Registrar, Dr D
Waikato District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Cases 16HDC01786 & 18HDC01259)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. In 2016, Mrs A, then aged in her twenties, was pregnant with her first baby. Mrs A's pregnancy proceeded normally until her lead maternity carer (LMC), registered midwife (RM) B, referred her to the Woman's Assessment Unit at the public hospital because of decreased fetal movement.

2. Mrs A was admitted for an induction of labour. At 2.30am an oxytocin infusion[1] was commenced.

3. At 1.30pm, RM B conducted a vaginal examination (VE) and recorded that Mrs A was fully dilated. Mrs A commenced pushing at 1.40pm. At 2.10pm, Mrs A was moved to the lithotomy position[2] to assist effective pushing. However, there was no further descent of the baby's head, and senior obstetric registrar Dr D was informed of the lack of progress. The CTG was normal.

4. No fetal head was palpable abdominally, and a VE found that Mrs A was fully dilated and the baby's position was right occipito-transverse/right occipito-posterior (ROT/ROP), central caput[3] and mild moulding[4] were present, and the station was +1.

5. Dr D discussed the findings with Mr and Mrs A, and explained the options of an attempted rotation of the fetal head and continued pushing, or of an instrumental delivery. Mrs A verbally consented to manual rotation of the fetal head, but that was unsuccessful.

6. Dr D decided to deliver the baby by ventouse, and Mrs A verbally consented to that. Mr and Mrs A said that the alternatives and risks were not discussed with them prior to Dr D deciding the delivery method.

7. At 3.15pm, Dr D applied a posterior ventouse cup and began the instrumental delivery. Following the first pull, the baby began to descend. During the fourth contraction, Dr D cut an episiotomy. The head had descended and rotated to an occipito-anterior (OA) position. Dr D considered that delivery was imminent, so she did not call the consultant. Following the episiotomy, two further pulls were required, and a total of six pulls were needed to deliver the baby's head. Firm traction was required to deliver the shoulders.

8. Baby A was born at 3.37pm, extremely white and floppy.

9. The placenta showed no signs of separating after birth and, after 30 minutes, Dr D transferred Mrs A to theatre for further analgesia and manual removal of the placenta with repair of the episiotomy.

[1] Oxytocin (Syntocinon) can be given by intravenous infusion to accelerate labour either as part of the process of induction of labour or during slow spontaneous labour. It can also be used to prevent or arrest postpartum haemorrhage as a result of uterine atony (when the uterus fails to contract after delivery).
[2] Lying on the back with the hips and knees flexed and the thighs apart.
[3] A diffuse swelling of the scalp caused by the pressure of the scalp against the dilating cervix during labour.
[4] The bones of the fetal head move closer together or overlap to help the head to fit through the pelvis.

10. Baby A was noted to have a heart rate greater that 100bpm, a superficial scalp laceration approximately 6cm in length, and a soft swelling of her scalp approximately 1.5cm in height under the location where the cup had been applied. A subgaleal haemorrhage[5] was queried.

11. Baby A had no spontaneous respiration, and was resuscitated in the Delivery Suite. After five minutes she was breathing spontaneously, but rapidly with increased effort. A venous cord blood gas[6] showed a baseline haemoglobin of 145g/L[7] and mild acidosis,[8] with an elevated lactate level.[9]

12. Baby A was transferred to the Neonatal Intensive Care Unit (NICU) at 4pm, and was seen by a paediatric consultant at around 4.30pm. The consultant said that when he carried out his assessment, a subgaleal bleed was apparent immediately.

13. Following a difficult catheterisation, Baby A was resuscitated with normal saline. Blood gas tests showed severe metabolic acidosis, secondary to hypovolaemia. Baby A was administered blood and blood products during the evening, but continued to bleed, and required more than three and half times her total blood volume before she was stabilised.

14. Baby A showed evidence of renal impairment, which is likely to be an on-going issue. Baby A's weight gain and blood pressure control improved, and she was discharged two months later.

Findings

15. It was found that Waikato DHB did not provide adequate guidance to staff in relation to seeking consultant support when undertaking potentially difficult deliveries, and that a number of staff did not respond sufficiently promptly and effectively to Baby A's subgaleal haemorrhage. Accordingly, Waikato DHB failed to provide services to Mrs A and Baby A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[10]

16. Adverse comment is made that Dr D did not fully discuss with Mrs A the risks of an instrumental delivery, and the option of a Caesarean delivery. Although there was no reason to recommend a Caesarean section, it was important that Mrs A understood the reasons for recommending a vaginal delivery with ventouse as the preferred option.

