General Surgeon, Dr A
District Health Board

A Report by the
Health and Disability Commissioner

(Case 20HDC01568)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. A woman underwent surgery for the repair of an umbilical hernia. During surgery, the decision was made to remove her umbilicus due to an unexpected complication.

2. The woman complained that postoperatively she was not advised that her umbilicus had been removed. She discovered this only when her dressings were removed about one week following surgery, and she found it very distressing.

3. This report considers the information provided by the surgeon both preoperatively and postoperatively.

Findings

4. The Commissioner found that the surgeon failed to explain the outcome of the procedure in a manner that enabled the woman to understand, and in an environment that enabled the surgeon and the woman to communicate openly, honestly, and effectively. The Commissioner concluded that the surgeon breached Rights 5(1) and 5(2) of the Code of Health and Disability Services Consumers' Rights (the Code).

5. The Commissioner also found that the surgeon failed to document the details of her preoperative and postoperative discussions with the woman, and breached Right 4(2) of the Code.

Recommendations

6. The surgeon agreed to undertake further training on communication and documentation.

7. The surgeon and the DHB are developing a brochure on umbilical/incisional hernia surgery, and agreed to consider standard use of the Royal Australasian College of Surgeons brochure on hernia surgery until the brochure has been completed.

8. The DHB also agreed to review its standard "Agreement to Treatment" form to include space on the form for specific risks discussed to be documented.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her by Dr A. The following issues were identified for investigation:

- *Whether Dr A provided Ms B with an appropriate standard of care between June 2019 and August 2019 (inclusive).*
- *Whether the district health board provided Ms B with an appropriate standard of care between June 2019 and August 2019 (inclusive).*

10. The parties directly involved in the investigation were:

Dr A	Surgeon/provider
Ms B	Consumer/complainant
Mr B	Consumer's partner
District Health Board (DHB)	

11. Further information was received from general surgeon Dr C and house officer Dr D. Information was also received from a second district health board.

12. Independent expert advice was obtained from general surgeon Dr Julian Speight (Appendix A).

Information gathered during investigation

Introduction

13. On 21 June 2019, Ms B underwent surgery for the repair of an umbilical hernia (when fatty tissue or part of the bowel push through a weakness in the abdominal muscle near the umbilicus (belly button)). During surgery, the decision was made to excise (remove) Ms B's umbilicus due to an unexpected complication.

14. This report considers the information provided to Ms B both preoperatively and postoperatively.

Background

15. In 2007, Ms B underwent a midline laparotomy (a vertical incision in the abdomen) for an ectopic pregnancy.[1] During surgery, Ms B suffered bowel damage that required the formation of a stoma,[2] which subsequently was reversed.

16. Following these events, Ms B developed an umbilical hernia, which became worse after she had children. On 4 October 2018, Ms B saw her GP, who referred her for an ultrasound and surgical opinion on the management of the hernia.

17. On 23 November 2018, an ultrasound scan confirmed the presence of a hernia at the site of Ms B's previous abdominal incision. The hernia was associated with a wide separation of the two main abdominal muscles, and was unable to be pushed back through the abdominal wall.[3] On 26 December 2018, Ms B was referred to the Outpatient Clinic for review.

[1] When a fertilised egg implants outside the uterus.
[2] An opening in the abdomen where a section of bowel is directed through to the outside of the skin, to allow waste to be removed.
[3] The hernia was documented as a midline anterior wall irreducible incisional hernia associated with wide separation of the rectus abdominis muscles.

Initial review — 8 April 2019

18. On 8 April 2019, Ms B was reviewed by Dr C (a general, acute care, and trauma surgeon) in the Outpatient Clinic.

19. Dr C assessed Ms B and recommended an open mesh repair of the hernia. This involves the insertion of mesh through an incision to help to hold the tissues together. In his clinic letter, dated 12 April 2019, Dr C documented:

> "This seems pretty straightforward for open-mesh repair and I have put her on the waiting list for that. … I have explained to her what is involved in surgery including risks of bleeding, infection, recurrence, seroma[4] and a possible small chance of damage to underlying structures."

20. Dr C noted that Ms B was happy to be placed on the waiting list.

21. Dr C told HDC that he did not specifically discuss with Ms B the possibility of excision of the umbilicus.

22. The DHB told HDC that the risks Dr C discussed with Ms B "would be the standard complications that a patient should be warned of for this operation". The DHB noted that it would not be standard practice to advise a patient of the risk of umbilical excision unless this was anticipated for a specific patient in a specific case. The DHB stated: "There is nothing documented in this case to indicate that excision of the umbilicus was considered to be required before the surgery commenced."

Preadmission clinic — 29 May 2019

23. On 29 May 2019, Ms B was seen in the pre-admission clinic by house officer Dr D.

24. Dr D told HDC that it was his routine practice to describe briefly what the procedure would involve. He stated:

> "It was not my standard practice, nor my role, to discuss specific aspects of surgical technique, and it was my ordinary practice to advise patients that they should discuss this with the operating surgeon."

25. In her complaint, Ms B stated: "I was kept very well informed of the procedure during my pre-assessment, which was a very detailed process and I was happy to proceed with the surgery."

26. Ms B's surgery was scheduled for 21 June 2019.

Preoperative consent — 21 June 2019

27. Ms B's surgery was performed by general surgeon Dr A on 21 June 2019.

[4] A build-up of clear fluid under the skin where tissue has been removed surgically.

28. Immediately prior to the operation, Dr A saw Ms B in the preoperative area, at which time she discussed the procedure with Ms B and obtained her consent.

29. Dr A told HDC that as part of the consent process, her usual practice is to discuss with the patient the pathology and the procedure, and the possible outcomes, including the risk of bleeding, wound infection, injury to surrounding structures, recurrence of the hernia, and chronic pain. Dr A stated:

> "While discussing the possibility of injury to surrounding structures, I mention the possibility of disfigurement of tattoos if they are present, the possibility of excision of the umbilicus and the surrounding skin, if it loses adequate blood supply, and the extension of the incision beyond what already exists if access is an issue."

