Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02905)

Complaint and investigation

1. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to him by Health New Zealand | Te Whatu Ora[1] (Health NZ). The following issues were identified for investigation:

- *Whether Health NZ provided Mr A with an appropriate standard of care during August and September 2021 (inclusive).*
- *Whether Dr B provided Mr A with an appropriate standard of care on 29 September 2021.*

2. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

[1] Previously known as Te Whatu Ora | Health New Zealand. On 1 July 2022 the Pae Ora (Healthy Futures) Act 2022 came into force and all district health boards were disestablished and their functions and liabilities merged into Health New Zealand | Te Whatu Ora.

3. On 29 September 2021, Mr A underwent an elective surgical procedure that resulted in an outcome he had not expected. This report considers the adequacy of the process of obtaining informed consent.

4. The following parties were directly involved in the investigation:

Mr A	Consumer/complainant
Dr B	Urology medical officer/operating surgeon
Health NZ	District healthcare provider

5. Further information was received from:

Pre-assessment anaesthetic clinic nurse	
Dr C	Urology registrar
Dr D	Consultant anaesthetist
Dr E	Consultant urologist
Scrub nurse	
ACC	

6. Anaesthetic nurse RN F is also mentioned in this report.

7. Independent clinical advice was obtained from a urologist, Dr Jonathan Masters (Appendix A).

8. Relevant standards are included as Appendix B.

Introduction

9. On 29 September 2021, Mr A, aged in his fifties, underwent a planned elective surgical procedure at a Day Surgery Unit (Health NZ) for the management of balanitis xerotica obliterans (BXO). BXO is a thin, white, scaly and inflammatory patch that appears on the foreskin[2] of the penis. The surgery resulted in a full circumcision,[3] which was an outcome that Mr A did not expect.

Background

10. Mr A had a history of bleeding from the frenulum[4] post intercourse, scarring on the penile area, and meatal stenosis.[5] Mr A had been known to the urology service since 2008, and in January 2021 consultant urologist Dr E diagnosed Mr A with BXO. Dr E advised Mr A to 'keep [an] eye on things and get back in contact should there be a problem'.

[2] The outer layer of skin that covers the head (the glans) of the penis.
[3] A surgical procedure to remove the foreskin.
[4] A thin strip of tissue found where the foreskin intersects with the head of the penis.
[5] Abnormal narrowing of the opening of the urethra (the tube through which urine leaves the body).

Timeline of events

Telephone consultation 17 August 2021

11. Dr E contacted Mr A on 17 August 2021 for a telephone consultation. Dr E told HDC that this was to avoid Mr A having to make a long trip for an in-clinic consultation. Dr E said that he had seen Mr A in person on 26 January 2021 and had established a diagnosis of BXO and told Mr A to get in touch if his condition progressed, as surgical intervention would be needed.

12. Dr B, a Urology medical officer and Mr A's operating surgeon, told HDC that the telephone consultation was usual practice at the time owing to the COVID-19 pandemic, which necessitated new conditions and restrictions. Dr B said that telephone consultations had replaced the usual process of seeing a patient in an outpatient setting prior to any procedures.

13. Dr E completed a verbal assessment via telephone and documented that 'the whiteness around [Mr A's] meatus ha[d] increased and the meatal opening ha[d] reduced'. Subsequently, Dr E recorded that [Mr A's] 'BXO had progressed'.

14. Dr E documented that the best course of action for Mr A would be to excise some of the foreskin/frenulum tissue under general anaesthetic, and to perform a meatotomy[6] with a possible circumcision at the same time.

15. Dr E told Health NZ:

> 'We discussed that he did not want a circumcision and it would be attempted to complete a more minor procedure, but there was a chance a circumcision would be required once the procedure had started. When talking on the phone it is of course not possible to know exactly the state of the foreskin[,] so that would be discussed at time of the consent with [the] patient present.
>
> During the consent it would be decided if any form of surgery to the foreskin was indicated. This could be circumcision, partial circumcision (biopsy) or a frenuloplasty[7] to release a tight foreskin.'

16. In relation to consent, Dr E told HDC:

> 'I could not [obtain] consent at this time [via the telephone consultation] as [Mr A] was not with me in person — nor would I have if he was as due to time estimated between consult and surgery the consent would have expired. Also as he was a pooled surgical patient it is the responsibility of the operating surgeon to obtain consent.'

17. Mr A was not provided with written information about the procedure, nor was he provided with a copy of the consultation documentation. Health NZ told HDC that sharing written

[6] Surgery to widen the meatus, which is the opening at the tip of the penis.
[7] Surgery to alter the frenulum (a small fold of tissue that is located on the underside of the penis).

documentation from telehealth and in-person appointments was not standard procedure for outpatient appointments.

18. Mr A told HDC that he expected Dr E to be operating on him. However, Dr E stated that he did not inform Mr A who would be carrying out the procedure as he did not have this information at the time. Dr E told HDC that patients in the public system are prioritised into 'availab[ility] lists', rather than left to wait for a particular surgeon, as this may delay their care unnecessarily.

Surgical booking form

19. Following the telephone consultation on 17 August 2021, Dr E completed the surgical booking form, which noted that Mr A's diagnosis was 'BXO around meatus with stenosis', and the procedure to be booked was 'meatotomy +/- circumcision'.

20. Dr E told ACC:

> '[Mr A was] booked for an excisional biopsy of his foreskin/frenulum. It was mentioned over the phone that he may require full circumcision — depending on findings at physical review prior to surgery (at time of consent).'

21. However, excision/biopsy was not written in the surgical booking form.

22. Health NZ's published operation list noted 'meatotomy +/- circumcision' as listed in the surgical booking form.

Further telephone discussion

23. On 6 September 2021, a registered nurse completed an anaesthesia assessment with Mr A by telephone. The anaesthesia assessment form noted the proposed operation as 'meatotomy +/- circumcision'. The form stated: 'Urology service to advise of surgical date, routine instructions, declined need for written anaesthetic information.' No concerns raised by Mr A were noted. The nurse told HDC that the purpose of an anaesthetic assessment is to establish anaesthetic suitability, and the surgical procedure itself is not discussed.

Day of surgery — 29 September 2021

Preoperative area

24. Mr A arrived at the Day Surgery Unit at 2pm on 29 September 2021. Health NZ told HDC:

> '[I]t is not standard for all day surgery cases to have a preadmission. However, if the operating and/or consenting surgeon is not the surgeon who assessed the patient in clinic and listed them for the procedure, clinical letters should be carefully reviewed [and] preadmission considered.'

25. Health NZ confirmed that consent for the procedure took place in the waiting area with registrar Dr C and Dr B, Mr A's operating surgeon. Health NZ said that Dr C was present for only part of the consenting procedure.

