Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 20HDC02122)

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Introduction

1. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner. The report discusses the care provided to Mrs A by Dr B, a plastic surgeon.

2. Mrs A's complaint concerns a surgical procedure she underwent on 10 September 2019, in which Dr B removed a lesion from her lower left cheek. Mrs A complains that Dr B carried out the procedure under general anaesthetic without her consent, and that he operated on her skin graft from a previous surgery without her consent.

3. The following issue was identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care in September 2019, including whether Mrs A was fully informed and gave informed consent for the use of general anaesthetic.*

4. Having carefully considered all relevant information, the Deputy Commissioner found that Dr B breached Right 6(2)[1] and Right 5(1)[2] of the Code of Health and Disability Services Consumers' Rights (the Code) by, respectively, failing to provide Mrs A with all the information she needed to make an informed choice, and failing to communicate effectively

[1] Right 6(2) states: "Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent."
[2] 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. Where necessary and reasonably practicable, this includes the right to a competent interpreter."

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

with Mrs A by giving her sufficient time to consider her options. Due to those failures, Dr B also breached Right 7(1)[3] of the Code by providing services to Mrs A without her fully informed consent.

5. The Deputy Commissioner further found that Dr B breached Right 4(2)[4] of the Code as his documentation fell short of acceptable standards.

6. The Deputy Commissioner recommended that Dr B, who is now retired, apologise to Mrs A. The Deputy Commissioner also recommended that the Medical Council of New Zealand consider her findings should Dr B apply to renew his practising certificate.

7. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	Plastic surgeon

8. Further information was received from:

Ms C	Practice Manager
Dr D	Anaesthetist

Relevant background

9. In 2014, Mrs A underwent three surgeries to remove melanomas in situ (MIS) from her left cheek.[5] The procedures were carried out by another surgeon, and Mrs A was then referred to Dr B for the first time for her follow-up care. Mrs A was referred back to Dr B in April 2019, after a biopsy found recurrent MIS in a scar on her left cheek.

10. On 4 June 2019, Dr B removed Mrs A's MIS under general anaesthetic (GA) at a private hospital. The operation note stated that the MIS was on her mid-left cheek, just beyond the nasolabial fold.[6] The area was closed with a skin graft.

11. During the procedure, Dr B took biopsies from the site of a previous incision biopsy and a pigmented lesion lower down on Mrs A's cheek. A pathology report completed the same day found that some of the biopsies confirmed the presence of further MIS.[7]

[3] Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."
[4] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."
[5] Melanoma in situ (or stage 0 melanoma) is the presence of cancer cells in the top layer of skin. The cells are contained in the area where they developed and have not grown into deeper layers of the skin, but if left untreated can develop into invasive cancer.
[6] Nasolabial folds are the creases in the skin from the sides of the nose to the corners of the mouth.
[7] The pathology report said sections taken from "Specimen 6: Main specimen multiple MIS left cheek" and "Specimen 7: further excision biopsy site lower pigmented lesion left cheek" confirmed MIS. The report noted

12. Mrs A decided to have additional surgery with Dr B at the private hospital to remove the new MIS.

Chronology — key events

25 June 2019

13. Mrs A attended a consultation with Dr B. His electronic record of the appointment states: "The lower incision biopsy is positive for melanoma in situ so a further procedure will be required. Review in clinic in six weeks … to develop a surgical plan for this. It may be possible to close this without a graft."

14. Dr B told HDC that Mrs A wanted to avoid another skin graft. He said that it was made clear to her that avoiding a skin graft "would depend on the extent of involvement on frozen section,[8] the size of the resultant defect after pathological confirmation of clearance, local conditions of tissue … and local tissue closure options". Dr B said Mrs A also asked that local anaesthetic (LA) and sedation be used for the procedure, rather than GA. In response to the provisional opinion, Dr B stated that "an undertaking to consult and see if the final procedure was feasible under LA was given … The patient made an active choice to accept advice and consented to having the procedure using GA if necessary."

30 July 2019

15. Mrs A attended a further consultation with Dr B. His electronic notes state:

> "Advised patient like first procedure FSC [frozen section control] + GA required. Patient keen on IV Sedation + Local anaesthetic, agreed to discuss with anaesthetist on the day. Emphasized that GA is more than likely required as uncertainty on exten[t] of surgery with Frozen Section and more complex local closure with avoidance of graft as requested. 90 mins."

16. An audit log was provided to HDC on request by Dr B's Practice Manager, Ms C. The audit log showed that the electronic record for this appointment was altered twice by Ms C, as follows:

- On 31 July 2019, when the record was created, it said: "Book for re excision lower lesion with FSC and flap repair or possible skin graft Local + Sedation GA 90 mins";
- On 11 August 2020, the term "GA" was removed from the record; and
- On 27 April 2022, the record was changed to the text set out in the above paragraph.

that MIS could not be excluded in "Specimen 5: Incision biopsy adjacent to pigmented area ?melanoma in situ".

[8] A frozen section allows for rapid diagnosis during surgery. Tissue is transferred from the operating room to a frozen tissue lab while the patient remains on the operating table. A section of the tissue is frozen before a razor-thin slice of tissue is cut from it. A pathologist can rapidly analyse the frozen section and advise the surgeon of the diagnosis and whether the entire lesion/cancer had been excised.

