Otolaryngologist, Dr A

ENT Clinic

A Report by the

Health and Disability Commissioner

(Case 20HDC01266)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary 1
Complaint and investigation 2
Information gathered during investigation 3
Opinion: Clinic — breach 12
Opinion: Dr A — breach and adverse comment 14
Changes made since events 17
Recommendations 18
Follow-up actions 19

Executive summary

1. This report concerns the care provided to an eight-year-old boy by an otolaryngologist and an ear, nose, and throat clinic. The report highlights the need to ensure that a consumer's (and, for a child, the consumer's parents') right to decide to refuse treatment is upheld, and the importance of providing the parents of the consumer with appropriate information and communication in order to obtain informed consent.

2. In December 2019, the family met with the otolaryngologist to discuss treatment of the boy's breathing and allergies. The parents agreed and consented to surgical treatment for the boy, which was to take place in April 2020. The consented and signed procedures included the removal of the boy's adenoids and tonsils, cleaning of his ears, and imaging of his voice box, windpipe, and ears.

3. In February 2020, the otolaryngologist wrote to the parents recommending that the boy undergo the cautery of his inferior turbinates (CIT) at the same time as the other planned procedures. The CIT procedure involves making an incision or cauterising the swellings on the side walls of the nose (the turbinates).

4. In March 2020, the otolaryngologist's clinic wrote to the mother to add the CIT procedure to the informed consent form and have it signed. However, the parents refused the CIT procedure. This was acknowledged by staff at the clinic. Despite the acknowledgement, the email in which the CIT procedure was declined was not placed in the boy's electronic file, which meant that the otolaryngologist was unaware that the boy's parents had refused the procedure.

5. Owing to the COVID-19 outbreak in 2020, the boy's surgery was postponed to July. On the day of surgery, the otolaryngologist consulted his records and recommendations for the boy on the electronic file. The file included the CIT procedure, which had not been removed after the boy's parents refused it.

6. Before the commencement of the surgery, there was miscommunication between the mother and the otolaryngologist in the preoperative room about consent for the procedures to be performed. This resulted in the CIT procedure being written on the consent form and signed, contrary to the parents' understanding that they had not consented to it.

7. The CIT procedure was performed, but the boy's adenoids were not removed because only an insignificant amount of adenoid tissue was present. A brief discussion regarding the outcome of the surgery took place between the otolaryngologist and the parents before the boy was transferred to another ward for recovery and monitoring. Around six hours later, the parents became aware for the first time that, contrary to their expectation, the boy's adenoids had not been removed, and that the CIT procedure had been performed despite their earlier refusal of consent.

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Findings

8. The Commissioner considered that the clinic was responsible for ensuring that the parents' decision to refuse the CIT procedure was actioned and communicated to the otolaryngologist. Because this critical information was not communicated to the otolaryngologist, the Commissioner found the clinic in breach of Right 7(7) of the Code.

9. The Commissioner considered that the otolaryngologist retained overall legal responsibility and accountability for obtaining informed consent to the procedures proposed for the boy. The otolaryngologist accepted that he did not provide the family with sufficient information about the CIT procedure. This was followed by a miscommunication on the day of surgery about whether the CIT procedure was to be included in the proposed procedures to be undertaken that day.

10. Although the Commissioner accepted that the otolaryngologist's lack of knowledge of the family's refusal of consent to the CIT procedure was affected by the clinic's systems error, she found that in performing the CIT procedure without the family's consent, the otolaryngologist breached Right 7(1) of the Code.

11. The Commissioner made adverse comment about the otolaryngologist's postoperative communication with the family regarding his decision not to remove the boy's adenoids.

Recommendations

12. The Commissioner recommended that the clinic provide a written apology to the family, and review the effectiveness of its new policy, which requires further consultation with the consumer when there is a delay greater than three months between the initial consultation and the day of surgery.

13. The Commissioner recommended that the otolaryngologist provide a written apology to the family, setting out the changes he has made in respect of their complaint.

Complaint and investigation

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

- *Whether Dr A provided Master B with an appropriate standard of care from December 2019 to August 2020.*
- *Whether the clinic provided Master B with an appropriate standard of care from December 2019 to August 2020.*

15. This report is the opinion of the Commissioner, Morag McDowell.

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16. The parties directly involved in the investigation were:

Dr A	Provider/otolaryngologist
Mrs B	Complainant/mother
Mr B	Complainant/father
Clinic	Provider

17. Further information was received from:

Private hospital	
Provider/anaesthetist	
Provider/anaesthetist assistant	
Ms C	Practice Manager at the clinic

Information gathered during investigation

18. This report concerns the care provided to an eight-year-old boy, Master B, by an ear, nose, and throat (ENT) specialist (otolaryngologist), Dr A, at an ENT clinic (the clinic) and, in particular, the performance of a procedure that Master B's parents had expressly declined. The report examines the adequacy of the consenting process that occurred.

