Lactation Consultant, Ms B

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC00988)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Baby A was born in 2016. When he was eight days old, his mother, Mrs A, rang a lactation consultant,[1] Ms B, for advice and support for her breastfeeding.

2. Ms B attended Mrs A at her home at 11.00am. Ms B assessed Baby A and Mrs A and diagnosed Baby A with a tongue tie.[2] Ms B offered to perform a frenotomy on Baby A and explained what the procedure would involve. She did not provide an information pamphlet or explain the non-surgical alternatives that were available.

3. Mrs A was upset and called her mother to discuss the procedure. She also asked to speak to her midwife but this request was ignored. Baby A's father, Mr A, signed the consent form.

4. At 12.00pm Ms B performed the frenotomy with the assistance of Mr A. The wound started bleeding immediately and, after 15 minutes, Ms B called an ambulance.

5. When the ambulance arrived, Ms B applied silver nitrate[3] to the wound and the bleeding stopped. A small blood clot was removed from the wound at 1.00pm and, when Baby A fell asleep, the paramedic left. A midwife arrived at 2.05pm and Ms B handed over care to her. Ms B left at 2.12pm.

6. At 2.30pm, the bleeding started again and an ambulance was called. Baby A was transferred to hospital — a journey that took over an hour — and the wound was repaired surgically.

Findings

7. When she performed the frenotomy, Ms B cut deeply into the floor of the mouth and the muscle underlying the tongue, and damaged an artery. Accordingly, she did not perform the frenotomy with reasonable care and skill and, as a result, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[4]

8. Ms B could have advocated further for Baby A's transfer to hospital when the first ambulance was called. Adverse comment was made about her failure to do so.

9. Ms B did not advise Baby A's parents of the non-surgical alternatives to a frenotomy, that there are conflicting views on the merits of a frenotomy, or that they could seek advice from other medical specialists. By failing to provide this information, Ms B failed to provide information that a reasonable consumer would need to receive to make an informed choice and, as a result, breached Right 6(2)[5] of the Code.

[1] A lactation consultant is a breastfeeding specialist trained to teach mothers how to feed their baby.
[2] Tongue tie is a condition in which the thin piece of skin under the tongue (the lingual frenulum) is abnormally short or tight and may restrict movement of the tongue. Tongue tie can interfere with a baby's ability to suckle efficiently at the breast.
[3] Silver nitrate sticks are used to cauterise skin chemically to stop minor bleeding.
[4] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."
[5] Right 6(2) of the Code 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."

10. By performing the frenotomy when informed consent had not been obtained, Ms B also breached Right 7(1)[6] of the Code.

Recommendations

11. It was recommended that Ms B provide a letter of apology to Mr and Mrs A, and a report to HDC outlining her discussion with an ear, nose and throat specialist and the changes made to her practice as a result.

12. It was recommended that the Midwifery Council consider whether a competence review of Ms B's performance of frenotomies is warranted.

13. It was recommended that the Ministry of Health consider formulating a consensus position on the efficacy of frenotomies, and consider developing guidelines for the diagnosis and performance of frenotomies by midwives.

Complaint and investigation

14. The Commissioner received a complaint, referred by the Midwifery Council of New Zealand, about the services provided to Baby A by Ms B.

15. The following issue was identified for investigation:

Whether Ms B provided Baby A with an appropriate standard of care in 2016.

16. This report is the opinion of Meenal Duggal, Deputy Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

17. The parties directly involved in the investigation were:

Baby A	Consumer
Mrs A	Complainant/consumer's mother
Mr A	Complainant/consumer's father
Ms B	Midwife/lactation consultant

18. Information was also reviewed from:

Dr C	Otolaryngologist
Ms D	Registered midwife
Ms E	Midwife and lead maternity carer
Midwifery Council of New Zealand	
District health board	
Ambulance service	
International Board of Lactation Consultant Examiners	

[6] Right 7(1) of the Code 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."

19. Independent expert advice was obtained from Ms Jacqueline Martin, a registered nurse, midwife, and lactation consultant.

Information gathered during investigation

Background

20. Baby A was born in 2016. His mother, Mrs A, started breastfeeding him with the support of her lead maternity carer (LMC) and midwife, Ms E. Mrs A experienced significant pain while breastfeeding and she rang Ms B for advice and support for her breastfeeding.

21. Ms B is a registered nurse, midwife, and lactation consultant. Ms B consulted with Mrs A in her capacity as a lactation consultant.

22. Ms B attended Mrs A at her home. Baby A was then eight days old.

Initial assessment of Mrs A and Baby A

23. Ms B arrived at Mrs A's home at 11.10am. Mrs A's husband, Mr A, and her brother were also present.

24. Mrs A stated that her goal was to be able to breastfeed Baby A without pain, and for Baby A to thrive. Ms B undertook a preliminary assessment and examination of Mrs A and Baby A and recorded her findings.