26. Dr B said that prior to the consent process, he reviewed Mr A's clinical notes, including the consultation with Dr E. Dr B stated that he learned that Mr A had been suffering from BXO for some time prior to the operation and had told his general practitioner that the BXO was bothering him to the extent that he was willing to undergo surgery.

27. Dr B and Dr E confirmed that no communication occurred between them about Mr A or his surgery. Health NZ said that it is not normal procedure for there to be a handover from the consulting surgeon to the operating surgeon (if they are not the same person), and in Mr A's case, no further information was requested by the operating surgeon from the consulting surgeon in Mr A's case.

28. Dr B said that his usual practice involves discussing the surgical procedure with his patients in his outpatient clinic before listing the patient for the surgical procedure, and he repeats this information in the preoperative area. He stated that if a patient is listed by another surgeon, he 'replicate[s] the approach that [he] follows in the outpatient clinic in the pre-operative area'.

29. The clinical documentation does not record whether a physical examination of Mr A was completed prior to the consenting procedure. Dr B told HDC that he cannot recall whether he conducted a physical examination but noted that 'it is common practice to rely on another surgeon who has seen the patient in the clinic and listed the patient for surgery'. He said that this is because of the frequent time constraints experienced in the day surgery list, which is not an 'uncommon phenomenon'.

30. Mr A told ACC that 'there was definitely NO physical review prior to surgery'.

31. Initially, Dr B told Health NZ:

> '[During the consenting process] I explained the procedure of circumcision, which is removal of foreskin, and that circumcision would lead to exposure of glans penis[8] and skin sensitivity and will subside after [a] few days … I also explained to him there is no role for preputioplasty[9] in BXO. The treatment for BXO is circumcision.' (Dr B's emphasis.)

32. Dr E also said that as BXO is a progressive disease, a 'full circumcision' is the standard of care for BXO.

33. The Medical Director of Surgical Services for Health NZ told HDC:

> 'A partial circumcision of half the foreskin would have left a loose unsatisfactory flap of remaining foreskin and been an inappropriate operation. A "partial circumcision" was only an appropriate option if a small area of foreskin was involved, and it could have been managed with a small "excision biopsy".'

[8] Tip of the penis.
[9] A surgical procedure performed to widen a tight foreskin.

34. Subsequently, Dr B told HDC that he recalled discussing the BXO disease in detail and the benefits of circumcision, as Mr A had been suffering from the disease for some time. Dr B recalled explaining that BXO can affect the meatus and urethra, which may require a cystoscopy.[10]

35. Dr B explained that his usual practice for undertaking informed consent included an explanation of the indication for the surgery and any risks and benefits associated with the surgery. He said that he also explains that the patient can refuse surgery if they decide at any time that they no longer wish to undergo surgery, and he repeats this in the preoperative area to ensure that the patient is still comfortable with the procedure.

36. The procedure listed on the surgical consent form was 'Circumcision + meatotomy/ cystoscopy', and the surgical consent form was signed by Dr B and Mr A on 29 September. Under the summary of the information provided about the healthcare procedure, the following risks were recorded: 'Minor bleeding, Infection, Scarring, Cosmesis,[11] Stricture.'

37. Health NZ said that Dr C documented 'Circumcision + meatotomy' on the consent form; therefore, the order of the procedures was reversed, when compared to the surgical booking form. In addition, Health NZ said that the '+/-' was not included, indicating that circumcision was a certainty (rather than a possibility).

38. Health NZ said that Dr B then added 'cystoscopy' to the surgical consent form, after further discussion with Dr C. Health NZ stated that Mr A and Dr E had not discussed this on 17 August 2021. Dr B stated:

> '[Dr C] and I discussed with [Mr A] about the BXO and that it can cause meatal (opening of the Urethra) stenosis which will need dilation (opening up) and will need cystoscopy to the urethra or the urine pipe.'

39. Health NZ told HDC that while 'ideally' the surgeon who sees the patient for consultation and discusses the procedure should be the one to write the procedure to be performed onto the surgical consent form, this may not always be possible or practical. Health NZ stated:

> '[I]f additional procedures, or alterations from what is on the published list, are proposed on [the] day of the surgery, there needs to be a distinct time-out/pause period between discussing the additional procedure proposed and the final signing of the consent.'

40. Mr A said that he was confused to see a 'random' doctor discussing the procedure with him and he became concerned when circumcision was mentioned. He said that at that time, he stopped the preoperative briefing and explained to Dr B the scope of work that had been agreed with Dr E, and re-enforced the fact that it 'DID NOT involve a full circumcision'. In a

[10] A procedure to view the inside of the bladder and urethra.
[11] A change in appearance.

further statement to HDC, Mr A reiterated: '[I told Dr B] directly to his face that I hadn't come in for a full circumcision.'

41. Dr B told HDC: 'At no point prior to the operation do I recall [Mr A] saying he did not want a circumcision to be performed.' Dr B also said that prior to the operation he did not see any clinical notes indicating that Mr A was not happy for a circumcision to be performed.

42. Health NZ said that Dr C cannot recall specific details of the case, but he recalls being present during the consenting process and stated that they would not have proceeded if refusal to circumcision had been raised during 'time-out'.

43. Mr A said that he was confused by the terminology used and told ACC:

> '[A]s I am a lay-person and not familiar with all urology terms[,] I assumed the cutting/removal of the scar tissue on the frenulum was a form of circumcision? (I didn't knowingly consent to a full circumcision).'

44. Health NZ told HDC:

> '[Mr A] said he was not sure he was heard or misunderstood. He said he was a little unsure what was meant by the different terms to describe the procedures and the forms of circumcision. He did believe he was consenting to have a partial circumcision to remove the small abnormal area. His understanding from clinic discussions was that there was only about [a] 2% chance he would need a full circumcision.'

45. The clinical notes do not record any concerns raised by Mr A in the preoperative area, and Dr B said that he does not agree with Mr A's recollection of what he said. Dr B reiterated that he would not perform surgery without informing a patient of exactly what was to be performed and any risks associated with the procedure.

Theatre

Sign-in

46. Mr A said that it was 'obvious' to him that Dr B was confused, and therefore he 'vigorously' raised his concerns again once entering theatre. Mr A told HDC that when he arrived in the operating theatre, he informed everyone present that the operation 'D[ID] NOT' involve a full circumcision.

47. Health NZ told HDC that Dr D, a consultant anaesthetist, confirmed that Mr A did state that he did not want a circumcision at the time he was brought into the anaesthetic area, and, in response, Dr D asked Mr A whether he had discussed this with his surgeon.

48. In a later statement, Dr D told HDC:

> '[Mr A] entered the operating room after having a discussion with the surgeon and made a statement along the lines of "this is not a full circumcision". I responded to him by asking if he had discussed this with the procedural surgeon, to which he replied that

> he had. This discussion had taken place immediately prior to [Mr A] entering the operating theatre.'