30. Dr A said that her usual practice is to explain the importance of minimising the chances of wound complication, which may lead to infection of the mesh and an increased chance of hernia recurrence, as well as the possibility that she may have to modify the procedure depending on the operative findings. Dr A stated: "I do not recall modifying my usual consent process for [Ms B]."

31. The "Agreement to Treatment" form signed by Ms B and Dr A on 21 June 2019 includes a standard statement that the proposed procedure was discussed and that Dr A "explained the reasons and expected risks to me of the procedure relating to my clinical history and condition". However, there is no record of exactly what was discussed with Ms B. In relation to the documentation of her preoperative discussion with Ms B, Dr A acknowledged that this was inadequate. She stated:

> "As a routine, while a detailed discussion about surgery and outcomes happen in the pre-operative area, the procedure alone is mentioned in the consent form. This has been my usual practice up until recently."

32. Ms B said that she was very "thorough with [her] questions with regards to risks and what could go wrong with [her] incisional hernia repair, the recovery process and what the procedure exactly involved". In the Pre-Assessment Health Questionnaire, which Ms B completed on 15 April 2019 prior to the surgery, she noted under the question regarding any concerns or questions about the surgery or anaesthetic:

> "Success rate? How long is recovery expected to be? Any long term effects from surgery? Follow up procedures? (post surgery)"

33. However, Ms B said that she was never advised that there was a risk that her umbilicus might need to be excised. She stated:

> "I was never advised or warned pre-surgery that I could end up without a navel and would have welcomed the opportunity to discuss the options with my family. Instead that decision was taken away from me."

Surgery

34. Dr A stated that the surgery was challenging because the hernia sac had adhered to the under-surface of the umbilicus. Dr A said that she attempted to separate the umbilical skin from the sac, but this resulted in a loss of adequate blood supply to the skin. Therefore, she decided to remove the umbilicus to prevent wound infection and further complications. The operation note, dated 21 June 2019 and sent to Ms B's GP, states:

> "The defect itself was measured about 2cm. The sac contained omentum.[5] The sac was very firmly adherent to the umbilicus. During dissection, umbilicus looked devascularised[6] and hence it had to be excised."

Postoperative care

35. Postoperatively, Ms B was transferred to the Post Anaesthetic Care Unit (PACU). On arrival at 1.33pm, Ms B was noted to be drowsy. She was administered 2mg IV morphine at 1.53pm, and at 2pm she complained of pain and was administered a further 2mg IV morphine at 2.14pm. By 2.45pm, Ms B was more comfortable and was transferred to the ward at 3.10pm. Ms B told HDC that while on the PACU she was still heavily sedated and has little recollection of that time.

36. Dr A told HDC that postoperatively she met with Ms B in the postoperative area to describe the procedure and follow-up. The PACU nursing records indicate that Dr A visited Ms B sometime between 1.33pm and 2pm. Dr A said that at that time she "mentioned about the excision of the umbilicus, placement of a drain and the referral that was made to the district nurse for drain management". Dr A stated:

> "The loss of blood supply (devascularisation) of the umbilicus during umbilical hernia surgery is a rare but known complication of surgery. My usual practice is to discuss this with every patient who has similar pathology. I do not recall deviating from this."

37. Dr A said that she also does an end-of-day ward round with a junior doctor, who documents the details of her reviews. Dr A said that at that time she assesses the patient and answers any questions they may have. She stated: "During these times, I mention if I have deviated from the routine procedure (in this case, excision of umbilicus). I do not recall deviating from this procedure."

38. Ms B told HDC that she vaguely recalls someone speaking to her immediately postoperatively, but she cannot recall who it was or the details of what she was told, as she was still very heavily sedated. She said that she has no recollection of being told that her umbilicus had been removed, and was led to believe that the surgery had gone very well. Ms B stated: "I totally understand that the surgeon had to make a decision there and then to remove my navel but I was never told post-surgery what had happened." Ms B said that she has no recollection of being seen again by Dr A later that day.

[5] Fatty tissue.
[6] The blood supply had been lost.

39. Dr A said that she also contacted Ms B's partner, Mr B, to relay the same information. She stated: "I also routinely call the support person to discuss [the surgical procedure and follow-up] … I do not recall deviating from this procedure." However, in a statement to HDC, Mr B said that when Dr A telephoned him, she assured him that everything had gone well. He commented: "I don't recall anything being said about the fact that she had to remove [Ms B's] entire navel."

40. None of these discussions are documented. Dr A told HDC that documentation of operation notes and discussion of operation findings with the patient postoperatively, as well as telephone calls with the support person, are completed between cases, at which time consent is also being carried out for the next patient for surgery. She stated: "Due to severe constraint in time, the details of discussion with the patient and the support person were not documented." She also noted that the junior doctor who performed the postoperative ward round with her did not document her conversation with Ms B. There is no record of the name of the junior doctor who accompanied Dr A during her ward round.

Discharge and follow-up

41. Subsequently, Ms B was discharged from hospital with a follow-up appointment for a district nurse to change the dressings in a week's time. The discharge summary, dated 22 June 2019, was provided to Ms B and sent to Ms B's GP. The summary does not refer to the excision of the umbilicus.

42. Ms B said that when the nurse removed her dressings on 28 June 2019, she was "horrified" to discover that her umbilicus had been removed. She stated that she went to see her GP the same day, and her GP reassured her that there would be a valid reason for the removal. The GP records state:

> "post op from umbilical hernia repair
> Was surprised no belly button but is a mesh procedure"

43. Ms B said that about a week later, when she had the energy, she attempted to contact Dr A to discuss what had happened. However, Dr A was on leave, and it was approximately three weeks later, after Ms B had contacted the DHB again, that Dr A called Ms B back and explained the reason for having had to remove the umbilicus. Dr A offered to refer Ms B to a plastic surgeon to explore the possibility of umbilical reconstruction. Dr A said that she does not routinely refer patients for plastic surgery review if the umbilicus is excised, unless the patient requests this.