Background

19. At the time of events, Master B had a history of restless sleeping,[1] fatigue, inflammation of the tonsils,[2] nasal symptoms, and allergies.

Usual procedures to obtain consent

20. Dr A explained to HDC that his usual process for obtaining consent for surgical treatment included the following steps:

a) For the most commonly performed procedures,[3] patients and families are asked to complete an online questionnaire and read the information provided on his website.

b) The next phase occurs during the consultation — where a recommendation for surgery is followed by discussion of the benefits, risks, and complications.

c) Patients and families are invited to call Dr A directly to discuss any questions they have following the consultation, and this invitation is also included in the consultation letter.

d) Patients and families are provided with a written information form (produced by either the Royal Australasian College of Surgeons or himself), which details the surgical

[1] Dr A's consultation notes document that Master B was a "habitual loud snorer" and was observed to have suffered brief periods of apnoea.

[2] Caused by bacterial or viral infection (tonsillitis).

[3] Procedures involving grommets, tonsils, and adenoids.

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procedure (unless a procedure is very minor — in which case neither he nor the College have separate information forms).

e) A recommendation for surgery is followed up with a face-to-face or telephone discussion about the operation prior to surgery, including the benefits, risks, and complications.

Initial consultation with Dr A

21. Following a referral by their family GP on 5 December 2019, Master B and his parents had an appointment with Dr A at his practice (the clinic).[4] Dr A examined Master B and diagnosed him with obstructive breathing whilst sleeping,[5] recurrent inflammation of the tonsils, and irritation and swelling inside the nose.[6]

22. Following the examination, Dr A recommended that Master B have both his adenoids[7] and tonsils removed.[8] Dr A also recommended that Master B's larynx (voice box), trachea (windpipe), and ears be examined[9] during the operation. Master B's ears were also to be cleaned. On the same day, a consent form for the procedures was signed by Master B's father, Mr B, documenting the following four procedures to be performed by Dr A:

> "Adenotonsillectomy
>
> Laryngotracheoscopy with laryngeal imaging
>
> Bilateral aural toilette +
>
> Bilateral examination of ears."

23. Surgery with Dr A was scheduled for 2 April 2020 at the private hospital.[10]

Recommendation of additional procedure

24. Dr A told HDC that during the December consultation with Master B and his parents, a cautery of the inferior turbinates (CIT) procedure should also have been recommended for Master B. The CIT procedure involves making an incision or cauterising (burning) the swellings on the side walls of the nose (turbinates).[11]

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[4] The clinic is located at a private hospital.

[5] Obstructive sleep apnoea is the intermittent blockage of airflow during sleep.

[6] Rhinitis.

[7] Adenoids are a patch of tissue that sits in the back of the nasal cavity. Like tonsils, adenoids help to keep the body healthy by trapping bacteria and viruses.

[8] Adenotonsillectomy (an operation to remove both the adenoids and tonsils).

[9] Laryngotracheoscopy (examining voice box and throat) with laryngeal imaging plus bilateral aural toilette (cleaning the ears) and examination of the ears.

[10] The private hospital provides clinical and hospital facilities to medical practitioners. Medical practitioners who treat patients at the hospital are independent specialists, and are not employees.

[11] Turbinates usually have an air-filtering function, and help to warm and moisten the air that is breathed. However, when swollen, turbinates can cause blockage and make breathing through the nose difficult. CIT shrinks the turbinates and increases airflow.

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25. On 24 February 2020, Dr A wrote to Mr and Mrs B[12] recommending that Master B undergo the CIT procedure at the same time as the other four procedures agreed to in December. The email from Dr A stated:

> "… Given his nasal symptoms, I thought he would be an excellent candidate to also have his inferior turbinates cauterized at the same time as his adenotonsillectomy and laryngotracheoscopy. This is a painless addition to his procedure but which would give him the benefit of enhancing the nasal airway for six to twelve months. The downside is that the nose would be a little more congested than usual for the first fortnight after the surgery. This can be managed simply by using a nasal spray as need be. …"

26. Dr A explained to HDC that at the time of events there was no specific written information for a CIT procedure because this was considered to be a minor and uncomplicated procedure,[13] and therefore he did not have a separate information form to provide to Master B's parents (as per his usual consenting process outlined above).

27. Dr A told HDC:

> "I fully accept that the explanation that I gave about cautery of the inferior turbinates was lacking in sufficient detail for his parents to be able to give their truly informed consent, and I did not have a separate information form on cautery of the inferior turbinates to provide to his parents."

Master B's parents' express withdrawal of consent for CIT procedure

28. On 20 March 2020, the Practice Manager of the clinic, Ms C, emailed Mrs B informing her that the CIT procedure had been added to the list of procedures for Master B's surgery. Ms C asked Mrs B to counter-sign the previously signed consent form (from 5 December 2019) to confirm the addition.

29. In response to Ms C's request, Mrs B expressly refused to have the CIT procedure, and replied by email stating:

> "With regards to this added procedure, we don't want to proceed with this part, but happy to proceed with other parts previously discussed and signed off. Thanks."

