Consent for hernia repair surgery

(Case 20HDC01893)

Introduction

1. The Health and Disability Commissioner (HDC) received a referral from the Nationwide Health and Disability Advocacy Service regarding a complaint by Ms A about the informed consent process for her hernia[1] repair surgery performed by general surgeon Dr B. Ms A was concerned that initially she was advised that surgical mesh[2] would not be used for her surgery, and her attempts to discuss her surgery with the surgeon prior to the surgery date were unsuccessful. She was also concerned about the process of informed consent on the day of the surgery, such that she felt coerced into agreeing to the use of surgical mesh.

2. Dr B was both an employee of Health New Zealand|Te Whatu Ora (Health NZ) Nelson Marlborough (previously Nelson Marlborough District Health Board)[3] and a contractor for an elective day surgery unit. He provided care to Ms A in both capacities.

3. The following issues were identified for investigation:

- *Whether Te Whatu Ora|Health New Zealand provided [Ms A] with an appropriate standard of care from December 2019 to September 2020 (inclusive), including whether [Ms A] was fully informed and gave informed consent for her surgery of 11 September 2020.*
- *Whether [the elective day surgery unit] provided [Ms A] with an appropriate standard of care from August 2020 to September 2020 (inclusive), including whether [Ms A] was fully informed and gave informed consent for her surgery of 11 September 2020.*
- *Whether [Dr B] provided [Ms A] with an appropriate standard of care from December 2019 to September 2020 (inclusive), including whether [Ms A] was fully informed and gave informed consent for her surgery of 11 September 2020.*

4. The parties directly involved in the investigation were:

Ms A	Complainant/consumer
Dr B	Provider/general surgeon

[1] When pressure causes abdominal organs to push through the surrounding tissue or muscle, resulting in a bulge.
[2] Sterile woven material.
[3] On 1 July 2022 the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Health NZ. All references in this report to Nelson Marlborough District Health Board now refer to Health NZ Nelson Marlborough.

Dr C	Provider/general practitioner (GP)
The elective day surgery unit	Provider
Health NZ Nelson Marlborough	Provider

5. Further information was received from:

Accident Compensation Corporation (ACC)	
The rural hospital	Provider

6. The Ministry of Health|Manatū Hauora is also mentioned in the report.

Information gathered

Background

7. The elective day surgery unit provides a range of services to support rural health in New Zealand. One of the services it offers is a unit for low-risk elective day surgery procedures. The unit is contracted by the Ministry of Health|Manatū Hauora to provide certain surgical procedures that are referred out of the public health system.

8. Ms A's surgery was to repair inguinal and femoral hernias. An inguinal hernia is a condition where soft tissue bulges through a weak point in the abdominal muscles. It occurs in the groin, just above the crease between the abdomen and leg. A femoral hernia is a bulge of intestine through the femoral canal that houses the femoral artery. It occurs in the groin, just below the crease between the abdomen and leg.

9. Dr B told HDC that there are differing treatment options for inguinal and femoral hernias. An inguinal hernia can be repaired with an 'open technique'[4] without the use of surgical mesh, but this technique does not allow for access to the femoral area. A femoral hernia can be repaired with stitches, but this approach does not allow for access to the inguinal area. Dr B explained that if both types of hernia are suspected, the recommended approach is a laparoscopic procedure[5] allowing access to the areas of both hernias and simultaneous repairs using surgical mesh.

Key events

10. In May 2019 Ms A consulted her GP, Dr C, about a small tender lump in her left groin, which was becoming increasingly painful. At subsequent consultations in May and June 2019, the lump was found to have increased in size.

11. Dr C made an urgent general surgery referral on 23 June 2019, requesting a clinical assessment of Ms A's left groin lump to rule out 'sinister causes'. Health NZ Nelson Marlborough accepted the referral on 3 July 2019.

[4] Using a cut through the skin and tissue to allow a full view of the structures and organs to be operated on.
[5] A small cut is made to allow the surgery to be performed by inserting small tubes and a camera.

General surgery at the hospital

12. On 4 December 2019 Dr B saw Ms A at the public hospital. Following this consultation, Dr B recommended that Ms A undergo surgery, with the specific procedure dependent on the findings from an ultrasound scan (USS).

13. Dr B's clinical impression and diagnosis from this consultation were recorded in a letter sent to Dr C after the consultation.[6] Ms A recalled that she was also sent a copy of Dr B's letter.

14. In the letter, Dr B wrote that on examination, Ms A appeared well, but when standing she had a lump that was just below and to the side of the top of her pubic bone. He wrote: 'I suspect this is a femoral hernia.' Dr B documented that he was requesting a USS to confirm that the hernia was a femoral hernia, as there would be 'quite a different way of approaching these as opposed to inguinal hernia'. He ended the letter by stating: '[I have] reassured [Ms A] that … depending on the outcome of her [USS], we can repair this for her if it remains symptomatic.'

