Emergency Medicine Registrar, Dr C

Urologist, Dr D

District Health Board
(now Te Whatu Ora: Health New Zealand)

A Report by the

Deputy Health and Disability Commissioner

(Case 19HDC00764)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman at a district health board (now Te Whatu Ora[1]) in 2017. The woman underwent a urethrocystoscopy to investigate symptoms of recurring UTIs, bleeding, urinary frequency, and pain. During the procedure, a suprapubic catheter was inserted. The woman was discharged home, but within 24 hours of being discharged she presented to the Emergency Department (ED) with abdominal pain, and was treated and discharged home. The following day she deteriorated again, and was admitted to ICU but, sadly, she died of septicaemia.

2. The report considers the care provided to the woman over this period — in particular, whether she was advised of the possibility that a suprapubic catheter might need to be placed and whether, prior to the surgery, she was informed of the associated risks adequately, whether she should have been discharged following the surgery, and whether she should have been readmitted to hospital when she presented to the ED within 24 hours of discharge.

Findings

3. The Deputy Commissioner found that the surgeon breached Rights 6(1)(b) and 7(1) of the Code for failing to provide information that a reasonable consumer in the circumstances would expect to receive before receiving treatment, namely, information about the possibility of the suprapubic catheter placement, and the associated risks of this.

4. The Deputy Commissioner made adverse comments about the ED doctor's standard of documentation and the ED discharge policy.

Recommendations

5. The Deputy Commissioner recommended that the surgeon provide a written apology to the family, provide evidence to HDC that he has a system in place for ensuring that all treatment plans and their associated risks are discussed clearly with patients and documented on consent forms or clinic letters, and reflect on how he can improve his informed consent processes.

6. The Deputy Commissioner recommended that the ED doctor provide a written apology to the woman's family and arrange for a peer-reviewed audit of his documentation.

7. The Deputy Commissioner recommended that Te Whatu Ora provide an update on its development of a regional electronic clinical record and standardisation of ED discharge summaries, its development of a policy regarding the return of recently discharged patients, and feedback on the support it is providing to its emergency medicine registrars and consultants to utilise bedside ultrasound in the ED.

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, resulting in all district health boards being disestablished. Their functions and liabilities were merged into Te Whatu Ora — Health New Zealand. All references in this report to the DHB now refer to Te Whatu Ora.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided by Dr C and a district health board (DHB) to her late mother, Mrs A, in 2017. The following issues were identified for investigation:

- *Whether the DHB provided Mrs A with an appropriate standard of care from Day 1[2] to Day 10 2017 (inclusive).*
- *Whether Dr C provided Mrs A with an appropriate standard of care on Day 10 2017.*
- *Whether Dr D provided Mrs A with an appropriate standard of care in 2017, including whether Mrs A was fully informed and gave informed consent to the placement of a suprapubic catheter.*

9. This report is the opinion of Deputy Health and Disability Commissioner Carolyn Cooper, and is made in accordance with the power delegated to her by the Commissioner.

10. The parties directly involved in the investigation were:

Mrs B	Complainant
Dr C	Emergency medicine registrar
Dr D	Urologist
District health board	Provider

11. Further information was received from Dr E, an emergency medicine specialist.

12. Independent advice was obtained from a haematologist, Dr Eileen Merriman, an emergency medicine specialist, Dr David Prisk, and a urologist, Dr Jonathan Masters (Appendices A, B, and C respectively).

Information gathered during investigation

Introduction

13. Mrs A had a history of an aortic valve replacement, atrial fibrillation,[3] diverticular disease[4] (which had required a bowel resection), and an acute kidney injury. She received regular blood transfusions every fortnight for a blood disorder,[5] and she was on long-term warfarin (an anticoagulant (blood thinner)). Mrs A was aged in her seventies at the time of these events. Sadly, she passed away.

[2] Relevant dates are referred to as Days 1-12 to protect privacy.
[3] Irregular and rapid heartbeat.
[4] A condition in which small, bulging pouches develop in the digestive tract.
[5] Paroxysmal nocturnal haemoglobinuria — a rare disorder in which red blood cells break apart prematurely.

14. In 2017, Mrs A was experiencing recurrent urinary tract infections, bleeding, and urinary frequency with associated pain. She was reviewed by a urologist, Dr D. Dr D noted that Mrs A had extended spectrum beta-lactamase (ESBL)[6] as a result of having received multiple doses of antibiotics. After assessment, it was decided that Mrs A would undergo a urethrocystoscopy[7] to investigate her symptoms. Given that Mrs A had a high risk of suffering thromboembolic complications[8] without anticoagulation, a decision was made to stop her warfarin temporarily, and use Clexane instead (an anticoagulant that has a shorter effect than warfarin).

Surgery

Information provided by Dr D

15. Mrs A was admitted to hospital to receive 24 hours of preoperative intravenous (IV) antibiotics for her ESBL infection. Following admission, Mrs A reported pain in one of her right toes, with associated purple discolouration. Dr D advised that a small embolic event (a blood clot) was considered to be the cause.

16. On Day 1, Dr D performed the urethrocystoscopy. He identified an ulcerated area near the urethra, which he advised made him suspicious of malignancy. He noted that the bleeding, discharge, and pain appeared to be arising from the necrotic (dead tissue) ulcerated area.

17. Dr D removed the necrotic tissue in an attempt to close the area to the outer skin, but the sutures would not hold. He advised HDC that in view of the severity of Mrs A symptoms and of his findings, he decided to put in place a suprapubic catheter (SPC).[9] Dr D said that care was taken in positioning the catheter, especially in view of Mrs A's incision from her previous bowel surgery.

18. In response to the provisional opinion, Dr D stated that Mrs A was "extremely miserable with the pain she experienced each time she urinated and was desperate to have something done to help her situation". Dr D acknowledged that Mrs A was quite frail and considered "a high risk for intervention", and stated that he would not have suggested an operation if he did not think it could have improved her quality of life.

19. The consent form for the procedure signed by Mrs A stated that she had agreed to Dr D and his team examining her bladder, urethra, and vulva. The consent form did not include the possibility that an SPC would be required, and there is no documented evidence that Dr D discussed this possibility with Mrs A ahead of the procedure.

20. In response to the provisional opinion, Dr D acknowledged that the consent form did not include Mrs A's consent for the placement of the SPC, and accepted that this was his omission. Dr D stated that he recalls the consultation well, and said that in gaining consent it was verbally agreed that he would do whatever he could to improve Mrs A's quality of life,

[6] An enzyme released by some strains of bacteria that neutralises the effects of antibiotics. EBSL can cause a variety of illnesses, including urinary tract infections, pneumonia, blood infections, and wound infections.
[7] A tube is passed through the urethra to allow visualisation of internal structures.
[8] Such as a blood clot.
[9] A hollow, flexible drainage tube inserted into the bladder through a small cut in the abdominal wall.

which was a responsibility he did not take lightly. Dr D said that Mrs A's situation was dire, with an infected, abscessed, necrotic urethra, and the decision to place an SPC was intended to try to address the pathology found, without putting Mrs A through further surgery and the risks that would entail.

21. On the evening following the procedure, Mrs A developed clots in her bladder, and a urethral catheter was inserted.[10] The SPC was irrigated with saline. Overnight, the SPC drained urine with blood present, and it was irrigated again. Dr D advised that Mrs A was slightly tender in the suprapubic region, but did not appear to have any abdominal swelling. Mrs A required a blood transfusion because of the blood present in her urine. In response to the provisional opinion, Dr D noted that he was surprised and relieved that a urethral catheter was able to be inserted while Mrs A was on the ward, as at the time of surgery his assessment was that a urethral catheter could exacerbate her already severe symptoms.

22. Dr D said that two days postoperatively, on Day 3, Mrs A was comfortable and was administered a limited dose of Clexane (40mg) for anticoagulant cover. Dr D advised that the dose was limited because of Mrs A's renal function.

23. Dr D said that on Day 5, there was a small amount of blood in Mrs A's urine but irrigation was not required, so the urethral catheter was removed. The SPC was left in place. The antibiotics that Mrs A had been receiving were stopped.

