Lactation Consultant, Ms B

A Report by the
Deputy Health and Disability Commissioner

(Case 16HDC01563)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. Baby A was born in 2012. When he was five 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. Ms B assessed Baby A and Mrs A, and diagnosed Baby A with a tongue tie.[2] Ms B recommended a frenotomy[3] to release the tongue tie and provided Mr and Mrs A with information about the procedure.

3. Ms B asked the parents whether Baby A had received a vitamin K injection at birth, and they told her that he had not. Ms B did not advise Mr and Mrs A that there is a potential for significant blood loss following a frenotomy if the baby has not received vitamin K at birth.

4. Ms B performed the frenotomy and there was some bleeding at the site as a result. Ms B controlled the bleeding with compression using sterile gauze. She instructed Mr and Mrs A to call her if the bleeding started again, and then left their home.

5. Later that afternoon the bleeding started again, and Mrs A controlled it with compression using sterile gauze.

6. At 6.30pm the bleeding started again. Mr A rang Ms B, who told him to use compression on the site and to call an ambulance if the bleeding continued. The bleeding stopped.

7. At 8pm, the bleeding started again and the parents were unable to control it. They called an ambulance but they were unable to contact Ms B. Baby A was transferred to hospital, where he received a vitamin K injection and the bleeding was controlled.

Findings

8. Ms B decided to perform the frenotomy despite Baby A not having been given vitamin K, and she failed to review Baby A in person or to refer him to hospital when she became aware of another episode of bleeding. Accordingly, the services provided to Mrs A and Baby A were not provided with reasonable skill and care, and I find that Ms B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[4]

9. Ms B did not offer Baby A's parents non-surgical alternatives to a frenotomy, and did not advise them of the increased risk of significant bleeding for a baby who has not received a vitamin K injection. In not providing this information, Ms B failed to give the parents the

[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 a 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] Frenotomy is a procedure in which the frenulum is cut.
[4] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

information that a reasonable consumer would need in order to make an informed choice, and, accordingly, Ms B breached Right 6(2) of the Code.[5]

10. Without the information outlined above, the parents were unable to make an informed choice and give informed consent to the frenotomy on behalf of Baby A. Accordingly, Ms B breached Right 7(1) of the Code.[6]

Recommendations

11. In the provisional opinion, it was recommended that the Midwifery Council undertake a competency review of Ms B's performance of frenotomies. The Midwifery Council has advised that a competency review was undertaken and specific recommendations made, and that no further action will be taken.

12. It was recommended that Ms B provide a letter of apology to Mr and Mrs A.

Complaint and investigation

13. The Commissioner received a complaint from Mrs A about the services provided to Baby A by Ms B. The following issue was identified for investigation:

- *Whether Ms B provided Baby A with an appropriate standard of care in 2012.*

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

15. The parties directly involved in the investigation were:

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

16. Further information was received from ACC, the district health board, and the ambulance service.

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

[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."

[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."

Information gathered during investigation

Background

18. Baby A was born in 2012. His mother, Mrs A, experienced difficulties breastfeeding Baby A, and called Ms B for advice and support.

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

20. Ms B attended Mrs A at her home at approximately 12pm. Baby A was then five days old. Mrs A's husband was also present.

Initial assessment of Mrs A

21. Mrs A told Ms B about her concerns regarding the latching and positioning of Baby A during breastfeeding, her cracked nipples, and her pain while breastfeeding. Mrs A stated that her goal was to breastfeed Baby A without pain.

22. Ms B recorded on her "client history" sheet that Mrs A had breastfed both her older children, and that initially she had had cracked nipples while doing so. Ms B noted that the two older children had been tongue tied and that their frenulum had not been cut. Tongue tie is a condition in which a 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.

23. Mrs A told HDC that she had breastfed her two older children with difficulty, but that she had managed to do so with the assistance of a lactation consultant.

Diagnosis of tongue tie

24. Ms B told HDC that she conducted an assessment of Mrs A and an oral assessment of Baby A, and observed Mrs A breastfeeding Baby A.