25. Mr and Mrs A told HDC that they were happy that a specialist was coming to help them with their breastfeeding concerns, but that when Ms B arrived she seemed rushed and performed only a brief assessment and examination of Mrs A and Baby A.

Diagnosis of a tongue tie

26. Ms B observed Mrs A breastfeeding Baby A. Ms B stated that Mrs A was using an appropriate technique, but that "[Mrs A] described [breastfeeding] as very painful and she could only tolerate it for about 2 minutes".

27. Ms B told HDC:

> "The nipples had hairline cracks around the base which, following observation of the feed indicated the baby was biting down with the gums with a shallow latch, because of a very tight, less than 1cm length frenulum[7] restricting tongue movement; baby was compensating despite mum's best efforts to achieve a deeper latch. Despite a very full breast, milk transfer was limited and the mother was experiencing a high level of pain."

[7] The frenulum is the thin piece of skin under the tongue.

28. Ms B told HDC that, having observed the tight frenulum, she then decided to assess the functional impairment of Baby A's tongue. Ms B used the Hazelbaker tool[8] to do this, and she diagnosed a tongue tie.

29. Using the tool, Ms B assessed Baby A with an appearance score of 6/10 and a function score of 7/14. She stated that where the appearance score is less than 8 and the function score is less than 11, then "a frenotomy is recommended because the tongue is clearly restricted in its ability to function". A frenotomy is a procedure in which the tongue is lifted and the lingual frenulum is cut, usually with scissors.

30. Having diagnosed a tongue tie, Ms B then used the classification-combined[9] system to categorise the type of tongue tie.

31. Under the classification-combined system there are five types of tongue tie. A type 5 tongue tie is described as a posterior tie where the frenulum is sub-mucosal[10] and attaches to the base of the alveolar ridge[11] or the floor of the mouth. Types one to four are tongue ties where the frenulum attaches at various points from the tip of the tongue to various points on the alveolar ridge, but are not sub-mucosal and do not attach to the floor of the mouth. Ms B stated:

> "I categorised the frenulum as mid-tongue anterior tie … it was a type 3–4. It was not a sub-mucosal[12] Posterior tie. Those I refer to a specialist, as I am not covered as a Specialist Midwife to release these more complex ties."

Scope of practice

32. The Midwifery Council of New Zealand[13] (Midwifery Council) sets out the midwife's scope of practice with regard to the assessment and diagnosis of a tongue tie and the practice of frenotomy. The statement provides that a frenotomy sits within the scope of practice of midwives who have completed specific training, and that "midwives undertaking frenotomy will be limited to performing simple lingual[14] frenotomy using an approved assessment tool such as the Hazelbaker tool and technique".

33. The statement states that posterior, labial, and other complex tongue ties should be referred to a specialist.

34. In addition, the statement provides that the midwife must ensure that informed consent to the procedure is obtained by providing full information on the risks and benefits of frenotomy, and the alternatives to surgical intervention.

[8] Assessment tool for lingual frenulum function — ATLFF (Hazelbaker, AK 1993) is widely used by midwives to diagnose tongue tie. The Hazelbaker tool objectively measures a tongue tie and assesses the functional impairment of the tongue and any visible anatomical abnormality.
[9] Classification-combined system developed by Coryllos, Genna, Salloum, Griffiths, and Todd.
[10] Submucosal means under the mucous membrane.
[11] Alveolar ridge is the jaw ridge on the bottom of the mouth below the lower teeth.
[12] Submucosal means under the mucous membrane.
[13] Midwifery Council statement on the midwife's scope of practice with regard to assessment and diagnosis of tongue tie and the practice of frenotomy (April 2016).
[14] Lingual means "of the tongue".

35. Ms B was employed by Mrs A as a lactation consultant but she is also a registered midwife.[15] The Midwifery Council told HDC that there is no specific training that midwives are required to undertake in order to perform simple lingual frenotomies. The Council stated that it "expects midwives have undertaken additional theoretical and practical training which mean they are skilled in the assessment and treatment of tongue tie". The Midwifery Council reviewed Ms B's training and advised that the midwife who carried out a competence review of Ms B's practice was satisfied that Ms B was appropriately educated.

Consent to the frenotomy

36. Ms B advised Mr and Mrs A that Baby A had a tongue tie, and she explained what a tongue tie is. She said that she could perform a frenotomy, which would release the tongue tie. Ms B explained what the procedure would involve, and that there was a small risk of extended bleeding or infection.

37. Ms B also outlined the problems that Baby A could experience if the procedure was not performed, including difficulties with feeding, speech, and dental hygiene. Ms B reassured Mr and Mrs A that she was experienced in performing frenotomies and that she had done four to five a week for the last 10 years. Ms B told them that it was a common, low-risk procedure, and that she had had only two cases where the wound had bled more than she would have liked.

38. Mr and Mrs A told HDC that Ms B did not offer any alternatives to a frenotomy. They said that when they asked about alternatives to a frenotomy Ms B advised only that they "could get it cut by laser which would involve a lengthy waiting time … [or] we could just fix it here for a small fee".