Referral to plastic surgeon

44. On 1 August 2019, Dr A sent a referral for plastic surgery review at another DHB, noting that Ms B had found the loss of her umbilicus "traumatising", and requesting consideration for reconstruction.

45. Initially, the referral was declined because it contained insufficient information and no clinical photograph. On 28 September 2019, Ms B's GP forwarded a photograph, and on 28 October 2020, Dr A re-referred Ms B for plastic surgery review. This was accepted, and Ms

B was reviewed on 26 February 2021. She was then placed on a surgical waitlist for an umbilicoplasty.[7] However, Ms B subsequently decided not to proceed with the surgery.

Further comment from Ms B

46. Ms B told HDC that she found the loss of her umbilicus very traumatic, and is "devastated" about how she feels and looks as a result of her umbilicus having been removed. Ms B said that although she accepts Dr A's reasoning for having to remove the umbilicus:

> "To assume that I'd be ok with not being told about my navel being removed is totally wrong in my opinion. The surgeon's advice was that she could refer me to a plastic surgeon. This is something that should have been discussed post-surgery without me having to chase her."

Further comment from Dr A

47. Dr A stated: "I am extremely sorry to read about the distress and mental anguish that this has caused [Ms B]. I sincerely apologise for this."

DHB guidelines

48. The "Informed Consent" policy recommends the use of its generic "Agreement to Treatment" form, as used in this case, and to include specific information "in patient information leaflets and, document in the clinical record specific issues of concern discussed". Further to this, the policy states:

> "The critical part of the process is the information imparted to the patient and the documentation in the clinical record. Information sheets and service protocols can be developed to cover common complications and risks that are to be routinely covered with patients."

Responses to provisional opinion

Ms B

49. Ms B was provided with a copy of the "information gathered" section of the provisional opinion and confirmed that she had no further comments to make.

Dr A and the DHB

50. Dr A and the DHB advised that they agree with the findings of the provisional opinion and the proposed recommendations.

[7] Umbilicus reconstruction.

Opinion: Dr A — breach

Introduction

51. This opinion considers the adequacy of the information provided to Ms B both preoperatively, as part of the consent process, as well as postoperatively.

52. Overall, I have concerns about the information provided to Ms B, particularly in the postoperative period. In making my decision, I have taken into account all the evidence collected during the course of the investigation, including information provided by Ms B and Mr B, Dr A, and the DHB. I have also considered independent expert advice from general surgeon Dr Julian Speight. I outline my concerns in more detail below.

Preoperative information provided and documented

53. During the initial assessment and pre-assessment consultations (with Dr C and Dr D respectively), Ms B was told what the proposed surgery would involve, and the general risks were explained. However, during these initial consultations she was not advised specifically of the risk that her umbilicus might need to be excised.

54. Dr A told HDC that when obtaining consent preoperatively, it is her usual practice to discuss the procedure and possible outcomes with the patient, including the risk of injury to surrounding structures. Dr A said that specifically, she discusses "the possibility of excision of the umbilicus and the surrounding skin, if it loses adequate blood supply". However, other than her statement that her usual consent process was followed, there is no other evidence that she did so in Ms B's case, and the details of Dr A's discussion with Ms B are not documented. The only documentation relating to Dr A's discussion is a standard statement on the "Agreement to Treatment" form, which states that the reasons and risks of surgery have been explained. Dr A acknowledged that she did not document specifically what she discussed with Ms B, but stated: "I do not recall modifying my usual consent process for [Ms B]."

55. Ms B told HDC that she does not recall ever being advised of the risk of her umbilicus being excised.

56. My expert advisor, Dr Speight, advised that as part of the consent process for surgical hernia repair, it would be expected that a patient would be informed of the immediate postoperative risks of surgery, including seroma formation, wound infection, mesh infection, and systemic complications. Dr Speight said that although excision of the umbilicus is necessary occasionally, there is no expectation that this be discussed explicitly at the time of consent. Dr Speight noted that the Royal Australasian College of Surgeons (RACS) brochure on surgical hernia repair, which he considers to be the "'gold standard' for patient information", does not include reference to umbilicus excision as a risk of surgery.

57. Overall, I accept Dr Speight's advice and am satisfied that at the time of obtaining consent, there was no expectation for Dr A to discuss with Ms B the specific risk of excision of the umbilicus. Therefore, I consider that it is not necessary for me to make a finding as to whether this risk was, in fact, discussed.

58. However, it is concerning that Dr A did not document her discussion with Ms B about the risks of the procedure.

59. While I am satisfied that Ms B was informed of the risks of the procedure prior to the surgery, as documented by Dr C following his consultation with Ms B on 8 April 2019, I note Dr Speight's advice that Dr A's failure to document the details of her discussion about the complications would be considered a moderate departure from expected standards. I accept Dr Speight's advice.

60. I also note Dr Speight's comment on the absence of space on the "Agreement to Treatment" form to facilitate the recording of any details of a discussion about the risks of surgery, which may have contributed to Dr A's failure to do so in this case. However, I consider that the lack of space on the form does not excuse Dr A's failure to document any of the details of her discussion with Ms B. I discuss this further below.

Decision to excise umbilicus and consent to procedure

61. After Dr A had commenced the operation, she found that the umbilicus had become devascularised and made the decision to excise it.

62. Dr Speight advised that in a situation such as this, "the surgeon needs to balance the medical risks of not removing the devascularised skin against the potential emotional distress to the patient from losing their umbilicus". Dr Speight stated:

> "It is my opinion that [Dr A] did not deviate from standard practice when excising the devascularised skin adjacent to an on-lay mesh repair of an incisional hernia adjacent to the umbilicus. The rationale for this was to avoid the increased risk of mesh infection, which I believe my peers would consider reasonable."

63. I accept Dr Speight's advice and am satisfied that in the circumstances, it was reasonable for Dr A to proceed with excising the umbilicus.

Information provided postoperatively

64. Dr Speight advised that in a situation where there is any deviation from the planned or expected surgery, this should be discussed with the patient postoperatively. I have concerns about the adequacy of the information Dr A provided to Ms B following the surgery, and the circumstances in which Dr A chose to convey relevant and important information to Ms B.