24. On Day 6, Mrs A's warfarin was recommenced with the aim of obtaining therapeutic levels.

25. On Day 7, Mrs A reported increased pain in the vulval region, and also developed pain at the site of the SPC. Dr D said that there was no sign of inflammation, discharge, or a haematoma.[11] Mrs A's urine had some blood in it, but no blood clots. She was treated with pain relief and medication for bladder spasms.[12]

26. Dr D advised HDC that Mrs A had improved by Day 8, and the SPC was draining well. She was discharged on Day 9. Dr D recalled that Mrs A had experienced some abdominal pain before being discharged, but it had appeared to be under control.

27. Dr D told HDC that in placing the SPC, he had hoped that it would relieve Mrs A of some of the pain she was experiencing. Dr D expressed his sincere condolences to Mrs A's family.

ED presentation Day 10

28. On the morning of Day 10, Mrs A activated her medical alarm, and a call to the ambulance service was made at 8.54am. An ambulance was dispatched at 9.01am and arrived at 9.13am.

29. Ambulance service records note that on arrival, Mrs A was alert and lying in bed, in obvious pain, which intensified on movement of her right leg and when sitting up. She also reported

[10] A drainage tube inserted into the bladder via the urethra.
[11] A collection of blood outside a blood vessel.
[12] Anticholinergic medication.

pain in the lower right-hand side of her abdomen, which radiated to her lower back. Mrs A was transported to the public hospital, and arrived at the Emergency Department (ED) at 9.49am. The triage nurse noted that Mrs A was grimacing in pain, and recorded her pain score as 7–8/10.

30. Mrs A was reviewed by emergency medicine registrar Dr C. Dr C noted that Mrs A had been discharged the previous day, and was experiencing severe lower abdominal pain, but that she appeared to be comfortable at rest, with "some pain around [the] catheter insertion site". Dr C documented that Mrs A had got out of bed to empty her catheter bag, and she had twisted, then had a sudden onset of severe pain in the lower abdomen, which felt worse on movement. Dr C noted that the catheter was draining well, the blood in Mrs A's urine was settling, and she had no nausea or vomiting. Dr C applied a topical anaesthetic and administered pain medication, and documented that these had an excellent effect. He discharged Mrs A home with codeine for pain relief, and advised her to return to ED if she had concerns or was unable to manage the pain.

Information from Dr C

31. Dr C told HDC that on arrival, Mrs A was triaged as category four[13] (to be seen within 60 minutes), and her vital signs were within normal limits. Dr C noted that there were no new concerning changes to her blood tests, and her renal function was stable. He documented that Mrs A's C-reactive protein (CRP — an indicator of inflammation in the body) was elevated, but he considered this not to be significant, and likely attributable to the catheter in place. Mrs A's warfarin was not yet at therapeutic levels.

32. Dr C said that based on Mrs A's history and his assessment, he considered that the pain was likely caused by a mix of muscular sprain/injury and irritation of the SPC site, exacerbated by the twisting movement.

33. Dr C stated that in light of Mrs A's response to the medication administered, and her normal vital observations and blood test results, he considered it appropriate to discharge her. He said that this decision was based on the following factors:

- Mrs A had returned four sets of normal vital signs and had a low pain score.
- Mrs A had declined further pain medication on ambulance transfer, and had a low Australasian Triage Scale (ATS) score of four.
- The history and examination undertaken were in support of muscular injury and SPC irritation, with the suprapubic pain present before Mrs A was discharged from hospital.
- There was no evidence of a large bleed on examination, and Mrs A's blood test results were unchanged.
- Finally, Dr C noted that there had been a significant improvement of symptoms with one dose of oral pain medication and topical anaesthetic, and Mrs A was showing signs of stability and improvement during her time in ED. Dr C also noted that Mrs A agreed with

[13] Using the Australasian Triage Scale.

the decision to discharge, there was planned urology follow-up, and safety-netting advice was provided.

34. Dr C expressed his condolences to Mrs A's family, and told HDC that he has reflected at length on Mrs A's presentation. He stated that changes will be made to both his own clinical practice and at a systemic level to reduce the risk of similar outcomes occurring in the future. Regarding his decision not to consult with the Urology Department, Dr C stated that as he was of the view that Mrs A's presentation was not related directly to her surgery, he did not believe it was necessary to consult with Urology.

Re-admission — Day 11

35. On the morning of Day 11, Mrs A activated her medical alarm again, and a call to the ambulance service was made at 9.18am. An ambulance arrived at 10.27am, and the ambulance officers found Mrs A alert and sitting in bed. She reported pain in her lower right-hand abdomen and told the officers that she had been vomiting overnight.

36. Mrs A was taken to the public hospital and admitted to the Intensive Care Unit (ICU). It was identified that she had internal bleeding, likely from the suprapubic area, and low blood pressure. Mrs A underwent a reversal of her anticoagulant medication. Dr D advised HDC that it was determined that surgery would not be appropriate because it was thought that clinicians would not be able to localise the bleeding, and intervening would stop the tamponade[14] effect of the bleed.

37. Mrs A's kidneys began to fail, and dialysis was commenced. Antibiotics for sepsis were initiated, but it was noted that there was evidence of an evolving infection despite treatment. Dr D advised HDC that despite best efforts, the combination of bleeding, kidney failure, hypotension,[15] and Mrs A's bowels not working meant that it was a non-recoverable situation. Sadly, Mrs A died a few days later.

Further information

ED presentation and appropriateness of discharge

38. In a response dated 27 May 2021, the DHB told HDC that from a review of Mrs A's clinical records, it is apparent that when she presented to the ED on Day 10, her clinical state was unchanged from her final three days of admission. She had similar pain, normal vital signs, and no significant drop in haemoglobin[16] to suggest active internal bleeding at that time.

39. The DHB told HDC that the lack of clinical or laboratory evidence of significant internal bleeding meant that Dr C's decision not to use a bedside ultrasound scan or request CT scanning, and to discharge Mrs A home was reasonable. The DHB stated that it is clear that Mrs A's condition deteriorated significantly at some point following her discharge, and that

[14] Compression.
[15] Low blood pressure.
[16] Haemoglobin is an iron-rich protein in red blood cells. It transports oxygen from the lungs to the rest of the body.

this could not have been foreseen, with her clinical state upon re-presentation to the hospital on Day 11 entirely different to that of her discharge on Day 10.

Dr D — SPC placement

40. In a further response, Dr D told HDC that in placing the SPC he had intended to make Mrs A more comfortable, and that use of an SPC was intended to keep the wound as dry as possible and lessen the risk of major ongoing infection postoperatively. Dr D said that he placed the SPC with extreme care, owing to the potential for bleeding within the rectus sheath,[17] and it was a decision he did not take lightly.

41. Regarding the issue of informed consent, Dr D noted that at times, situations during surgery may necessitate a change of plan that may not have been discussed or documented in the consent process. He told HDC that with difficult cases, he always discusses the potential for cardiovascular and respiratory problems as a rare complication, and has always made a point of drawing pictures and diagrams to explain procedures.

Responses to provisional opinion

Mrs A's family

42. Mrs A's family were given the opportunity to respond to the "information gathered" section of the provisional opinion. Mrs B stated that their concerns about the care their mother received had always centered on the process relating to her discharge, namely, the lack of support plan and consideration of her mother's significant underlying health issues. Mrs B queried the decision not to perform a bedside ultrasound scan on Day 10, and stated that, at a minimum, the family would like Te Whatu Ora to review its discharge processes and ensure that elderly patients are not sent home without an adequate care plan in place.

Dr D

43. Dr D was given the opportunity to respond to the provisional opinion. His response has been incorporated into this report where relevant.

44. Dr D accepted the finding in the provisional opinion that in deciding to place the SPC without having discussed the risks and benefits of the procedure and having obtained consent for the procedure, he breached Rights 6(1)(b) and 7(1) of the Code, and he apologised for this. He also apologised for the complications that ensued.