30. Ms C acknowledged Mrs B's email and asked Mrs B to send back a counter-signed copy of the consent form with the CIT procedure crossed out. This was completed on 22 March — initialled and dated by Mr B. The counter-signed form was received and acknowledged by Ms C via email.

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[12] Dr A's letter to Mr and Mrs B on 24 February 2020 stated that Master B would be an excellent candidate to have his inferior turbinates cauterised. This was described as a painless procedure that would give him the benefit of enhancing the nasal airway for six to twelve months. Dr A wrote that although the downside would include the nose being a little more congested than usual, this could be managed by a nasal spray.

[13] Dr A told HDC that the Royal Australasian College of Surgeons also does not have a separate information sheet about cautery of the inferior turbinates.

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Counter-signed consent form not placed into Master B's electronic file

31. Dr A advised HDC that the email from Mrs B with the CIT procedure declined was not placed in Master B's electronic file as it should have been. Dr A stated: "It is a requirement that all communications with patients and their families are documented in the electronic record and on this occasion, this was not done."

32. The clinic advised HDC that when new clinical information is received, the usual administrative process at the practice is to email the information to Dr A and to file the email in the patient notes. The clinic told HDC that there is "no acceptable explanation" as to why the email was not filed into Master B's electronic file, but said that the timing of the first New Zealand COVID-19 lockdown caused considerable stress to clinic staff because of the increased cancelling and re-booking of appointments at the time. Clinic staff also had no access to printers and scanners whilst working from home.

33. The clinic acknowledged the omission in this instance, and stated:

> "This was a very regrettable act of omission during a crisis period, as it is [the clinic's] standard (unwritten) procedure to record and file clinical correspondence in the patient electronic file."

34. The clinic also stated that it was their usual practice for staff to verbally follow up with Dr A in order to confirm that the email had been received and actioned. The clinic acknowledged that Dr A was "not fully and clearly informed verbally about [Master B's] parent's decision" at this point in time.

35. Additionally, Ms C stated that as a result of the lockdown, the clinic team was unable to discuss Master B's parents' decision not to proceed with the CIT procedure with Dr A in their regular Thursday meeting. In summary, Dr A was not informed of Master B's parents' decision not to proceed with the CIT procedure.

36. Dr A explained to HDC that there was no face-to-face or telephone discussion about the planned surgery with Master B's parents due to the postponement of the date of surgery from the COVID-19 lockdown in New Zealand.

Deferral of surgery to 1 July 2020

37. Two months after the postponement of Master B's surgery, Ms C emailed Mrs B on 22 May, advising her that the surgery for Master B had been rescheduled to 1 July 2020. Master B's parents were advised by the private hospital to complete the pre-admission forms again (including the consent form) as they had expired due to the time elapsed.[14]

38. The pre-admission forms[15] were sent to the private hospital by Master B's parents. However, the private hospital told HDC that they did not receive the up-to-date consent

[14] According to the private hospital, the pre-admission forms were valid for only 30 days.
[15] This included the admission form signed 13 June 2020 and the patient health questionnaire.

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form from Master B's parents. As a result, the private hospital inserted a blank consent form into Master B's file, to be completed by Dr A on the day of surgery.

39. The private hospital advised that the placement of a blank consent form (in the absence of one) was not an "uncommon situation". It was also explained by Dr A that when documents do not arrive on time, are incomplete, or when there is a lapse of time,[16] then a new consent form can be prepared and filled in by the surgeon on the day of surgery.

40. On 30 June 2020, a nurse from the private hospital telephoned Mrs B to complete the preoperative assessment. The completed preoperative assessment form did not document the CIT procedure as part of the planned procedures.

Operation at private hospital on 1 July 2020

Day of surgery

41. On 1 July 2020, Master B and his parents presented to the private hospital for the planned surgery with Dr A. A routine pre-operation check was carried out for Master B by the admission nurse. Because of issues with the prior patient, Master B's original scheduled operation was delayed for around two hours.

42. Dr A told HDC that Master B's surgical and anaesthetic consent forms that had been pre-prepared were not present in his file, so a new blank consent form was required to be filled in (as discussed above).

43. Dr A told HDC that he consulted his records and recommendations on Master B's electronic file "to detail [Master B's] correct operative procedure" — which mistakenly included the CIT procedure as it had not been updated. According to Dr A, there was also no record of any correspondence from Master B's parents in his file mentioning their concerns and the refusal for the CIT procedure.

Usual procedures to obtain consent on day of surgery

44. The private hospital stated that all medical care is provided by independent medical specialists, and ultimately those practitioners are responsible for obtaining patients' consent to undergo surgery.

45. Dr A explained to HDC that the normal process for him in obtaining consent on the day of surgery included:

a) Using consistent phrasing as part of the consultation, and asking patients or families if they feel well informed and if they have any further questions about the procedure(s).

b) Directing the patient or family to read the "fine print" before signing. The consent form states that the signatory confirms that they have received a satisfactory explanation of the reasons for risks and likely outcomes of the operation and alternatives, and that they have had an opportunity to ask questions and understand that they may seek more information at any time.