15. The letter does not document any discussions relating to differential diagnoses, the different treatment or surgery options, how the USS results would be communicated, or whether a further consultation would take place prior to surgery.

16. Ms A refuted that Dr B's initial finding was of a femoral hernia. She said that she was told only about an inguinal hernia, and there was no mention of a femoral hernia until after the surgery.

17. Ms A said that she was not provided with any pamphlets or information sheets about her condition or treatment options during or after her consultation with Dr B despite having asked for information several times. Health NZ Nelson Marlborough told HDC that it has a patient information pamphlet 'Surgery to repair Hernia' available for clinicians to provide to patients, but use of the pamphlet is at the discretion of individual clinicians. If the pamphlet is provided to a patient, this is recorded by way of a sticker, reading 'treatment information pamphlet', applied to the clinical documentation. There is no such sticker on Ms A's documentation.

18. In response to the provisional opinion, Dr B said that the hernia pamphlets are 'freely available' in the Surgical Outpatients area and in clinic rooms. Dr B said that he does not recall Ms A asking for further information. Regarding the absence of a sticker on Ms A's clinical documentation, Dr B said that the use of stickers became obsolete in 2018 when the service moved to dictated electronic records. There are no longer any paper records on which to place the sticker.

19. In relation to treatment options, Dr B told HDC that because he suspected that Ms A had only a femoral hernia and therefore surgical mesh would not be an issue, he did not discuss the use of surgical mesh with Ms A and told her that femoral hernias can be repaired with

[6] Dr B documents all his consultation clinical notes in a letter to the patient's GP. Any handwritten notes taken during the consultation are destroyed after the letter is dictated.

stitches. Dr B said that he did not expect an inguinal hernia to be present, and the presence of an inguinal hernia 'would have changed the discussion'.

20. In response to the provisional opinion, Dr B added that in the context of a clinic workload that allows only 15 minutes per patient, it is not feasible to discuss treatment options for differential diagnoses that, at the time, he did not consider the patient had.

Preoperative USS

21. Ms A underwent a USS of her left groin on 19 March 2020. The USS report identified an 'indirect left inguinal hernia' with 'no evidence of a femoral hernia'.

22. There is no indication on the USS report, or other information provided to HDC, that these results were communicated to Ms A at that time. Health NZ Nelson Marlborough told HDC that it 'do[es] not have a record of the [USS] being discussed with [Ms A] prior to the handover of her care'. Dr C told HDC that she did not contact Ms A to discuss the results of her USS because, although Dr C was copied into the report, she was not the requesting clinician. Ms A told HDC that she had no discussion about the results of the USS with any health professional, even after several attempts by her to gain information. Ms A stated: 'Then I finally got through to [Dr B's] receptionist because I cried on the phone begging for help, she then assured me that no mesh would be used.'

23. Health NZ Nelson Marlborough said that, in general, patients would require a follow-up appointment with the surgeon if results from pre-surgery investigations (such as the USS) were 'unexpected and/or impacted on safe delivery of the planned procedure'. The need for follow-up would be determined by the surgeon after review of any pre-surgery investigation results. Health NZ Nelson Marlborough said that in this case the USS results did not 'materially change' the diagnosis or decision to offer hernia repair surgery. Health NZ Nelson Marlborough stated:

> 'We sincerely apologise to [Ms A] for not providing adequate opportunity for her to discuss her concerns around her proposed surgery with a clinician prior to the surgery date. We refer clinically appropriate patients to have their procedure [in the unit] so they can receive care in a timely way. We acknowledge our processes around this need to ensure patients are able to have discussion with a clinician if they have questions about their procedure at any time prior to our handover of care to [the elective day surgery unit]. We will provide feedback on [Ms A's] experience to staff to remind them to respond effectively to patients requesting to discuss informed consent with their surgeon in the lead up to their surgery date.'

24. Dr B told HDC that he saw the results of the USS in late April 2020, and he considered that a follow-up appointment was not necessary, as the only purpose of ordering the USS was to assist the operating surgeon by documenting the diagnosis of a femoral, rather than inguinal, hernia. Dr B also explained that COVID-19 lockdowns placed limitations on service provision, which led to a backlog of new referrals and scarcity of appointments, making it impractical to call patients back to the hospital to discuss their hernias.

25. Dr B said that he was not aware of any communication attempts by Ms A or Dr C following release of the USS results.

Scheduling surgery

26. Dr B completed the booking form on 14 April 2020. The booking form identified Ms A as a suitable candidate for referral to receive her procedure in the unit.

27. The booking form to schedule Ms A's surgery was entered into the booking system on 4 May 2020, and the surgical preadmission team received the booking form on 11 May 2020.

28. The booking form documents the diagnosis as '[Left] Inguinal/Femoral hernia' with the procedure documented as 'Laparoscopic Repair, LEFT groin hernia'. Dr B said that he 'deliberately omitted the word mesh' as he was not certain whether mesh was required due to the difference between the USS results and his clinical findings regarding the type/s of hernia involved.