65. Dr A told HDC that in a situation where she has deviated from the expected surgical outcome, such as the removal of the umbilicus, it is her usual practice to discuss this with the patient and their support person postoperatively. Dr A said that she met with Ms B immediately postoperatively, as well as during her end-of-day ward round. Dr A said that at the immediate postoperative meeting, she mentioned to Ms B that it had been necessary to excise her umbilicus. Dr A stated that she also spoke to Ms B's partner by telephone. She told HDC that she does not recall deviating from her usual practice in this case.

66. In contrast, Ms B said that she was not advised that her umbilicus had been removed, and was of the understanding that her surgery had gone well. Although Ms B does recall someone speaking to her immediately postoperatively, she told HDC that she was still heavily sedated and has no recollection of who this was or the exact details of what was said. Ms B also said that she has no recollection of Dr A reviewing her again later that day. Mr B also does not recall being told that Ms B's umbilicus had been excised.

67. There is no documentation regarding the details of either of Dr A's discussions with Ms B, or of her discussion with Mr B. Dr A explained that she did not document these discussions because of time pressures.

68. I accept that Dr A did speak to Ms B immediately postoperatively, as supported by the PACU nursing records, and that she also spoke to Mr B (which he accepts). I also accept that Dr A more likely than not completed a ward round later in the afternoon (based on her usual practice — although there is no other evidence that this occurred). However, it is not possible to determine with any degree of certainty what was conveyed in those conversations. On the one hand, Dr A is reliant on her usual practice, as she did not document the discussions; on the other hand, Ms B has no recollection of the postoperative conversations, which likely was due to her sedation, and Mr B does not recall being told that Ms B's umbilicus had been excised.

69. That said, I have no difficulty accepting that up until the point when her dressings were removed, Ms B lacked knowledge about the excision of her umbilicus. This is indicated by her surprise, distress, immediate visit to her GP, and her complaint. It therefore calls into question the effectiveness of Dr A's postoperative communication, if indeed she did attempt to convey the relevant information.

70. There is no doubt that Dr A should have advised Ms B that it had been necessary to deviate from the expected surgery and excise the umbilicus, and Dr A should have documented the details of her discussion. This is information that a reasonable consumer, in Ms B's circumstances, would expect to receive. Additionally, every consumer has the right to communication in a manner that enables them to understand the information provided, in an environment that enables both the consumer and provider to communicate effectively.

71. I note Dr Speight's advice on the risk of undertaking a conversation with the patient immediately postoperatively, as the patient may still be sedated. I also note the challenges faced by Dr A due to time pressures. However, ultimately, Dr A had a responsibility to communicate to Ms B that it had been necessary to deviate from the expected surgery and to excise her umbilicus, in an environment and manner that enabled Ms B to understand, process, and retain the information. In my view, immediately postoperatively was not the appropriate time or environment for Dr A to undertake this conversation with Ms B, given that likely she was still sedated and not thinking clearly. To the extent that Dr A may have discussed the surgery with Ms B at the ward round, clearly this was not done in a manner that enabled Ms B to understand that her umbilicus had been removed. Further, I am of the view that Dr A's duty in this respect was to her patient, and was not discharged by speaking to Ms B's partner.

Response to concerns

72. Initially, Ms B tried to contact Dr A approximately one week following her surgery to discuss her concern about her umbilicus having been excised. Unfortunately, Dr A was on leave at this time, and so did not contact Ms B immediately. It was not until Ms B contacted the DHB again that Dr A telephoned Ms B to discuss her concerns. While I agree with Dr Speight that this delay in Dr A contacting Ms B was disappointing, and added to Ms B's stress, Dr A did contact Ms B on the day after her return from leave.

Conclusions

73. Overall, as set out above, I am satisfied that preoperatively there was no requirement for Dr A to advise Ms B of the specific risk of a possible need to excise the umbilicus. However, Dr A was required to explain to Ms B the outcome of the procedure, in a manner that enabled Ms B to understand, and in an environment that enabled Dr A and Ms B to communicate openly, honestly, and effectively. I consider that immediately postoperatively was not an appropriate time or environment in which Dr A could discuss the outcome of the surgery with Ms B effectively, and I conclude that if information about the excision of the umbilicus was given at the ward round, it was not communicated effectively. Accordingly, I find that Dr A breached Rights 5(1) and 5(2) of the Code of Health and Disability Services Consumers' Rights (the Code).[8]

74. I am also critical of Dr A's documentation.

75. The relevant standard in relation to documentation is set out by the Medical Council of New Zealand's publication *Good Medical Practice*, which states that a doctor "must keep clear and accurate patient records that report [the] information given to patients …".

76. Dr A failed to document the details of her preoperative and postoperative discussions with Ms B. The failure to document care and information adequately can affect a number of things, not least the ability to fairly and reasonably investigate events in and around the provision of care when a complaint has been made.

77. Accordingly, I find that Dr A also breached Right 4(2) of the Code.[9]

78. I am satisfied that Dr A carried out the surgery with reasonable care and skill. In particular, I consider that when Dr A encountered difficulties during the surgery, it was reasonable for her to proceed with excising the umbilicus.

[8] Right 5(1) states: "Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided."
Right 5(2) states: "Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively."

[9] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Opinion: District Health Board — adverse comment

79. At the time of these events, the DHB used a standard "Agreement to Treatment" form, which included a standard statement that the proposed procedure had been discussed and the surgeon had explained the reasons and expected risks of the procedure in relation to the patient's clinical history and condition. There was no space on the form to document any specific details of that discussion.

80. I note Dr A's advice that prior to this complaint, her routine practice had not been to record specific details of her preoperative discussions. As discussed by Dr Speight, the lack of space to do this on the form may have been a contributing factor. Although the "Informed Consent" policy recommended that specific information be provided to the patient in information leaflets, and that any "specific issues of concern discussed" be documented in the clinical records, and ultimately it is the clinician's responsibility to document their discussions, I agree that the format of the consent form did not prompt Dr A to document the specific details of her discussion with Ms B. In response to the provisional opinion, the DHB agreed to make changes to the form. I also note that Dr A and the DHB are in the process of developing an information brochure for umbilical/incisional hernia surgery, which will also help to address this issue.