25. Ms B said that she assessed the functional impairment of Baby A's tongue by using the Hazelbaker tool,[7] her breastfeeding assessment, and the history she had obtained from Mrs A. Ms B stated that she recorded "the elevation, lateralization, cupping, extension of tongue, suck swallow ratio, snap back and a thorough assessment of how the baby was feeding and pain and damage being caused to the mother's nipple tissue".

[7] The 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.

26. Ms B told HDC that she then used the Coryllos and Watson Classification (2004) system to classify the tongue tie as a type 3 anterior tongue tie. She recorded in her notes that Baby A had a thick frenulum and a type 3 tongue tie.[8]

27. Mrs A told HDC that Ms B assessed Baby A and his latch while breastfeeding and determined that Baby A had a tongue tie.

Consent to frenotomy

28. Ms B recommended a frenotomy to release the tongue tie. She provided Mr and Mrs A with written and verbal information about the procedure.

29. In respect of the written information, Ms B told HDC that she provided Baby A's parents with her standard written material about tongue tie and frenotomy. She provided an information pamphlet to HDC and explained that it was an updated version of the information pamphlet she had used at the time. She told HDC: "This is similar to that given to the [family] but will have been since updated." The information pamphlet describes a tongue tie, the indicators of a significant tongue tie, the assessment for tongue tie, and an explanation of the procedure to release a tongue tie. The pamphlet does not provide any information on alternatives to a frenotomy.

30. Mrs A told HDC that Ms B provided her with an information pamphlet, and recalls that the information pamphlet "noted that often there is no bleeding but in some cases it can be a drop or two".

31. In respect of the verbal information provided, Ms B told HDC that she cannot recall the exact conversation she had with the parents, but that it is her standard practice to advise parents that other providers, including a general practitioner or a dentist, can also perform a frenotomy.

32. Ms B stated:

> "If … I had identified that the baby was not tongue tied, or that it was a mild tongue tie not requiring release, then certainly, I would have explored further treatment and strategies undertaken by [Mrs A] to successfully breastfeed her previous two children, as clearly that would have been relevant and important information."

33. Ms B told HDC that in her view the alternatives to frenotomy were unlikely to have been successful in improving Baby A's breastfeeding. Alternatives to frenotomy include exploring positioning and latching options, nipple shields, pumping and feeding expressed milk, and adopting a wait-and-see approach.

[8] A type 3 tongue tie is described as a mid tongue superior attachment with an inferior attachment in the middle of the floor of the mouth. A type 4 tongue tie is described as a posterior superior attachment with an inferior attachment at the base of the tongue.

34. Mrs A told HDC that Ms B assessed Baby A's latch to her breast, but did not explore or discuss any alternative positions or latching techniques. Mrs A said that she was not offered any non-surgical alternative to frenotomy.

35. Ms B asked whether Baby A had received a vitamin K injection at the time of his birth. She was advised by Baby A's parents that he had not. Vitamin K helps to clot the blood and prevent serious bleeding. In newborns, a vitamin K injection can prevent a rare, but potentially fatal, bleeding disorder called Vitamin K Bleeding Disorder (VKBD).

36. Mrs A told HDC that Ms B did not tell her that if a baby has not received vitamin K at birth, there is the potential for significant blood loss following a frenotomy.

37. Ms B told HDC that she mistakenly assumed that the parents understood that there would be an increased risk of bleeding in the absence of a vitamin K injection. She stated that this "assumption was based on the fact that [Baby A] was the couple's third child, had been [a] home and water birth and that [Mr A] had deleted the vitamin K reference from the consent form, together with his signature". She acknowledged that she "should have discussed with the [parents] explicitly the increased risk".

38. Mrs A told HDC that she was aware of the controversy about the efficacy of frenotomies but that Ms B advised her that the frenotomy would be no more invasive than the Guthrie test.[9] Mrs A said that Baby A hardly bled after the Guthrie test, so she felt reassured by this advice. She told HDC that she was feeling vulnerable, and that she felt rushed into making a decision. She and her husband decided to proceed with the frenotomy.