Process for the elective day surgery unit

29. The Memorandum of Understanding between the elective day surgery unit and Health NZ Nelson Marlborough includes under 'District Responsibilities' that the district will:

> '1) Undertake appropriate clerical work from patient referral to discharge. This will include:
>
> …
>
> (iv) client bookings including liaison with patients.'

30. The unit is based on a rural hospital site in the region. Health NZ Nelson Marlborough has a Contract for Services with the rural hospital under which the hospital provides support and services to the unit while it is providing surgical services in the region. The description of services to be provided by the rural hospital under the contract includes:

> 'c) Undertake appropriate clerical work from referral to post discharge coding. This will include client bookings including liaison with patients.'

31. The elective day surgery unit provided HDC with its ' … Patient Clinical Pathway (Pre-Operative), 2019' (Pre-Operative Pathway), which sets out the pathway for referral to the unit. The Pre-Operative Pathway sets out the following steps:

- After the doctor's visit, the Health NZ Nelson Marlborough booker will place the patient on the waitlist for surgery according to their priority.
- Six months in advance the scheduler will organise surgery dates and medical specialists for each rural area.
- The Health NZ Nelson Marlborough booker will select patients who meet the criteria for treatment in the unit in liaison with the surgeon, and an operating list is chosen for the surgery dates in that rural area.

- The Health NZ Nelson Marlborough booker will contact the patient to offer a surgery date.
- After the surgery date is accepted by the patient, the Nelson Marlborough booker will send the patient a 'Patient Information Folder'. The booker will also enter the patient into the unit's clinical system so that relevant records are available to the unit's staff. The Patient Information Folder contains: Admission instructions, waiting time, anaesthetic information, guides titled 'Before you come to hospital' and 'When you leave hospital', the 'Routine Pre-Admission Questionnaire', and a blank consent form.
- A week prior to the surgery date, the Health NZ Nelson Marlborough booker will receive the 'Routine Pre-Admission Questionnaire' completed by the patient, and this is scanned into the unit's patient file. The Clinical Nurse Manager at the unit will read this questionnaire to confirm suitability.
- A week prior to the surgery date, a nurse from the rural hospital will call each patient. Any issues are then passed on to the unit's Clinical Nurse Manager so they can be followed up with the patient.
- Two days prior to the surgery date, an automated text message is sent to patients to remind them of their surgery. Any replies or questions prompted by this text are followed up by the unit's Clinical Nurse Manager.

32. Health NZ Nelson Marlborough also provided its 'Referral of Elective Patients to [the unit's] Process', which largely correlates with the Pre-Operative Pathway provided by the unit. However, the Health NZ Nelson Marlborough process varies by stating: 'Administration staff at the site … contact patients to book and confirm surgery.' The process also states that patient concerns are relayed back to Health NZ Nelson Marlborough and, where needed, an outpatient consultation with the surgeon can be arranged prior to the day of the surgery.

33. The rural hospital told HDC that its staff contact the patient to inform them that they are on the surgery list, and staff will tick a form confirming that the patient is happy to receive surgery in the unit. The rural hospital confirmed that its staff would not provide a patient with medical information about the procedure or discuss informed consent. Following the booking call, the hospital sends out the Patient Information Folder provided to the hospital by Health NZ Nelson Marlborough, and staff will telephone the patient two days before the surgery to confirm that the patient understands the preoperative requirements and still intends to attend the surgery. The rural hospital said that if a patient has questions around the procedure, they would be encouraged to contact Health NZ Nelson Marlborough. The hospital also said that it does not keep any records of the conversations between patients and administrative staff, unless a patient has raised concerns, in which case those concerns are passed onto staff at Health NZ Nelson Marlborough.

Attempts to contact surgeon

34. Ms A said that she was on the waiting list for an 'inguinal hernia repair' for 12 months, and Health NZ Nelson Marlborough staff contacted her after COVID-19 Level 4 Lockdown[7] to advise her that she would be booked into the unit.

35. On 14 July 2020 a Health NZ Nelson Marlborough medical secretary documented on Ms A's file that she was unable to have surgery until after 15 August 2020. Dr B said that he was scheduled to operate in the unit on 11 September 2020, and he chose Ms A's name from the list of potential patients for that list as he had seen her in outpatients, and he knew about the discordant ultrasound report and felt confident that he could resolve her problem on the day. Dr B said that most patients awaiting hernia surgery are on a pooled waiting list and do not find out who their surgeon will be until they receive their admission papers.

36. Ms A said that she asked to speak with the surgeon to 'discuss the surgery and her concerns about the use of mesh'. Ms A stated that she telephoned Health NZ Nelson Marlborough five times following up on her request to speak to the surgeon, but her request was not followed up, and the staff she spoke with could not provide details about the surgeon who would be performing her surgery.