39. Ms B said that she was aware that Mrs A was already expressing milk and feeding Baby A with a bottle or a cup. Ms B stated:

> "Although I could not professionally indicate that alternative approaches would meet the client's expressed wishes, I could more clearly have provided advice about the likely results from alternatives."

40. Ms B said that she advised Mrs A that trialling different positions for breastfeeding Baby A and for latching Baby A to the breast would not improve Baby A's ability to breastfeed.

41. Ms B told HDC that, given Baby A's anatomical restriction, adopting a "wait and see" approach would not have assisted Mrs A. However, Ms B did not discuss this with Baby A's parents.

42. Ms B also told HDC that she did not consult with Mrs A's midwife to obtain further information because she felt that she had all the relevant information. Ms B also did not suggest an assessment by a chiropractor or an osteopath because she did not think it was indicated.

[15] The International Board of Lactation Consultant Examiners authorises lactation consultants to perform frenotomies only if the lactation consultant is separately authorised to perform frenotomies within that lactation consultant's country or jurisdiction.

43. Ms B did not offer Baby A's parents the option of seeking advice from another health professional, such as Mrs A's midwife or a paediatrician, ear, nose and throat surgeon, or an oral surgeon. She also did not offer Baby A's parents additional time to consider their decision. Ms B told HDC that she had an information pamphlet that she usually gave to clients when a frenotomy was being contemplated. The information pamphlet described a tongue tie, the indicators of a significant tongue tie, and the circumstances in which a release of a tongue tie could be performed, and provided an explanation of the procedure and the risks of the procedure. The pamphlet did not provide any information on alternatives to a frenotomy. However, on this occasion Ms B did not have the information pamphlet with her, and said that she would email it later.

44. Mrs A said that she was upset with the news that Baby A had a tongue tie, and she called her mother to talk about it. Mrs A told HDC that she was crying on the phone to her mother. Ms B said that she also spoke to Mrs A's mother about the procedure and advised her of the risks of the procedure. Mrs A told HDC that several times she expressed her desire to speak to her midwife before the procedure took place, but that Ms B ignored the request. Mrs A stated that she felt rushed into making a decision. Mr and Mrs A said that at this point Mrs A was visibly distraught.

45. Ms B told HDC: "Had the mother's later apparent anxiety been evident during my consultation prior to the procedure I would not have proceeded on that day." She also told HDC: "I do accept it is now clear that [Mrs A] was still carrying doubts."

46. Ms B gave Mr A the consent form. She explained the procedure again and that there would be a small amount of blood and pain for Baby A.

47. The consent form stated in part:

> "I have read the information pamphlet and understand the benefits of the above treatment and the procedure itself.
>
> I have had the options explained.
>
> I understand the procedure and the risk of a little pain and a little bleeding at the site for a minute or two."

48. Mr A signed the consent form even though he had not been provided with a copy of the information pamphlet and therefore had not read the information pamphlet.

49. Mr and Mrs A also told HDC that Ms B did not offer them any alternatives to a frenotomy.

50. Ms B told HDC that she believed that Mr and Mrs A understood why she was recommending the frenotomy and what the risks and benefits were. Ms B stated:

> "I acted in good faith, believing both parents understood and were giving their informed consent to the procedure. I now understand that was not the case, that it was my responsibility to ensure they were 100% comfortable, and I apologise unreservedly to them."

The frenotomy

51. At 12.00pm, fifty minutes after Ms B had arrived at Mrs A's home, Ms B and Mr A took Baby A to the bedroom, wrapped him up, and laid him on a firm surface in good light. Mr A held Baby A's head while Ms B used a grooved retractor to elevate Baby A's tongue and stretch the frenulum. She used sterile iris scissors[16] to cut the frenulum.

52. Ms B told HDC that she cut the frenulum at the thinnest mid-point. She did not state whether she cut the frenulum twice on this occasion, but she did state that sometimes a second snip is needed. She said that the frenulum is like a strand of rope that frays as it is divided, and that it can take two tiny snips to fully divide it. Ms B stated that she used sterile gauze on her gloved finger to blunt dissect[17] laterally to achieve a diamond-shaped wound. She then checked that the tongue was released, applied sterile gauze to stem any blood loss, and returned Baby A to Mrs A to be breastfed.

53. Mr A told HDC that during the procedure Ms B said that the frenulum felt gristly and that she had cut it twice.

54. Ms B told HDC that she cannot recall the exact words she used. She stated that "sometimes the tongue tie can be thicker and more fibrous but that does not mean that the tie is a submucosal one".

Bleeding following frenotomy

55. The diamond-shaped wound started to bleed immediately. Ms B told HDC:

> "In this case, given the bleeding, I considered that I must have nicked a rogue vessel accidentally. The blood was a dark venous blood and not a bright red that I would expect to see with arterial bleeding.[18]"

56. Ms B attempted to control the bleeding by applying gauze pads to the wound but she was unable to stop the bleeding. Mr and Mrs A told HDC that Mr A was asked to fetch extra gauze strips from Ms B's car. After 15 minutes, Ms B said that the wound was still bleeding lightly and she needed medical back-up. An ambulance was called at Ms B's instruction.