Changes made

81. Dr A told HDC that she now ensures that she documents all the issues discussed during the consent process. In addition, she now makes sure that postoperative ward rounds are documented by junior doctors adequately and clearly.

82. As I note above, Dr A advised that following this incident she volunteered to develop an information brochure on umbilical/incisional hernia surgery. The DHB advised that this is currently in the process of being developed.

Recommendations

83. In response to the provisional opinion, Dr A agreed to undertake further training on communication and documentation, and has provided confirmation of her enrolment in a relevant communication course run by the Royal Australasian College of Surgeons.

84. In response to the provisional opinion, the DHB agreed to:

a) Provide a copy of its completed brochure on umbilical/incisional hernia surgery.

b) Consider standard use of the Royal Australasian College of Surgeons brochure on hernia surgery until the above brochure has been completed.

The DHB should provide an update to HDC on recommendations a) and b) within three months of the date of this report.

c) Review its standard "Agreement to Treatment" form to include space for specific risks discussed to be documented on the form, and provision for the patient to sign a copy of any patient information sheet provided, such as the umbilical/incisional hernia surgery brochure, indicating that they have had an opportunity to discuss the information with their surgeon.

The DHB should provide an update to HDC on its progress in the development of this form within six months of the date of this report.

Follow-up actions

85. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and the Royal Australasian College of Surgeons, and they will be advised of Dr A's name.

86. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from general surgeon Dr Julian Speight:

> "Thank you for asking me to provide an opinion on the care provided to [Ms B] at [the DHB] in June 2019. I have read and agree to follow the guidelines laid out in the 'Guideline for independent advisors' 2019.
>
> **Qualifications: Mr Julian Speight BSc (lions) MBBS(Lond) FRCS(Ed) FRACS**
>
> I am a consultant General Surgeon working at Kew Hospital, Southern DHB. I hold a current New Zealand practising certificate (vocational registration in General Surgery) 25548. I am a Fellow of the Royal Australasian College of Surgeons, and a Fellow of the Royal College of Surgeons of Edinburgh. I am a Senior Clinical Lecturer for the University of Otago and a past President of the New Zealand Association of General Surgeons (NZAGS), and remain on the executive committee. I also sit on the executive committee for the Rural Section of the Australasian College of Surgeons (RSS).
>
> **In Particular you have asked me to comment on:**
>
> 1) What risks should be discussed with a consumer prior to surgical repair of an umbilical hernia. In particular, whether a consumer should be informed of the risk of or potential for umbilical excision.
> 2) Assuming that the risk of umbilical excision is not discussed with the consumer pre-operatively, what steps could or should be taken if, during surgical repair of umbilical hernia, it is discovered that the umbilicus has been devascularised. For example, could or should the surgeon:
>   (a) Leave the umbilicus in-situ and complete the procedure, and discuss the need to excise the umbilicus once the consumer is awake.
>   (b) Proceed with the excision of the umbilicus without discussing with the consumer.
>   (c) Take any other action, and if so, please explain such action(s).
> 3) Whether removal of the umbilicus should be explicitly discussed with a consumer following surgery and, if so, whether such a discussion should be documented. Please also comment on whether your advice would change if the risk of umbilical excision was not discussed with the consumer preoperatively.
> 4) Any systemic issues that you consider may have contributed to the events in this case.
> 5) Any other matters in this case that you consider warrant comment.
>
> For each question you have asked me to comment on:
>
> 1) What is the standard of care/accepted practice
> 2) If there has been a departure from the standard of care or accepted practice, how significant a departure (mild, moderate, or severe) do you consider this to be?

3) How would it be viewed by your peers?
4) Recommendations for improvement that may help to prevent a similar occurrence in the future.

Documents provided:

1) Copy of complaint dated 24 August 2020.
2) [The DHB's] response (including comments from [Dr A]) dated 13 November 2020.
3) Clinical records from [the DHB] relating to [Ms B's] surgical hernia repair in June 2019.
4) Further response from [Dr A] (undated).
5) Further response from [the DHB] dated 17 June 2021 (and appendices).

1) What risks should be discussed with a consumer prior to surgical repair of an umbilical hernia. In particular, whether a consumer should be informed of the risk of or potential for umbilical excision.

The Royal Australasian College of Surgeons have developed peer review patient information pamphlets in conjunction with Mi-Tec Medical publishing. One such pamphlet is titled: 'Surgery to repair hernia' [1]. This deals with all types of abdominal hernia repair, including umbilical, inguinal and incisional hernias.

The American College of Surgeons has also produced a more specific patient information pamphlet regarding adult umbilical hernia repair alone: 'Adult Umbilical Hernia Repair' [2]. Both pamphlets deal with the immediate post-operative risks including local complications such as seroma formation, wound infection, mesh infection, and systemic complications such as DVT, PE, UTI, LRTI and even death. They also discuss the risk of recurrence of the hernia dependent on the type of technique used. Neither pamphlet specifically discusses the potential need to excise the umbilicus.

I cannot find any specific evidence based literature that has audited the rate of excision of umbilicus at the time of surgery for umbilical or incisional hernia repair. However it is well recognised throughout the surgical community that on occasion it is necessary to excise the umbilicus during a difficult umbilical or incisional hernia repair. This is usually due to the skin overlying the hernia sac being particularly attenuated and/or adherent to the hernia sac. Clearly this becomes more likely the larger the hernia sac is. I strongly suspect surgeons tailor their consent process, and would only usually discuss the potential need to excise the umbilicus if the risk seemed high due to skin immediately adherent to the hernia sac. [Dr A] states in her (undated) correspondence to [HDC] that she routinely discusses the potential risk of needing to excise the umbilicus for every patient undergoing umbilical hernia repair. This would probably be more information than routinely given by most surgeons. Indeed, the patient pamphlets from the American and Australasian Colleges of Surgeons could be considered the 'gold standard' for patient information, and are routinely provided as the information upon which surgical consent is gained. Yet neither publication specifically mentions excision of the umbilicus as a potential risk.