17. Dr B said he told Mrs A that the procedure had been booked as a GA on the theatre list, but the anaesthetist had been advised of her preference for LA and sedation.

18. Mrs A said that she requested LA and sedation at this appointment as the lesion was small. She said Dr B told her he would like the anaesthetist on stand-by in case the frozen section showed that more tissue had to be removed and, if that were the case, GA would be used from that point only. Mrs A felt that this made sense and said that at subsequent appointments "it was always understood that it was going to be under local anaesthetic". Mrs A said Dr B did not mention operating on the skin graft from her surgery in June 2019, and previously told her it should not be operated on for about a year.

27 August 2019

19. Mrs A attended another consultation with Dr B. His electronic notes state: "Further discussion regarding the additional area of in situ change requiring excision. Patient reassured, operation discussed. Should be able to do with SFs [skin flaps] rather than having to [resort] to further grafts but we'll see."

20. Dr B said that this appointment was arranged to clarify details with Mrs A, as he was concerned that their last discussion may not have been fully understood. Mrs A stated that she raised her wish to avoid GA again at this appointment, and Dr B told her that he would do the operation under LA. However, Dr B said that he "again expressed doubt that this would be possible because of the likely extent of the procedure that may be required. [He] undertook to discuss this with the anaesthetist at the time of operation but emphasised that [he] doubted that this would be possible."

5 September 2019

21. Ms C sent the following email to Dr D, the anaesthetist for Mrs A's procedure: "[Mrs A] is due to have a further excision on in situ melanoma removed on 10 Sept. She['s] spoken to [Dr B] about doing a local with sedation and [Dr B] was OK with that. But you can discuss as you see fit."

8 September 2019

22. Mrs A emailed Ms C to advise that the private hospital had contacted her and told her that she "was down for a general anaesthetic". Mrs A asked Ms C to confirm with Dr B that LA and sedation would be used, as discussed at her last appointment. Ms C told Mrs A that she had emailed Dr D, and the information already sent to the private hospital could "easily be altered to a LA + sedation … it will be the anaesthetist['s] decision at the end of the day".

23. Mrs A completed and signed the admission form. Under the Admission Details section, "GA" had been circled by hospital staff. Mrs A annotated and signed the form in this area, writing: "Please note: Not GA!"

10 September 2019

24. Mrs A's operation was scheduled for 1.30pm at the private hospital, as a day case. The surgery booking form shows that Mrs A was due for admission one hour prior, at 12.30pm.

Consent documentation

25. The patient consent form that was completed for Mrs A's surgery comprised two sections: Consent for Surgery (CFS) and Consent for Anaesthesia (CFA). In the CFS section, Dr B described the operation as "[e]xcision and F/section clearance insitu melanoma L lower cheek graft or flap" and wrote his name, confirming that he was the doctor Mrs A had discussed the operation with. The CFS section lists seven bullet points the patient agrees to, or confirms, when giving consent, including:

> "• *I confirm that I have received a satisfactory explanation of the reasons and expected risks and outcomes of the operation, during my pre-operative consultation and again on admission today …*
>
> • *I understand that any further treatment/procedure may be carried out should they be found necessary during the course of the operation/treatment …*
>
> • *I understand that I may withdraw my consent at any time prior to having the procedure/surgery without adversely affecting my future care or treatment.*"

26. The CFS section includes a box entitled "Discussion/Comments", which is empty. Mrs A's signature appears at the bottom of the page, along with Dr B's. The CFS did not mention a plan or possible intention to operate on Mrs A's June 2019 skin graft.

27. The CFA section requires the planned anaesthesia technique to be confirmed by ticking a box. The "Sedation" and "LA" boxes are both ticked. "+/-" appears in the "General" box, which is circled. The CFA section lists five bullet points the patient agrees to, or confirms, when giving consent, including:

> "• *I acknowledge that I have received a satisfactory explanation of the reasons for, risks and likely outcomes of the anaesthesia and alternative procedures …*
>
> • *I understand the proposed anaesthesia may change as deemed necessary by the Anaesthetist."*

28. The CFA's "Discussion/Comments" box has "usual risks"[9] written in it. Mrs A's signature appears at the bottom of the page, as does Dr D's.

29. On the operation record for Mrs A's surgery, Dr D wrote the following in the "Patient Assessment" section: "Prefers sedation but [Dr B] uncertain that is the best option given his surgical requirements → amenable to GA." Under "Previous Anaesthesia Problems", Dr D noted: "[T]ired post op."

30. The anaesthetic record confirms that Mrs A's surgery went ahead using GA.

Consent to anaesthesia prior to surgery

31. Mrs A said that she signed the CFS with Dr B "about 15–30 minutes" before surgery. She said: "[A]s far as I remember the '+/- GA' was not on the consent form, it certainly was never explained to me what it means. I have worked as a health professional for many years, but

[9] The quoted words, while not illegible, are difficult to read.

have never seen this abbreviation. The LA and sedation was ticked." Mrs A queried whether "+/- GA" was added after she saw and signed the consent form.

32. Mrs A told HDC that she was misled to believe that LA and sedation would be used "until minutes before [she] was wheeled into theatre". She said that Dr D saw her just prior to her being taken into theatre, at which time LA was still planned. Dr D then spoke to Dr B, who was already in theatre. Mrs A said that her "vivid recollection" is that Dr D returned and told her that Dr B "ha[d] changed his mind" and would use GA. Mrs A said that she asked why Dr B had made that decision, and Dr D replied: "[M]aybe he thought you could not handle it."