49. Health NZ told HDC that with the knowledge of Mr A having discussed the procedure with his surgeon, it was 'assumed' that the details of partial versus full circumcision had been covered.

50. Health NZ said that prior to anaesthetic induction when Mr A was still awake, an anaesthetic nurse, RN F, confirmed with Mr A the procedure to be undertaken (as part of theatre protocol). Health NZ said that RN F cannot recall the procedure that was stated but said that 'she would normally read it directly from the consent form'. RN F signed the 'Perioperative pathway', indicating satisfactory completion of this final check. Dr B also said that '[Mr A] did not raise any questions or object when the nurse explained the surgery and took him from the pre-operative area into the operating theatre'.

51. Health NZ's informed consent policy at the time of the events stated that the anaesthetic nurse is to '[c]larify that the operation procedure stipulated on the iPM operating list and the consent form are the same. If not, clarify with [the] surgeon and check that consent is correct.'

Time-out

52. Health NZ told HDC that the discrepancy in the procedure should have been picked up during the 'time-out' process. According to Health NZ's informed consent policy, 'time-out is the final verification of the correct patient, procedure, and site by active communication among all members of the perioperative team'. The policy also states that 'time-out' is surgeon led and is carried out after induction and before surgical incision.

53. Health NZ said that it is expected practice that when concerns have been raised by the patient to other members of the operative team, this is to be communicated to the operating surgeon, as per the World Health Organization (WHO) guidelines for 'time-out', and in Mr A's case, this did not occur.

54. The operation note for Mr A's procedure confirmed that a 'WHO time-out' had been completed.

55. Dr B told HDC that he does not recall there being any objection or concerns raised from any of the surgical team, anaesthetist, or the theatre nurse when the 'time-out' process was completed in theatre.

56. Similarly, the scrub nurse designated for the surgery, told HDC that during the 'time-out' phase:

> '[T]he surgeon went through the checklist and verbally stated the patient's identity, site of operation, procedure as written in the consent form which remained unchanged with the signatures of both surgeon and patient, and allergies that the patient has. The whole team agreed to what was said and the procedure then ensued.'

57. In contrast, Dr D stated: '[B]efore the surgery commenced, I expressed [Mr A's] concerns regarding circumcision to the [s]urgeon.' Dr D did not say whether this occurred at 'time-out' and he did not say what Dr B's response to this was.

58. Health NZ said that it has a surgical safety checklist to guide the 'time-out' process, and this is on the wall in the operating theatre. Health NZ said that it audits 50 procedures on a quarterly basis to assess compliance with the surgical safety checklist, but this document does not form part of the clinical record. Health NZ did not indicate the compliance rate for previous audits.

Recovery

59. Following completion of the surgery, Mr A was transferred to the recovery area at 4.10pm. The postoperative report confirmed the completion of a cystoscopy, meatal dilation, and circumcision under general anaesthetic. The intra-operative findings were 'chronic scarring around the frenulum and meatal stenosis possibly consistent with BXO', and it was noted that the cystoscopy was 'normal'.

60. Postoperative instructions written by the surgical team stated:

> 'Home today
>
> No intercourse [for six weeks]
>
> Dissolvable sutures
>
> Follow up**:** No urology [follow up].'

61. Mr A was reviewed by Dr C and then discharged at 6pm on 29 September. Health NZ said that Dr C advised Mr A that a circumcision had been performed as part of the procedure, and Mr A voiced no concerns in that regard.

62. Mr A was provided with written and verbal postoperative advice and discharge medications. The recovery notes written by nursing staff stated: '[Discharged] [no] problems.'

63. Mr A told ACC that when he came out of the procedure there were bandages on the postoperative site, so he did not realise that a full circumcision had been undertaken until a few days later. He reiterated that he did not consent to the circumcision and stated that he 'specifically told them I didn't want that'.

Subsequent events

64. Mr A told ACC that he suffered adverse symptoms after the operation, such as physical irritation, discomfort, and a significant reduction in sexual contact with his partner due to increased sensitivity on the penis.

65. Mr A told HDC that Dr B failed to remove the scar tissue, which 'was the actual procedure [he] agreed to'. Dr B said that he did not order a biopsy of the glans penis as the BXO was not affecting the glans at the time of the procedure. Health NZ told HDC:

> '[Dr E's] discussion with the patient centred around the "whiteness around the urethral meatus". His reference to excising some of the scar tissue was most likely interpreted by the patient as excision of some of that white tissue (around the meatus), which would be a reasonable interpretation … The patient likely had the expectation that a biopsy of the scar tissue (white tissue around the meatus) and opening up the meatus were the main aims of the procedure.'

66. Mr A lodged a formal complaint with Health NZ. Health NZ informed Mr A that it was completing an adverse event review (AER), and a copy of the review was shared with Mr A. The Head of Surgery provided a verbal apology to Mr A. Mr A also expressed his concerns to Dr E, who told HDC: 'I talked to [Mr A] twice on the phone and via zoom, apologised for his outcome and agreed to investigate/assist with any investigation/complaints process.'

67. A copy of the AER was provided to HDC. The event analysis found that the main factors contributing to Mr A's unexpected surgical outcome were:

a) An incongruence between the surgical procedure understood by Mr A (during the telephone consultation on 17 August 2021) and the surgical procedure consented for on 29 September 2021. The usual surgical treatment for BXO is a full circumcision.

b) Inconsistency in the procedure on the theatre waitlist form (completed by Dr E) and the surgical consent form (written partially by Dr C and signed by Dr B).

c) The nature of what was involved in an adult circumcision; in particular, the difference between partial and full circumcision was not fully understood by Mr A.

68. Health NZ undertook a prospective audit of consent forms in July/August and November 2022 of 176 consecutive patients presenting for elective surgeries (across a variety of disciplines) and provided these results to HDC. The purpose was to assess the consistency of what was written on the consent form and what was on the published planned surgical procedure (electronic copy). The latest audit demonstrated that 87% of consent forms were a direct match with the electronic published surgical procedure. However, 10% of cases (17 surgeries) had minor discrepancies — this was because the handwritten version included an expanded description of the surgery. A further 3% (6 cases) had discrepancies as a body 'side' was not cited.

ACC

69. An ACC claim for treatment injury was lodged by Dr E. In October 2022 ACC informed Mr A that it could not confirm where the failure occurred and that it was unable to provide cover for treatment or mental injury.

Responses to provisional report

Health NZ

70. Health NZ was provided with a copy of the provisional report and given an opportunity to comment. Health NZ noted the findings and accepted the recommendations. Further comments from Health NZ have been integrated under the 'changes made' section of this report.

Dr B

71. Dr B was provided with a copy of the provisional report and given an opportunity to comment. Dr B confirmed to HDC that he did not wish to make any comments.