45. Dr D stated that in his many years as a urologist, he had not been faced with a similar situation. However, he noted that the suggestion that he could have placed a urethral catheter and come back after gaining consent for the SPC fails to account for Mrs A's frailty, the need for further time off anticoagulation, and the need for a further anaesthetic.

Dr C

46. In response to the provisional opinion, Dr C stated that he has taken on board the comments regarding his documentation, and he accepted the Deputy Commissioner's recommendations.

[17] The fibrous compartment that encloses the rectus abdominus and pyramidalis muscles.

DHB (Te Whatu Ora)

47. Te Whatu Ora was provided with an opportunity to respond to the provisional opinion, and accepted the recommendations made.

Opinion: Dr D — breach

Introduction

48. Mrs A underwent a urethrocystoscopy led by consultant urologist Dr D, to investigate her symptoms of recurring UTIs, bleeding, urinary frequency, and pain. Mrs A had been receiving long-term warfarin treatment, and this was changed to Clexane (a shorter-acting anticoagulant) to maintain anticoagulant cover but reduce the risk of bleeding. During the procedure, an SPC was inserted. Dr D told HDC that the placement of the SPC was intended to relieve Mrs A of her symptoms. He said that the SPC was intended to keep the wound as dry as possible and lessen the risk of major ongoing infection postoperatively, and that its placement was not a decision he took lightly.

49. To assist with my consideration of the care provided by Dr D, I obtained advice from urologist Dr Jonathan Masters.

Placement of SPC

50. Dr Masters noted that this was a complex case with clinical risks, and I accept Dr Masters' assessment that "in placing the suprapubic catheter, it would seem that [Dr D] believed he was acting in [Mrs A's] best interests". Regarding Dr D's decision to place a SPC during surgery, Dr Masters advised that placement is not without clinical risk, with the risk increased in patients (such as Mrs A) who are anticoagulated or have had previous lower abdominal surgery.

51. Dr Masters said that given these risks, and the lack of documented discussion around the possibility of a SPC on the consent form or clinic letter, he would regard the placement of the SPC as a departure from the expected standard of care. Dr Masters stated:

> "The guidelines around suprapubic catheter use suggest that patients should have a chance to discuss the risks and benefits and in this case there was no obvious consent around the suprapubic catheter placement. The rest of the care that [Mrs A] was given was of a very high standard but I would find the placement of the suprapubic catheter without any obvious consent process a moderate departure from the expected standard of care."

52. I accept Dr Masters' advice, and I am concerned that there is no documented evidence that the possibility of SPC placement was discussed with Mrs A prior to the procedure, or that her consent was obtained for this. I acknowledge Dr D's comments about situations arising during surgery that may necessitate a change of plan that was not discussed or documented in the consent process. However, I note that this was not an emergency situation. Given the

risks associated with the placement of an SPC, it was important to obtain informed consent, particularly in Mrs A's circumstances where the risks were heightened in light of her medical history. I note Dr Masters' comment that a urethral catheter could have been placed in the interim. If the placement of a urethral catheter had been discussed with Mrs A prior to the surgery, the placement of a urethral catheter would have afforded Mrs A time to consider whether she agreed to the placement of a SPC.

53. Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights (the Code) states that "[e]very consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option". In my view, Dr D did not provide information that a reasonable consumer in Mrs A's circumstances would expect to receive before receiving treatment, namely, information about the possibility of SPC placement, and the associated risks of this. Accordingly, I find that Dr D breached Right 6(1)(b) of the Code.

54. It follows that Dr D also breached Right 7(1) of the Code, which states that "services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent". By failing to discuss with Mrs A the risks associated with the placement of an SPC, Mrs A was not in a position to make an informed choice about her treatment.

Opinion: Dr C — adverse comment

Introduction

55. On Day 10, Mrs A experienced a sudden onset of severe abdominal pain and was transported to the ED. She was reviewed on arrival by ED registrar Dr C. Following administration of pain medication, Mrs A was again discharged home. To assist with my consideration of the care provided by Dr C, I sought advice from emergency medicine specialist Dr David Prisk.

Assessment and documentation

56. Ambulance service records note that upon arrival, Mrs A was in obvious pain that intensified on movement of her right leg and when sitting up. The triage nurse noted that Mrs A was grimacing in pain, and documented a pain score of 7–8/10. In contrast, on review of Mrs A, Dr C documented that she appeared to be comfortable at rest, with "some pain around [the] catheter insertion site".

57. Dr Prisk noted that it is not documented whether Dr C considered the possibility of an internal bleed or other serious cause of Mrs A's abdominal pain, or whether Dr C considered imaging Mrs A's abdomen with ultrasound. Dr Prisk advised that given that Mrs A's vital signs at that time were normal, and she appeared to be in no distress while at rest, she may have been clinically well enough to consider that the use of ultrasound to evaluate her abdominal pain was not indicated.

58. Dr Prisk considered that Dr C's documented history and the physical examination undertaken at the time appear to be "just at [the] standard" that could be expected. Dr Prisk noted that the ambulance service records that document Mrs A having been in obvious pain are not acknowledged or referred to by Dr C. Dr Prisk was critical of Dr C's failure to clearly document his medical decision-making, or the general and specific advice given to Mrs A prior to her discharge. Dr Prisk described this as a moderate departure from expected standards, and noted that the lack of documentation had made assessment of the care provided by Dr C challenging.

59. It was not recorded whether Dr C considered speaking to a registrar or consultant from the hospital's Urology Department. Dr Prisk advised that based on Mrs A's documented normal vital signs and bloodwork, a surgical consultation does not appear to have been indicated. However, he noted:

> "[Mrs A] was discharged from hospital less than 24 hours prior to her ED presentation, and a call to the Urology service might have been made not just out of professional courtesy, but to gain insight into [Mrs A's] acute condition."

60. I agree with Dr Prisk's comments and note that this would have been an opportunity to share information about Mrs A's current condition, particularly given the timing of Mrs A's presentation to ED. While it would have been optimal for Dr C to have contacted Urology, I do, however, acknowledge Dr C's rationale for not contacting the department, and consider this decision to have been reasonable in the circumstances.

Conclusion

61. Dr Prisk noted in his advice that the issues in this case "are more systemic than individual". I acknowledge Dr Prisk's comments and, as discussed below in the DHB section, agree that there were systemic issues at play. However, I do consider that Dr C had a clear individual responsibility to undertake adequate assessments and to document these clearly, and to note the safety-netting advice given to Mrs A.

62. I acknowledge the changes Dr C has made to his practice since these events, including to his documentation, and these changes appear to be appropriate. However, notwithstanding this, I remain mildly critical that Dr C did not record his assessment and safety-netting advice to Mrs A adequately, and mildly critical that Dr C did not contact the Urology Department.

Opinion: DHB (Te Whatu Ora) — adverse comment

Introduction

63. I consider that several aspects of the care provided to Mrs A fell below expected standards. As identified by my clinical advisors and set out above, a number of these were individual failings. However, systemic issues were also identified.

Preoperative and postoperative management — other comment

64. My clinical advisor, haematologist Dr Eileen Merriman, advised that Mrs A's anticoagulation management during, prior to, and after the procedure on Day 1 was appropriate, and consistent with expected practice. Dr Merriman advised that the management plan clearly identified Mrs A as being at high risk of thromboembolism,[18] and that Mrs A's warfarin was discontinued appropriately.

65. Dr Merriman advised that given the severity of Mrs A's pain during her presentation to ED on Day 10, repeat imaging to determine the extent of her haematuria[19] should have been considered. Dr Merriman stated:

> "Ideally an INR[20] [test] should have been performed on the day of discharge as [Mrs A] was instructed to take both [Clexane] and warfarin for four days with no repeat testing, which puts her at a risk of having an INR in the therapeutic range (or supratherapeutic[21]) while still taking [Clexane]."

66. Dr Merriman noted, however, that the INR[22] measured in ED on Day 10 was not concerning, with over-anticoagulation not a factor increasing her risk of bleeding, but that ideally a repeat INR on the day of discharge should still have been undertaken.