33. Mrs A said that Dr B did not have her consent to use GA from the start of the procedure. She had only agreed to "changing to GA" if the frozen section showed that more tissue had to be removed. She felt she "had no choice whether to continue … as [she] was prepped for the operation".[10] Mrs A saw Dr B when signing the CFS, but said that he did not speak to her again about the change to GA as he was already in theatre. She said she "ended up having a general anaesthetic against what [she] was expecting".

34. Dr B stated: "Consent for the procedure is obtained separately by surgeon and anaesthetist. It is the anaesthetist['s] role to obtain consent for the type of anaesthesia to be given. The surgeon can request and discuss."

35. In his 26 January 2021 response to HDC, Dr B said that the anaesthetic was discussed in a team briefing before surgery, by which time the CFS had already been signed. He stated: "I decided [GA] was safer from [Mrs A's] perspective [to] achieve adequate … analgesia for what could be quite an extensive procedure." Dr B said that it was also decided that he would defer the surgery and discuss the options with Mrs A again in future if she was not "completely happy" to have GA.

36. In a further response of 4 May 2022, Dr B told HDC that Mrs A signed the CFS after he discussed the need for GA with her. He then spoke to Dr D, who advised him that the CFA had been signed. Dr B said that he went to see Mrs A for a second time to ensure that she was fully consented. He said he also advised her that she could choose to defer the surgery if she wished. Regarding the need for GA, Dr B said that Mrs A said: "[Y]es, it is for the best." He stated that she reacted "with equanimity both in the first and second period of consent procedures and was very relaxed and eager to have her problem dealt with in as comfortable [a] manner as possible".

37. There is no record of the discussion/s between Dr B and Mrs A just prior to her surgery. Dr B told HDC that "[d]ictation on the discussions held regarding consents is not normally done as [Mrs A] was very agreeable".

[10] The consent conversations with Mrs A took place while she was in the anaesthetic room immediately adjacent to the operating theatre.

38. Dr D stated: "After examining [Mrs A] on the day of the surgery, [Dr B] discovered that the facial cancer was much larger than expected … [He] decided that local sedation was not going to be suitable because the surgery was going to be longer and more difficult than initially expected." Dr D said that she "was not present" when Dr B discussed the GA with Mrs A.

39. Dr D told HDC that once a GA had been decided on, she ticked "general anaesthesia" and wrote on the front sheet of the CFA that "in this conversation [Mrs A] was 'amenable' to general anaesthetic". Based on Mrs A's account, these annotations to the CFA were made by Dr D after she returned to see Mrs A for a second time, to inform her that Dr B had decided that GA was needed. Dr D stated: "Surgical and anaesthetic plans are often modified or improved upon as we are in theatre dealing with the case, hence the '+/- GA' on the consent form."

Consent to operate on skin graft

40. Mrs A said that "at no time" did Dr B mention realigning or working on her June 2019 skin graft during the operation. She said that he did not have her informed consent to do so.

41. Dr B told HDC: "This is untrue, the technicalities were discussed with the patient as indicated in the notes and the surgical consent signed." Neither Mrs A's notes nor the CFS include mention of her skin graft being worked on, or potentially worked on, during her procedure.

42. Dr B advised that when trying to close the lesion, it was obvious that the nasolabial fold was the "best and simplest option". To do that it was necessary to remove some of the previous skin graft, as there was going to be a "significant" dogear[11] extending into the graft and ridged area. Removing the section of the graft containing the ridged contour area was "serendipitously" done with the upper portion of the dogear removal. This allowed Dr B to slide all the cheek skin down to the nasolabial fold and retain the fundamental contour of the face in the nasolabial line. He said that one of the fundamental principles of plastic surgery is to try to achieve closure lines "in the lines of facial aesthetic units", and closure in the nasolabial fold "is a real win for the patient".

Post-surgery complaint to Dr B

43. Mrs A made a complaint to Dr B on 8 August 2020, stating that he did not obtain her informed consent for the procedure. Dr B replied to Mrs A on 26 August 2021. He said that he "saw the opportunity to … improve the outcome by realigning scars in the best direction and still give good clearance of the [MIS] lying below and separate". Dr B told Mrs A that this was discussed with her, and that he had hoped to use LA and sedation but it was not possible as he needed to "extend the excision quite a long way up around the old graft to make things neat, tidy and reduce lax redundant tissue and leave all the scars in the best possible aesthetic lines as well as clearing the melanotic lesion".

[11] Excess skin and tissue at the end of an incision that puckers or protrudes above and/or below the wound.

Correspondence with Dr D

44. On 4 September 2020, Mrs A emailed Dr D in relation to her above complaint about Dr B. Mrs A reminded Dr D that she had told her, on the day of her procedure, that Dr B had changed his mind and decided to use GA. Mrs A asked Dr D: "By you saying [Dr B] has changed his mind, a few minutes prior to the operation your information was obviously LA and sedation … could you please confirm this?"

45. On 12 October 2020, Dr D replied to Mrs A by text message, saying that she had been in hospital and would write more formally once she was better. Dr D said that she agreed with Dr B "that both the surgical, GA and anaesthetist plans can …[12] given different situations on the day".