57. Mrs A asked for her midwife, and Ms B told Mrs A that "her LMC would more than likely be unavailable at the time". In any event, Mrs A's brother called Mrs A's LMC, Ms E, who then arranged for a backup midwife, Ms D, to come to support Mrs A.

58. At 12.30pm a paramedic arrived. Ms B told HDC that the paramedic said that there was "insufficient bleeding to warrant a transfer". Ms B stated:

> "I was expecting to transfer baby to hospital at this point, and was thrown by the paramedic's differing opinion. I regret in hindsight that I did not challenge it. At the time, I understood the paramedic had made the decision to not transfer baby, and without my consent and with no discussion with anyone present, to stand the ambulance down."

[16] Iris scissors are fine, sharp scissor with short blades.
[17] Separate the tissue using fingers or a blunt instrument.
[18] Arterial bleeding is bleeding from an artery. A severed artery is more serious than a severed vein because there is a lot of bleeding initially, and the cut may take longer to seal.

59. Ms B said that in future, if bleeding continued for more than 15 minutes, she would insist on a hospital transfer regardless of whether or not the bleeding had stopped. Ms B said that she insisted that the paramedic remain in the house until the bleeding had stopped, and that the paramedic instructed her and Baby A's parents to call an ambulance immediately if the bleeding started again.

60. The wound continued to bleed lightly, and Ms B asked the paramedic for a silver nitrate stick to stem the blood flow completely. Ms B applied the silver nitrate stick to the wound. Baby A's parents told HDC that the paramedic questioned Ms B about the use of the silver nitrate stick.

61. The DHB's policy for the control of bleeding following a frenotomy in place at the time of these events included the use of silver nitrate when all other interventions had failed.

62. At 1.00pm Ms B removed a small blood clot from Baby A's mouth and noted that the bleeding had stopped. Ms B told HDC that the wound was dry, 1cm in diameter, and slightly blackened by the silver nitrate. She stated: "This wound appearance was a diamond shape and was of normal 1cm diameter that is expected following a simple frenotomy."

63. The paramedic remained at the house until the bleeding had stopped and Baby A had breastfed and fallen asleep. The paramedic left at 1.15pm.

64. Ms D arrived at Mrs A's home at 2.05pm, and Ms B briefed her on the events of the previous few hours. Ms D told HDC that the diamond-shaped area under the tongue "appeared to be a nearly black 1cm x 1cm square in the tissue where the tongue attached to the floor of the mouth. It was not visibly bleeding." Ms B said that she then handed over the care of Mrs A and Baby A to Ms D because Mrs A and her family had lost confidence in her and they no longer wanted her to be involved in their care. Ms B left at 2.12pm.

Transfer to hospital

65. At 2.30pm the bleeding started again and Baby A was transferred to the public hospital by ambulance. The journey took over an hour. Attempts were made to control the bleeding both in the ambulance and at the hospital but they were unsuccessful. Ms B was not contacted.

66. The ambulance service Patient Report Form records a "[laceration] under tongue, cut by Lactation Specialist — approx. 2–3cm — for tongue tie."

67. By the time Baby A had reached the hospital at 4.08pm he had soaked 11 white gauze squares with blood from his wound.

68. The Emergency Department clinical record noted a 1.5cm transverse laceration across the floor of the mouth and that the laceration bled when pressure was not applied, and queried whether there were "exposed muscle fibres".

69. That evening, Baby A was taken to theatre and the laceration to his tongue was repaired by Dr C, an otolaryngologist. The bleeding from the lingual artery was controlled with diathermy[19] and the tongue muscles were stitched back together.

70. The handwritten operation record states:

> "No evidence of [anterior] tongue tie or any significant frenulum residue. Wide and deep laceration into tongue/floor of mouth. Extending from midline just above s.m. papillae[20] and well laterally into tongue, both submandibular ducts exposed and as far as could be determined intact. Laceration deep into tongue base with arterial bleeder located to left of midline deeply in tongue muscles. Several smaller venous bleeders closer to mucosa."

71. The operation record, dictated by an ear, nose and throat registrar, notes:

> "[A] 1cm wide transverse incision was found. This descended down into the extrinsic muscles of the tongue. It appeared that the sub-mandibular ducts were intact, although it was impossible to determine this with certainty."

72. The operation was successful and Baby A was discharged from hospital after a period of observation.

Subsequent events

73. The following week, Dr C saw Baby A at his clinic and recorded:

> "[Baby A] was recently in hospital, having had a very large and deep laceration to his tongue by a lactation consultant apparently to relieve a possible tongue tie. The laceration was bleeding since it was made and he came in with ongoing bleeding and required surgical closure of the wound under general anaesthetic."