2) Assuming that the risk of umbilical excision is not discussed with the consumer pre-operatively, what steps could or should be taken if, during surgical repair of umbilical hernia, it is discovered that the umbilicus has been devascularised. For example, could or should the surgeon:

(a) Leave the umbilicus in-situ and complete the procedure, and discuss the need to excise the umbilicus once the consumer is awake.

(b) Proceed with the excision of the umbilicus without discussing with the consumer.

(c) Take any other action, and if so, please explain such action(s).

As the question alludes to, there are really two options if the surgeon is concerned regarding the vascularity of the skin overlying the hernia once separated from the underlying hernia sac. Clearly, if excision of the umbilicus has already been discussed, and the patient has specifically agreed to this on the consent, then the conundrum becomes less troublesome. In the event that no such specific consent has been obtained, then the surgeon needs to balance the medical risks of not removing the devascularised skin against the potential emotional distress to the patient from losing their umbilicus. There are a number of factors that may influence the surgeon's decision. There are a number of surgical techniques available when undertaking an open repair of an umbilical/incisional hernia. The repair can be achieved with sutures into the fascial layer alone. This may be a simple mass-closure or an overlapping 'double-breasted' technique. This is often employed in younger patients without confounding co-morbidities (such as obesity, diabetes, poor fascial strength from older age etc). The literature would suggest this is reasonable if the hernia neck is under the size of 1cm. Above this size the recurrence rate is unacceptably high. The advantage of this technique is that it avoids the use of mesh. In [Ms B's] case avoiding mesh would have made option (a) safer, as the potential for wound infection associated with skin necrosis would not have the more significant sequelae of mesh infection. However, [Ms B's] hernial orifice was estimated on both pre-operative radiology and at the time of surgery as 2cm. This would generally preclude the suture technique unless the patient had specifically requested the avoidance of mesh.

If mesh is to be employed to reinforce the repair there are a number of positions into which the mesh may be inserted. The fascia can simply be approximated with sutures, and then the mesh placed over the top of this repair to strengthen it. This is referred to as an 'on-lay' technique. The advantage is that this is a simple technique, and has a very low recurrence rate. The disadvantages are that the mesh lies directly in the subcutaneous plane, and is at risk of exposure to infection if the wound develops a superficial infection (SSRI) or the skin wound dehisces. Necrosis of the skin flap overlying the repair would considerably increase the risk of mesh infection. Seroma formation is another common complication associated with this technique, and subsequent infection of the seroma can also lead to mesh infection. The mesh can be placed in either a pocket created directly superficial to the peritoneum (pre-peritoneal mesh repair), or into a pocket fashioned anterior the posterior rectus fascia (pre-fascial repair). These are essentially equivalent techniques, and have the advantage that the

mesh is buried once the anterior fascia is closed over the top. Although this does not preclude subsequent mesh infection, it certainly reduces the risk in the context of an SSRI. A third option is to employ a coated mesh, and place this deep to the peritoneal layer (intra-peritoneal repair). The coating is required to prevent the mesh from adhering to intra-abdominal contents (most importantly bowel). This technique is more commonly employed when undertaking a laparoscopic approach, but is still possible to perform as an open technique. It has all the advantages of the pre-peritoneal/pre-fascial approaches, but has the added risk of iatrogenic injury to intraperitoneal organs.

In her typed operation note [Dr A] states that she was unable to safely achieve a pre-peritoneal pocket, and for this reason she elected to undertake an on-lay technique. This seems a reasonable decision. It may have been possible to obtain a pre-fascial pocket even if the pre-peritoneal plane was too fibrosed by scarring. This would have allowed the mesh to be buried. In the context of concerns around skin vascularity and subsequent SSRI, it may have allowed [Dr A] more leeway with regards to attempting to preserve the umbilicus. However, the presence of rectus divarification (noted on pre-operative radiological imaging), would make this technique difficult. I strongly suspect [Dr A] did not recognise that the skin of the umbilicus was compromised until she came to close the skin, in which case she would already have selected and completed the on-lay repair. Having undertaken an on-lay repair, in the context of a devascularised umbilicus, the decision to excise the umbilicus seems reasonable. It should be remembered that [Dr A] recalls having mentioned the risk of needing to excise the umbilicus as part of her routine consent process. In this context, she would have had far fewer concerns around pursuing this course.

A third option [option(c)], would be to consider immediate reconstruction of the umbilicus at the time of surgery. As the skin overlying an umbilical hernia is usually stretched, there is often quite an excess of skin at the time of closure. Even if some of this skin has been devascularised by dissection of the sac, there may be sufficient to fashion an inverted skin tube to replicate the excised umbilical cicatrix. I suspect [Dr A] would have considered this alternative, although she has not specifically mentioned it in her reply to the complaint. I can only infer that the area of devascularised skin was too extensive to entertain this option.

With regards to trying to assess the potential emotional harm from excising a patient's umbilicus without express consent, this is a much more subjective decision. The surgeon might take into account the age and sex, and possibly type of employment of the patient, but this would be very difficult to assess without input from the patient pre-operatively. I believe it is the consensus among surgeons that most patients in the middle age and beyond are not upset by the loss of their umbilicus. Especially when the repair has removed an unsightly protruding hernia, and has resolved any troublesome symptoms. But clearly each individual will feel differently about the loss of their umbilicus. Once again, there is no evidence-based literature to guide us. It should again be noted that at the time of surgery [Dr A] was under the impression she had gained consent for removal of the umbilicus if required.

When all is said and done, there remains the option to reconstruct the umbilicus at a separate operation. Although this requires a second anaesthetic and operation, with all the incumbent risks, it may well have a higher success rate than immediate reconstruction or even preservation of marginally vascularized tissue.

3) Whether removal of the umbilicus should be explicitly discussed with a consumer following surgery and, if so, whether such a discussion should be documented. Please also comment on whether your advice would change if the risk of umbilical excision was not discussed with the consumer preoperatively.