39. Ms B asked Mr A to sign the consent form. The consent form stated:

> "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."

40. The next line on the consent form stated: "My baby has had vitamin K at birth and there are no bleeding disorders in our family." Mr A deleted the first part of the sentence that read "My baby has had vitamin K at birth" and signed both the deleted words and the consent form. Ms B also made a note on the consent form that recorded: "[N]o trouble with bleeding after Guthrie test."

Scope of practice

41. The Midwifery Council of New Zealand (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 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) provides that a frenotomy sits within the scope of practice of midwives who have

[9] The Guthrie test is also known as the heel-prick test. It is a blood screening test developed to detect phenylketonuria in newborn babies.

completed specific training, and that "midwives undertaking frenotomy will be limited to performing simple lingual[10] frenotomy using an approved assessment tool such as the Hazelbaker tool and technique".

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

43. Ms B was employed by Mrs A as a lactation consultant, but Ms B is also a registered midwife.[11] 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 Midwifery 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.

Frenotomy

44. Ms B performed the frenotomy. She told HDC: "I should not have performed the frenotomy in the absence of vitamin K and I accept criticism on this point."

45. Following the frenotomy there was some bleeding at the site, which Ms B controlled with compression using sterile gauze. Ms B told HDC that the bleeding stopped completely within ten minutes, and that Baby A then latched well to the breast.

46. Ms B stated:

> "I performed a standard tongue tie release procedure. The appearance of the 1cm diamond shaped wound was as expected. Following the breastfeed … the wound site was dry and was of normal appearance. There was no indication of any excess bleeding at the time or following the procedure."

47. Mrs A told HDC that when the bleeding had stopped and she had breastfed Baby A, she noticed "a hole at the base of his tongue".

48. Ms B told HDC that she wrote a feeding plan for Baby A and discussed his post-procedure care. She gave Mrs A sterile gauze and advised the parents to use compression with the gauze under the tongue and to call her if the wound started to bleed again. She then left their home.

[10] Lingual means "of the tongue".

[11] 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.

Subsequent bleeding

Afternoon

49. Mrs A told HDC that later that afternoon Baby A awoke with blood around his mouth, and she used the sterile gauze to apply pressure to the wound. The bleeding stopped, and Mrs A breastfed Baby A and put him down to sleep. She did not telephone Ms B.

6.30pm

50. When Baby A woke again around 6.30pm he had blood around his mouth and Mrs A tried to control the bleeding with the sterile gauze. She asked her husband to call Ms B and ask her if something had gone wrong. Mrs A stated: "[Ms B] wasn't concerned but [she said] that if the bleeding didn't stop within five minutes we would need to call the ambulance." The bleeding stopped after a few minutes, and Mrs A breastfed Baby A and put him down to sleep.

51. Ms B told HDC that Mr A called her at 6.26pm and that she advised him to apply pressure with the gauze and to call an ambulance if the bleeding did not stop within five minutes. She said that five minutes later she called back Mr and Mrs A and was advised that the bleeding had stopped and that Baby A was breastfeeding well. Ms B advised the parents to call her and an ambulance if there were any further concerns overnight, and told them that she would call them in the morning.

52. Ms B said that she was unaware of the earlier bleeding episode in the afternoon. She told HDC: "If I had realised that … I would have advised the parents differently and especially to call the ambulance at that point."

53. Mrs A told HDC that her husband could not recall the exact nature of his conversation with Ms B and, in particular, whether the afternoon bleed was discussed.

8.00pm

54. Mrs A told HDC that when Baby A woke again at about 8pm the wound was bleeding. She tried to control the bleeding by applying pressure to the wound with sterile gauze, and a large blood clot was released. She said that she was unable to control the bleeding and she called an ambulance. A paramedic arrived and tried unsuccessfully to contact Ms B on both her landline and her mobile. Ms B told HDC that she checked her phone during the evening and noticed that she had received a call from a "private" number. She said that the paramedic did not leave a message, and she was unaware that Baby A was being taken to hospital. She said that if the paramedic had left a message, she would have attended the family and provided full information to the doctor on duty.