[16] A lapse of three months or more between receiving original documents and the surgical date.

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c) Having the signed consent form re-checked by the surgeon, anaesthetist, and surgical team prior to the start of the surgery.

Obtaining consent on day of surgery

46. Prior to surgery, Dr A took Master B and Master B's parents into the preoperative room. Dr A talked briefly to Master B before handing Mrs B the consent form to fill out the basic information (name, date, and relationship of person giving consent) on Master B's behalf.

47. Mrs B recalled that when the form was handed to her, the surgical procedures were not filled out. After the basic information was filled in and the form was handed back to Dr A, he proceeded to ask Master B's parents what procedures were to be done that day. According to Mrs B, she said out loud to Dr A in simple language the four procedures agreed: "ear check, vocal cord check, adenoid and tonsil removal". Dr A then proceeded to document these procedures using their respective medical terms before handing the consent form back to the parents to sign. Mrs B recalled:

> "We laughed and said we wouldn't understand the medical jargon, and repeated its fine as long as it's only ear check, vocal cord check, adenoid and tonsil removal. [Dr A] confirmed this was what he wrote."

48. Dr A told HDC that he is unable to recall the details of the discussion, other than that he sat opposite to Master B and his parents to write out the consent form. However, Dr A recalled asking Master B's parents if they felt informed and if they had any further questions. He acknowledged that he did not separately point out that Master B would undergo the CIT procedure.

49. Dr A stated that often there is no further discussion about the benefits or risks of the surgery on the day of the operation, so it was not unusual when Master B's parents did not ask further questions in the preoperative room.

50. The consent form that was signed by Dr A and Mrs B showed the CIT procedure listed as part of the surgical procedures for Master B.

51. Dr A considers that Master B's parents would have been familiar with the medical words on the consent form, given that these had been provided on the original consent form in December 2019. In contrast, Master B's parents told HDC that they did not know what the medical terms meant, although Mr B acknowledged that the CIT procedure was mentioned on the day but potentially misunderstood as "medical jargon". Mr B stated:

> "Given the significant delays on the day, and a desire to get everything over and done with, I completely understand how a patient may gloss over 'Bilateral bipolar linear cautery of inferior turbinates' on one form in a bunch of paper work without an appreciation for what it means. As you can appreciate it's not quite a layperson explanation. I understand that it too was mentioned by [Dr A] on the day. Doctors routinely use so many medical terms and abbreviations, and unfortunately that approach leads to misunderstandings when the patient or parent doesn't fully understand medical jargon."

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52. At this point in time, Dr A was still not aware that the parents had expressly refused the CIT procedure previously in March. At the same time, Master B's parents understood that they had already declined the CIT procedure to Ms C.

53. As a result of signing the consent form with the CIT procedure listed as part of the planned procedures, Master B's parents appeared to have agreed to the CIT procedure.

54. At around 3.55pm, the anaesthetic technician met with Master B's parents in the preoperative room and checked Master B's consent form by showing it to Master B's parents, reading the procedures out loud from the consent form, and verifying the signatures.

55. At around 4.00pm, Master B was taken into the surgical theatre. There was a further check with the anaesthetist and the surgical team to confirm Master B's identity and the procedures to be performed as part of the "Sign In" process.[17] The surgical team recalled that Mrs B "agreed that what had been read from the consent form were the correct procedures to be performed". The anaesthetist told HDC that the routine consent checks were carried out with Mrs B, confirming that the procedures were those agreed to on the consent form.

56. Master B's parents recall that they were told repeatedly to recite their understanding of the procedures to be performed by the various clinical providers, but they feel that their understanding was never once questioned or corrected by these checks, or "recognised to be missing a key part".

57. Dr A explained that he had informed the theatre team on the day that the CIT procedure was a consented change to the operation list. Dr A noted that it is common for small changes to be made to the operation list when it involves children, and that typically this occurs when patients or families request additional procedures at the last minute.

Surgery and postoperative discussion

58. Master B's surgery commenced at around 4.10pm and ended around 4.45pm, and the procedures undertaken included the CIT procedure. As no significant adenoid tissue was found in Master B's upper throat behind the nose, an adenoidectomy was not performed (that is, Master B did not have adenoids to remove).

59. Dr A told HDC that following Master B's surgery, he showed photographs of Master B's nasal passages to Master B's parents. Dr A explained to Master B's parents that the primary reason for Master B's obstructive breathing was that a part of Master B's nostrils was enlarged. Dr A acknowledged to HDC that he did not explain to Master B's parents at the time that Master B's adenoids were absent, and apologised for this.

[17] The anaesthetist is responsible for the "Sign In" safety check, which includes a surgical safety checklist that must be completed before the induction of anaesthesia. The surgeon is responsible for the "time out" process (before skin incision) to confirm the patient and the procedure/s.