74. On the same day, Dr C dictated a letter to Ms B expressing his concern about the frenotomy. He stated:

> "I do have concerns about the way the tongue was incised. The incision was at least 2.5 x 2 cm deep, well into the tongue base, which caused significant bleeding from a branch of the lingual artery. I am not sure of the circumstances at the time, but this is clearly more resection than was needed for a posterior tongue tie."

75. Dr C suggested that Ms B attend the Tongue Tie Clinic to discuss her technique with a specialist.

76. In a letter to HDC, Dr C explained the difference between an anterior tongue tie and a posterior tongue tie:

> "[A]n anterior tongue tie is a tight frenulum which anchors the tongue to the floor of the mouth and prevents tongue extrusion, and represents an abnormality of normal anatomy. A 'posterior tongue tie' remains a reasonably controversial diagnosis and the

[19] A surgical technique that uses heat to clot bleeding vessels.
[20] Submandibular papillae are the small rounded protuberances on the salivary excretory ducts.

> diagnosis is made by palpation of the floor of the mouth and is said to represent a thickening within the lining of the tongue if it attaches to the floor of the mouth. It is said to ofte[n] co-exist with the common anterior tongue tie."

77. Dr C also explained how a frenotomy performed for an anterior tongue tie differs from that for a posterior tongue tie:

> "When an anterior tongue tie is divided the lingual frenulum is cut leaving a trace of frenulum both on the tongue and floor of the mouth, generally it is not necessary to incise into the tongue itself. A posterior tongue tie when divided involves incising into the mucosa on the floor of the mouth possibly and the superficial part of the tongue."

78. Dr C concluded:

> "Given the depth and extent of the incision I suspect that the clinical diagnosis of the Lactation Consultant was of a posterior tongue tie and this is what she attempted to divide. The fact that I could not see any remnant of an anterior tongue tie does not mean there was not one present, I just could not see any sign of it. Having said that the laceration was fairly 'jagged' and could easily have disrupted the remnants of a lingual frenulum."

79. Dr C advised HDC that Baby A's parents "seemed to have no idea about what was being done or why".

80. Dr C also expressed his concern about the performance of the frenotomy. He stated:

> "The incision was done in a way which was potentially life threatening. I am not sure how the initial operation was performed but clearly a ragged incision had been made deep within the tongue and I assume this was probably done with a pair of scissors being opened and closed into the tongue base. This was obviously done far too deep to release the tongue tie."

Other information provided by Ms B

81. Ms B submitted that Dr C's statement in his letter that the wound was 2.5 x 2cm deep was a typographical error, and was inconsistent with other accounts of the wound.

82. Ms B told HDC that she has made several changes to her practice as result of this incident.

83. Ms B stated that when bleeding persists for more than 15 minutes after a frenotomy she will insist on a transfer to hospital. She will contact the registrar to obtain support for the transfer, and will request blood tests upon admission.

84. Ms B said that she will no longer perform frenotomies in the region or at any other location where the distance or the location could result in a delay in getting to hospital.

85. Ms B told HDC that she has revised the consent form for frenotomies to ensure that the benefits and risks of the procedure are clearly laid out and that the client understands them. In particular, the consent form now states that there is a very small risk of extended bleeding, and there is an acknowledgement that alternative treatments and providers have been discussed and an opportunity given to decline or defer the procedure.

86. Ms B advised HDC that, at the time of the incident, the use of silver nitrate on a frenotomy wound was included in the DHB's policy for the management of post-frenotomy bleeding when all other interventions had failed. Ms B said that following this incident she was advised not to use silver nitrate to stop post-frenotomy bleeding, and she now follows this advice.

87. Ms B also told HDC that she reviewed the incident with an ear, nose and throat surgeon as part of her professional reflection and learning.

Frenotomy services in New Zealand

88. There are differing clinical viewpoints about whether frenotomies should ever be performed on newborn babies in order to reduce nipple pain for the mother and/or to improve breastfeeding for the baby. In addition, there is no national or international standard for the assessment, diagnosis, or classification of tongue tie other than the Midwifery Council statement. There is also no unanimity on the technique that should be employed to perform a frenotomy, and whether the frenotomy should be performed by a medical specialist or other health professional, or in a clinical setting.

89. As outlined above, midwives in New Zealand are authorised by their Council to perform frenotomies in limited circumstances, and are required to use an approved tool and technique.

Responses to provisional opinion

Mr and Mrs A

90. Mr and Mrs A were given an opportunity to comment on the "information gathered" section of the provisional opinion. Their response, where appropriate, has been incorporated into the report.

Ms B

91. Ms B was provided with an opportunity to comment on the provisional opinion. Her response, where appropriate, has been incorporated into the report.

92. In response to the expert advice, and again in response to the provisional opinion, Ms B submitted that the frenotomy was not performed deep into the mouth, and that the wound could have been made deeper by the constant pressure applied to the site by other care providers after the frenotomy had been performed. She stated that there was a period of two hours before Baby A arrived at the public hospital, and submitted:

> "[I]f there is constant pressure applied to the area, the membrane, which is very delicate, could very easily be further dissected and the wound made deeper into the genioglossus muscle and the sub-mandibular ducts."