67. Dr Prisk considered that given Mrs A's normal vital signs, benign clinical appearance, and history of transfusion-dependent haematuria, repeat imaging may not have been indicated. However, Dr Prisk noted that it would have been helpful to have had this decision-making documented.

68. I accept both Dr Prisk's and Dr Merriman's comments that Mrs A's preoperative and postoperative anticoagulation was well managed, and note Dr Merriman's advice that although earlier imaging may have helped to identify the bleed earlier, it may not have changed the final outcome.

Documentation and ED discharge policy — adverse comment

69. In addition to the issues in the care provided to Mrs A by individual clinicians, Dr Prisk identified issues that lay with the DHB at a systemic level. In particular, Dr Prisk noted that an electronic discharge summary for patients discharged from ED would have been helpful. Dr Prisk also noted that the DHB should consider developing a guideline or policy for when a recently discharged patient returns to ED within a certain timeframe.

70. In my view, both of these would have been useful in Mrs A's case. A standardised electronic discharge summary would have supported the communication between the clinicians and Mrs A and her family. A guideline supporting clinicians with their decision-making when a

[18] Blood clots.
[19] Blood in the urine.
[20] Measures length of time the blood takes to clot.
[21] Higher levels than are used in treatment.
[22] INR at this time was 1.5.

patient returns to hospital after a recent discharge would have assisted with Mrs A's continuity of care.

71. I acknowledge the information provided by the DHB (see the "changes made" section below) regarding Te Whatu Ora's planned implementation of standardised medical notes and electronic discharge summaries. I also note that Te Whatu Ora plans to develop a policy requiring ED contact with the clinical service from which a patient was discharged, if the patient presents to the ED within 72 hours of discharge. This will assist with continuity of care and provide guidance on the management of acute symptoms.

72. I recognise that these events occurred in 2017, and that significant service changes have been made or proposed by Te Whatu Ora (see "changes made" section below). I consider these to be appropriate remedial actions in the circumstances.

Changes made

73. Dr D told HDC that he now pays particular attention to questions around the use of anticoagulation drugs and anticoagulation plans for his patients, and ensures that he seeks advice from his cardiology, haematology, and anaesthesia colleagues when appropriate.

74. Dr D stated that when obtaining consent he now ensures that any diagrams he draws to assist with discussions are kept in the notes, and he continues to discuss both planned outcomes and any potential problems or complications, as well as alternatives to the procedure. Dr D stated that this experience has reinforced the need to discuss the fact that there may be additional procedures required and to gain consent for those as broadly as possible.

75. Dr C told HDC that he has reflected on his clinical practice since this complaint was brought to his attention, and noted that this case highlighted areas of his documentation that could be improved — namely, the explicit documentation of review of paramedic notes, clinical decision-making, and safety-netting advice. Dr C said that he has improved the clarity and thoroughness of his documentation in these areas.

76. Dr C advised that he now routinely asks for a specialty review of patients who have presented to ED within 72 hours of discharge from an inpatient team. Dr C noted that he has placed himself on a waiting list for an ultrasound training course. Te Whatu Ora told HDC that as part of a wider project to develop a regional electronic clinical record, new ED discharge summaries were developed for implementation at the end of May 2021. In response to the provisional opinion, Te Whatu Ora stated that it has a functioning regionalised electronic discharge summary on the clinical portal platform. This form provides separate sections for clinicians to make follow-up advice and return for review precautions for both the patient and primacy care practitioner.

77. Te Whatu Ora also advised that a policy regarding notification of a specialty when a recently discharged patient returns to ED within 72 hours of discharge will be developed.

Recommendations

78. I recommend that Dr D:

a) Provide a formal written apology to Mrs A's family for the breaches of the Code identified in this report. The apology should be sent to HDC, for forwarding to Mrs A's family, within three weeks of the date of this report.

b) Provide evidence to HDC, within three months of the date of this report, that he has in place a system for ensuring that all treatment options and their associated risks are discussed clearly with patients, and documented on consent forms or in clinic letters.

c) Reflect on how he can improve his informed consent process to ensure that he discusses and seeks consent for procedures that may be required during surgery.

79. I acknowledge the changes Dr C has made to improve the care he provides, and recommend that he:

a) Provide a formal written apology to Mrs A's family. The apology should be sent to HDC for forwarding to Mrs A's family, within three weeks of the date of this report.

b) Arrange for a peer-reviewed audit of his documentation. The audit should review a random sample of 10 of his patient clinical records. The results of the audit, and details of any further changes made as a result, are to be sent to HDC within three months of the date of this report.

80. I recommend Te Whatu Ora:

a) Provide HDC with an update on its progress in developing a regional electronic clinical record and standardising ED discharge summaries. The update is to be provided to HDC within one month of the date of this report.

b) Provide HDC with an update on its progress in developing a policy regarding the notification of a specialty when a recently discharged patient returns to ED within 72 hours of discharge. The update is to be provided to HDC within one month of the date of this report.

c) Provide feedback to HDC on any support it is providing to its emergency medicine registrars and consultants to utilise bedside ultrasound in the ED, within one month of the date of this report.

Follow-up actions

81. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's and Dr D's names.

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

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from ED consultant Dr David Prisk:

"My full name is David Lee Prisk. I graduated from the West Virginia School of Osteopathic Medicine in Lewisburg, WV, USA, in 2002, and completed a categorical residency in emergency medicine at East Carolina University/Pitt County Memorial Hospital in Greenville, NC, USA, in 2005. I became certified by the American Board of Emergency Medicine in 2007 and became a Fellow of the Australasian College for Emergency Medicine in 2016. I have been a consultant emergency physician in the Palmerston North Hospital Emergency Department since 2012 and have served as clinical director/medical lead of the department since 2014.

I have been asked to provide an opinion to the Commissioner on case number **C19HDC00764.**

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Documents Reviewed

I have reviewed the following documents provided by HDC:

1. Copy of complaint dated 30 April 2019
2. [DHB] responses dated 9 August 2019 and 1 December 2020
3. [Dr C's] responses dated 5 July 2019 and 15 February 2021
4. Response and notes from the ambulance service dated 12 July 2019
5. Clinical records from [the DHB] for [Mrs A's] ED admission on [Day 10]

Advice Requested

I have been asked to comment on:

1. The adequacy of [Mrs A's] assessment in ED given the severity of her abdominal pain.
2. Whether reasonable consideration was given to the possibility of an internal bleed.
3. Whether appropriate follow-up contingencies were put in place, including safety-netting advice.
4. Whether surgical services should have been consulted.
5. Any other matters which warrant comment.

For each question, I have been asked to advise:

1. The standard of care/accepted practice.
2. If there has been a departure from the standard of care or accepted practice, how significant that departure is considered to be.
3. How this departure would be viewed by my peers.

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

Advice

1. The adequacy of [Mrs A's] assessment in ED [Day 10] given the severity of her abdominal pain.

[Dr C's] history is largely consistent with the history obtained by [the ambulance service] paramedics, namely that [Mrs A] had the sudden onset of right sided abdominal pain radiating to her back after she reached to her left when changing her catheter bag the morning of [Day 10].

[The] paramedics noted that [Mrs A] had pain in the right lower side of her abdomen that radiated to her lower back; paramedics noted that [Mrs A] felt something 'give way' on her right side when she twisted. Additionally, they noted that she was in obvious pain that intensified when she moved her right leg and sat up. While it is not called a psoas sign or an obturator sign specifically in [the ambulance service] notes, this could very well be a description of either, and either could have been a sign of peritoneal or retroperitoneal irritation or muscular strain. [Dr C] wrote in his note that [Mrs A] had 'some pain around catheter insertion site though pain in lower abdomen feels different to this.' He documented a somewhat cursory abdominal exam that revealed [Mrs A] was sore over the right lower quadrant to the right of the suprapubic catheter insertion site and that there was no peritonism. It is not detailed what elements of the abdominal exam reassured [Dr C] that there was no peritonism. There is no documented examination of the suprapubic catheter insertion site.