Further information — Mrs A

46. Mrs A told HDC that she felt that GA was unnecessary for the operation, and she was mindful that it is "not so good for older people, especially twice within 3 months". Her healthcare experience made her fully aware of a clinician's obligation to obtain informed consent prior to a procedure, and she said that clinicians should not "get away with" failing to obtain that consent. Mrs A stated that "informed consent is everyone's right", and referenced the 1988 Cartwright Inquiry (which found significant informed consent failures in National Women's Hospital's treatment of women with cervical cancer from the mid-1960s until the 1980s).[13] Mrs A does not want anyone else to have the same experience she did, and hopes to prevent that as a result of her complaint.

Further information — Ms C, Practice Manager

47. Ms C told HDC that her role as Practice Manager is administrative and she does not have a clinical background. She types the surgeons' dictation and has the ability to alter electronic patient notes. Ms C said that she takes this responsibility very seriously and is aware of the audit trail, and that anything amiss on any record, such as missing dictation, is first checked with the surgeon. Any changes to patient notes are "always directed by the surgeon … (unless spelling errors or add[ing] minor detail which does not affect the file note eg. surgery details given afterward".

48. Ms C said that, at times, the surgeon's dictaphone is still turning but the voice stops mid-way through or the end button is pressed accidentally. She said that this "requires going back into the notes to complete the dictation". She stated: "With [Dr B] this [dictaphone issue] happened [in] about 1 in 3 clinics."

49. Ms C recalls Dr B discussing Mrs A's treatment plan at the end of the clinic on 30 July 2019. He said that Mrs A was to be booked for "? Local + IV Sedation or GA", and had asked to avoid a graft and have LA and sedation. Ms C said that Mrs A was instructed to prepare "for

[12] Denotes word missing in original quote.

[13] The Cartwright Inquiry considered "the treatment of cervical cancer at National Women's Hospital, and other related matters". Dame Silvia Cartwright published the Report of the Committee of Inquiry on 5 August 1988. Amongst other findings, she was critical that cervical cancer patients at National Women's Hospital had not always been properly informed of the treatment and options available to them, and that the "great majority" of the patients did not know they were participants in a clinical trial.

a GA subject to discussion with the anaesthetist on the day, for her request, Local + IV sedation". Ms C stated that she received an email and three phone calls from Mrs A, as she was worried that her procedure had been booked as a GA. Ms C said that she advised Mrs A that she "had booked GA in [the] first instance subject to discussion" and reassured her that "her requests would be taken into full account, discussed and subject to a recommendation".

50. Regarding the two alterations to the 30 July 2019 electronic record, Ms C said:

- The first change (on 11 August 2020) was made in discussion with Dr B to "add missing dictation. This was started but not completed, [they] were interrupted with other matters. This was then forgotten"; and
- The "forgotten" change "was not picked up until the latter date when [she] requested [Dr B] … look at it again and he re-dictated" (this refers to the second alteration made to the record on 27 April 2022).

Responses to provisional opinion

Mrs A

51. Mrs A received a copy of the section of the provisional opinion concerning the information gathered during the investigation. She responded to it, briefly confirming the key aspects of her complaint.

Dr D

52. Dr D was sent the sections of the provisional opinion relating to her and invited to comment on them. Dr D confirmed that she had nothing she wished to add.

Dr B

53. Dr B was provided with the sections of the provisional opinion that related to him and invited to submit comments. In response, Dr B made the following remarks:

a) The extent of Mrs A's surgery was unknown, and it "was not a defined procedure that could be characterised exactly" beforehand. Dr B said it was appropriate and common practice to discuss and decide the procedure and the anaesthetic method on the day of surgery, as that accorded with the "Royal College of Anaesthetists' safety checks, the hospital policies and modern medical practice".

b) He did not consider it was realistic in practice to arrange anaesthetic input prior to the day of the procedure, but noted that it was standard practice for the anaesthetist to be alerted to relevant medical conditions prior to the day of the surgery.

c) It would not have been appropriate for him to have documented his discussion with Mrs A about the use of GA in the "Discussions/Comments" box on the Consent for Surgery form, as "the determination of the anaesthetic technique to be used is ultimately the decision and responsibility of the anaesthetist".

d) Mrs A was informed and aware that GA may be necessary if the extent of the surgery required it. Earlier opportunities were used to discuss the potential use of GA and her

preference for LA and sedation was "kept in mind". Mrs A was "very agreeable to undergoing the procedure using GA".

e) He did not have an equal opportunity to address Mrs A's complaint as HDC's provisional opinion was issued three and a half years after Mrs A's surgery, and some of the practitioners involved had difficulty recalling it. Dr B said four nurses and two anaesthetists were present during the procedure and all but one (who no longer works at [the private hospital]) "[did] not recall anything out of the ordinary" about it.

f) Dr B provided a statement from an anaesthetic technician who was present at Mrs A's surgery. Dr B quoted from that statement, saying the anaesthetic technician had confirmed that "due diligence and correct procedures were adhered to" before, during and after the surgery, and "all required consent information was shared" with Mrs A. Dr B said Mrs A confirmed her consent to the anaesthetic technician as well as to him, though the anaesthetic technician did not make that point in his statement.