Mr A

72. Mr A was provided with a copy of the 'information gathered' section of the provisional report and given an opportunity to comment. At the outset, Mr A said the report had highlighted the inadequate processes, 'incomplete/misleading' paperwork and breakdown in communications. Mr A disputed the fact that Dr C and Dr B were unaware of Mr A's desire not to have a circumcision. In addition, Mr A said he did not understand the various medical terminology used and indicated that a layperson would not be expected to understand this information.

Opinion: Health NZ — breach

73. On 29 September 2021, Mr A received planned elective surgical treatment for BXO, which resulted in an unexpected surgical outcome. This opinion considers whether the events leading up to Mr A's surgery impacted the informed consent process.

74. As a healthcare provider, Health NZ is responsible for providing services in accordance with the Code of Health and Disability Services Consumers' Rights (the Code). Having carefully reviewed all the information available, I consider that Health NZ did not provide a reasonable standard of care to Mr A.

75. In my opinion, several events leading up to the surgery affected the preoperative workup for Mr A and ultimately resulted in an unexpected surgical outcome. I set out my decision and the reasons for this below. In forming my decision, I sought advice from an independent clinical advisor, urologist Dr Jonathan Masters, and I have incorporated his advice in relevant areas of my opinion.

Communication and information provided to Mr A prior to 29 September 2021

76. It is expected that prior to presentation for an outpatient procedure, patients will be well prepared and informed of the nature of the procedure to be undertaken. I am concerned that Mr A was not provided with adequate information prior to his procedure. I have identified four areas of concern below.

77. First, I note Mr A's confusion about the medical terminology used, and Health NZ's AER findings that Mr A did not fully understand what was involved in an adult circumcision. Mr A said that he did not consent to a 'full' circumcision and understood the procedure to involve the removal of the scar tissue on the frenulum, as a form of circumcision (ie, partial circumcision). Mr A also told HDC that the scar tissue resulting from the BXO had not been removed, which 'was the actual procedure [he] agreed to'.

78. Dr E said that during the appointment on 17 August 2019 he informed Mr A that there was a chance that a circumcision would be required once the procedure had started, which could involve a full circumcision, a partial circumcision, or a frenuloplasty. Health NZ said that

circumcision was mentioned as a possibility but not a certainty. As such, it was not unreasonable for Mr A to assume that he would be undergoing a partial circumcision as the primary procedure.

79. Health NZ also said that Dr E's discussion in August 2021 had centred around the whiteness around the urethral meatus, and therefore Mr A had interpreted the surgery to involve excision of this tissue, which was a reasonable assumption.

80. Dr Masters advised that Mr A's understanding of the procedure differed from what was listed on the consent form, and this was a moderate departure from the expected standard of care. I accept this advice. It is clear that Mr A did not fully understand the nature of the surgery to be undertaken.

81. It is not uncommon for consumers to misunderstand the information conveyed during consultations. However, this risk could have been mitigated by the provision of written information. I note that Mr A was not provided with any written information about his surgery. As the preoperative consultation had occurred by way of a telehealth appointment, I would have expected Mr A to have been provided with further details of the surgery, to review at his own pace.

82. Health NZ told HDC that sharing of written documentation from telehealth and in-person appointments was not part of its standard operating procedure for outpatient appointments at the time of the events.

83. I am concerned about Health NZ's practice of not sharing written information. Written information would have provided Mr A with an opportunity to enhance his understanding of the proposed procedure, the associated risks, and the available alternatives. Written material can be a valuable tool for communication and to reinforce any verbal discussions held. A dual approach of verbal and written communication promotes clarity and transparency and empowers consumers to participate in the decision-making process actively.

84. Secondly, I note that Mr A's appointment with Dr E on 17 August 2021 took place via a telephone consultation. Dr E said that this was because he had already seen Mr A in January 2021, and also so that Mr A could avoid the eight-hour round trip for an in-clinic consultation. This meant that a physical examination of Mr A's condition did not occur, and the surgery that was booked was based on the visual findings of the January 2021 appointment and Mr A's observations.

85. Dr E acknowledged that it was not possible to know the state of Mr A's foreskin and said that he had advised Mr A that this would be discussed during the consenting stage on the day of the procedure. Therefore, it is possible that a full circumcision may have been recommended had a physical examination occurred in August 2021, which in turn would have changed the nature of the surgery listed on the surgical booking form.

86. Dr B said that the consultation with Dr E occurred during the COVID-19 pandemic, when telephone consultations were usual practice.

87. I acknowledge that telephone consultations are common, and that this was particularly so during the COVID-19 pandemic, and that Dr E was trying to save Mr A from having to travel a long distance. However, telephone consultations carry a risk of miscommunication and limit the ability to carry out a full clinical assessment. This risk could have been mitigated with a video consultation or an in-patient admission prior to the surgery taking place, as is suggested within Health NZ's policy in circumstances when the operating surgeon is not the consulting surgeon.

88. Thirdly, Dr Masters advised that circumcision in adult males requires some counselling. The glans penis is known to become supersensitive, and along with changes in the appearance of the penis, can have a 'knock on effect with confidence and sexual performance in some men'. However, there is no record in the clinical notes that Mr A received such counselling, and it appears that most of the preoperative communication focused on the whiteness of the meatus.

89. Finally, I note that Mr A was not advised of who the operating surgeon would be. Mr A assumed that Dr E would undertake his surgery and was surprised to see another surgeon completing the consenting process. This most likely created an element of shock and affected Mr A's ability to engage with Dr B during the consenting stage.

90. Health NZ's policy states that normally the patient should be informed about who, specifically, will be performing the treatment. This is particularly important if the treatment is provided by someone other than the person expected by the patient, or with whom the patient has had previous discussions. In addition, the Code states that every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

91. Dr E said that he did not inform Mr A that he would not be carrying out the procedure as he did not know this fact at the time of the consultation. Mr A was part of a pooled system in which the operating surgeon is not scheduled until closer to the time. Dr Masters advised that the omission to inform Mr A about which surgeon would be carrying out his surgery was a minor departure from the expected standard of care. I accept this advice.

92. I acknowledge Dr E's reasoning and understand that in a pooled system, it is difficult to know who the operating surgeon will be. However, consumers have a right to know in advance who their operating surgeon will be, and further explanation about Health NZ's pooled system and the possibility of having a different operating surgeon could have been explained to Mr A. Although Dr E had the opportunity to relay this information during his telehealth appointment on 17 August 2021, Health NZ could also have relayed this information closer to the time when the details of the operating surgeon had been confirmed. This is particularly an issue when, as in this case, surgeons may have different thresholds of decision-making in respect to the type of surgery that is required.

93. In summary, I find that Mr A was not provided with adequate information prior to his surgery; in particular, there was a lack of clarity about the nature of circumcision, Mr A was not provided with written information or counselled about the risks relating to circumcision,

and he was not advised of who would be operating on him. Therefore, I find that Health NZ breached Right 6(2)[12] of the Code. It follows that without being adequately informed of the type of procedure to be undertaken, Mr A was not in a position to give his informed consent to the procedure. Therefore, I find that Health NZ also breached Right 7(1)[13] of the Code.