It is not documented if [Dr C] reviewed the notes made by [the ambulance service] paramedics, who wrote that [Mrs A] was in obvious pain but also noted that she was chatty and travelled well to hospital. [Dr C] noted that [Mrs A] appeared to be comfortable at rest, despite [Mrs A] providing a pain score of 7–8/10 to the triage nurse, who also noted she was grimacing in pain and that she appeared to be very sore.

In short, there appears to be inconsistency between the assessments made by [the] paramedics, the ED triage nurse, and the assessment made by [Dr C]. At rest, she appeared to be well, but with movement she was in marked pain. [Dr C] does not appear to have tried to elicit pain with any provocative clinical testing.

[Dr C] has written that he was reassured that [Mrs A's] vital signs were normal, and as it does not appear that [Mrs A] was on any rate-controlling medication for atrial fibrillation (according to [the ambulance service] record), this reassurance appears to be justified. [Mrs A] remained normotensive and had a normal heartrate in the ambulance and during her stay in the ED. I have not been provided with the hospital electronic discharge summary from Urology or electronic medication list [Dr C] had access to on [Day 10], and as [Dr C] has stated that it is his normal practice to review the electronic medical records of his patients, I must assume that [Dr C] saw nothing of concern.

The documented history and physical exam are just at standard. [Ambulance service] notes are not acknowledged and confirmation or refutation of paramedics' findings is not documented. Medical decision making is not documented, and this would be considered by my peers to be at least a moderate departure from the standard of care.

Standardised medical notes, with space to acknowledge paramedic notes and electronic medical records (including medications), might be developed to help ensure that such potentially critical information is routinely reviewed.

2. Whether reasonable consideration was given to the possibility of an internal bleed.

It is not documented if [Dr C] considered the possibility of an internal bleed, or some other serious cause of [Mrs A's] abdominal pain. [Dr C] has said that he was reassured by [Mrs A's] normal vital signs and bloodwork and her benign clinical appearance while at rest. It was noted that [Mrs A] suffered from transfusion-dependent haematuria, and that she received blood every fortnight. It is not documented when [Mrs A's] last transfusion occurred, nor the trend in her haemoglobin values. Therefore, it is not clear if [Mrs A's] bloodwork should have been reassuring.

It is not documented if [Dr C] considered imaging [Mrs A's] abdomen with ultrasound (either formally or at the bedside) or CT. [Dr C] has stated that although he had access to an ultrasound machine in the ED on [Day 10], he did not think its use was indicated, as it is his normal practice to use ultrasound only when evaluating trauma patients or patients who might have an abdominal aortic aneurysm (AAA). [Dr C] has stated that he is not certified in ultrasound and has implied that he does not feel comfortable using ultrasound outside of those two specific scenarios. As informal bedside ultrasound in the ED is used in trauma patients and in patients with AAA to look for signs of haemorrhage, it seems that [Dr C] did not consider that [Mrs A] was suffering from an internal bleed.

Informal bedside ultrasound is rapidly becoming an important tool in the evaluation of acutely ill and injured patients in the emergency department, but it is not yet considered standard of care in Australasia. [Mrs A] had normal vital signs and while at rest appeared to be in no distress; she may have been clinically well enough that use of ultrasound to evaluate her abdominal pain on [Day 10] was not thought to be indicated. It would be easy to speculate that provocative clinical testing to elicit a psoas or obturator sign might have changed [Dr C's] mind, but these sorts of tests may also have supported the diagnosis of muscle strain.

Consideration was not given to the possibility of an internal bleed, and this may or may not have been reasonable.

3. Whether appropriate follow-up contingencies were put in place, including safety-netting advice.

[Dr C] has documented that he gave [Mrs A] safety-netting advice but is not specific about the advice given.

This would be seen as a mild departure from the standard of care by my peers.

An electronic discharge summary for patients discharged from the Emergency Department would be helpful for both patients and staff; general advice as well as specific recommendations, including indications to seek medical attention (particularly indications to return to the ED) could be included in such a dedicated ED discharge summary. This has the potential to improve the aftercare of patients discharged from the Emergency Department.

4. Whether surgical services should have been consulted.

It is not documented if [Dr C] considered speaking to a registrar or consultant from Urology, the service from which [Mrs A] had been discharged the day before her ED presentation.

[Dr C] documented that [Mrs A] did not have peritonism, and she had normal vital signs and normal bloodwork. Based on these things, a surgical consult does not appear to have been indicated. However, [Mrs A] was discharged from hospital less than 24 hours prior to her ED presentation, and a call to the Urology service might have been made not just out of professional courtesy, but to gain insight into [Mrs A's] acute condition.

This would be seen as a moderate departure from the standard of care by my peers. [Mrs A] had recently undergone an invasive procedure on her pelvis and returned to the ED less than 24 hours after hospital discharge with abdominal pain. [Dr C], in his letter of 15 February 2021, has stated that there is no DHB policy requiring notification of a specialty if a recently discharged patient returns to the ED within a certain time frame. Consideration might be given to the development of such a guideline.

5. Any other matters which warrant comment.

In his response to the HDC, [Dr C] lists reasons why he 'was of a view that [Mrs A] was appropriate for discharge.' Several of these reasons are problematic.

One of these is 'a low concern triage score (4).' The Australasian Triage Scale (ATS) indicates only how long a patient can wait to be seen, based on the quick clinical impression of a trained clinician, most often an ED triage nurse. It indicates neither patient complexity nor patient disposition, indicates neither kind nor degree of investigations or treatment necessary, and should not be used to determine whether a patient is safe for discharge. Using the ATS in a manner other than that for which it is intended would be inappropriate.

Another reason [Dr C] gives for discharging [Mrs A] is 'a history and examination supportive of a muscular injury and SPC irritation.' While this may have been so, the history and examination noted by paramedics suggested other potential causes. It is not documented whether other potential causes were considered and, if they were, why they were not pursued. [Dr C] acknowledges that [Mrs A's] pain was different to pain at the SPC insertion site but does not then write why further investigations were not

indicated. As mentioned previously, there is no documentation of medical decision making.

[Dr C] also notes that [Mrs A] experienced significant improvement of her symptoms with a single dose of oral analgesia and lignocaine jelly and that this, too, indicated she was safe for discharge. Response to analgesia is not diagnostic and does not rule out a serious cause of pain; response to analgesia is also not justification for an abbreviated evaluation and is not justification for discharge.

Summary and General Recommendations

[Mrs A's] assessment by [Dr C] in the Emergency Department on [Day 10] appears to have involved mild to moderate deviations from the standard of care, and highlights opportunities for improvement.

Standardised electronic medical documentation in the ED, with prompts to review paramedic notes, electronic medical records, and patient medications would help provide a more complete clinical picture and guide investigations. Such standardised medical notes might also include prompts for different parts of the physical exam and for medical decision making. Standardised electronic discharge summaries — apart from the medical notes — might also be developed, as these would enhance communication between clinicians and patients/whānau.

Development of a guideline or policy requiring contact with the clinical service from which a patient was discharged within 24, 48, or 72 hours of their presentation to the emergency department would help with continuity of care and could guide an acute evaluation.

The Australasian Triage Scale should be used only for triage, and only for estimating how long a patient might wait to be seen by a clinician. Any other use is inappropriate.

The use of ultrasound by emergency medicine registrars and consultants deserves active support, as the use of ultrasound to evaluate a variety of conditions — including abdominal pain — will soon be standard of care.

Response to analgesia should not be used to support a diagnosis or patient disposition. This should be socialised among all emergency medicine registrars and consultants.

Thank you for giving me the opportunity to provide advice on this case, and please do not hesitate to contact me should you require more information or clarification of my advice.