[5] Subgaleal haemorrhage is a rare but potentially lethal condition found in newborns. It is caused by rupture of veins between the scalp and the skull, and can lead to severe loss of blood.
[6] The pH, base excess, and pCO_2 (acid-base status) of arterial blood flowing through the umbilical cord provides evidence of the metabolic condition of neonates at the moment of birth.
[7] Normal newborn haemoglobin is 140 to 240g/L.
[8] Metabolic acidosis in a newborn infant is most often secondary to disorders resulting in hypoxia or poor tissue perfusion, and will be corrected by the appropriate treatment for these conditions.
[9] Measurement of blood or plasma lactate concentrations gives an indication of the adequacy of recent or current oxygen delivery to tissues.
[10] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Recommendations

17. It was recommended that Dr D undertake refresher training on informed consent.

18. Waikato DHB agreed to undertake the following recommendations:

a) Review the "Practice Recommendation on the Management of Neonatal Subgaleal Haemorrhage" with a view to adopting the guideline or preparing a guideline specific to Waikato DHB, and report the outcome to HDC.

b) Review the implementation of the protocol "When to call the SMO", to ascertain whether registrars do call for support from consultants for all instrumental rotational deliveries.

c) Include in the SMO[11] and RMO[12] "Responsibilities and the limits of delegation of responsibilities to RMOs" policy a statement about what to do if any concerns arise while undertaking procedures, when the policy is renewed in November 2019.

19. It was also recommended that Waikato DHB provide a written apology to Mr and Mrs A, and review the effectiveness of its "Speaking up for Safety" programme and the pathway to follow in serious events with adverse patient outcomes.

Complaint and investigation

20. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the care provided to his wife, Mrs A, during the birth of their daughter, Baby A.[13]

21. The following issues were identified for investigation:

- *Whether Waikato District Health Board provided Mrs A with an appropriate standard of care in 2016.*
- *Whether Dr D provided Mrs A with an appropriate standard of care in 2016.*

22. Subsequently, the investigation was extended to include the following issue:

- *Whether Waikato District Health Board provided Baby A with an appropriate standard of care in 2016.*

23. This report is the decision of Deputy Health and Disability Commissioner Rose Wall, and is made under the power delegated to her by the Commissioner.

[11] Senior Medical Officer.
[12] Resident Medical Officer.
[13] Mrs A supported the complaint.

24. The parties directly involved in the investigation were:

Mrs A	Consumer
Mr A	Complainant/consumer's husband
RM B	Registered midwife
RM C	Registered midwife
Dr D	Registrar
Dr E	Senior paediatric house officer
Dr F	Paediatric consultant
RN G	Clinical nurse specialist
Dr H	Registrar

Also mentioned in this report:

Dr I	Clinical Director of Obstetrics
Dr J	Neonatal paediatrician

25. Independent expert advice was obtained from a consultant paediatrician, Dr Thorsten Stanley (**Appendix A**), and an obstetrician and gynaecologist, Dr Cynthia Farquhar (**Appendix B**).

Information gathered during investigation

Pregnancy

26. In 2016, Mrs A, then aged in her twenties, was pregnant with her first baby. Mrs A stated that many times during the pregnancy she expressed concerns about her small frame and whether she would be able to give birth naturally.

27. Mrs A's pregnancy proceeded normally until 39+3 weeks' gestation (Day 1[14]), when her lead maternity carer (LMC), RM B, referred her to the Woman's Assessment Unit at the public hospital with a history of decreased fetal movement. She had electronic fetal monitoring (a CTG[15]), which was normal. An ultrasound scan (USS) was requested for the following day to assess the baby's growth, liquor volume,[16] and dopplers.[17]

[14] Relevant dates are referred to as Days 1–9 to protect privacy.
[15] Cardiotocography (CTG) monitoring is the combined monitoring of the baby's heartbeat in utero and the mother's uterine contractions, if any. This allows for an interpretation of the fetal heart rate either alone or in relation to the contractions, and may be used to assist with the identification of fetal well-being and/or distress.
[16] A baby regularly swallows amniotic fluid, and passes it out of its body as urine. This means that the amount of fluid in the amniotic sac normally rises and falls every day. The amount of amniotic fluid initially increases as the pregnancy progresses, but from 38 weeks' gestation the fluid gradually begins to reduce.
[17] Doppler ultrasound uses sound waves to detect the movement of blood in vessels. It is used in pregnancy to study blood circulation in the baby, uterus, and placenta.