55. Ms B told HDC that, in her view, "the lack of vitamin K was the cause of the on-going bleeding episodes that developed after the events".

56. Baby A was transferred to a public hospital. The journey took approximately one hour. The Emergency Department record states: "[The] tongue appears to have macerated area around site of cut, some clot overlying, not actively bleeding."

57. Baby A received a vitamin K injection and by midnight the bleeding had stopped. The following morning, Baby A was discharged from the hospital.

Changes to practice/additional information

58. Since these events, Ms B has attended two conferences on the use of the Hazelbaker assessment tool, and she has adjusted her practice in accordance with the developments to the assessment tool.

59. Ms B stated that she no longer performs frenotomies in Mr and Mrs A's area because the distance from the hospital may lead to a delay in specialist medical attention.

60. Ms B said that she has improved her information pamphlet and consent forms, and she no longer performs frenotomies if vitamin K has not been given.

Responses to provisional opinion

Mr and Mrs A

61. Mr and Mrs A were given an opportunity to comment on the "information gathered" section of the provisional opinion. They said that they would not have consented to the procedure if they had been informed of the increased risk of bleeding.

Ms B

62. Ms B was given an opportunity to comment on the provisional opinion, and her response has been incorporated into this report.

Opinion: Ms B

Standard of skill and care — breach

63. This report considers whether Ms B provided Baby A with an appropriate standard of care. It is not the role of this Office to determine what caused Baby A's ongoing bleeding following the frenotomy, and I do not make findings as to whether the bleeding was caused by the lack of vitamin K or any other cause.

Decision to perform the frenotomy

64. Ms B was aware that Baby A had not received vitamin K at birth. She also understood that this increased the risk of bleeding with the frenotomy.

65. Independent expert advice was obtained from a midwife and lactation consultant, Jacqueline Martin. Ms Martin advised:

> "[T]he omission of vitamin K at birth did increase the likelihood of significant bleeding and it would be expected that [Ms B] would have considered this as a reason not to perform the frenotomy, especially in a family home and without available medical support. As classical onset of VKBD can occur up to the first week of life, it may not be

> appropriate to consider minimal bleeding following the new-born metabolic screening [the Guthrie test] as being reassuring."

66. Ms Martin further advised that "it was inappropriate for Ms [B] to perform a frenotomy on this occasion on [Baby A] when he had not received vitamin K". Ms Martin also advised: "[Ms B] did not appropriately consider the potentially increased risk of bleeding [and] this placed [Baby A] at risk and is a moderate departure from accepted practice."

67. Ms B accepts that she "should not have performed the frenotomy in the absence of vitamin K and [she] accept[s] criticism on this point".

68. Ms B is an experienced health professional. She was aware of the increased risk of bleeding for a baby who has not received vitamin K. I am very concerned that Ms B decided to perform the frenotomy knowing that Baby A had not received vitamin K. In addition, I note that the family home where the frenotomy was carried out is located some distance from the hospital and specialist medical attention.

69. Ms B no longer performs frenotomies when vitamin K has not been administered, and I consider this to be an appropriate change to her practice.

70. I am also concerned that Ms B stated that the procedure was no more invasive than a Guthrie test, when the result of the procedure was a 1cm by 1cm wound in Baby A's mouth.

Failure to refer to hospital

71. The wound started bleeding immediately following the frenotomy, and Ms B managed it with compression.

72. Mr A called Ms B at about 6.30pm and advised her that the wound was bleeding. Ms B provided advice at the time of Mr A's call. I accept that she also telephoned Mr A back to provide further support, and that she was advised that the bleeding had stopped. Ms B did not return to the family's home or refer Baby A to the hospital for specialist care. Ms B told HDC that she was not aware of the afternoon bleed, and said that she was under the impression that the phone call she received at 6.30pm related to the only bleed subsequent to the initial bleed when the frenotomy was performed.

73. Ms Martin advised:

> "I would have expected [Ms B] to either promptly return to the [family's] residence or phone for an ambulance/paramedic to attend following *any* reports of ongoing bleeding due to the fact that [Baby A] had not had vitamin K."