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60. Master B's parents told HDC that there was no explanation from Dr A about the non-removal of the adenoids, nor the CIT procedure performed. Given the significant delays on the day, they were feeling "anxious" and had a "desire to get everything over and done with". In response to the provisional opinion, Dr A told HDC that he had explained to Mrs B that Master B's inferior turbinates were enlarged and their enlargement was the reason for the obstructive breathing, not the adenoids.

Discovery of CIT procedure performed

61. At around 10.35pm, when Master B was to be discharged, the nurse documented that Mrs B questioned some ooze coming from Master B's nose, and the nurse at this point noted that the signed consent form differed from the operating notes on the hospital system — namely, that the removal of adenoids had not occurred.

62. The nurse informed Master B's parents that the adenoids had not been removed. The nurse documented that the parents were very upset, as they felt that the surgeon did not fully explain the findings to them, and they were under the impression that it was the adenoids causing the obstructive breathing. The nurse telephoned the surgeon to clarify the procedures, and, through this, the parents were also made aware that the CIT procedure had been performed contrary to their understanding. Dr A told HDC that he did explain to Mr B on the telephone the reason why Master B did not have his adenoids removed.

63. Dr A stated:

> "I discussed in detail the surgery performed, including showing [Mr and Mrs B] photographs taken during the surgery so that they could understand exactly what had been making [Master B] unwell. I made a point informing them that the inferior turbinates were very large and that their enlargement was the reason for the nasal obstruction, and not the adenoids, and that cauterizing the inferior turbinates was the correct and appropriate treatment for [Master B]."

64. However, Dr A also acknowledged:

> "I did not state to [Mr and Mrs B] that the adenoid was absent at that time and I apologise for this. His parents discussed this question with the ward nurse who telephoned me prior to Master B's discharge and I was able to explain this to [Mr B] prior to [Master B's] return home from hospital."

65. According to Master B's parents, they had arrived home late that night after the surgery and returned the missed calls from Dr A. Mrs B said that she felt "belittled" during this conversation, and that she was informed of the details of the CIT procedure. Mrs B stated that she made it clear to Dr A that they had not agreed for the CIT procedure to go ahead, and that prior to the surgery they had emailed the clinic about their refusal of the CIT procedure.

66. Dr A told HDC that this was the first time he learned that Master B's parents had refused the CIT procedure. In response to the provisional opinion, Dr A told HDC that he had made subsequent calls to Mrs B, as part of his normal routine, to check on Master B's wellbeing

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following the surgery. Dr A said that those calls were not returned. He stated that he also offered Mrs B an opportunity for a second review and opinion about the consequences and benefits of the CIT procedure.

Post-surgery follow-up consultations

67. After the surgery, Dr A tried to follow up Master B's health with Master B's parents as part of his routine contact. The surgery and Master B's health were discussed with Mrs B on the weekend following the surgery, and Dr A explained that the reason the adenoids were not removed was that they were not present significantly.

68. On 22 July 2020, Master B and his parents presented to Dr A for a postoperative check. According to Dr A, Master B had recovered as planned. Master B's parents told HDC that they did not want to attend the postoperative appointments but thought it was in Master B's best interest.

Further information

69. Master B's parents told HDC that they feel they were "taken advantage of" with an unnecessary procedure that was carried out without their consent. They do not want this to happen to anyone else. In relation to the surgery performed, Master B's parents told HDC that they want accountability and acknowledgement that things could have gone better for Master B on the day of surgery. They stated that there were "multiple opportunities" to correct their understanding, and that the informed consent process was "patchy at best". They hope the concern raised can lead to a review of the process and prevent something similar happening to another young patient.

70. Dr A has acknowledged the seriousness of Master B's parents' concerns, and is very sorry that they found his consent process lacking its usual rigour for Master B, and that this was very stressful for them. Dr A explained that as a result of this complaint, he has made meaningful changes to his and the clinic's practice, as set out below.

Responses to provisional decision

71. Mr and Mrs B were provided with an opportunity to comment on the relevant sections of the provisional opinion. Mr and Mrs B emphasised the issue of medical professionals expecting individuals to understand medical jargon, which they feel does not allow for safe informed patient consent.

72. Dr A was provided with an opportunity to comment on the provisional opinion, and responded on behalf of both himself and the clinic. Dr A did not disagree with the conclusion or the recommendations reached by the Commissioner, but raised some points for clarification, some of which have been incorporated into the "information gathered" section above.

73. Dr A told HDC that his recollection of some of the events differs to that of Mrs B. He stated that the procedures were written on the consent form after reviewing the medical records, and prior to Mrs B signing the form. His recollection is that — contrary to Mrs B's version of events — the procedures were not recited to him, with emphasis on the four procedures,

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otherwise he would not have performed the CIT procedure. Dr A said that the procedures were confirmed and recited off the signed consent form subsequently with both the anaesthetic technician and the anaesthetist.