28. The scan performed on Day 2 showed slowing of the growth velocity and an abnormal CPR (cerebro-placental ratio[18]). An induction of labour (IOL) was booked in accordance with the Waikato District Health Board (DHB) "Cervical Ripening and Induction of Labour Protocol".

Induction of labour

29. Mrs A was admitted for an IOL on Day 4 at around 12.30pm. A CTG showed a normal result, and at 3.30pm a vaginal examination (VE) was performed. The Bishop's score[19] documented is 0. At 3.30pm, dinoprostone[20] was administered. A further CTG was again reported as normal, and CTG monitoring was discontinued at 4.05pm.

30. A VE on Day 5 at 4.15pm indicated a Bishop's score of 1. A second dinoprostone pessary was administered. A further VE was performed at 4.20pm on Day 6. At that stage the Bishop's score was 7, which indicated that an artificial rupture of membranes (ARM) could be carried out. A CTG was normal. RM B informed the core midwives that she would take over Mrs A's care once she was in established labour following the ARM.

31. On Day 7 at 11.15pm, Mrs A was transferred to the Delivery Suite for the ARM.

Labour

32. The ARM was performed around midnight, at which time Mrs A's cervix was 2–3cm dilated. At 2.30am on Day 8, an oxytocin infusion[21] was commenced. By 5.30am, Mrs A's cervix was 7cm dilated and the baby's head was at the level of her ischial spines, station 0.[22]

33. At 6.20am on Day 8, RM B took over Mrs A's care. RM B recorded at 7am that Mrs A was saying that she did not feel that she could continue, and that she was feeling pressure with contractions. The contractions were occurring three times in 10 minutes, and Mrs A was using Entonox[23] for pain relief.

34. At 7.15am, Mrs A requested an epidural. RM B contacted the medical team at 7.20am, and an epidural was approved by the obstetric consultant at 7.45am. The anaesthetist attended and sited the epidural at 8.20am.

[18] A cerebro-placental ratio may be an indicator of fetal well-being. When this ratio falls, it is a sign of redistribution of blood supply to the brain, and is an indicator of failing placental function.
[19] The Bishop's score is the scoring system used to assess the favourability of the cervix for induction of labour. A score of 6–7 is the stage where the cervix is considered favourable.
[20] Dinoprostone is a prostaglandin — a hormone-like substance that is naturally produced by tissues in the body. It is used in a pregnant woman to soften and open the cervix (opening of the uterus) in preparation for inducing labour.
[21] Oxytocin (Syntocinon) can be given by intravenous infusion to accelerate labour either as part of the process of induction of labour or during slow spontaneous labour. It can also be used to prevent or arrest postpartum haemorrhage as a result of uterine atony (when the uterus fails to contract after delivery).
[22] "Station" is an assessment that determines the descent of the fetal head through the woman's pelvis using the ischial spines as an anatomical mark. The station is measured in centimeters above (negative) or below (positive) the ischial spines.
[23] Entonox is a gas mixture (50% nitrous oxide and 50% oxygen) used for analgesia.

35. At 8.55am, Mrs A was reviewed by the obstetric consultant, who noted that she was to continue the oxytocin and remain on continuous CTG. He recorded that the fetal status was reassuring.

36. At 10.30am, RM B conducted a further VE and found that Mrs A's cervix was 9cm dilated and the fetal head remained at station 0. RM B recorded "? position". At 11.30am, RM B conducted a further VE, which revealed an anterior lip of the cervix.[24]

37. At 11.45am, senior obstetric registrar Dr D[25] reviewed Mrs A, and the oxytocin was increased to 8ml per hour.

38. Mr and Mrs A told HDC:

> "We believe a thorough assessment done at that time could have identified the cluster of risk factors that were present which would have elevated this birth into the 'High Risk' category. Alternatives such as a caesarean were not considered or offered to us despite the risks."