74. Ms Martin further advised that this was a moderate departure from accepted practice.

75. I accept the advice that any reports of ongoing bleeding should have resulted in immediate action from Ms B, either to attend the family at their home or to arrange a transfer to hospital.

76. Taking into account that Ms B decided to perform the frenotomy despite Baby A not having been given vitamin K, and that she failed to review Baby A in person or to refer him to hospital when she became aware of another episode of bleeding, I consider that the services provided to Mrs A and Baby A were not provided with reasonable skill and care. Accordingly, I find that Ms B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

Informed consent — breach

Failure to offer alternative to a frenotomy

77. Following her assessment of Mrs A and Baby A, Ms B offered to perform a frenotomy to release the tongue tie. She may have offered the parents the option of having the frenotomy performed by a GP or a dentist, but she did not offer them any non-surgical alternatives to a frenotomy in order to improve breastfeeding.

78. Mrs A told HDC that she was not offered any non-surgical alternatives to a frenotomy.

79. Ms Martin advised that alternative options to the performance of a frenotomy included positioning and latching advice, the use of nipple shields, pumping and feeding the expressed milk by other means, and, given that Baby A was only five days old, adopting a wait-and-see approach. She also advised that consultation with another lactation consultant, the LMC, an osteopath, or a chiropractor could also have been explored.

80. Ms Martin advised:

> "It is accepted practice that all alternative treatment or non-intervention treatment options are discussed and offered.
>
> …
>
> Given that [Mrs A] had successfully breastfed 2 other babies with tongue ties, her professional experience and knowledge and the fact that vitamin K had not been administered should have I believe led [Ms B] to suggest and assist with alternative treatments to a frenotomy."

81. I note that the Midwifery Council's statement on the midwife's scope of practice with regard to assessment and diagnosis of tongue tie and the practice of frenotomy requires that alternatives to surgical intervention must be offered to consumers.

82. I accept Ms Martin's advice that alternatives to frenotomy should have been offered and explored in these circumstances, and I am critical that they were not.

Failure to advise of increased risk of bleeding without vitamin K

83. Ms B did not advise the parents of the risks associated with performance of a frenotomy when vitamin K has not been administered. Based on the fact that Baby A was their third child, that he was born at home, and that Mr A amended the consent form, Ms B assumed that the parents were aware that there was an increased risk of bleeding. However, Mr and Mrs A were not aware of the risk.

84. Ms Martin advised that "insufficient information was provided for the parents to make an informed decision regarding the frenotomy for [Baby A]".

85. In my view, it was unacceptable for Ms B to assume that Baby A's parents understood the risks associated with a frenotomy when vitamin K had not been administered. I agree with Ms Martin that once Ms B had decided that it was appropriate to perform a frenotomy without Baby A having been administered vitamin K, it was her responsibility to ensure that the parents were properly informed, and she did not do so.

86. 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.

87. I am critical that Ms B did not advise the parents of the risk of significant bleeding associated with the performance of a frenotomy on Baby A. This was information that a reasonable consumer would need to receive to make an informed choice or give informed consent to the proposed treatment. I am also critical that Ms B failed to advise Baby A's parents of the non-surgical alternatives to a frenotomy that were available to them. Baby A's parents had a right to know that there were alternatives to a frenotomy and to be given the option of exploring the non-surgical alternatives. By failing to provide this information, I find that Ms B failed to provide information to the parents 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.

88. 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 they were unable to make an informed choice and give informed consent to the frenotomy on behalf of Baby A. 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

89. In the provisional opinion, I recommended that the Midwifery Council undertake a competency review of Ms B's performance of frenotomies. The Midwifery Council has advised that a competency review was undertaken and specific recommendations made concerning Ms B's practice, and that no further action will be taken.

90. I recommend that Ms B provide a letter of apology to Mrs and Mr A. This is to be provided to HDC within three weeks of the date of this report, for forwarding to Mrs and Mr A.

Follow-up actions

91. 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.

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