Yours sincerely

Dr David Prisk, FACEM

28 February 2021"

The following further advice was received from Dr Prisk:

> "Thank you for giving me the opportunity to review my advice given on 28 February 2021 regarding the emergency care provided to [Mrs A] by [Dr C] on [Day 10] at [the DHB].
>
> I have been provided with copies of the response to you by [the] Chief Operating Officer of [the DHB], the Case Review by [Dr E], Consultant in Emergency Medicine and Acting Head of Department, and the reflection and response to my comments by [Dr C].
>
> I wish to make comment on some of [Dr E's] and [Dr C's] statements, and to clarify some of my own advice.
>
> In Part B: Review of HDC documentation, [Dr E] states that there is no inconsistency between the pain assessments made by [the ambulance service], ED triage, and [Dr C]. In my original advice, I stated that there appeared to be inconsistency between these clinicians in the assessment; I did not specify that I was referring to the overall assessment, not simply pain assessment. I stand by my original statement. While pain assessments may have been similar between clinicians, the overall assessment was not. [Dr E] criticises the mention of psoas and obturator signs, as these are of low sensitivity and not regularly performed by himself or his colleagues; I do not disagree that these signs are not always helpful, but as they were suggested by paramedic assessment, it may have been wise to confirm or refute these findings with a more comprehensive exam.
>
> I have revised my advice to develop a template on which a review of ambulance notes could be acknowledged. I now believe that [the ambulance service's] electronic Patient Record Forms (ePRFs) — or any pre-hospital service's electronic records — should be fully integrated with the hospital's electronic medical records. In this way, it will be easier for important pre-hospital findings not to be missed, and easier for clinicians to document their review of ambulance notes.
>
> [Dr E] states that while there is scope for improvement in [Dr C's] documentation, this does not equate to sub-standard provision of care. [Dr E] also states that 'more expansive clinical notes would have helped support [the] clinical impression.' As he knows, the notes are all that remain of this clinical encounter and all that can be used to evaluate the case. [Dr E] seems to be under the impression that retrospective bias can be removed to see the case more clearly. [Dr E] states, 'based on the clinical impression alone, having in my view removed retrospective bias, there is no certainty that an assessing urological registrar would not have also discharged the patient home.' There is also no certainty that a urological registrar would not have admitted [Mrs A] or pursued further investigations. I find it difficult to review this case apart from the medical notes and in any way other than retrospectively, which will always have an irredeemable bias. [Dr C's] follow up statements make me think that he very likely did not provide substandard care to [Mrs A], but his medical notes suggest otherwise.

[Dr E] also takes issue with the concern I expressed regarding use of the Australasian Triage Scale as criteria for [Mrs A's] discharge. He states that I misrepresent [Dr C's] own statement, which read in part that he reached the conclusion [Mrs A] was appropriate for discharge because she had a 'low concern triage score (4).' I find it difficult to read [Dr C's] statement in a different way; he clearly lists a low triage score as a reason for discharge. However, I do accept [Dr C's] subsequent statement that he was simply trying to reflect that other clinicians in the department did not have concerns [Mrs A] was critically ill, and that he does not use the ATS as part of his criteria for discharging patients. [Dr E's] and [Dr C's] subsequent statements about proper use of the ATS are reassuring but were not present in [Dr C's] original response.

[Dr C], in his follow up statement, also writes that I have misinterpreted his original statement regarding the use of response to analgesia as criteria for discharge. Again, I have simply taken from [Dr C's] own original statement, and while I find it challenging to interpret this statement in a different way, perhaps my comments need some clarification. Although response to analgesia can be an indication for discharge, I would urge caution in cases where there may be diagnostic uncertainty. Good response to analgesia can be used as criteria for discharge in the presence of objective findings such as a broken bone or ureteric stone, or in cases of chronic pain previously investigated. Closely reading [Dr C's] follow up statement, it seems that [Mrs A's] pain was taken as something previously recognised and addressed when she was admitted under urology and may have qualified — if not as a chronic issue — as an issue that was subacute; in this instance, her good response to analgesia may indeed have been an indication for discharge. However, I must again reiterate that a call to the urology service might have provided more insight into [Mrs A's] condition. It is good to know that [Dr C] has reflected on this case and now makes contact with the service from which a patient was discharged if that discharge occurred within the previous 72 hours.

It is also good to read that [Dr E] and [Dr C] agree with many of my recommendations. I wish to be clear that many of the issues identified in this case are systemic and I hope that they will be addressed at that level. [Dr C's] documentation of this case was less than ideal, and I still believe that his documentation would be seen by my peers as being at least a mild departure from the standard of care. [Dr E] mentions that I have found [Dr C] in breach of standards of care, and I wish to point out that I have not found [Dr C] in *breach* of anything as it is not my place to do so; I am, however, in a position to identify *departures* from what my peers and I would consider our standard of care.

Thank you again for allowing me to make additional comment on this case, and please let me know if you require anything further.

Yours Sincerely

Dr David Prisk, FACEM

9 September 2021"

Appendix B: Independent clinical advice to Commissioner

The following advice was obtained from haematologist Dr Eileen Merriman:

> "Thank you for asking me to provide a report on [Mrs A], [DOB], regarding her death in September 2017 due to a significant abdominal bleed following abdominal surgery for ongoing uterine issues in [2017]. My report is based on records sent to me from [the DHB.
>
> I have been provided with copies of:
>
> *Complaint from [Mrs B] (daughter) dated 30/04/2019*
>
> *Response to complaint from [Dr D], Consultant Urologist dated 29 July 2019*
>
> *Response to query from HDC by [Dr D] dated 23 November 2020*
>
> *Clinical records from [the DHB] [2017]*
>
> *Radiology and laboratory reports from [2017]*
>
> *Emergency Department discharge summary dated [Day 10]*
>
> *[The DHB's] Perioperative anticoagulation guideline for 'management of oral Anticoagulation during invasive procedures according to risk of thromboembolism' dated [2017]*
>
> *Letter dated [2017] from [visiting Haematology Registrar]*
>
> I am a consultant haematologist and the Clinical Director and Lead Thrombosis Clinician at North Shore Hospital, Auckland. I graduated from Otago Medical School (Dunedin) in 2001. I have been a fellow of both the Royal Australasian College of Pathologists and the Royal Australasian College of Physicians since 2010. I am the past President and New Zealand councillor for the Thrombosis & Haemostasis Society of Australia and New Zealand (THANZ; 2017–2019). I am fully compliant with ongoing registration and annual college recertification requirements. I have no personal or professional conflicts related to this case.
>
> To summarise, [Mrs A] was seen in [Dr D's] private rooms [in 2017]. At this time, [Mrs A] reported recurrent urinary tract infections, disabling urinary frequency/nocturia and aching in the vulval region. This was accompanied by blood on the paper when she wiped before voiding, and bleeding after bowel motions which was 'not from her bowel'. A recent vaginal examination by the gynaecology team had revealed a dry, atrophic mucosa with no lesion/source to explain the bleeding. A cystoscopy performed by [Dr D's colleague] showed a 'very red, sore looking bladder/urethra but no sign of a tumour or stone'; this was thought to be due to infection and treated with antibiotics.
>
> [Mrs A] had a number of comorbidities. At the time [Dr D] saw her in clinic, her creatinine clearance was 26ml/minute. She was also an ESBL carrier, had a St Jude's valve for aortic stenosis, paroxysmal nocturnal haemoglobinuria (PNH; 22 years history)

requiring fortnightly blood transfusions, atrial fibrillation, diverticular disease and a history of acute kidney injury following a traumatic hip fracture in 2012.

[Dr D] recommended an examination under anaesthetic as an elective procedure, with planned cessation of warfarin and bridging with Enoxaparin. [Mrs A] was advised to stop her warfarin (as per the patient instruction sheet filed in her notes) and to start Enoxaparin 80mg once daily (1mg/kg once daily rather than twice daily due to her renal impairment), with the last dose to be given [two days before surgery]. [Dr D] notes that her recorded weight was 68kg, however it is not unusual to round the dose to the nearest vial size, which in this case is 80mg.

[Mrs A] was admitted to [the public hospital] to allow 24 hours of preoperative antibiotics (Meropemen) due to ESBL colonisation of her urine. The on call house officer reviewed [Mrs A] that evening for right toe swelling/pain and noted a dark purple area over the dorsal aspect of the right fourth toe. It was noted that the toe had normal capillary refill and although this could represent thrombosis, that the patient was on treatment dose Enoxaparin in any case. Presumably the house officer was referring to a self-administered dose given that morning (prior to admission), as the first Enoxaparin charted in the notes was 40mg on post-operative day 1 ([Day 2]).