74. Dr A advised HDC that his Australasian colleagues would support his view that CIT is a minor procedure. He noted that he had performed the procedure many times, for over a thousand children. Dr A also stated that he would expect that "most Australasian Otolaryngologists would not accept that cautery of the inferior turbinates is associated with any pain, fever or epistaxis [bleeding from nose]".

Opinion: Clinic — breach

Introduction

75. Mr and Mrs B expressly refused consent for their son to receive the CIT procedure. Right 7(7) of the Code of Health and Disability Services Consumers' Rights (the Code) states: "Every consumer has the right to refuse services and to withdraw consent to services."

76. The principle of informed consent is at the heart of the Code. Services may be provided to a consumer only if that consumer (or a person entitled to consent on behalf of the consumer, including the parent of a child under 16 years of age[18]) makes an informed choice and gives informed consent.

77. The informed consent process began when the family presented to the clinic and Dr A for Master B's ongoing breathing issues. It was acknowledged by the clinic that deficiencies in the administrative process directly resulted in the refusal of the CIT procedure not being communicated to Dr A. Unfortunately, a chain of errors then caused the CIT procedure to be performed without informed consent having been given by Master B's parents. This case shows the importance of documentation filing and of verbally communicating key clinical decisions between clinical and administrative staff.

Express refusal for CIT procedure

78. During the initial consultation with Dr A in December 2019, the four procedures Master B was to undergo in April 2020 were recorded clearly, discussed, and consented to. During this consultation there was no discussion or consent to the CIT procedure for Master B.

79. In March 2020, a month before Master B's surgery, the clinic's Practice Manager, Ms C, emailed Master B's parents stating that the CIT procedure had been added to the list of procedures, and asking them to sign the consent form that included the CIT procedure. Mrs B expressly refused to have the CIT procedure added to the procedures agreed to in

[18] Clause 4 of the Code states: "'Consumer' means a health consumer or a disability services consumer; and, for the purposes of Rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer."

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December. The CIT procedure was crossed out and counter-signed by Mr B, and this was acknowledged by Ms C on 22 March 2020.

80. Up to this point, there is no dispute and uncertainty about the care consented to. However, despite the countersigned form being received by the clinic, there were deficiencies related to the consent process that followed, as acknowledged by both the clinic and Dr A.

81. First, it is acknowledged by Dr A that the email containing the countersigned form from Master B's parents dated 22 March 2020 was never put into Master B's clinical file as it should have been. It is an appropriate requirement of the clinic that all communications with patients and their families are documented in the electronic file, as Dr A relies on this medical record to determine the correct operative procedures on the day of surgery. The clinic stated that there is "no acceptable explanation" as to why the email was not filed into Master B's electronic file, but suggested that the timing of the COVID-19 lockdown could have contributed to the error.

82. Second, the clinic stated that when new clinical information is received, the usual administrative process is that the new information is emailed directly to Dr A. However, in this case that did not occur. Furthermore, due to the COVID-19 lockdown, staff were unable to hold their usual weekly meetings. This meant that Dr A was not informed verbally about Master B's parents' decision to decline the CIT procedure.

83. I acknowledge that the onset of the COVID-19 lockdown likely caused a degree of uncertainty and disruption to normal service and practice, and may have contributed to the email to Dr A being overlooked by Ms C or another administrative staff member.

84. However, despite the potential impact of COVID-19, at a service level the clinic was nevertheless responsible for ensuring that its system, including its support staff, appropriately actioned Master B's parents' refusal of consent to the CIT procedure. The information was significant, as it would have altered the treatment plan proposed for Master B. In my view, the failure to ensure that this critical information was communicated to Dr A, as the operating surgeon, rests with the clinic as an organisation.

Conclusion

85. As stated above, every consumer has the right to refuse consent to health services. In my view, it was the responsibility and obligation of the clinic to ensure that Master B's parents' decision to refuse the CIT procedure was actioned and communicated to Dr A. Accordingly, as this did not occur, I find the clinic to have breached Right 7(7) of the Code.

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Opinion: Dr A — breach and adverse comment

86. Dr A is an experienced otolaryngologist who consulted with Master B's parents and Master B in December 2019. The operative procedures were agreed and a consent form signed in this consultation, and there is no dispute here. Dr A then performed the surgery on Master B on 1 July 2020 after the initial date of surgery in April was postponed due to the COVID-19 lockdown.

87. As the operating surgeon, Dr A retained overall legal responsibility and accountability for obtaining informed consent to the procedures proposed for Master B. From the outset, I want to acknowledge Dr A's earnest responses and the areas for improvement he has identified retrospectively. The issues to be considered in this case are set out below.

Consent to CIT procedure

Discussions prior to surgery

88. In February 2020, Dr A sent a letter to Master B's parents by email stating that he should have recommended the CIT procedure for Master B. A brief outline of the procedure detailing the benefit and expected outcomes was set out in the email, which stated that the procedure was painless and would give Master B the "benefit of enhancing the nasal airway for six to twelve months". The email described the potential downside of the CIT procedure for Master B as being that his nose would be a "little more congested than usual for the first fortnight after the surgery", but could be managed using a nasal spray.