g) In terms of consent to operate on her skin graft, Dr B said Mrs A "understood and signed the surgical consent for a graft or flap, as all surgical options were on the table. This precluded any discussion of the former graft as it was close to the second area of malignancy and was within the field of surgical manoeuvre."

h) Dr B provided a statement from the principal surgeon at the clinic, who confirmed that the same dictaphones remain in use in the business, and occasionally parts of dictation are missing from a recording. Dr B said his practice manager (Ms C) requested that his notes of the 30 July 2019 appointment were amended for that reason. Dr B acknowledged that the amendments should have been marked as corrections.

i) Dr B also said that "it would have been preferable and helpful to keep better records of [Mrs A's] acceptance to proceed using GA in the notes, and to better record [their] discussion during [their] pre-operative consultations".

j) He concluded that Mrs A was informed on numerous occasions that her procedure may need to take place under GA, and that confirmation of this would be advised following discussions with the anaesthetist on the day of the procedure. Dr B said that undertaking the procedure under GA was the most appropriate course of action for the surgery. Mrs A accepted the recommendation for GA and consented accordingly, and expressed satisfaction with the outcome.

Opinion: Dr B — breach

54. This investigation considered whether the information Dr B provided to Mrs A during the consent process complied with the relevant law and standards (set out below) and was sufficient to enable Mrs A to provide informed consent for her procedure.[14]

[14] Mrs A did not make a complaint about Dr B's surgical decision-making or the outcome of her 10 September 2019 surgery.

55. Overall, I have concerns about the adequacy of the information provided to Mrs A in this respect, both in her preoperative consultations with Dr B and her contact with him on the day of surgery.

56. In forming my opinion, I have taken account of relevant law and standards, including the following:

- The Code of Health and Disability Services Consumers' Rights 1996 (the Code);[15]
- Medical Council of New Zealand (MCNZ) Informed Consent statements (March 2011 and September 2019);[16]
- MCNZ Managing Patient Records statements (October 2019 and December 2020);
- The MCNZ Good Medical Practice standard (November 2021); and
- The private hospital's Informed Consent policy.

57. The MCNZ 2019 informed consent statement sets out that "[c]onsent is an interactive process, not a one-off event".[17] It states that the process involves shared decision-making to help the patient understand their condition and their options in relation to it. The 2019 statement advises, in part, that doctors must give patients the information they need to make a fully informed decision, and reasonable time to make that decision. Further, doctors must keep clear and accurate records noting the information discussed; any specific risks highlighted; any request or concerns expressed; and any decisions made and the reasons for them.

58. When a complaint about informed consent is investigated, full and accurate clinical records are essential to demonstrating that an appropriate consent process has taken place. MCNZ's *Good Medical Practice* states that doctors "must keep clear and accurate patient records that report: relevant clinical information, options discussed, decisions made and the reasons for them, information given to patients, the proposed management plan, [and] any medication or other treatment prescribed".

Informed consent to anaesthetic technique

59. I accept that Mrs A clearly and consistently expressed her wish to avoid GA from the point of her first appointment with Dr B about the new MIS on 25 June 2019. I accept that consent to anaesthesia is the responsibility of the anaesthetist, and I have considered the care provided by Dr D in a separate section. In respect of Dr B, I am concerned with how Dr B managed Mrs A's request, and how he communicated with Mrs A about her options.

[15] https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/

[16] Medical Council of New Zealand, "Information, choice of treatment and informed consent" (March 2011); and MCNZ, "Informed Consent: Helping patients make informed decisions about their care" (September 2019).

[17] MCNZ's September 2019 informed consent statement was applicable at the time of Mrs A's surgery. At the time of her preoperative appointments, MCNZ's 2011 informed consent statement applied. The statements are very similar in terms of the key principles set out in paragraph 57.

60. I am critical of Dr B's electronic records of Mrs A's preoperative appointments on 25 June 2019 and 27 August 2019. These records do not adequately reflect the information Dr B said he gave Mrs A on those occasions. I will comment on Dr B's electronic record of Mrs A's preoperative appointment on 30 July 2019 separately below.

61. Dr B said that at the June consultation, Mrs A asked for LA and sedation, and to avoid a skin graft, and he explained the factors that would affect his ability to close her incision without a graft. Neither these factors nor Mrs A's requests were recorded in Dr B's brief electronic record of the appointment.

62. Dr B said that he arranged the August appointment specifically to ensure that Mrs A understood the information he had provided at her July consultation. However, his brief electronic note about this appointment refers only to "further discussion" about the excision area, "patient reassured, operation discussed", and "should be able to do … [skin flaps] rather than … grafts". This record does not provide sufficient evidence that Dr B again discussed and clarified the potential anaesthetic requirements with Mrs A as he stated. This is especially noticeable given that the aim of the appointment was to ensure that Mrs A was properly informed before surgery.

63. As an aside, it is not difficult to see that Mrs A's email communication with Ms C two days before her surgery may have contributed to confusion about the anaesthetic plan. While Ms C advised Mrs A that the type of anaesthetic would ultimately be the anaesthetist's decision, Ms C also said that the information already sent to the private hospital about Mrs A's surgery could "easily be altered to a LA + sedation". As I will discuss, this reinforced to Mrs A that an anaesthetic plan of LA and sedation for her procedure was a real possibility.