The surgery took place on [Day 1], having been postponed the day before for reasons that are not clear in the medical notes. The operation note states that there was an ulcerated area anterior to the urethra that was suspicious for malignancy, but that the urethra appeared normal posteriorly and throughout its length, and that the bladder looked 'a little inflamed, mildly trabeculated, no stone or lesion'. A urethrocystoscopy was performed, with excision of part of the ulcerated area. An attempt was made to bring some of the proximal urethera out to the outer skin, however the sutures would not hold. [Dr D] notes 'we seemed to have good haemostasis'. A suprapubic catheter (SPC) was placed instead, with no obvious bleeding at the end of this procedure.

Post-operatively, the SPC was draining 'rose haematuria' and 'lots of clots overnight' were noted in the ward round note the following day. For this reason, [Mrs A] was commenced on a prophylactic rather than treatment dose of Enoxaparin on [Day 2] (40mg once daily). The Hb was recorded as 92g/L and in view of her ongoing haematuria and history of PNH, [Mrs A] was charted 3 units of red blood cells. Light haematuria was noted on [Day 3] and 'urine clear' on [Day 4], at which point the Enoxaparin was increased to 80mg once daily and the Meropenem was stopped. Warfarin loading was recommenced on [Day 5] with Enoxaparin cover; it is unclear what doses of warfarin were charted from the notes available to me. On [Day 6], [Mrs A] was noted to have frequency and dysuria and her SPC was washed out, draining old dark clots, after which her symptoms were reported to have improved.

On the evening of [Day 7], the on call house officer was asked to review [Mrs A] as she was complaining of pain around her vulva and suprapubic catheter, which felt deep rather than superficial, and was constant with superimposed spasms. The house officer noted light PV ('fresh bleeding') in [Mrs A's] pad with no clots, and that the SPC was

draining rose-coloured urine. On examination, she was tender adjacent to the SPC, with no inflammation or purulent discharge, and no masses or guarding. The vulval examination revealed a small amount of fresh blood, with no abnormal discharge. [Mrs A] was charted a stat dose of oxybutynin and prn fentanyl, and was noted to be more comfortable one hour later when the same house officer came to review her once more. The impression on the ward round the next day was 'vulval pain/bladder spasm', and a manual wash-out of the SPC was performed.

[Mrs A] was reviewed on [Day 9] and was noted to have a comfortable night with minimal spotting, and subsequently discharged with a plan to continue Enoxaparin and warfarin with an INR check on [Day 11], outpatient clinic follow-up in two weeks, and advice to return to hospital if she experienced large volume bleeding. The dose of warfarin was not stated on the discharge summary, but is recorded as 'started warfarin at regular dose on [Day 5]'.

[Mrs A's] daughter, [Mrs B], notes in her complaint that she took her mother home on Friday afternoon and was then contacted by her mother early the next morning complaining of abdominal pain. [Mrs B] took her mother to the Emergency Department for review ([Day 10]). The Emergency Department discharge summary documents that [Mrs A] reported severe lower abdominal pain, which came on after [Mrs A] got out of bed to empty her catheter bag. They noted 'catheter draining well, haematuria settling'; they have also recorded the pain score as 'none'. The emergency doctor's examination was reported as: 'sore over RLQ to R side of SPC insertion site. No peritonism' and 'blood — no concerning changes'. They suggested codeine along with topical lignocaine to the SPC insertion site. I note a blood test taken on [Day 10] showed creatinine of 171micromol/L (stable/baseline), a CRP of 20mg/L, APTT 37, INR 1.5, and a Hb of 120g/L (126g/L two days prior) with platelets 115 x 10^9/L, WCC 7.0 x 10^9/L with a normal differential. However [Mrs B] reports that her mother was still in pain on arrival home. The next morning (Day 11), [Mrs B] received a call from her father saying that he was concerned re [Mrs A's] state of health. An ambulance was called and [Mrs A] was taken to [the public hospital], where she was admitted to the intensive care unit (ICU).

I have not been provided with the inpatient notes relating to the second hospital admission ([from Day 11]). However [Dr D] states in his response to the complaint that '[Mrs A] was admitted shortly after discharge, and by this time had obviously had a bleed, probably from the suprapubic area internally and was hypotensive due to abdominal wall haematoma'. This is consistent with the CT report from [Day 11], which found a large subacute haematoma in the right anterior abdominal wall, along with a rectus haematoma (24 x 9.7 x 9.4cm). The Hb had fallen to 100g/L, with a therapeutic INR of 2.4 and APTT 42; at this stage [Mrs A] was acidotic with a pH of 7.21 (lactate 3.5 mmol/L). The Hb fell further to 89g/L six hours later, at which stage the INR had fallen to 1.5 with an APTT of 43 and fibrinogen of 2.6g/L.

[Dr D] states that the anticoagulation was 'reversed', and that the general surgeons and urologists felt that it was not in [Mrs A's] best interest to intervene surgically, as they would not be able to localise the bleeding, and were concerned that intervening would

stop the tamponade effect of the haematoma. Further extensive discussions were conducted by [Dr D] with his colleagues, including 'general surgery, cardiology and the ICU team' about ongoing management. A repeat CT on [Day 12] showed that the right abdominis rectus muscle haematoma and haemoperitoneum had increased in size; with ongoing haemorrhage evidenced by a small blush of contrast material in the region of the abdominis rectus muscle on the right. Despite dialysis and antibiotics, [Mrs A] developed acute renal failure and hypotension, and died [a few days later]. [Dr D] states that the suprapubic catheter, in retrospect, likely resulted in a bleed from the rectus sheath/muscle, which was then exacerbated by the recommencement of anticoagulation/increasing mobility.

I have been asked to provide an opinion on whether the care provided to [Mrs A] by the Haematology Department at [the public hospital] was reasonable in the circumstances, and why.

In particular, I have been asked to address the following points, which I will address in a sequential fashion:

(1) The appropriateness of [Mrs A's] anticoagulation management during, before and after her surgery.

This was appropriately managed. [Mrs A], with a history of atrial fibrillation, a mechanical aortic valve (St Jude's) and PNH, was high risk for both arterial and venous thrombosis. Her warfarin was stopped and Enoxaparin bridging commenced with appropriate timing and doses. Due to the haematuria post-operatively, her Enoxaparin dose was reduced to 40mg once daily, and as the haematuria began to settle, this was appropriately increased back to full treatment dose for her creatinine clearance/weight (80mg once daily) on [Day 4]. As stated above, [Dr D] noted that [Mrs A's] actual body weight was 68kg however it is common practice to round the dose to the nearest vial size, which in this case would be 80mg.The warfarin was recommenced on [Day 5]. This is consistent with accepted practice/standard of care and I believe my peers would view this similarly, although some may have advocated for a 70mg dose. I do not, however, believe that a difference of 10mg in [Mrs A's] Enoxaparin dose would have significantly increased her risk of bleeding, and believe that my peers would agree.

[Mrs A] was recommenced on warfarin and discharged ([Day 9]) on a combination of Enoxaparin and warfarin, as her INR had not yet increased to the target range (1.2 on [Day 8]), with a plan to repeat the INR three days after discharge (with GP follow-up). I cannot see an INR result performed on [Day 9], the day of discharge, meaning that this would leave four days between INR testing. Ideally an INR should have been performed on the day of discharge as the patient was instructed to take both Enoxaparin and warfarin for four days with no repeat testing, which puts her at a risk of having an INR in the therapeutic range (or supratherapeutic) whilst still taking Enoxaparin. However, I note the INR measured in ED on [Day 10] was 1.5, so this was not a concern, and over-anticoagulation was not a factor in increasing her risk of bleeding. I believe the majority of my peers would agree with my view on the need for a repeat INR test on day of discharge, which is simple and easy to do. At the time of her ED admission, it is difficult

to assess the degree of her haematuria as the notes merely state 'haematuria settling' however I noted that her Hb was stable at 120g/L (126g/L on [Day 8]), and therefore it was not unreasonable to continue her anticoagulation at that point. When [Mrs A] returned to hospital the following day, the anticoagulation was appropriately stopped and reversed. Given the severity of her pain, I do think repeat imaging at the time of the ED presentation on [Day 10] should have been considered. I believe my peers would concur with my opinion.