37. Ms A told HDC that she then contacted an administrative staff member[8] at the rural hospital, who advised her to call Health NZ Nelson Marlborough back. Ms A said that after not getting any information from Health NZ Nelson Marlborough, she phoned the staff member back very upset and requested help. The staff member was then able to get the surgeon's secretary to call Ms A. Ms A recalled this secretary telling her that surgical mesh would not be used during her surgery. Dr B stated that he did not have a secretary in 2020.

38. Ms A was unable to recall the dates of the telephone calls she made but recalls that the discussion with 'the surgeon's secretary' took place a week prior to her surgery. Dr B checked the phone diaries of the General Surgery department secretaries and was unable to find an entry for a telephone call with Ms A. He noted that it would be 'extremely unusual' for a secretary to discuss the technical aspects of a surgery.

39. Dr B told HDC that the booking form he filled out for Ms A in April 2020 following her USS states, '**Diagnosis:** Left Inguinal/femoral hernia **Procedure:** Laparoscopic repair left groin hernia,' and it is possible that Ms A was told that 'there is no mention of mesh on the booking form', which she may have interpreted as 'mesh will not be used'.

40. On 25 August 2020 Ms A completed the elective surgery day unit's pre-admission questionnaire and returned it to the unit. Among other details, the questionnaire asks the patient to fill out their surgeon's name. Ms A filled in this section with '?'.

[7] COVID-19 Level 4 Lockdown took place between 26 March 2020 and 28 April 2020.

[8] The staff member was an administrator at the rural hospital and the contact person for patients receiving the unit's surgical services in the region.

41. The elective surgery day unit told HDC that after the questionnaire was returned, it confirmed that Ms A was fit to have surgery at the unit, and Ms A's surgery was scheduled to be carried out on 11 September 2020.

Preoperative consenting process

42. The elective day surgery unit provided HDC with its ' … Patient Clinical Pathway (Day of Surgery), 2019' (Surgery Day Pathway), which sets out the process on the day of surgery. The Surgery Day Pathway includes the following steps:

- A rural hospital nurse will complete a nurse assessment when the patient arrives at the hospital.
- The surgeon and anesthetist will separately consent the patient in a room at the rural hospital.
- A rural hospital nurse will complete the first part of the day of surgery checklist and provide paper copies of forms (including a consent form) to be included in the patient folder taken into the unit.

43. The elective day surgery unit said that normally 30 to 90 minutes pass between a patient being seen by the surgeon in the pre-admission area at the rural hospital and being taken into the unit. Once in the unit, the surgeon will obtain the written consent of the patient.

44. Further to the Surgery Day Pathway, the elective day surgery unit also has an 'Informed Consent Policy', which has the stated purpose of ensuring that patients are provided with the information needed to make informed choices and provide informed consent. The Informed Consent Policy sets out the following key principles:

- Consent is a process rather than a one-off event, involving 'effective communication, full information, and freely given, competent consent'.
- There should be no pressure on a person to provide their consent.
- Communication must occur in an environment that enables the parties to communicate in an open, honest, and effective manner.
- The information provided should include discussion of the options available, answers to specific queries, and the right to refuse treatment or procedures.
- The patient has the right to consider the information fully and seek further opinion.
- The patient should be given time to reflect on information and discuss it with others.
- Written consent must be obtained for invasive procedures such as surgery, and all procedures undertaken in the unit.
- Documentation of the informed consent process should consist of brief notes outlining the information provided, when this information was provided, specific queries made by the patient, and any wishes of the patient.

Ms A's recollection of the consent process

45. Ms A told HDC that on 11 September 2020 (the day of her surgery), she arrived at the rural hospital for her pre-surgical consultation with Dr B, which included the informed consent process.

46. Ms A said that at the end of the consultation she asked Dr B what would be used as an alternative to mesh, and he told her that he would be using surgical mesh. Ms A recalled explaining her mother's past reaction to surgical mesh to make him aware of her aversion to the use of it, and that in response Dr B dismissed her concerns by advising that 'it [was] different for hernias'. Ms A felt that any alternative to mesh was 'made to sound less than satisfactory'.

47. Ms A also recalled raising her concerns about trying to contact her surgeon prior to the surgery to discuss the use of surgical mesh, and Dr B's response was, '[W]ell that is the public health system.'

48. Ms A said that she was provided 'only a few minutes [to decide] and [Dr B] was in the room with us waiting'. Ms A said that ultimately, she 'felt she had to agree to the mesh at the time'.

Dr B's recollection and records of the consent process

49. Ms A was the fifth surgery on the treatment list for 11 September 2020. Dr B recalls that he saw Ms A for the pre-surgical consultation before the fourth surgery of the day, which is the elective day surgery unit's standard practice. Dr B said that this consultation took place in the reception area of the rural hospital, with Ms A's daughter present, and took 'more than 15 minutes'.