89. Before giving consent to health services, consumers are entitled to be given information that a reasonable consumer, in their circumstances, would expect to receive, and need to receive to give informed consent.[19] This will include information about the risks and benefits of having the treatment (or other options for treatment) before a decision is made.

90. At the time of events, the CIT procedure was considered by Dr A as both minor and not complicated, and therefore there was no separate information sheet. Dr A advised HDC that his Australasian colleagues would support his view that CIT is a minor procedure. He noted that he had performed the procedure many times, for over a thousand children.

91. Whilst the CIT procedure may have been minor and simple according to Dr A, this does not mean that Master B's parents were not entitled to information that a reasonable consumer in their circumstances would expect to receive. Dr A accepts that Master B's parents would not have been able to give their "truly informed consent" based on the information he provided in his letter. It is further understood that Master B's parents may have been concerned about the implications of the procedure and temporary nature of any benefits. Communication either verbally or in writing did not provide the parents the opportunity to have this issue (or indeed any other questions they may have had) addressed. I accept Dr A's acknowledgement that he did not provide sufficient information about the CIT procedure to Master B's parents, and am critical that this did not occur.

[19] Right 6 of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."

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Discussions on day of surgery

92. On 1 July 2020, Master B and his parents presented to the private hospital for the planned operation with Dr A. The private hospital's policy stipulated that a time lapse of three months or more between receipt of original documents and the surgical date necessitated completion of new documents. Therefore, the pre-treatment forms that had been signed previously were discarded, and new forms including the consent form had to be resent by Master B's parents. The private hospital did not receive the signed consent form prior to the day of surgery, and had to insert a blank consent form into Master B's file for Dr A to complete on the day. This situation was not uncommon.

93. As there was a blank consent form for Master B's surgery, Dr A had to consult the electronic records and recommendations on Master B's electronic file to ascertain the operative procedures to be performed. There was no record of any correspondence from Master B's parents detailing their refusal of consent to the CIT procedure, nor the counter-signed consent form. As a result, Dr A assumed that the CIT procedure he had recommended had been agreed to. In my view, and as outlined above in respect of the practice, this was a significant systemic factor. However, despite the systems error, I am critical about the information Dr A provided to the family, as discussed further below.

94. There are some points of difference between Dr A's and Master B's parents' accounts of the consent conversation on the day of the surgery. Dr A has also indicated (in statements prior to the provisional opinion) that he is unable to recall the exact details of the preoperative discussion he had with Master B's parents at this time.

95. Dr A told HDC that once he had taken Master B's parents into the preoperative room, he asked Mrs B to fill out some details on the consent form for Master B. In his response to the provisional opinion, Dr A clarified that the operative procedures, including the CIT procedure, were already written down on the consent form when it was given to the family to fill out the relevant details and sign.

96. In contrast, Mrs B told HDC that the procedures were not written on the form when it was handed back. Mrs B stated that she filled in the basic information, including her name, her relationship to Master B, and the date of surgery, and when she did so the procedures section of the form was blank. She said she then handed the consent form back to Dr A, and Dr A then asked Mrs B to recite the operative procedures aloud whilst he wrote them down on the consent form using the respective medical terms. Although Dr A told HDC that he presumed Master B's parents to be familiar with the medical words on the consent form before it was given back to Mrs B to sign, Master B's parents told HDC that they did not know what the medical terms meant, as they considered it to be medical jargon.

97. Mrs B also emphasised that she had recited to Dr A only the four procedures that were agreed to in December, those being "ear check, vocal cord check, adenoid and tonsil removal" despite the signed consent form having included the CIT procedure. She said that these were the same four procedures she had recited to the other nursing staff at the private hospital before meeting with Dr A.

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98. On the other hand, Dr A told HDC that these procedures were not emphasised, because if they had been he would not have performed the CIT procedure. In response to the provisional opinion, Dr A also said that the procedures were not recited to or by him as part of his consenting process with the family, but in a separate process between the family and the anaesthetic team.

99. As an additional point, I note that the pre-admission form does not document the CIT procedure as having been mentioned or planned.

100. I acknowledge that there is disagreement about whether Mrs B recited her understanding of the procedures to Dr A. However, having examined the evidence, I do not consider it necessary to resolve the factual conflict. It remained Dr A's duty to ensure that relevant information about the procedure was conveyed to the family. This meant that he needed to ensure that he informed the family that the CIT procedure was proposed, in such a way as to enable them to understand that information.

101. I accept the family's evidence that they did not understand the medical jargon, and that in signing the consent form Mrs B did not understand that the CIT procedure, which the family had earlier refused, was to be carried out.