I believe any deviation from the planned or expected surgery is best discussed with the patient afterwards. Clearly this becomes more pertinent if the procedure (or part thereof) has deviated from what was expressly discussed at the time of consent. In the context of both needing to place a drain, and needing to excise the umbilicus, discussion in the postoperative setting is strongly encouraged. It would be possible to defer this conversation to the post-operative follow-up in outpatients, but the immediate post-operative period would be considered best practice. [Dr A] states that she saw the patient in the recovery area and discussed both of these issues. She later phoned [Ms B's] partner to relay the same information over the phone. The risk of undertaking a conversation with a patient within the setting of recovery is that some of the anaesthetic agents may not have fully worn off. Many analgesics, and specifically anxiolytics such as Midazolam, can cause both antegrade and retrograde amnesia. This may well explain why [Ms B] has no recollection of discussing the loss of her umbilicus with [Dr A]. However, in her complaint [Ms B] states that her partner has no recollection of this conversation either. The third person present at the time of [Ms B] and [Dr A's] conversation was the House Surgeon. Disappointingly, the documentation of this encounter is poor. Unfortunately for [Dr A], the maxim 'if it isn't written down it hasn't happened' becomes important here. [Dr A] concedes that her documentation requires improvement.

4) Any systemic issues that you consider may have contributed to the events in this case.

I note that [the DHB's] 'Agreement to Treat' form has no space to hand-write any specific complications discussed. Alternatively, the Mi-tec/RACS patient leaflet has a detachable sticky label that can be adhered to the consent form indicating that the patient information pamphlet has been provided. Unfortunately, even if a surgeon provides the pamphlet, this is not irrefutable evidence that they discussed the potential risks laid out in the pamphlet. Nor is it in turn, evidence that the patient understood the conversation if the complications were indeed discussed (with or without the use of a patient information pamphlet). This case seems to highlight this issue, as the surgeon is adamant that they did indeed discuss the risks and complications in some depth, yet the patient has no recollection of any such discussion. Short of video-recording every consent process, this paradox is very hard to resolve. As mentioned above, benzodiazapines (BDZ) such as Midazolam can cause retrograde amnesia. So if consent is gained immediately prior to surgery, subsequent administration of a BDZ at the time of induction of anaesthesia can render the conversation forgotten. I note from the

anaesthetic chart that 2mg of Midazolam was given on induction at 12:26. The patient arrived in theatre at 12:22, but I am unable to tell from documentation at what time [Dr A] undertook her pre-operative conversation. I am also uncertain whether 2mg of Midazolam would be sufficient to cause retrograde amnesia. Certainly the combination of anaesthetic agents and opiate analgesia administered post-operatively might render the patient sufficiently drowsy to forget a conversation held in the recovery ward. This is a common occurrence. [Dr A] did then undertake a ward round at the end of the day, but once again the records pertaining to this are poor. This should really be attributed to [the house officer], who would have been expected to take notes while [Dr A] was rounding.

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

Although you have not asked me to comment on the issue of involvement of the Plastic Surgeons for reconstructive surgery, I think it is pertinent to the over-arching issue around whether [Dr A] should have excised [Ms B's] umbilicus. Once [Dr A] had been made aware that [Ms B] was very upset to have had her umbilicus removed, she immediately wrote to the Plastic Surgeons to request potential reconstruction. It is disappointing that there was quite such a delay between [Ms B] contacting the hospital regarding her concerns, and [Dr A] returning her call (phone-call to ward from patient 10/7/2019, phone-call to patient from [Dr A] 30/7/2019). I believe this may be in part due to the fact [Dr A] was on leave for some of that time period? It is also disappointing that the plastic surgical department then delayed accepting the referral while awaiting photos from the GP. [Dr A] states that had she known that there was a delay in processing the referral, she would have intervened on the patient's behalf. A request for treatment injury has been appropriately filled, and I gather the case has been accepted by ACC. Indeed, the patient has subsequently been offered a surgical date, and by the time of writing the patient may well have had her corrective surgery.

Summary

It is my opinion that [Dr A] did not deviate from standard practice when excising the devascularised skin adjacent to an on-lay mesh repair of an incisional hernia adjacent to the umbilicus. The rationale for this was to avoid the increased risk of mesh infection, which I believe my peers would consider reasonable. If [Dr A's] recollections are to be believed, then at the time of excision of [Ms B's] umbilical cicatrix, [Dr A] was under the impression she had already discussed this pre-operatively and had the patient's consent. She then discussed the rationale for removing the patient's umbilicus with [Ms B] immediately after surgery, and then a little later with [Ms B's] partner by phone. This would seem to meet all expectations for standard of care.

Unfortunately [Ms B's] recollection of events differs to [Dr A's]. [Ms B] does not recall discussing the possible need for umbilical excision pre-operatively, nor does she recall being told about this having been undertaken in the post-operative setting. Nor does [Ms B's] partner recall discussing the removal of the umbilicus in the post-operative setting. Instead, [Ms B] only became aware that her umbilicus had been removed when the dressings came down some days later.

[Ms B's] distress was then further heightened by the delay between complaining and being able to talk to the surgeon. It would seem that after the conversation with [Dr A], [Ms B] then accepted the rationale for excision of her umbilicus: 'I *have had correspondence (sic) via phone where the surgeon after chasing for three weeks she confirmed the reasons for what she did, which I accept'[3].* However she remains upset about the mental anguish this has caused.

It is possible that [Ms B] has no memory of a discussion around the risk of potential umbilical excision due to the subsequent administration of Midazolam for induction of anaesthesia. It is also possible that [Ms B] has no memory of the discussion in the recovery ward explaining the need for removal of the umbilicus due to the sedative effects of the anaesthetic and opiate analgesia (which can take a number of hours to wear off). Unfortunately documentation around the initial consent process and subsequent postoperative discussion is poor. The former is the responsibility of the Surgeon, but the latter may be at least in part the responsibility of [Dr D] (the House Surgeon). Both [Dr D] and [Dr A] concede that their documentation was inadequate, and have undertaken to improve this into the future.