50. Dr B said that he discussed the letter and the USS results identifying an inguinal hernia, and re-examined Ms A, as he was not confident about the USS finding that there was only an inguinal hernia in light of his clinical finding of a suspected femoral hernia at the initial consultation. Dr B recalls recommending a laparoscopic rather than an open approach (as would be used for an inguinal hernia) and that surgical mesh should be used 'as it is not possible to do a laparoscopic repair without mesh'.

51. In relation to Ms A's specific concerns about surgical mesh, Dr B said that he recalls explaining that the pelvic floor and abdominal wall are different structures, and mesh was proven to be successful for abdominal wall hernia repairs, while acknowledging the known concerns about the use of mesh in pelvic floor procedures. Dr B told HDC that he did not intend to cause distress but wanted to 'clarify the use of mesh in hernia surgery'.

52. Dr B also said:

> 'It is my standard practice to answer patients' questions … on the day of surgery during the preoperative consultation. It is my standard practice to discuss why we use mesh, the benefits thereof and the risk of infection or recurrence.'

53. Dr B explained to HDC that his intent with the statement quoted at paragraph 47 was to empathise with the difficulty that patients on a pooled waiting list experience when attempting to discuss preoperative concerns prior to surgery.

54. Dr B said that he explained to Ms A that if she did not want to proceed, 'she was free to cancel and have her surgery done by another surgeon in a different manner'. Dr B also reiterated:

> '[Ms A] had a right to refuse consent, and I would have sent her home with a surgical follow-up appointment in place as it would have been clear to me that she needed far more than the usual discussion about surgery and mesh.'

55. Dr B also expressed that it was not his intention for Ms A to feel pressured to consent, and he gave Ms A 'extra time to consider the procedure [he] proposed'.

56. Dr B said that after the fourth surgery of the day was completed, Ms A was brought onto the unit, where her written consent was taken in the waiting area. Dr B estimates that this was approximately 60 to 90 minutes after the initial consent discussion. Dr B recalled asking Ms A if she was 'happy to proceed', and Ms A confirmed that she was and signed the consent form.

57. The elective day surgery unit provided the 'Patient Consent Agreement' form for Ms A's surgery. The form was signed by Ms A and Dr B and dated 11 September 2020. The form states that Ms A provided consent for the following procedure: 'Laparoscopic Repair LEFT groin hernia.' There is no mention of the use of surgical mesh or of any risks.

58. The consent form states that the patient agrees to the named procedure and 'further or alternative operative measures as may be found necessary'. The form also states that the patient considers that the surgeon has undertaken the following prior to the surgery:

> 'Explained to me the reasons for, and the possible risks of the procedure, and I have had adequate opportunity to ask questions and have received all the information that I want. I understand that I am welcome to ask for more information if I wish.'

Surgery

59. The operation took place after Ms A provided her written consent. The operative record documents findings of both a left femoral and left inguinal hernia, and that Dr B reduced[9] both hernias and placed a 12cm by 9cm piece of Parietex mesh to cover the direct (weakness in the abdominal wall), indirect (through the inguinal ring), and femoral (through the femoral canal) openings. Postoperative follow-up was arranged to take place with Ms A's GP two weeks later. In the patient operative record, Dr B documented the following regarding the consent discussion: 'CONSENT COMPLETE: Yes — discussed issues re use of mesh.' There are no further details about the specific information discussed.

[9] By pushing the lumps back through the abdominal wall.

Subsequent events

60. The elective day surgery unit sent two text messages to Ms A as part of its postoperative feedback process. Ms A responded requesting a phone call, which took place on 22 October 2020. The call is noted in the patient operative record, and it is documented that Ms A had concerns and feedback about the surgery.

61. Ms A's concerns are not documented in detail, but the elective day surgery unit told HDC that she was 'unhappy with the consent process and the use of mesh'. Following this call, Dr B offered Ms A a free appointment at his private room to discuss her concerns. The elective day surgery unit documented that it provided Ms A with Dr B's contact details for her to arrange an appointment.

62. The experience of the surgery and use of surgical mesh had a detrimental effect on Ms A's emotional state, leaving her 'sick' and having frequent panic attacks due to feeling like there was a 'ticking time bomb' inside her. Dr C referred her to another surgeon for a second opinion, with an initial consultation taking place four weeks after the surgery performed by Dr B. A further consultation with the second surgeon took place nine weeks post-surgery and, by this point, Ms A had begun to experience severe pain in her left groin and shooting pain down her thigh.

63. An ACC claim for mesh-induced fibrosis resulting in inguinal nerve injury was accepted in December 2020.[10] Ms A underwent further surgery for removal of the mesh and suture repair of her hernia on 13 September 2021.

64. Ms A told HDC that ACC found that Dr B had incorrectly attached the mesh to her femoral artery. However, the operative record from the 13 September 2021 surgery has the finding of 'no evidence of any complication from mesh placement'.