64. I am also critical of Dr B's failure to document his consent discussion with Mrs A while she was in the anaesthetic room prepped for surgery. Based on the information gathered, it is evident that Dr D obtained Mrs A's consent for anaesthesia, but Dr B made the decision to undertake the procedure under GA rather than LA and sedation. There was dedicated space in the "Discussion/Comments" box on the CFS form to have recorded details of the discussion about surgery. As it had been an important issue from the outset, I would have expected Dr B to have recorded his discussion with Mrs A about the change of anaesthetic technique, including the reasons for the change and her right to defer surgery due to the change of anaesthetic if she wished.

65. As it is, there is no record of Dr B having discussed the change to GA, the rationale for it, and the right to defer surgery with Mrs A at this time. Dr B asserted that there was no need to make a record as Mrs A was "very agreeable" to GA during their discussion/s. This is directly at odds with Mrs A's account, her consistently expressed desire to avoid GA, and that she was surprised by the change to GA just before surgery and wanted to know the reason for it, but did not receive an explanation.

66. Dr B provided two different accounts about when he first spoke to Mrs A to obtain her consent for surgery: he advised HDC that he first saw her before he made the decision to use GA during the team briefing, but later said that he first saw Mrs A after he made that

decision. Dr B also asserted that he spoke to Mrs A for a second time before surgery, but Mrs A is clear that this second conversation did not happen. I accept that Dr B visited Mrs A once prior to surgery, as both parties agree that was the case. The lack of documentation about their discussion/s immediately before surgery means that I cannot reconcile these different versions of events further.

67. However, in any case, I am concerned that Mrs A did not have adequate time to properly consider and consent to Dr B's proposal to carry out her surgery using GA. Based on Dr B's comments to HDC, he felt from the outset that Mrs A's procedure was unlikely to be possible using LA and sedation. This should have been communicated to her, but instead Mrs A was given the impression in the entire lead-up to the surgery that her preference for LA and sedation could be accommodated.

68. Telling Mrs A on the day of her procedure, just prior to her being taken into theatre, that her only option was GA put her in a difficult position, where she felt that she had no choice but to proceed. That situation was unsatisfactory and unnecessary given the multiple earlier opportunities to discuss the proposed procedure, anaesthetic, and Mrs A's preferences.

69. Dr B said that he told Mrs A that a final decision about the anaesthetic technique would be made on the day of surgery, after input from the anaesthetist, and that Mrs A was agreeable to this approach. There is a lack of documentation to support this submission. While I acknowledge that Mrs A likely accepted that further discussions closer to the day of surgery would occur, there is no evidence to suggest Mrs A understood that performing the procedure under LA and sedation was unlikely to be possible. Furthermore, and despite what is written in the retrospective edits to the consultation note of 30 July 2019 (which I discuss below) and Dr B's submissions, I do not accept that Mrs A anticipated having to make a decision about whether she was comfortable to have a GA just prior to surgery, or that she was agreeable to doing so. The evidence is consistent that Mrs A repeatedly communicated her preference for LA and sedation, and that was being considered by Dr B as a potentially viable option.

70. In my view, given that Dr B was not sure that LA and sedation would be possible, he should have attempted to clarify the anaesthetic technique and appropriate options for proceeding with Dr D much earlier. The only documented contact with Dr D prior to Mrs A's surgery was Ms C's email of 5 September 2019, which advised Dr D that Mrs A wanted LA and sedation "[b]ut you can discuss as you see fit".

71. Dr B waited more than two months, until the day of surgery, to personally discuss the anaesthetic technique with Dr D. In his response to the provisional opinion, Dr B said this was common practice and it was appropriate to decide the anaesthetic method on the day of surgery. In my view, even if this is common practice in ordinary circumstances, Mrs A's particular circumstances, whereby she had repeatedly expressed a strong preference not to have GA, warranted appropriate and proactive steps to be taken to accommodate them and ensure she was fully informed of her likely options.

72. I do not accept that Mr Dr B's actions, in informing Mrs A about the anaesthetic change imminently prior to her surgery, were appropriate. Dr B should have contacted Dr D to discuss Mrs A's clearly expressed anaesthetic preference and determine the available options in the circumstances. Dr B could then have presented those options to Mrs A at an earlier point in time, to enable her adequate time to consider her options and make an informed choice about whether to proceed.

73. Even if it was not possible to arrange appropriate discussions before the day of surgery, at a minimum, Dr B could have arranged for Mrs A to have arrived earlier for her surgery to enable those discussions to occur, or spoken to Mrs A about the anaesthetic change when she arrived at hospital one hour prior to surgery, so that she would have sufficient time to consider her options. In the absence of ensuring Mrs A was informed of the eventual decision to proceed with GA with appropriate time to consider her options, I conclude that Mrs A did not provide fully informed consent for the use of GA in her surgery.

Informed consent to operate on skin graft

74. Mrs A said that Dr B did not tell her that her June 2019 skin graft may be operated on during her procedure, and he did not have her informed consent to do so.

75. Dr B did not clarify exactly when the "technicalities" of Mrs A's procedure, which he said included operating on her skin graft, were discussed with her. He advised, however, that "the size of the resultant defect" and "local tissue closure options" were discussed with Mrs A at her June appointment. In the context of such a discussion, the fact that Mrs A's June 2019 skin graft was just above the planned surgery area would have been potentially relevant. Dr B's response to HDC on this matter is not supported by his records. The possibility that Mrs A's skin graft might be involved in her surgery is not recorded as being discussed anywhere in the patient notes or on the CFS.