Environment for undertaking consent

94. I note that the informed consent process for the procedure on 29 September 2021 took place in the waiting area while Mr A was in a hospital gown. I am concerned that this affected Mr A's ability to engage in the consenting process with Dr B effectively.

95. I consider the waiting area to be an inappropriate place to undertake an effective discussion. Undertaking the informed consent process while a patient is in a hospital gown compromises the patient's comfort and dignity, which in turn can inhibit the patient's ability to focus on the details of the discussion, leading to an inadequate understanding of the procedure. Health NZ acknowledged that this was not an 'ideal environment' in which to gain consent.

96. Dr Masters advised that whilst in reality it is common for the consent form to be signed with the patient in the preoperative area, this is not ideal practice. I accept this advice. I remind Health NZ that the consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively. A private area is crucial to this to promote confidentiality, allow the patient to ask questions freely, and ensure a focused discussion on the details of the procedure. A private area also establishes comfort where patients can express concerns, leading to a more comprehensive and genuine informed consent process.

97. As such, I ask that Health NZ reflect on the environment in which informed consent takes place, and I make recommendations in relation to this below.

Surgical consent form

98. As discussed above, Mr A said that he did not consent to a 'full' circumcision and understood the procedure to be a removal of the scar tissue on the frenulum, as a form of circumcision (ie, partial circumcision).

99. Health NZ said that circumcision was mentioned to Mr A by Dr E as a possibility but not a certainty. Meatotomy was listed as the primary procedure, and circumcision was listed as a secondary procedure with '+/-' prior to 'circumcision' on the surgical booking form and published operating list, to indicate that circumcision may or may not be necessary.

[12] Right 6(2) states: 'Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.'

[13] Right 7(1) states: 'Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.'

100. However, the procedure was transcribed differently on the surgical consent form, which listed the procedure as '[c]ircumcision + meatotomy/cystoscopy'. Therefore, circumcision was listed as the primary procedure and '+/-' was missed, meaning that circumcision was a certainty rather than a possibility. Health NZ said that Dr C started the transcribing process and by the time Dr B had seen the consent form, circumcision had already been transcribed as the primary procedure. Health NZ acknowledged that while 'ideally' the surgeon who sees the patient for consultation and discusses the procedure should fill out the surgical consent form, this may not always be possible or practical.

101. However, I note that Health NZ's internal audit showed that 13% of the audited surgical consent forms had discrepancies when compared with the published operation list. I am concerned about these discrepancies and whether consumers are adequately informed about any changes to their procedure.

Theatre safety culture

102. As part of Health NZ's informed consent policy, 'sign-in' is an opportunity to check that the correct procedure is listed on the surgical consent form.

103. Mr A said that once he entered theatre, he raised his concerns regarding circumcision with the theatre staff. At this point, Dr B and Dr C were not in theatre to witness this, and they believed that no one had raised any concerns during 'sign-in'. Dr D stated that Mr A did raise his concerns, but RN F and the scrub nurse said that Mr A did not raise any concerns.

104. Initially, Health NZ did not note whether Dr D had relayed his concerns to Dr B and stated that staff had assumed that Mr A had already discussed his concerns with Dr B. However, in a later statement, Dr D said that he raised his concerns with Dr B, although Dr D did not specifically state when this occurred or what Dr B's response was to this.

105. I acknowledge that significant time has passed since these events, and, understandably, the providers involved in Mr A's care may not remember details of the care provided. However, I am concerned about discrepancies in Dr D's version of events. As such, I consider that it is more likely than not that Dr D did not raise Mr A's concerns with Dr B during the 'time-out' procedure.

106. 'Time-out' is the third and final opportunity to ensure that the right procedure is about to take place. Dr B said that none of the theatre staff raised any concerns about the procedure. Dr C also told Health NZ that they would not have proceeded with the surgery had refusal to circumcision been raised during 'time-out'. Clinical notes indicate that 'time-out' did occur, and it supports Dr B and Dr C's version of events. As no one raised concerns, it was reasonable for Dr B, who also expected a full circumcision to be the standard operation for the treatment of BXO, to continue with the procedure listed on the consent form.

107. Dr Masters advised that it was reasonable for Dr D and RN F to assume that the surgery had been discussed with the surgeon. However, Dr Masters also noted that in a safe and proactive theatre environment, staff should be confident that they can call in the surgeon and clarify the procedure at the sign-in stage before proceeding with the surgery. Dr Masters

said that 'time-out' was another missed opportunity for staff to have raised their concerns, and he considers this to be a mild departure from the expected standard of care. I accept this advice.

108. I consider that a lack of mutual understanding amongst the providers, resulting from ineffective communication processes and the absence of a proactive environment, contributed to Mr A's unexpected surgical outcome. 'Sign-in' and 'time-out' are essential steps as part of the consenting process to protect the safety of the consumer during the final verification stages. It is vital that the consumer's right to refuse treatment or seek information is always upheld. I remind Health NZ staff that informed consent is an ongoing process, and it is the responsibility of staff to communicate any concerns to the operating surgeon.

Conclusion

109. To summarise, several unfortunate events cumulatively led to a poor overall standard of care for Mr A. I consider that the fallibilities within Health NZ's system, in particular the ineffective preoperative workup, ineffective communication processes, the absence of written information, the less-than-ideal environment for undertaking informed consent, the practice of not transcribing what is on the operation list accurately, and the poor theatre safety culture resulted in Mr A undergoing a procedure to which he felt he did not consent. As a result, I find that Health NZ breached Rights 4(1),[14] 6(2), and 7(1) of the Code.

Opinion: Dr B — adverse comment

Introduction

110. This opinion considers whether the consenting processes on 29 September 2021 were reasonable.

111. As Mr A's operating surgeon, Dr B had a responsibility to ensure that services were provided in accordance with the Code. I have carefully reviewed all the information on file, including the responses received from Dr B, Mr A, Health NZ, and other providers, and I set out my decision and the reasons for this below.

Informed consent for circumcision — no breach

112. Mr A said that he did not consent to a 'full' circumcision and understood the procedure to be a removal of the scar tissue on the frenulum, as a form of circumcision (ie, a partial circumcision).

113. Health NZ's informed consent policy states that the primary responsibility for obtaining informed consent lies with the person responsible for the procedure. This was Dr B, as the lead operating surgeon. However, each case is unique. In this case, the procedure was an elective day-stay procedure. Under these circumstances, it is expected that consumers come well prepared and informed prior to the surgery. As discussed above, several

[14] The right to services of an appropriate standard.

unfortunate events affected the preoperative workup for Mr A. As a result, Mr A made assumptions and had several misunderstandings relating to his procedure.