Responses to provisional opinion

Health NZ Nelson Marlborough

65. Health NZ Nelson Marlborough was given the opportunity to respond to the provisional opinion. It accepted the findings and recommendations.

Dr B

66. Dr B was given the opportunity to respond to the provisional opinion. His comments have been incorporated into this report where appropriate.

Ms A

67. Ms A was given the opportunity to respond to the provisional opinion. She reiterated her disagreement with parts of Dr B's evidence but had no further comment to make.

[10] An ACC advisor reported that, on balance, an inguinal nerve injury was likely given the description of signs and symptoms Ms A presented with. ACC concluded that the mesh-induced fibrosis resulting in nerve injury was caused by the treatment Ms A received.

The elective day surgery unit

68. The elective day surgery unit was given the opportunity to respond to the provisional opinion. Its comments have been incorporated into this report where appropriate.

Opinion: Dr B — adverse comment

69. The issue for me to determine is whether Ms A was consented for her hernia surgery appropriately on 11 September 2020.

70. Informed consent under the Code of Health and Disability Services Consumers' Rights (the Code) is a process with three essential elements — effective communication between the parties (Right 5); the provision of all necessary information to the consumer (Right 6); and the consumer's informed consent (Right 7). It is not a one-off event, but rather ongoing communication between the provider and consumer.

71. On 4 December 2019 Ms A saw Dr B at the public hospital. In his clinical letter, Dr B wrote: 'I suspect this is a femoral hernia.' As he suspected that there was only a femoral hernia (which he repairs with stitches), and therefore he was of the view that surgical mesh would not be an issue, he did not discuss the use of surgical mesh with Ms A. Dr B said that he did not expect an inguinal hernia to be present, and that the presence of an inguinal hernia 'would have changed the discussion'.

72. Health NZ Nelson Marlborough said that the informed consent discussion at the hospital should include an explanation of the clinical rationale for the procedure, along with the potential risks and benefits. Given that Dr B had not yet reached a firm diagnosis, at that time he was not in a position to have a discussion about the surgical approach, although he did advise Ms A of the option for surgical repair subject to the outcome of a USS, which he ordered.

73. Dr B requested the USS to confirm that the hernia was a femoral hernia and to ensure that Ms A's surgeon on the day would have sufficient diagnostic information. The USS report identified an 'indirect left inguinal hernia' with no evidence of a femoral hernia as Dr B had expected. Dr B saw the USS report in late April, but at that time he did not contact Ms A to discuss the result, the planned procedure, any risks, and the options. Dr B explained that he considered that a follow-up appointment was not necessary because it was 'standard practice' that a patient's questions about hernia surgery would be addressed on the day of surgery.

74. It is also relevant context that Ms A's USS occurred just prior to New Zealand's first lockdown in the Covid pandemic, and that follow-up appointments both during and after lockdown were scarce owing to the backlog of new referrals that had developed in that time.

75. Ms A was then placed on a pooled waiting list for laparoscopic repair of her left groin hernia. Dr B was scheduled to operate on 11 September 2020, and he chose Ms A's name from the list of potential patients for that list as he had seen her in outpatients and knew about the discordant ultrasound report, and he felt confident that he could resolve her problem on the day.

76. Ms A's evidence is that once informed of being on the waiting list, she tried on multiple occasions via phone to speak to the surgeon. Specifically, she wanted to discuss whether mesh would be used in her surgery. It is not known to my investigation how Ms A learned of the potential use of mesh, noting that this had not been discussed with her by Dr B.

77. I will address Ms A's failed attempts to contact the surgeon in the next section of this opinion.

78. Dr B met with Ms A on the day of the surgery to discuss the proposed procedure. Dr B and Ms A provided differing accounts as to the content of this discussion and the time Ms A was given to consider her options.

79. Dr B's evidence is that this consultation occurred before his fourth surgery that day, 60–90 minutes before Ms A's procedure. He said that this consultation took place in the reception area of the rural hospital, with Ms A's daughter present, and took 'more than 15 minutes'. He said that he went over the clinical letter, as well as the USS findings, and he re-examined Ms A as he was not confident of the USS findings (he still suspected a femoral hernia). He recommended laparoscopic repair, which necessitated the use of surgical mesh.

80. Ms A said that she asked Dr B what would be used as an alternative to mesh, and he told her that he would be using surgical mesh. Ms A recalled explaining the reasons for her aversion to the use of mesh and said that in response, Dr B dismissed her concerns by advising that 'it [was] different for hernias'. Ms A felt that any alternative to mesh was 'made to sound less than satisfactory'.

81. In contrast, Dr B recalls explaining that the pelvic floor and abdominal wall are different structures, and that mesh was proven to be successful for abdominal wall hernia repairs, while acknowledging the known concerns about the use of mesh in pelvic floor procedures.