After an internal inquiry into this case [Dr A] has undertaken to write a patient information pamphlet specific for umbilical hernia repair. If it contains the information she has stated she usually includes in her verbal consent process, then it is likely to be considerably more detailed than pamphlets provided by both the Australasian and American Surgical Societies. My only other recommendation is that [the] consent form contains a suitable section to allow hand-written record of the risks/complications discussed. It may also be sensible to have a space for the patient to be able to sign this section independently from the form as a whole. I would also recommend that there is provision made for the patient to be able to sign a copy of the patient information sheet provided, indicating that they have had an opportunity to discuss the information contained with their surgeon (this should then be retained in the notes). The patient should then also be able to have a second copy to take away to read at their leisure.

The whole process has clearly been distressing for [Ms B], and I hope that her subsequent plastic-surgical reconstruction of her umbilicus goes at least some way towards redressing this.

[1] Mitec.com.au

[2] https://www.facs.org/-/media/files/education/patient-ed/adultumbilical.aspx

[3] HDC website complaint form provided in documents."

Further advice

Dr Speight provided the following further clarification in relation to the standard of documentation in this case:

"With regards to the documentation around the initial consent process: although [Dr A] recalls discussing a number of possible complications during the consent process, none

of these are specifically written down on either the consent form itself, or the patient notes. This could be considered a 'moderate' departure from best practice. It would have been mitigated if the RACS pamphlet (or other written patient information) had been given to the patient, which is what I was alluding to. Unfortunately, the consent form did not appear to have any space set aside to document such complications discussed either. That having been said, the specific information around potential excision of an umbilicus during surgery would not have been on either the RACS or the American College's written information either. I think my peers would agree that it is usual practice to make some kind of note to specify complications discussed, and usually there is space provided on the consent form to achieve this.

The record keeping around the post-operative ward-round is absent also. This would be considered a 'mild' departure from best practice, but would have gone a long way towards substantiating [Dr A's] recollection of events (ie: informing the patient of the need to excise her umbilicus)."

Dr Speight provided the following further comments in relation to accepted practice for informed consent:

"I think this case is a very interesting example of the issues surrounding informed consent. We are taught during our training that 'if it's not written down, then it hasn't happened', meaning that documentation is key. Of course, this is a little over simplistic, as it is entirely possible to write down falsehoods, or forget to document something that has indeed occurred. It gets even more difficult when considering informed consent: because simply explaining the risks and benefits of a procedure is not enough. It is incumbent upon the Surgeon to try to ensure that the patient has understood the information, thus enabling them to make an informed decision. There is much debate around what level of detail is required. Should a surgeon discuss every conceivable complication, even if some are vanishingly rare? In the past a cut-off of 1% was suggested (i.e., if a complication happened in less than 1% of cases it did not merit discussion). But this approach is problematic, because although some complications are extremely rare, if they do occur, they can be devastating. To this end I believe the current consensus is that any complications that may have a significant adverse effect should also be discussed, however rare that event is. But then one must decide which outcomes would be considered 'devastating'. Obviously, loss of life or limb is a case in point. But would one consider loss of your umbilicus a 'devastating event'? Then the surgeon needs to document this conversation in a manner that both accurately reflects the information provided, and also demonstrates that the patient has fully understood the information and its implications. Patient information pamphlets have become the most commonly used method. But as this case has amply demonstrated, they are not perfect. Had [Dr A] provided the FRACS pamphlet it would not have specifically mentioned the risk of excising an umbilicus during surgery. I suspect the authors did not include this specific complication as it is rare and not considered particularly 'adverse' (although clearly this patient would disagree with the last part of this statement). But even if a pamphlet has been provided, the onus is still on the Surgeon to ensure the patient has both read and understood its contents (I personally read through the

pamphlet with the patient at the time of consent and try hard to explain anything they do not understand). But even then, the patient can either claim the information was not in fact provided (as in our case) or claim that they did not actually understand what was being said. As I mentioned in my original letter: the only real way around these problems is to video-record the consultation. But this is not particularly practical, and is certainly not common practice.

Currently many DHBs utilise a consent form that simply states the name of the procedure, and then has the patient's and the surgeon's signature. Often the document is in fact signed on behalf of the surgeon undertaking the procedure by one of their team (usually the Registrar as the NZMC have deemed it inappropriate for the house-surgeon to gain consent). These consent forms may also contain information around use of blood products, the need for blood samples in the event of a needle-stick injury, presence of medical students etc. In recent times there has been a recognition that consent forms need to be more detailed, and to this end they have become larger and larger documents. Our DHB's consent form is now four A4 pages long. There is usually space provided to write down specific complications discussed. If I have used a patient information pamphlet, I stick the sticker from the pamphlet here to indicate its use, and do not document anything else unless it is additional to the information available in the pamphlet. I know of surgeons who have a standard list of complications that they add to their clinic note or have as part of their own consent form, but just because these are documented does not mean they have actually been discussed. So, as you can see, the consent process is complicated and varies between both institutions and individuals.

To answer your question: the lack of documentation of the complications discussed would be considered a 'moderate' departure from accepted practice. But the lack of documentation around excision of the umbilicus (in particular) would not, as it is such a rare event with such low perceived significance within the surgical community. I believe my peers would expect some documentation around the complications discussed (and a patient information pamphlet would suffice in this context). But I do not think my peers would expect explicit discussion around the potential excision of the umbilicus (especially as it is not mentioned in the information pamphlet co-badged by the Australasian College of Surgeons). I brought to your attention the fact that there was no space on [the DHB's] consent form to hand-write any complications discussed, and I believe this is a systems issue. In part this explains why [Dr A] did not document the complications discussed. Also, it would appear [the DHB] did not provide/encourage the use of the FRACS pamphlet on hernia repair? Certainly, [Dr A] did not use this for the basis of her conversation with this particular patient. The DHB has now asked [Dr A] to produce their own institutional pamphlet, which I suspect will be considerably more detailed than the generic FRACS one currently available."