114. On 17 August 2021, Dr E completed a telephone consultation with Mr A and mentioned that full circumcision might be required for his BXO. At this point, Mr A was also informed that the exact procedure to be undertaken would be confirmed at the time of consenting. Dr E then completed a surgical booking form, which noted that the procedure proposed for Mr A was a 'meatotomy +/- circumcision'.

115. The published operation list also stated the procedure as a 'meatotomy +/- circumcision'. However, Dr C transcribed this onto the surgical consent form as '[c]ircumcision + meatotomy', which meant that circumcision was listed as the primary procedure and a certainty, rather than a possibility.

116. Dr B said that prior to surgical consenting he reviewed Mr A's clinical notes. The notes indicated that Mr A had been suffering from BXO for some time and it was bothering him to the extent that he was willing to undergo surgery. Dr B also said that circumcision is required in the majority of BXO cases, and he discussed the procedure with Mr A prior to him consenting to the procedure. There is no documentation indicating that Mr A did not want a circumcision, and the consent form signed by Mr A following the consenting process clearly listed 'circumcision'.

117. Although Mr A said that he raised concerns about the procedure with Dr B, both Dr B and Dr C denied this. Dr B also emphasised that he would not perform surgery without informing a patient of exactly what was about to be performed and any risks associated with the procedure. This is not an unreasonable statement given Dr B's many years of surgical experience.

118. Following the consent process, Mr A was taken to theatre, where 'sign-in' and 'time-out' processes occurred. When Mr A raised his concerns in theatre, neither Dr B nor Dr C were present. Although Dr D acknowledged that Mr A did have concerns, this was not conveyed to Dr B during the sign-in or time-out process. As a result, Dr B had no reason to discontinue the procedure.

119. In light of the above, I consider that it was reasonable for Dr B to undertake the circumcision procedure.

Completion of consent form — adverse comment

120. Dr Masters advised that the biopsy from the glans penis was left off the consent form, and the consent form did not include super-sensitivity of the glans penis as a risk.

121. Dr B said that he did not order a biopsy of the glans penis as the BXO was not affecting the glans penis at the time of the procedure. I accept Dr B's reasoning. If the glans penis was not affected by the BXO, there was no reason to include this on the consent form.

122. I also acknowledge Dr Masters' comment that super-sensitivity is a risk of circumcision. However, sensitivity is an expected effect from any procedure, and I consider that it was not necessary to include this on the consent form.

123. However, I note that Dr B added a new procedure, ie, 'cystoscopy', to the surgical consent form, and it appears that this procedure was not discussed during the consultation of 16 August 2021. Although the procedure was explained to Mr A on 29 September 2021 and was clinically appropriate, it was a decision made very close to the time of operation.

124. Health NZ's informed consent policy states that consumers must be given sufficient time to absorb information and to discuss the information with others if desired. I am concerned that Mr A was not given sufficient time to think carefully about the risks involved with this new procedure because the consenting process occurred just prior to the procedure. Whilst no departure from the expected standard of care is identified in this regard, I remind Dr B of his responsibilities as a lead surgeon, including his responsibility to ensure that the consumer is adequately informed of any new procedures discussed on the day of the surgery.

Physical examination — no breach

125. Mr A was listed for a surgical procedure following a telephone discussion with Dr E. Therefore, a physical examination was not undertaken on 17 August 2021.

126. Dr Masters advised that under these circumstances, he would have expected the operating surgeon to have a look at the preputial skin to see whether a circumcision was needed. Clinical documentation did not mention a physical examination, and Mr A told ACC that no physical examination occurred.

127. Dr B cannot recall whether a physical examination took place on 29 September 2021 but said that because of time constraints experienced in the day-surgery list, it was common practice to rely on the surgeon who had listed the patient for surgery.

128. I acknowledge Dr Masters' reasoning that it was important to check the preputial skin to see whether a circumcision was needed. However, surgery cannot take place without first examining the site, even if this occurs on the operating table immediately before incision. In addition, it is not uncommon for the operating surgeon on a day-surgery list to rely on the consulting surgeon's assessments, as often operations occur back-to-back. Therefore, I am satisfied that Dr B completed a reasonable assessment prior to undertaking the procedure.

Conclusion

129. Whilst I am critical of Dr B's decision to include cystoscopy on the consent form, I am not critical of his decision to undertake a circumcision, for the reasons noted above. As such, I do not find Dr B in breach of the Code.

Changes made since events

130. Health NZ acknowledged that effective communication between the surgical team and Mr A did not occur at the time of consent. To support full understanding of the procedure to be undertaken, Health NZ has planned to send to patients a written summary of consultations (with decisions and agreements made with patients), along with information about the consent form, prior to the surgery taking place.

131. Health NZ's Theatre Operational Leadership Team will continue regular audits of consent forms of patients presenting for elective surgery.

132. Health NZ said that it communicated this event to staff and reinforced the need to ensure that the operation tallies with the operating list and consent form, and the need for staff to speak up if in doubt, and to pause proceedings.

133. Dr B said that he has reflected on his practice and has made changes to the way he communicates with patients; in particular, he uses closed loop communication to check the patient's understanding of the procedure.

134. In response to the provisional recommendations, Health NZ stated the following:

- It has considered allocating a separate area within the day-surgery unit for undertaking informed consent processes with its patients. Health NZ said that 'for specific cases where the patient needs more time to consider what has been discussed, staff will try to provide a quiet space for the process of obtaining consent'.
- It confirmed that access to the NetworkZ programme, as recommended by Dr Masters, has been in place since 2020 and that the theatre team has undertaken 'a lot of work' in relation to the improvement of theatre safety culture.
- It has considered making preadmission appointments for those patients who are undergoing procedures in the day surgery unit, but this is not possible due to lack of physical space and staffing capacity across the surgical directorate. In addition, it stated that consenting on the day of surgery is done for all day surgery patients across the surgical directorate by the operating surgical team and this reduces incongruence as much as possible.

Recommendations

135. I acknowledge the changes made by Health NZ. I recommend that in addition, Health NZ:

a) Provide a formal written apology to Mr A for the deficiencies identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.

b) Provide an update to HDC on its implementation of the new system that supports sharing of clinical appointment letters with its patients, within six months of the date of this report.

c) Provide evidence of the training provided to theatre teams since 2021 and provide a description of how this training has improved the theatre safety culture, within three months of the date of this report.

d) Remind its surgical team of the importance of informing patients, where appropriate in advance of elective procedures, that the operating surgeon may not be the consulting surgeon and remind staff that patients should be given adequate time and opportunities to ask questions about the proposed surgery. Health NZ is to confirm that this action has been completed within three weeks of the date of this report.