82. Ms A also recalled raising her concerns about trying to contact her surgeon prior to the surgery to discuss the use of surgical mesh, and Dr B's response was: '[W]ell that is the public health system.'

83. Dr B explained to HDC that his intention when he said, '[W]ell that is the public health system,' was to empathise with the difficulty that patients on a pooled waiting list experience when attempting to discuss preoperative concerns prior to surgery.

84. Ms A said that she was provided 'only a few minutes [to decide] and [Dr B] was in the room with us waiting'. Ms A said that ultimately, she 'felt she had to agree to the mesh at the time'.

85. On the other hand, Dr B said that at the end of his other surgery, after Ms A had had time to consider their earlier discussion, he met Ms A in the unit, and it was at this time that she indicated that she was happy to proceed and signed the consent form. In addition, he said that he explained to Ms A that if she did not wish to proceed, she was free to cancel and have her surgery done by another surgeon.

86. I note that Dr B's operation note states that issues regarding the use of mesh were discussed.

Discussion

87. I am satisfied on the evidence that Ms A had significant concerns about the use of mesh and that she had endeavoured without success to discuss those concerns with the surgeon. Following a phone call with an unknown person prior to the surgery, she understood that mesh would not be used. This investigation has not been able to determine with whom that call occurred, or the content of the call. However, with such understanding in mind, to be confronted with information about the use of mesh on the day of surgery would no doubt have been difficult for her.

88. I am equally satisfied on the evidence that prior to the day of surgery, Dr B was unaware of Ms A's efforts to obtain a pre-surgery discussion, and unaware of her significant concerns regarding the use of mesh.

89. This put both Ms A and Dr B in an unsatisfactory position.

90. I note that the Medical Council of New Zealand's statement on 'Information, choice of treatment, and informed consent'[11] states: 'The patient must have the opportunity to consider and discuss the relevant information with the treating doctor.' Effective communication leading to voluntary consent must also take into consideration the environment and situation in which information is given and consent obtained. Certainly, there have been cases where the HDC has determined that providing new and salient information on the day of surgery in the operating environment has not allowed for proper consent. However, each case must be determined on its own facts.

91. I have little doubt that Ms A felt somewhat pressured during the consent process. In my view, her circumstances, particularly her significant concerns about the use of mesh, warranted a time and place that would have allowed her the opportunity to consider the information and treatment options fully. A day-of-surgery consenting discussion was inadequate to effect this for her.

92. I accept that at the public hospital appointment on 4 December 2019, Dr B's clinical examination indicated that Ms A had a femoral hernia only, and it was therefore reasonable that he did not discuss the treatment options for an inguinal hernia during this appointment. However, I am critical that Dr B did not give Ms A the patient information pamphlet 'Surgery to repair Hernia', particularly given the limited time available to discuss her diagnosis and treatment options during the consultation. Furthermore, I am critical that when he received the USS report, Dr B did not attempt to contact Ms A to discuss the report and the potential changes to her treatment options.

93. In mitigation, I note that the operation was considered suitable for day surgery in the unit (usually low-risk clinical care), and I accept Dr B's evidence that, at the time, the usual practice regarding hernia repair was for same-day discussions. That is, even following

[11] March 2011.

receipt of the USS that indicated that a different surgical approach would be needed, the practice was to have that discussion on the day of surgery. In my view, it was the system that did not support the effective communication for Ms A in this instance. Specifically, the opportunity for a preoperative discussion was not facilitated or enabled. I discuss this further below.

94. It is, however, also important to acknowledge that for consumers, the use of surgical mesh even for hernia repairs could cause anxiety. In recent years there has been substantial media coverage about the horrific complications from mesh used in pelvic floor conditions, and it cannot be assumed that consumers necessarily understand the different procedures in which mesh is used with lesser concerns.

95. I therefore consider that surgeons should take a more cautious approach to consenting discussions where mesh is used for hernia repair — specifically, that earlier preoperative discussion may be necessary. Provision of written information sheets would also assist (and I note that in Ms A's case it appears that she did not receive the written information sheet that was available). In this respect, I note that Dr B's practice has now changed such that he makes contact with his patients by telephone a few days before their surgery, during which any concerns about the upcoming operation can be addressed. This is an appropriate practice change.

Opinion: Health NZ Nelson Marlborough — breach

96. Health NZ Nelson Marlborough said that consent is a process with multiple steps that occur over time. It stated that the process starts at the hospital, once the clinician has determined that the patient would benefit from a surgical procedure, and the informed consent discussion at the hospital includes an explanation of clinical rationale for the procedure along with potential risks and benefits. In Ms A's situation, a fulsome discussion regarding surgical approach was not undertaken, given a level of diagnostic uncertainty and pending the results of an ultrasound. However, I am satisfied that Ms A was advised about the option for surgical repair of her hernia subject to the outcome of a USS.