93. Ms B also stated:

> "[A]after [Baby A] arrived at [the public hospital] there [was] a further period of some hours before the surgery and it is recorded in the notes that there was persistent pressure; that [Baby A] was distressed; to different people applying pressure to the wound and that a significant number of gauzes were used in the process."

94. Ms B noted that Baby A was in the recovery room at 7.10pm.

95. Ms B told HDC that she has attended a forum on informed consent and a symposium on tongue ties.

Opinion: Ms B

Introductory comment

96. Frenotomies have been a controversial subject in New Zealand in recent years. The question of whether frenotomies should be performed on newborn babies has been widely debated in both the medical community and the general community. There is no consensus on who should perform frenotomies and whether they should be performed by specialists or other health professionals.

97. The Midwifery Council informed HDC that the general informed opinion is that tongue ties are over diagnosed and over treated. The Midwifery Council states that a frenotomy sits within the scope of practice for midwives who have completed specific training. However, it is unclear what the specific training entails and whether there is a formal pathway in order to qualify to perform frenotomies.

98. There is no consensus on national standards for the assessment, diagnosis, or classification of a tongue tie, and this may be reflected in the variation in frenotomy rates across the country. Similarly, there is no consensus on the techniques that should be employed to perform a frenotomy, and whether the procedure should be performed exclusively in a clinical setting.

99. This report considers the care provided to Baby A, including the assessment, diagnosis, and performance of a frenotomy by Ms B.

Standard of skill and care

100. Ms B diagnosed Baby A with a simple anterior tongue tie and attempted a simple lingual frenotomy to release it. Ms B's performance of the frenotomy was sub-standard and resulted in a deep laceration to the muscle under the tongue and a severed artery.

Diagnosis of tongue tie

101. The Midwifery Council of New Zealand's scope of practice regarding the assessment and diagnosis of tongue tie and the practice of frenotomy states that midwives who have completed specific training may perform simple lingual frenotomies for simple anterior tongue ties. Midwives may not perform frenotomies when the tongue tie is complex or posterior. The Midwifery Council reviewed Ms B's training and advised that the midwife who carried out a competence review of Ms B's practice was satisfied that Ms B was appropriately educated.

102. Ms B used the Hazelbaker tool to diagnose Baby A with a simple anterior tongue tie, and the classification-combined system to categorise it as a type 3–4, mid-tongue anterior tie.

103. Independent expert advice was obtained from a midwife and lactation consultant, Jacqueline Martin. Ms Martin advised that Ms B's use of the Hazelbaker tool and the classification-combined system was appropriate.

104. I accept that Ms B is a suitably qualified midwife who diagnosed Baby A with a simple anterior tongue tie using an appropriate assessment tool. Ms B was therefore authorised by her regulatory authority to perform a simple lingual frenotomy on Baby A. I am unable to make a finding on whether the diagnosis of a simple anterior tongue tie was correct.

Performance of the frenotomy — breach

105. Ms B told HDC that she performed a simple lingual frenotomy but that during the procedure she "nicked a blood vessel". Ms B also told HDC that an hour after the procedure the diamond-shaped wound was dry and had a "normal 1cm diameter". Ms B did not comment on whether there was damage to the floor of the mouth or the tongue, but stated that the bleeding appeared to be of a dark venous nature rather than arterial. Ms B said that the frenotomy was not performed deeply and submits that subsequent treatment may have exacerbated the wound.

106. There are some discrepancies in the description of the wound. Ms D describes the wound as a 1cm by 1cm square in the tissue where the tongue attaches to the floor of the mouth. In the ambulance report the wound is described as being between approximately 2cm and 3cm. The Emergency Department clinical record at the hospital describes a 1.5cm transverse laceration, and the operation record states that a 1cm wide transverse incision was found. Dr C, the otolaryngologist who repaired the wound, described in his letter to Ms B a laceration that was "at least 2.5cm by 2cm deep".

107. In a statement to HDC, Dr C said that a "ragged incision had been made deep within the tongue". Surgery was required to repair the laceration to the muscle under the tongue and the artery. Dr C expressed the view to HDC that the incision was performed in a "potentially life-threatening" manner.

108. In addition to Dr C's statement to HDC, the handwritten operation note described a deep laceration into the tongue and floor of the mouth. The operation record also described an incision that descended down into the extrinsic muscles of the tongue. The Emergency Department clinical record queried whether the muscle fibres were exposed.

109. Dr C was sufficiently concerned about the manner in which the procedure had been performed that he wrote to Ms B shortly after he had repaired the wound and suggested that she discuss her technique with a specialist. In this letter he states that the incision was "well into the tongue base, which caused significant bleeding from a branch of the lingual artery".