Follow-up actions

136. A copy of this report with details identifying the parties removed, except the clinical advisor on this case will be sent to Health New Zealand|Te Whatu Ora and the Medical Council of New Zealand and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Deputy Commissioner

The following independent clinical advice was received from Dr Jonathan 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 urological cancers in general. I do not have any conflicts of interest in this case. You have asked me to review this case and, to please comment on:
>
> 1. What are the indications for a partial versus full circumcision in BXO?
> 2. What is the probability of requiring a full circumcision in [Mr A's] circumstances?
> 3. What alternate treatment options exist for managing BXO?
> 4. The adequacy of information provided to [Mr A] prior to surgery; in particular, the absence of written information;
> 5. The appropriateness of the surgical booking form completed by [Dr E], prior to [Mr A's] surgery;
> 6. The adequacy of the informed consent processes that took place between [Mr A] and [Dr B];
> 7. The absence of a physical review by [Dr B] prior to surgery;
> 8. The adequacy of the policies at Health NZ;
> 9. The adequacy of the documentation, handling and communication of [Mr A's] concerns by [Dr D] and [RN F];
> 10. The adequacy of the pre-operative check undertaken by [RN F]; in particular, the failure to clarify the inconsistency between the surgical booking form and consent form;
> 11. The adequacy of the "time-out" process; in particular, the discrepancy in the procedure not being picked up at "time-out";
> 12. Any other matters in this case that you consider warrant comment.
>
> **1) What are the indications for a partial versus full circumcision in BXO?**
>
> A circumcision is performed when the inner layer and the outer layer of preputial skin are divided to remove an affected area of skin. Traditionally the inner layer is shortened to leave a 5mm cuff around the corona of the glans penis and the outer layer is shortened to level with the corona of the glans penis. These 2 layers are then joined back together to complete the circumcision and this will leave the glans penis and the corona exposed. For adult men this newly exposed glans penis can be very sensitive initially. More recently some men have only wanted the abnormal skin removed so much longer portions of both the inner layer and outer layer of the preputial skin are left behind so that when the two layers are joined back together there is still partial cover of the glans penis. In the presence of BXO depending on how much of the preputial skin is involved with the disease process it may be possible to perform a

circumcision with longer portions of the inner and outer layer left behind and just remove the abnormal area. However this runs the risk of multiple operations if more of the preputial skin becomes involved or a BXO affected area is missed at the first operation. Traditionally then in the presence of BXO on the preputial skin a circumcision is performed that removes the preputial skin with a 5mm inner layer cuff and an appropriately shortened outer cuff. This approach has the least likelihood of recurrence if the BXO affects the prepuce.

2) What is the probability of requiring a full circumcision in [Mr A's] circumstances?

This question is impossible to answer. BXO not only affects the preputial skin but also the glans penis and the urethral meatus and can affect the rest of the urethra as well. It affects the urethral meatus by narrowing the meatus so the stream becomes progressively finer and ultimately it can be very difficult to pass urine. From the letter from the clinic ((phone consult letter available), but a follow up of a face-to-face consult for which there is not a letter available) it would seem the main area of concern was the white changes on the glans penis and the narrowing of the urethral meatus. [Mr A] had previously raised issues with regards his splitting frenulum but this is not mentioned in the letter and neither is the state of the preputial skin. Therefore whilst it is clear that the glans penis and the meatus of the urethra were involved it is not clear from any of the descriptions that the preputial skin was involved with BXO. The full final histology report of the preputial skin is not available but on page 261 of the ACC documentation it is recorded "histology of foreskin: Mild patchy chronic inflammatory cell infiltrate and fibrosis consistent with phimosis". It is not clear to me that this is describing BXO or if the preputial skin was basically normal. If the foreskin was not involved then the only reason for performing a circumcision would be if the surgeon believed that the circumcision would slow the rate of progression of the BXO elsewhere on the glans penis and in the urethra. This point is controversial with some studies in children suggesting circumcision prevents further BXO changes elsewhere on the penis. In adults traditionally it was taught that getting rid of any retained urine under the preputial skin with a circumcision also reduced the progression of BXO elsewhere and hence if the surgeon believed this then he would perform a circumcision. The honest answer is we do not know the pathogenesis of BXO and there are not good studies to support or refute the performance of a circumcision if the preputial skin is not involved by the BXO. A different surgeon may have concentrated on the troublesome areas of BXO namely the glans penis and the urethral meatus and if the preputial skin did not look significantly involved and rolled backwards and forwards easily simply not have performed a circumcision. So the probability of requiring a full circumcision in [Mr A's] case depends not only on the examination of the preputial skin but also on the understanding of the surgeon about what the correct thing to do is with the preputial skin if there is BXO on the glans penis or the meatus.

3) What alternate treatment options exist for managing BXO?

Surgery is necessary if the physical effects of the scarring are causing symptoms (difficulty passing urine and non retractile foreskin). If there are changes consistent with

BXO then the alternative to surgery is the topical application of strong steroids which can be very effective (1).

4) The adequacy of information provided to [Mr A] prior to surgery; in particular, the absence of written information;

In the letter and the booking form it is clear that the intent of the surgery was to dilate the urethral meatus and to get tissue from the white area on the glans penis to establish a diagnosis. I believe this is what was discussed with [Mr A] and what the booking surgeon expected would happen within the operation. The circumcision seems to have been added as a precaution if on examination on the day there was clearly BXO on the preputial skin and to save [Mr A] an additional procedure. I do not believe written information would have made this clearer. The issue is with the circumcision which I believe that both the booking surgeon and [Mr A] believed would probably not be necessary. Circumcision in adult males does require some counselling, the glans penis can be supersensitive initially and then sometimes less sensitive in the long run, the appearance of the penis of course changes and this can have a knock on effect with confidence and sexual performance in some men. There is no description of what a circumcision would involve in the clinic letter but again I believe this was because the surgeon did not expect it to be performed. The other issue that is raised by [Mr A] in his correspondence was that he fully expected the surgeon that he spoke to in clinic to perform the operation and in his correspondence he expresses some anger and regret that this was not the case on the day he turned up for surgery. Running pooled operating lists makes good sense for efficiency but I believe that the fact it could be a different surgeon performing the operation should have been made explicit to [Mr A]. I would regard this and the lack of any written record of a preoperative discussion around a circumcision as being minor departures from the expected standard of care.

5) The appropriateness of the surgical booking form completed by [Dr E], prior to [Mr A's] surgery;

I do not think there is any issue with the booking form. I would regard it as appropriate.

6) The adequacy of the informed consent processes that took place between [Mr A] and [Dr B]

If there had been no issues with the consent process then there would have been no complaint and so clearly the consent process has not been adequate. With the written record on the consent form the emphasis of the surgery has been changed from the booking form so that circumcision is stated first and then meatal dilation. A cystoscopy has been added which seems a reasonable addition and the biopsy of the glans penis has been omitted. The information recorded on the consent form is adequate though it does not include supersensitivity of the glans penis which clearly troubled [Mr A]. However whilst [Mr A] has signed the form it is clear from his comments in theatre recalled by the anaesthetist that [Mr A] had a different understanding of what the operation would involve from the form he had signed and what actually occurred in theatre. In reality whilst it is common for the consent form to be signed with the patient in the pre operative area this is not ideal and very far from ideal if the operation is

changed from what the patient is expecting. I would regard this as a moderate departure from the expected standard of care.