102. Dr A acknowledged that often there is no further discussion about the benefits or risks of the surgery on the day of the operation (if a discussion has already occurred). However, the CIT procedure was an additional procedure that had not been discussed previously in person (albeit briefly disclosed via the email in February 2020), and it would have been appropriate for Dr A to have described the procedure in plain language, and allowed the family the opportunity to ask any questions. Furthermore, if Dr A did ask Mrs B to recite information back to him, he needed to ensure that the information recited back reflected the information recorded on the consent form — which in this case it did not.

103. The questions and checks carried out prior to surgery should also ensure that informed consent is truly obtained. The process should not be performed perfunctorily or superficially, but clinicians should engage with the consumer and their family and listen actively. Once Mrs B had signed the form, Dr A believed that consent had been given for the CIT procedure. For Master B, there was a lost opportunity to have identified the misunderstanding about the surgery between his parents and Dr A.

Conclusion — consent to CIT procedure

104. I accept that Dr A's knowledge of the family's refusal of consent to the CIT procedure was affected by the systems error, for which the clinic is responsible. However, I remain critical of the information and communication Dr A provided to Master B's parents on the day of the surgery. The bottom line is that it remained Dr A's duty, as the operating surgeon, to obtain consent for the CIT procedure, and in this case no such consent was given.

105. I find that in performing the CIT procedure when Master B's parents had not given informed consent to it, Dr A breached Right 7(1) of the Code.

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Postoperative communication — adverse comment

106. Master B's surgery took place without any issues. The procedures signed off as consented to, including the CIT procedure, were performed. However, during the course of the operation, no significant adenoid tissue was found in Master B's upper throat, so the adenoidectomy was not performed as planned. Following the surgery, Dr A had a discussion with Master B's parents about the enlargement of Master B's nostrils that had caused the obstructive breathing, and showed them photographs of Master B's nasal passages. However, it was acknowledged by Dr A that he did not inform Master B's parents at that time about the non-removal of the adenoids, or that the CIT procedure had been performed.

107. When Master B was about to be discharged, a nurse informed Master B's parents about the CIT procedure (following their enquiry about the ooze from Master B's nose) and the non-removal of the adenoids. It is documented that Master B's parents were upset because Dr A had not explained the findings to them fully at their initial postoperative consultation. Dr A was telephoned by the nurse immediately to clarify the procedures performed, and for him to explain that no significant adenoid tissue had been present, so no adenoidectomy could be performed. There was a later conversation that night, which, according to Dr A, was the first time he learned that Master B's parents had declined the CIT procedure.

108. Whilst I accept that during the immediate postoperative consultation Dr A did provide information about what happened during the procedure and his findings about the cause of Master B's breathing problems, it is accepted by him that he did not explain to Master B's parents that Master B's adenoids were absent, and accordingly that the adenoidectomy was not performed. This is information that Master B's parents were entitled to receive, as it was a change to the operating procedures to which Master B's parents had consented, and expected. I am therefore critical that this information was not conveyed during the initial postoperative conversation. The parents' distress on learning that the CIT procedure had occurred contrary to their wishes, in combination with this lack of information, negatively affected their trust in the therapeutic relationship.

109. I remind Dr A of the importance of postoperative communication to patients and their family, which I would expect to cover procedures expressly consented to that did not occur (and the reasons for that).

Changes made since events

110. Dr A and the clinic told HDC that as a result of the complaint made by Master B's parents, they have instigated the following changes to the practice:

    a) A further consultation will now be required if there is a delay of greater than three months between the initial consultation and the surgical operation day, and if additional procedures are contemplated.

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b) A new written policy has been developed, which details that the communications with patients and families are always recorded in the patient file.

c) A new policy has been developed regarding the steps of the booking procedure with the private hospital, including information about the consent form and hospital admission documents.

d) A new information sheet about cautery of the inferior turbinates has been produced, and is to be provided to both patients and families.

e) The practice software was upgraded on 7 February 2021, which allows filing of PDF documents into the software without printing and scanning.

f) All surgical consent forms will be type written to make the form easier for patients to read.

g) Dr A will be notified in advance of any discrepancy between the booking form and any consent form.

111. The private hospital told HDC that as a result of the complaint made by Master B's parents, it conducted an internal event review and provided education and communication to all theatre staff to:

a) Cross-check the signed consent form with the documented procedure. This action was audited, observed, documented, and completed in November 2020.

b) Understand the correct process for sign-out. This action was audited, observed, documented, and completed in November 2020.

Recommendations

112. I recommend that the clinic review the effectiveness of the implementation of the new policy that mandates that the clinic will provide a further consultation with a consumer when there is a delay of greater than three months between the initial consultation and the day of surgery. The review should consider whether the policy achieves its intended purpose, and is to be sent to HDC within three months of the date of this report.

113. In the provisional opinion, I recommended that the clinic and Dr A provide a written apology to the family. I have now received these apology letters, and, in light of the submissions within the letters, these will be attached to the end of this report, and will be forwarded to the family.

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Follow-up actions

114. 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 A's name.

115. 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.

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