110. I am unable to determine the exact width of the laceration. However, taking into account all of the above, I accept that the laceration in Baby A's mouth as reported by the public hospital staff was deep and went into the floor of the mouth and tongue. It descended into the extrinsic muscles of the tongue. I also accept that the incision caused bleeding from a branch of the lingual artery, which required diathermy for control. The wound also required sutures, deep into the muscle and mucosa, in order to stop the bleeding.

111. Ms B submits that damage to the wound may have been caused by pressure applied during subsequent treatment. In response to the provisional opinion, she submitted:

> "[I]f there is constant pressure applied to the area, the membrane, which is very delicate, could very easily be further dissected and the wound made deeper into the genioglossus muscle and the sub-mandibular ducts."

112. Ms B submitted that there was persistent pressure on the wound from the time she left Baby A to the time of the surgery, with a number of gauze squares being used. She also noted that there was a period of five hours between her departure from the family's home to the time at which Baby A was in the recovery room post surgery.

113. Ms Martin advised:

> "[T]he treatments would have to have been very forceful to sustain the damage caused described by [Dr C]. Such actions would have also caused considerable distress for [Baby A]. I do not recall reports, other than at the time of the frenotomy and just following, that [Baby A] was described as being distressed."

114. In order for me to find that the incision performed by Ms B was deep into the floor of the mouth and tongue, and caused bleeding from a branch of the lingual artery, I need to consider, in light of all the information available to me, that this was more likely than any other alternative to cause of the depth of the wound.

115. I accept that there is some possibility that during the four- to five-hour period between the procedure and the treatment at the public hospital, there was an intervening forceful treatment that may have caused the wound to deepen substantially and cause damage to the lingual artery.

116. However, I accept the advice of Ms Martin that the treatment would have had to have been very forceful to sustain the damage caused. I acknowledge that there is some discussion of the use of pressure to stem the bleeding. However, I find no evidence of "very forceful" treatment subsequent to the frenotomy. The clinical records indicate that at times during his treatment Baby A was distressed, but there is no evidence that this distress was more than would ordinarily be expected following a procedure of this kind with ongoing bleeding.

117. Taking into account all the above information, I consider it is more likely that the incision by Ms B was made deeply in the mouth. This is the account of the procedure that I accept.

118. Ms Martin advised HDC that the performance of the frenotomy as described above "was not an acceptable standard of practice as it resulted in a deep laceration/wound and significant bleeding". She considers this to be "a moderate to severe departure from acceptable practice".

119. I accept Ms Martin's advice and am critical of the manner in which Ms B performed the simple lingual frenotomy. Ms B cut the frenulum, which is expected for a simple lingual frenotomy, but she also cut deeply into the floor of the mouth and into the muscle underlying the tongue, and damaged an artery.

120. Taking into account the above, I consider that the frenotomy that Ms B performed on Baby A was not performed with reasonable care and skill. Accordingly, I find that Ms B breached Right 4(1) of the Code.

Transfer of Baby A to hospital — adverse comment

121. Ms Martin advised that the blood clot that formed on the wound following the procedure should have prompted transfer to hospital.

122. Ms B's decision to call an ambulance was appropriate.

123. Ms B told HDC that the paramedic said that there was "insufficient bleeding to warrant a transfer". Ms B stated:

> "I was expecting to transfer baby to hospital at this point, and was thrown by the paramedic's differing opinion. I regret in hindsight that I did not challenge it. At the time, I understood the paramedic had made the decision to not transfer baby, and without my consent and with no discussion with anyone present, to stand the ambulance down."

124. Ms B told HDC that she insisted that the paramedic remain in the house until the bleeding had stopped. Prior to leaving, the paramedic instructed the parents and Ms B to call the ambulance immediately if the bleeding started again.

125. While I consider that Ms B took some steps towards transferring Baby A to hospital in response to the bleeding after the procedure, I consider that she could have advocated further for Baby A in her interactions with the paramedic, and am critical that she failed to do so. The hospital was over an hour's drive away and the wound had been bleeding for more than 15 minutes. Ms B responded to the situation by cauterising the wound with silver nitrate — a response that was justified only when all other interventions had failed. In addition, Ms B should have recognised that the formation of a blood clot should have triggered transfer to hospital. I note Ms B's own regret in relation to this matter.

Silver nitrate — other comment

126. Ms B used silver nitrate to cauterise the wound. At the time of these events, the DHB recommended the use of silver nitrate to control bleeding only when all other interventions had failed. Ms Martin advised me that, although silver nitrate is still used, it is not recommended because if it is used on broken skin it can cause chemical burns to the surrounding skin. I note that Ms B no longer uses silver nitrate to stop post-frenotomy bleeding. I commend her change in practice.

Informed consent — breach

127. The "consent for frenotomy" form used by Ms B was clearly intended to be used in conjunction with the information pamphlet and with a discussion of the options available to the parents. Ms B verbally provided Baby A's parents with information about the risks and benefits of the frenotomy, but did not give them the information pamphlet.