(2) The appropriateness of [the DHB's] anticoagulation management protocol in place at the time.

A clear pre-operative management plan was given to [Mrs A] and this was managed appropriately during her admission. The perioperative management protocol provided in the notes clearly identifies [Mrs A] as being at high risk of thromboembolism by virtue of her mechanical aortic prosthetic valve with coexistent AF and age >75 years. Her enoxaparin was discontinued as per the protocol, with the last dose given at least 24 hours prior to the surgery (in this case, the last dose appeared to have been given 48 hours prior). The post-operative part of the protocol was also followed, with prophylactic doses of LMWH used while [Mrs A] was having heavy haematuria, and increasing once the bleeding settled. The plan is consistent with standard of care/international guidelines. I believe my peers would concur with this.

(3) Compliance with the anticoagulation management protocol by staff involved in [Mrs A's] care.

Addressed above.

(4) Any other matters in this case that I consider warrant comment.

This is an unfortunate case of severe haemorrhage post an excision of a necrotic part of the urethra (stated as likely to be cancer) followed by suprapubic catheter placement, in a patient at high risk for thrombosis. Her pre and post-operative anticoagulation was well managed. The bleed could perhaps have been identified earlier at the time of the first ED presentation (one day after discharge), but given her Hb was stable (only a slight drop, which is not unexpected in the context of her known PNH), this is a contentious issue and it is difficult to know if earlier imaging and reversal of anticoagulation would have changed the final outcome. Patients at high risk of both thrombosis and bleeding can be exceedingly difficult to manage, and if her anticoagulation had not been recommenced at the time points above, then she could instead have suffered a life-threatening/fatal episode of thrombosis. I do not have any major concerns over how this patient's case was managed, but believe some of my peers may have recommended earlier imaging at the time of the ED presentation on [Day 10], depending on the patient's degree of pain.

Yours sincerely,

Dr Eileen Merriman
Clinical Director, Clinical Haematologist & Lead Thrombosis Clinician
Dept of Haematology I Waitematā DHB
MBChB BMLSc FRACP FRCPA PhD"

Appendix C: Independent clinical advice to Commissioner

The following advice was obtained from urologist Dr Jonathon Masters:

"My name is Jonathan Masters. My Medical Council Number is 26350. I am a Urologist and my specialist interests are in prostate and bladder cancer and bladder function. I do not have any conflicts of interest in this case. In this case you have asked me in particular, to please comment on:

1. The reasonableness of the decision to undertake the urethrocystoscopy;
2. The adequacy of the care provided during the procedure. As part of this, please comment on the reasonableness of the decision to place a suprapubic catheter at that time;
3. The adequacy of the post-operative care provided to [Mrs A] prior to her discharge;
4. The reasonableness of the decision to discharge [Mrs A] on [Day 9]; and
5. Any other matters in this case that you consider warrant comment.

For each question, please advise:

1. What is the standard of care/accepted practice?
2. If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?
3. How would it be viewed by your peers?
4. Recommendations for improvement that may help to prevent a similar occurrence in the future

1) <u>The reasonableness of the decision to undertake the urethrocystoscopy</u>

I think it was an entirely appropriate decision to perform a urethrocystoscopy and urethral biopsy in [Mrs A. She had very significant and bothersome lower urinary tract symptoms and [Dr D] the urologist correctly was concerned that this may represent a cancer.

2) <u>The adequacy of the care provided during the procedure. As part of this, please comment on the reasonableness of the decision to place a suprapubic catheter at that time</u>

[Mrs A] had very significant health issues including a mechanical heart valve and positive urine cultures. In order to ensure she had a safe operation she was admitted a day before surgery so that her anticoagulation could continue to be changed to bridging clexane safely and the procedure could be covered with 24 hours of pre-operative intravenous antibiotics. The operation itself seemed to be uneventful. It is not unusual to find that on excising a urethral lesion it is difficult to bring the urethral tissue down to cover the deficit. It would seem from the operation note the decision to place the suprapubic catheter was made on the basis that this area could cause pain on passing urine and so a suprapubic catheter was felt to be appropriate. In his reply to the complaint, [Dr D] gives a slightly different reason, but a valid one, and that was to relieve [Mrs A] of her terrible symptoms and nocturia. A suprapubic catheter is a much better

long term option in women than a urethral catheter and [Mrs A] was anesthetized anyway so it would seem a very sensible time to place a catheter.

I would regard the placement of a suprapubic catheter in this instance as a moderate departure from an expected standard of care. Primarily because on the consent form and in the clinic letter there is no discussion or mention of a suprapubic catheter. Suprapubic catheter placement is not without clinical risk and this risk is increased in patients who are anticoagulated and have had previous lower abdominal surgery. (See attached PDF file BAUS guidelines (updated 2020)). [Mrs A] was not given an opportunity to discuss these issues. Secondly a urethral catheter would have achieved the same aim in the short term and in fact one was placed within 24 hours of surgery without any obvious significant issues.

3) The adequacy of the post-operative care provided to [Mrs A] prior to her discharge

[Mrs A] had a fairly prolonged and difficult post-operative recovery. Her recovery was complicated by significant issues with haematuria. Her Haemoglobin dropped to 92 and on discussion with the haematologists who managed her paroxysmal nocturnal haemoglobinuria she was transfused 3 units of blood. On the first night when she had issues with a poorly draining catheter [Dr D] the operating surgeon came in to assess her and plan her management after 2200 hours at night. There were ward rounds every day and most of these were consultant led ward rounds by [Dr D]. I do note that [Mrs A] had pain around her suprapubic catheter site on [Day 7] but this did seem to settle without any intervention by the day of discharge on [Day 9] and therefore this pain was not investigated further. Great care was taken to manage the anticoagulation she needed for the St Jude's heart valve and in the management of the antibiotics, social workers were involved in planning her discharge and referrals were made to the district nurses. Eventually she was discharged on a Saturday in the company of her daughter in the afternoon. I believe she received very high quality post-operative care.

4) The reasonableness of the decision to discharge [Mrs A] on [Day 9]

[Mrs A] was being discharged to a complicated home situation as her husband had dementia. It is not clear to me whether her husband was in respite care or at home. Care was taken on the day of discharge to discuss going home with [Mrs A] and her daughter as [Mrs A] had not completely transitioned from her clexane to warfarin for her St Jude's heart valve. Patients do need to be discharged and this discharge had been planned over several days prior to [Mrs A] actually leaving. Whilst a discharge at the weekend is not ideal, I would still regard this as a reasonable decision and within the accepted standard of care.

5) Any other matters in this case that you consider warrant comment

I would like to pass on my condolences to [Mrs A's] family. This is a tragic case where despite everyone acting with the best of intentions, the patient died as a consequence of the surgical procedure. In placing the suprapubic catheter, it would seem that [Dr D] believed he was acting in [Mrs A's] best interests (relief of symptoms without having to undergo yet another surgical procedure) and by the end of [Mrs A's] stay and with the

suprapubic catheter working this certainly seemed to be the case. Furthermore why the suprapubic was placed was explained to [Mrs A] the day after surgery and she accepted this without any apparent concern recorded in the notes. Unfortunately, it is most likely that the catastrophic bleed was as a consequence of the suprapubic catheter placement and her need for anti-coagulation. The guidelines around suprapubic catheter use suggest that patients should have a chance to discuss the risks and benefits and in this case there was no obvious consent around the suprapubic catheter placement. The rest of the care that [Mrs A] was given was of a very high standard but I would find the placement of the suprapubic catheter without any obvious consent process a moderate departure from the expected standard of care.

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Reference:

1) British Association of Urological Surgeons suprapubic catheter practice guidelines — revised. BJU Int 2020; 126: 416–422 doi:10.1111/bju.15123 (Please note 2020 update is the latest addition of the guidelines which were available in 2017.)”