on the QTc interval. This is a common combination used, especially in patients undergoing haematopoetic stem cell transplants. The first paper was in haematology patients and most of the azole used was fluconazole, whereas most of the quinolone used was levofloxacin. The findings were of a mean increase in the QTc of 6.1ms, with 21/94 patients demonstrating a clinically significant increase in the QTc. There were 0/6 patients on ciprofloxacin with a significant increase in the QTc. Hypokalaemia was an important co-factor for clinically significant changes in the QTc. (Zeuli et al. AAC; 2013; 57: 1121–27)

The second paper specifically addressed fluconazole and ciprofloxacin in 170 patients. Eight (4.7%) patients developed a prolonged QTc with a mean increase of 10.7ms and no patients developed significant QTc prolongation. The conclusion from this paper was that the combination of fluconazole and ciprofloxacin did not result in significant QTc prolongation and that routine ECG monitoring in patients on this combination should be reconsidered. (Berger et al. BJCP 2018; 84: 369–78)

It is unclear whether [Mrs A] had commenced the oral ciprofloxacin, as it was prescribed to commence once her intravenous antimicrobials were completed on the 18 [Month10]. The prescription was provided after her clinic review following discussion with [Dr E] and it is unclear to me when she would have received it. It is possible that she was mistaken as to when to start her oral anti-bacterials and had taken a few doses (maximum of 3 doses) when she was admitted on the 16 [Month10].

The most significant factor contributing to torsades de pointe in [Mrs A] was the hypokalemia. It is not clear prior to the development of the torsades de pointe that [Mrs A] had a significantly prolonged QTc. It is difficult to accurately determine the QTc on the ECGs on the 16 [Month10] prior to the development of the torsades de pointe due to tachycardia and poor quality traces. Later in the day her QTc was only mildly prolonged at ~474ms (manually calculated). This is just in the borderline QTc range, with a QTc interval of >500 ms most strongly associated with ventricular arrhythmias. ECGs earlier in the year indicate a QTc of 440–450ms. From the account of [Dr E], [Mrs A] had an ECG demonstrating a normal QTc while on fluconazole (10 [Month9]) although I am unable to confirm this as not all ECGs have the date visible on the photocopies. It is probable that if attention had been paid to [Mrs A's] new hypokalaemia in late

[Month9] to early [Month10] she may not have suffered the collapse and arrhythmia on the 16 [Month10].

It is unclear to me what mechanisms are in place within the Infectious Diseases and OPIVA teams at [the DHB] to regularly review and respond to the blood test monitoring taken for patients on outpatient intravenous antibiotic therapy, or who this responsibility is devolved to. The Infectious Diseases team need to ensure that a rigorous system is in place for reviewing laboratory tests in a timely manner and acting on abnormal tests in an appropriate way.

In addition, there appears to be a consistent delay between outpatient blood sampling and receipt and analysis in the laboratory. The OPIVA team should liaise with the laboratory to review the processes involved to ensure more timely blood separation or appropriate transportation. This would result in serum potassium results being more accurate and meaningful to the clinical team.

Yours sincerely

Dr Sarah Metcalf"

The following further advice was obtained from Dr Metcalf:

"Thank you for asking me to provide further expert advice regarding [Mrs A].

In my initial expert advice dated 25/06/2019 the only concern I raised was the apparent failure to address [Mrs A's] hypokalemia in early [Month10].

I have now been provided with a number of items of additional information which were not available to me when I provided my initial advice regarding this case.

These include:

Evidence of a prescription for potassium replacement, dated 05 [Month10]

Further clinical records and laboratory test results, including details regarding timing of specimen collection and receipt in the laboratory

Copies of OPIVA email correspondence

Copies of OPIVA notes and documentation

[Public hospital] Infectious Diseases and OPIVA department and procedural information and patient information

Letters from [Dr E] and [the Chief Medical Officer (CMO)].

The additional documentation provided indicates that [Mrs A's] hypokalemia was appropriately addressed on the 5th of [Month10] with a prescription for 3 days of potassium replacement in response to the serum potassium of 2.9 mmol/L recorded on the 4th [Month10]. This was communicated to [Mrs A], as documented, on the 5th [Month10]. The Pharmacy Service Manager has advised [the CMO] that the script would have been collected, as otherwise it would not remain visible in the TestSafe/Clinical Portal.

In response to the potassium replacement [Mrs A's] serum potassium increased to 3.2 mmol/L on 07 [Month10] and further to 3.4 mmol/L on 11 [Month10], at which time [Mrs A] was no longer on potassium replacement.

The laboratory information provided reassures me, that in spite of the automated laboratory comment stating 'Potassium may be falsely elevated due to delay in specimen separation', there was in fact no significant delay in specimen separation due to the use of serum separation tubes and all relevant samples being separated within 3 hours (at most) which is an acceptable time delay and unlikely to lead to significantly false elevation of serum potassium.

The OPIVA and Infectious Diseases team appear to have robust systems in place for regular blood test monitoring of OPIVA patients and timely review and action of results as indicated by their documentation pertaining to this case as well as their procedural information provided.

I have no ongoing concern regarding the care provided to [Mrs A] by the Infectious Diseases and OPIVA teams.

Yours sincerely

Dr Sarah Metcalf"