76. Further, in his response to the provisional opinion, Dr B said that "any discussion" of Mrs A's previous skin graft was in fact "precluded". His rationale for this view, that Mrs A's skin graft was "within the field of surgical manoeuvre" as it was close to the area she had consented to being operated on, is not persuasive. It implies that Mrs A should have known, without being specifically told, that her skin graft might be operated on during the surgery.

77. Regarding the surgery to Mrs A's skin graft, I have considered the relevance of the standard clause (at bullet point three) on the CFS, which states that the patient understands "any further treatment/procedure may be carried out should they be found necessary during the course of the operation/treatment". HDC has previously found that a standard consent form clause of this nature cannot negate a consumer's rights under the Code to make an informed choice and to give informed consent to services.[18]

78. The evidence indicates that Dr B likely anticipated that he might need to operate on the skin graft area in order to close the new incision without using a further graft. Based on the documentation, this was an aspect of the surgery that Dr B failed to discuss with Mrs A at

[18] 17HDC02004.

all. She had specifically requested that another skin graft be avoided, making it especially relevant for Dr B to have informed her that avoiding a new graft could result in her existing skin graft being operated on. I am critical that Dr B did not provide this information to Mrs A. It meant that Mrs A did not have the opportunity to consider the matter and give informed consent for her skin graft to potentially be operated on.

Record of 30 July 2019 consultation

79. I have already expressed concern about the overall quality of Dr B's records of his conversations with Mrs A at her preoperative consultations and on the day of surgery. In his response to the provisional opinion, Dr B accepted that it would have been 'preferable and helpful' if he had kept better records of these discussions.

80. I am particularly critical of Dr B's electronic record of his 30 July 2019 appointment with Mrs A (the July record). The audit log provided shows that this record originally read "Book for re excision lower lesion with FSC and flap repair or possible skin graft Local + Sedation GA 90 mins", but was subsequently altered on two occasions.

81. MCNZ's 2019 and 2020 "Managing Patient Records" statements, which applied at the time of the first and second alterations respectively, set out the legal requirements doctors must observe when handling patient records. In terms of altering records, they state:

> "If you need to correct or add notes to your patient's records sometime after an event, these must be clearly identified as corrections or additions. The notes must be initialled or signed, and accurately dated as to when the changes were made. The earlier entry must not be changed or deleted as that might raise suspicion about covering up an error in treatment or diagnosis."

82. The two changes to the July record do not comply with these requirements. The original entry was changed, then deleted, and neither change was signed and dated as an alteration.

83. The first alteration, the removal of "GA", was made three days after Mrs A's complaint to Dr B of 8 August 2020. The second alteration was made on 27 April 2022, one week before Dr B provided his response to HDC's investigation, which included a copy of the July record that read:

> "Advised patient like first procedure FSC [frozen section control] + GA required. Patient keen on IV Sedation + Local anaesthetic, agreed to discuss with anaesthetist on the day. Emphasized that GA is more than likely required as uncertainty on exten[t] of surgery with Frozen Section and more complex local closure with avoidance of graft as requested. 90 mins."

84. The alteration made on 27 April 2022 was significant. It meant that, overall, the July record went from not providing details of any discussion with Mrs A and referencing the use of both LA and sedation and GA, to a record that makes specific reference to Mrs A's wishes and implies that Dr B gave her a detailed description about the anaesthetic possibilities and how a final decision on the anaesthetic technique would be made.

85. Having considered Ms C's comments, I accept that the alterations she made to the July record were made at the request of Dr B. There was no obvious reason for Ms C to initiate the alterations herself. In his response to the provisional opinion, Dr B did not dispute this, but confirmed that he was asked to correct the record by Ms C due to a dictaphone recording problem.

86. Neither of the alterations complied with the requirements of the MCNZ "Managing Patient Records" statement. In requesting these changes to the July record, Dr B failed to comply with his professional and ethical obligations. It was inappropriate to have requested two retrospective alterations to the record without ensuring that the alterations complied with the relevant MCNZ guidance.

Conclusion

87. Dr B told HDC that he advised Mrs A about the anaesthetic options for her procedure and that her skin graft might be operated on, to the extent that she was in a position to provide informed consent on the day of surgery.

88. While I acknowledge that the options of both GA and LA and sedation were discussed, I do not accept that Dr B adequately conveyed his reluctance to perform the procedure without GA, as Mrs A had the impression that her preference for LA and sedation was going to be accommodated unless and until the frozen section found that further excision was required. After Mrs A expressed her preference not to have GA, Dr B should have discussed that preference with an anaesthetist, determined the appropriate options for proceeding, and then communicated that clearly to Mrs A before the day of surgery, or if that was not possible, sufficiently prior to her surgery to allow her adequate time to consider her options and make an informed choice about whether to proceed. Providing this information just before her surgery was not appropriate. Dr B's actions culminated in Mrs A being put in a situation where she felt that she had to proceed under GA regardless of her wishes, as she was prepped and about to be taken to theatre.