128. In addition, Ms B did not provide any information about the non-surgical alternatives to a frenotomy. I note that the Midwifery Council requires a midwife to present the alternatives to surgical intervention as part of obtaining informed consent to the procedure. The only

options presented to Baby A's parents were that the frenotomy could be performed immediately or after a lengthy wait for a laser procedure.

129. I also note that Ms B did not advise Baby A's parents of the lack of consensus in the medical community on the efficacy of frenotomies, or that they could consider consulting with another medical specialist such as a GP, paediatrician, or an ear, nose and throat or oral surgeon.

130. Ms B considered that the alternatives to frenotomy would not have assisted Mrs A with her goal of pain-free breastfeeding and, as a result, Ms B did not make it clear to Baby A's parents that alternatives to a frenotomy were available. Those options included continuing to express milk and feed Baby A with a bottle or cup, trialling different positions for holding Baby A while breastfeeding, and exploring different approaches for latching Baby A to the breast.

131. Ms Martin advised that other options such as using nipple shields, or referral to an osteopath or chiropractor, should have been explored. Ms Martin also stated: "Given that [Baby A] was only [eight] days old, a wait and see approach … would have been accepted practice."

132. Mrs A was upset about the diagnosis of Baby A's tongue tie and the proposed treatment. She rang her mother to discuss the frenotomy, and told Ms B several times that she wanted to speak to her LMC, Ms E, about it. Mr and Mrs A describe Mrs A as being visibly distraught, and say that Ms B ignored Mrs A's request to contact her LMC.

133. Ms B told HDC that Mrs A's anxiety was not apparent to her at the time, and that she would not have proceeded with the frenotomy if it had been. Ms B said that if Mr A or Mrs A had shown any hesitation or concern, she would not have undertaken the procedure.

134. Ms B was aware of Mrs A's initial discussion with her mother and her repeated requests to discuss the matter with her LMC. Ms B was also aware that Mrs A did not wish to be present during the procedure because she was upset about it being performed. I accept that Mrs A was visibly upset and consider that Ms B was aware that Mrs A had some degree of anxiety and uncertainty about the procedure being performed.

135. Under Right 6(2) of the Code, every consumer has a right to the information that a reasonable consumer, in that consumer's circumstances, needs to receive to make an informed choice or give informed consent.

136. I am critical that Ms B failed to advise Baby A's parents of the non-surgical alternatives to a frenotomy that were available to them. Ms B was of the view that the non-surgical alternatives were not appropriate for Baby A. However, Baby A's parents had a right to know that there were alternatives to a frenotomy, and to hear Ms B's opinion on those alternatives. They were not given the option of declining the frenotomy and exploring the non-surgical alternatives. In addition, Baby A's parents were not advised of the conflicting views on the merits of a frenotomy, or that they could seek advice from other medical specialists. This was information that a reasonable consumer would need to receive to make an informed choice or give informed consent to the proposed treatment. By failing to provide this information, I find that Ms B failed to provide information to Mr A and Mrs A

that a reasonable consumer would have needed to receive to make an informed choice. Accordingly, I find that Ms B breached Right 6(2) of the Code.

137. In addition, I am critical that despite Ms B being aware that Mrs A was anxious and wanted to discuss the procedure with others, Ms B performed the procedure within a short time frame after diagnosis. Ms B also failed to respond to several requests from Mrs A to contact her LMC for a second opinion. As a result, Baby A's parents were not given time to reflect on the information they had received, nor an opportunity to consult a trusted person, and felt rushed into making a decision.

138. Right 7 of the Code provides that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Because Ms B failed to provide Mr and Mrs A with the information outlined above, I am of the view that Mr and Mrs A were unable to make an informed choice and give informed consent to the frenotomy on behalf of Baby A. This was exacerbated by the fact that Ms B was aware that Mrs A was feeling anxious and doubtful and wanted a second opinion from her midwife. It follows, therefore, that by performing the frenotomy when informed consent had not been obtained, Ms B also breached Right 7(1) of the Code.

Recommendations

139. I recommend that Ms B:

a) Provide a letter of apology to Mr and Mrs A. This is to be provided to HDC within three weeks of the date of this report, for forwarding.

b) Provide a report to HDC outlining the details of her discussion with the ear, nose and throat specialist, and the changes she has made to her practice as a result. The report is to be sent to HDC within three weeks of the date of this report.

140. The Midwifery Council has already undertaken a case review of Ms B's decision-making. I recommend that the Midwifery Council consider whether a competence review of Ms B's performance of frenotomies is warranted.

141. I recommend that the Ministry of Health consider formulating a consensus position on the efficacy of frenotomies, and consider developing guidelines for the diagnosis and performance of frenotomies by midwives. It would be appropriate to consult with all relevant health professionals, including midwives, lactation consultants, paediatricians, ear, nose and throat surgeons, and oral surgeons.

Follow-up actions

142. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Midwifery Council of New Zealand, and it will be advised of Ms B's name.

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