7) The absence of a physical review by [Dr B] prior to surgery

[Mr A] had a telephone follow-up and was listed for a surgical procedure with a possible circumcision without a repeat physical examination in the clinic because of course this was not possible. I would expect the operating surgeon to have a look at the preputial skin to see whether a circumcision was indeed needed. I cannot be certain from the documentation provided whether a physical examination took place or not. If there was no examination I would regard this as a moderate departure from the expected standard of care.

8) The adequacy of the policies at Health NZ.

I have read the following policies from [the DHB]:

a) Informed consent policy 2021

b) Informed consent policy 2022

c) Surgical safety check list

d) Checking patients prior to surgery

e) Correct patient side and site marking

f) Completion of the perioperative pathway

In general these hospital policies are well thought out and easy to follow. I would like to know how many people in the operating theatre that day had read these documents. Often these policies are not read by the people for whom the policy has been written.

9) The adequacy of the documentation, handling and communication of [Mr A's] concerns by [Dr D] and [RN F];

10) The adequacy of the pre-operative check undertaken by [RN F]; in particular, the failure to clarify the inconsistency between the surgical booking form and consent form;

11) The adequacy of the "time-out" process; in particular, the discrepancy in the procedure not being picked up at "time-out";

[Mr A] had the operation he was consented for. It was reasonable for [Dr D] and [RN F] to assume the surgery had been discussed by [Mr A] with the surgeons prior to him coming into theatre. Therefore I believe their responses are reasonable. However, in a safe and proactive theatre environment either or both of [Dr D] or [RN F] should have been confident that they could call in the surgeons and have this clarified again in the sign in before proceeding with surgery. In this case that would particularly be with the nature of the circumcision. I do not believe that the nurse signing the patient in would check the patient's expectations against the surgical booking form but rather the signed consent form. Finally before the operation began there was one more opportunity for

the nature of the surgical procedure to be clarified and that was with the "Time-out" at the beginning of the procedure where the operating surgeon should confirm the operation and with the consent form being available and with the rest of the theatre staff. The operation note records this as taking place. Once more this should be where staff in theatre speak up if there are concerns. This was an opportunity missed given that [Mr A] had clearly expressed he was not having a full circumcision. The documentation and the procedures followed in the operating theatre are of the expected level; it is simply that no one spoke up at the times that are available for concerns to be expressed (Sign in and time-out). I would regard this as a mild departure from the expected standard of care.

The NetworkZ programme is an excellent way of improving theatre culture and all surgeons and theatre personnel should have the opportunity to be involved. It covers issues such as speaking up. I hope [the DHB] are involved in this.

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

On reviewing this case there are a whole series of little events that have ended up with [Mr A] having an operation that he did not expect or want.

First due to Covid restrictions and geography the consultation that resulted in [Mr A] being listed for surgery was a telephone consult. Given the operation was about changes to the glans penis and preputial skin this was never going to be visual confirmation of the changes and this resulted in a booking form that included the possibility of a circumcision even though this was not the main area of concern.

Second the operation was part of a pooled operating list. I do not see that [Mr A] was ever informed that his surgery would be performed by someone other than [Dr E]. I believe that had [Dr E] been the surgeon performing the surgery, there would have been a different outcome as he had previously met [Mr A]. I do think [Mr A] had a right to know the surgeon would not be the one he had met and I would regard this as a minor departure from the expected standard of care.

Third the consent form was started by the junior registrar even though it was signed by the medical officer, [Dr B], who was the senior surgeon. That resulted in the circumcision becoming the main part of the operation rather than only to be performed if necessary, which is what the booking form implied. In addition to this it also resulted in the biopsy from the glans penis being left off the consent form altogether. It is possible that the description on the consent form then directed the discussion during the consent process. This could have been corrected if the outpatient letter had been read again. I also think from the comments that [Dr B] has made in [the DHB's] response that he genuinely believed that a full circumcision was the appropriate treatment for BXO of the penis.

To quote [Dr B] "*I also explained to him there is no role for preputioplasty in BXO. The treatment for BXO is circumcision*" (preputioplasty being another term for a partial circumcision).

I therefore think that regardless of the appearance of the preputial skin [Dr B] would have performed a circumcision because he believed this was the correct procedure for this condition. We do not have good medical evidence to support or refute this belief. It is also clear that whilst [Dr B] believed he had explained this clearly and that [Mr A] signed the consent form, [Dr B] and [Mr A] ended up with very different expectations about the nature of the surgery. This cannot be informed consent. I would regard this as a moderate departure from the expected standard of care.

Finally whilst the process of sign in and time-out were correctly followed the opportunity to speak out or clarify with the surgeon and the patient about exactly what was due to happen in the surgery was missed. The consent form and the operation performed tallied but the patient was expressing something different. As I have stated previously this is about theatre culture. Avoiding the outcome that has happened here is precisely why sign in and time-out are part of the process but it requires an environment where people know it is okay to speak up. I would regard this as a minor departure from the expected standard of care.

Reference List:

(1) Medical Management of Penile and Urethral Lichen Sclerosus with Topical Clobetasol Improves Long-Term Voiding Symptoms and Quality of Life Joshua P. Hayden,* William R. Boysen and Andrew C. Peterson THE JOURNAL OF UROLOGY Vol. 204, 1290–1295, December 2020

Yours truly,

Jonathan G Masters

August 17th 2023’

Appendix B: Relevant Standards

The Medical Council of NZ guidelines for informed consent [1] state that the doctor undertaking the treatment is responsible for the overall informed consent process. The guidelines state:

> 'Obtaining consent is a process of shared decision-making where you help the patient understand their medical condition and the options for treating (or not treating) that condition. It is more than signing forms and completing paperwork. Take the time to ask questions so that you understand what matters to your patient, and what their concerns, wishes, goals and values are. (See Right 1(3) of the Code.)
>
> …
>
> Effective communication is critical in the consent process. Establish what matters to your patient. Share information in a way that helps your patient understand what you are saying. This could include highlighting risks specific to your patient, and giving your patient pamphlets, brochures, or website links that provide more information about their condition.
>
> …
>
> If you are worried that your patient is making a decision that is not in their best interests, you should explain your concerns clearly to them and outline the possible consequences of their decision.'

[1] Medical Council of NZ. (2021). Informed Consent: Helping patients make informed decisions about their care. https://www.mcnz.org.nz/assets/standards/55f15c65af/Statement-on-informed-consent.pdf