89. I recognise that Dr B obtained a statement from the anaesthetic technician, attesting to the fact that Mrs A was properly consented prior to her surgery. However, as an anaesthetic technician, his responsibilities[19] would not be expected to extend to involvement in the consenting process on the day of surgery. His statement is written in general terms, and does not include any specific details about exactly what was discussed with Mrs A. As such, his evidence does not persuade me to change my findings about the information that was or was not provided to Mrs A.

90. I consider that by failing to adequately advise Mrs A of her options for treatment, and the possibility that her recent skin graft would be involved in the surgery, Dr B breached Right

[19] As set out in "Responsibilities of an anaesthetic technician", Auckland University of Technology (AUT) "Perioperative Practice at AUT" brochure, https://nzats.co.nz/wp-content/uploads/2022/05/Perioperative-Practice-at-AUT-Digital-v2.pdf. The New Zealand Anaesthetic Technicians' Society, which represents registered and trainee anaesthetic technicians, states that graduates of this AUT programme can apply to register as an anaesthetic technician with the Medical Sciences Council of New Zealand, the regulatory body for anaesthetic technicians.

6(2) of the Code by failing to provide Mrs A with all the information she needed to make an informed choice. In addition, by not providing Mrs A with sufficient time to consider her options, I find that Dr B did not communicate effectively with Mrs A and breached Right 5(1) of the Code. It follows that by not providing such information, Dr B also breached Right 7(1) of the Code by failing to obtain Mrs A's informed consent for her surgery.

91. In addition, Dr B's documentation fell short of acceptable standards, and I find that Dr B breached Right 4(2) of the Code by failing to keep full, accurate patient records that complied with the relevant professional and ethical standards.

Opinion: Dr D — other comment

92. Mrs A told HDC that Dr D obtained her consent for LA and sedation on the CFA on the day of her procedure, before returning to inform her that Dr B had decided to use GA from the outset instead. Mrs A did not make a complaint about Dr D's role in the informed consent process.

93. I have nevertheless considered Dr D's actions as part of this investigation, as she was also necessarily involved in the consent process for Mrs A's surgery and GA as the anaesthetist.

94. The Medical Council of New Zealand (MCNZ) 2019 "Informed Consent" statement sets out that "[c]onsent is an interactive process, not a one-off event". It states that the process involves shared decision-making to help the patient understand their condition and their options in relation to it. The 2019 statement advises, in part, that doctors must give patients the information they need to make a fully informed decision, and reasonable time to make that decision. Further, doctors must keep clear and accurate records noting the information discussed; any specific risks highlighted; any request or concerns expressed; and any decisions made and the reasons for them.

95. When a complaint about informed consent is investigated, full and accurate clinical records are essential to demonstrating that an appropriate consent process has taken place.

96. Once Dr B made the decision to proceed with GA from the start of Mrs A's surgery, Dr D was obliged to have, and document, a new discussion with Mrs A about any specific risks the change of anaesthetic technique entailed, the rationale for the change, and any requests and/or concerns Mrs A expressed about it.

97. Mrs A has confirmed that a second conversation took place, and Dr D's notes in the Patient Assessment section of the operation note record that an explanation was provided to Mrs A about why GA was to be used: "Prefers sedation but [Dr B] uncertain that is the best option given his surgical requirements." There is evidence that any problems with previous anaesthesia were discussed, as Dr D recorded that Mrs A had experienced tiredness postoperatively. There is no reference here to Mrs A's concern about the possible risk of having a second GA within three months. Mrs A has not claimed to have mentioned this to Dr D, however, or to have said that she specifically objected to going ahead with the surgery under GA at that time. In that respect, I see no clear basis to question Dr D's record that Mrs A was "amenable to GA" at their second conversation.

98. I note Mrs A's evidence that she does not recall seeing "+/- GA" on the CFA when she signed it, and her suggestion that this annotation may have been added afterwards. Dr D told HDC that suggestion was correct, stating: "[A]naesthetic plans are often modified or improved upon as we are in theatre dealing with the case, hence the '+/- GA' on the consent form." It would have been much clearer for Dr D to have ticked the GA box, rather than writing "+/- GA", as Dr B had made a definite decision to use GA by that point. However, on balance, I am not critical of Dr D's actions in this respect. There is evidence that Dr D had a second conversation with Mrs A about the change to GA as expected, and her annotation of "+/- GA" broadly reflects that conversation and is supported by her documentation on the operation note.

99. In reaching my above conclusion, I have taken into account that Mrs A is knowledgeable about the requirements of informed consent from her background as a health professional. She has also reviewed the records from her surgery, and reviewed and commented on all the submissions Dr D and Dr B made to HDC prior to the provisional opinion.

Recommendations and follow-up actions

100. I recommend that Dr B provide a written apology to Mrs A for the deficiencies identified in this report. The apology should be sent HDC, for forwarding to Mrs A, within three weeks of the date of this report.

101. In making the above recommendation, I have taken into account that Dr B no longer has a current practising certificate and advised HDC that he retired from practice during 2022.

102. However, I recommend that the Medical Council of New Zealand consider my findings in this investigation in the event that Dr B applies to renew his practising certificate.

103. I intend to take the following follow-up actions:

a) A copy of this report, with details identifying the parties removed, will be sent to the Medical Council of New Zealand and the Royal Australasian College of Surgeons, and they will be advised of Dr B's name in the covering letter.

b) A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.