97. As noted above, I am also satisfied that when she was placed on the waiting list for her hernia surgery, Ms A attempted to talk to someone about her surgery, and in particular her concerns about the potential use of mesh. Notwithstanding those efforts, ultimately Ms A was unable to arrange that discussion, which resulted in her finding out about the proposed use of mesh on the day of surgery. This was wholly unsatisfactory given Ms A's understandable and significant worries regarding mesh.

98. I acknowledge the context within which this episode of care occurred, namely, the first stages of the COVID-19 pandemic, during which the ability to see patients in outpatient clinics was difficult, and that the surgery occurred in the unit (signalling that it was low-risk surgery suitable for day surgery). However, I am concerned that a pre-surgical discussion with the surgeon could not be facilitated for Ms A despite her efforts to seek that. It is also concerning that there is no documentation of Ms A's phone contacts with Health NZ Nelson Marlborough.

99. Hospital systems and the remote provision of care (such as occurred in the unit) require robust processes to ensure rights compliance. Ms A's situation illustrates the importance of systems that are responsive to requests for information, and the proactive provision of information (for example, for pooled waiting lists, the name of the surgeon once known and enquired about, and relevant information sheets for the proposed procedure/surgery). There should also be adequate documentation and escalation processes to enable an adequate response to patient queries about their upcoming surgeries/procedures. Health NZ Nelson Marlborough has acknowledged this, stating:

> 'We acknowledge our processes around this [care in the unit] need to ensure patients are able to have discussion with a clinician if they have questions about their procedure at anytime prior to our handover of care to [the elective day surgery unit].'

100. Prior to the day of surgery, Dr B was not aware that Ms A wanted to speak to the surgeon or that she had concerns about the use of mesh. The failure to respond to her reasonable requests for information meant that the consenting processes on the day of her surgery were compromised. I have therefore concluded that the failure of Health NZ Nelson Marlborough to have adequate processes in place to document, escalate, and follow up her reasonable enquiries about her upcoming surgery meant that Health NZ Nelson Marlborough failed to provide services to Ms A with reasonable care and skill, in breach of Right 4(1) of the Code. [12]

Opinion: Elective day surgery unit — no breach

101. I have considered whether the elective day surgery unit bears any responsibility for the issues arising from Ms A's care in relation to informed consent and the failure to respond to her legitimate and reasonable requests for preoperative information.

102. In the circumstances, I am satisfied that the elective day surgery unit had appropriate procedures and processes in place regarding the booking of patients and informed consent. When Ms A raised concerns with the elective day surgery unit contact person at the rural hospital, she was assisted appropriately to speak to a staff member at Health NZ Nelson Marlborough.

103. Other than that, on the information available to me, it appears that prior to her surgery, Ms A did not contact the elective day surgery unit seeking information about her surgery. The unit has indicated that if such enquiries are received, usually these are forwarded to Health NZ Nelson Marlborough to manage. The unit said that there was no contact with Ms A prior to surgery apart from an automated text reminding her of the surgery date. I am therefore not critical of the elective day surgery unit.

[12] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

Changes made since events

104. Dr B informed HDC that he no longer performs laparoscopic hernia repairs in the elective day surgery unit. He also calls patients listed for hernia repair a day or two prior to surgery to ask whether they have any questions or concerns.

105. Health NZ Nelson Marlborough provided its staff with Ms A's feedback about her attempts to contact staff, as a reminder to respond to patients asking to discuss informed consent with their surgeon in the lead-up to surgery.

Recommendations

106. I recommend that Health NZ Nelson Marlborough provide a written apology to Ms A for the issues identified in this report. The apology is to be provided to HDC within three weeks of the date of this report.

107. I recommend that Health NZ Nelson Marlborough and the elective day surgery unit separately consider amending their surgical informed consent processes for all procedures involving surgical mesh to ensure that consumers, as far as reasonably practicable, have had the opportunity to discuss the use or potential use of mesh with the operating surgeon before the day of the scheduled surgery. Health NZ Nelson Marlborough is to report back to HDC on the results of its consideration, and details of any changes made or to be made, within six months of the date of this report.

108. I recommend that Health NZ Nelson Marlborough amend its pre-surgical processes to ensure that patients on a waiting list for surgery are advised how to raise any concerns about their surgery. The process should require that any concerns are documented, escalated, and followed up appropriately to address the concerns raised, including, as required, consideration of booking pre-surgical appointments or telephone conversations to address those concerns. Health NZ Nelson Marlborough is to report back on changes made, including the communication to staff and training about those changes (if made), within six months of the date of this report.

Follow-up actions

109. A copy of the sections of this report that relate to Dr B will be sent to the Medical Council of New Zealand.

110. A copy of this report with details identifying the parties removed, except Health NZ Nelson Marlborough, will be sent to the Medical Council of New Zealand, the Ministry of Health, the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), the Health Quality & Safety Commission, and the Royal Australasian College of Surgeons, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.