39. At 12.30pm, RM B pushed the anterior lip away, and at 1.30pm she conducted a VE and recorded that Mrs A was fully dilated. Mrs A commenced pushing at 1.40pm. At 2.10pm, Mrs A was moved to the lithotomy position[26] to assist effective pushing. However, there was no further descent of the baby's head, and Dr D was informed of the lack of progress. At that stage, the CTG was normal.

Decision for ventouse extraction

40. Dr D stated that Mrs A, although exhausted, was comfortable, with an effective epidural block. No fetal head was palpable abdominally, and a VE found that Mrs A was fully dilated and the baby's position was right occipito-transverse/right occipito-posterior (ROT/ROP), central caput[27] and mild moulding[28] were present, and the station was +1. Dr D stated that the findings were discussed with Mr and Mrs A, and the clinical situation explained. Dr D said that she discussed the options of an attempted rotation of the fetal head and continued pushing, or of an instrumental delivery. She stated that Mrs A verbally consented to manual rotation of the fetal head, which was attempted, but was unsuccessful.

41. Dr D said that she managed to rotate the position of the fetal head to occiput anterior manually but it rotated back with further pushing, so she felt that she would be able to rotate the head with the ventouse in the delivery room.

42. Mr and Mrs A told HDC that Dr D told them that despite attempts to manipulate the baby for delivery, the baby was not in an ideal position. They said that Dr D stated that Mrs A

[24] A small rim of cervix remaining on one side.
[25] Dr D told HDC that she had been credentialled to undertake instrumental deliveries independently.
[26] Lying on the back with the hips and knees flexed and the thighs apart.
[27] A diffuse swelling of the scalp caused by the pressure of the scalp against the dilating cervix during labour.
[28] The bones of the fetal head move closer together or overlap to help the head to fit through the pelvis.

has a tight/hard pelvic floor that was making things difficult. Mr and Mrs A stated: "Alternatives such as a caesarean were not considered or offered to us, despite the apparent risks."

43. Dr D recorded:

> "d/w [discussed with] [Mr and Mrs A] further pushing for half hour v/s [versus] assisted delivery [with] ventouse given positioning & slow progress — elected & consented to ventouse."

44. In response to the provisional opinion, Mr and Mrs A said that it is untrue to say that Mrs A elected and consented to a ventouse delivery, and that "the only discussion had at that time was [Dr D's] decision to use the ventouse and [Mrs A] agreeing due to trust that this was the safest method of delivery".

45. Mr and Mrs A stated that once Dr D decided to use the ventouse, the room "filled with neonatal doctors". Mr and Mrs A told HDC:

> "The reasons for this were not communicated to us effectively, along with the risks associated for using this instrument. We did not feel that adequate risk assessment was taken by [Dr D] prior to making her decision or during the birth process. We as parents were never consulted and provided options to address any concerns during the birth and possible actions to take to reduce possible risks. [Mrs A] was in a calm and stable condition due to the epidural."

46. Dr D told HDC:

> "I did not discuss Caesarean section because from my experience that would not be recommended best practice in this situation. I did however discuss continued pushing as there was no fetal distress and manual rotation."

47. Dr D stated that her discussion with Mr and Mrs A included the risk of bruising and swelling on the baby's head at delivery, and that Mrs A said, "Do whatever you think is best," on two occasions. However, Dr D's clinical records contain no mention of risks being discussed.

48. Dr D told HDC that when she examined Mrs A, who had been pushing for one and a half hours, the station was at +1, with further descent while pushing. Dr D stated:

> "I felt my VE and abdominal findings were consistent with a vaginal delivery being achievable in the [delivery] room. Earlier reviews also by the LMC are unable to define the position. My VE findings are comprehensive and complete, and define both position and level of the head, caput, and moulding. The correct placement of the cup supports my assessment."

49. Dr D stated that her findings on examination indicated that a vaginal delivery was achievable, and hence she undertook it in the delivery room. She said that this is not

uncommon or unreasonable practice, and it is up to the individual clinician to decide where a delivery will take place, and there was no requirement to go to the operating theatre.

50. Dr D stated that the delivery unit has its own theatre, centrally located in close proximity to the six delivery rooms. She said that the theatre is fully staffed from 8.00am until 4.30pm, and at the time of the instrumental procedure she knew that the theatre and staff were available for immediate transfer if she deemed it necessary.

51. Waikato DHB stated that after the birth, Dr D said that according to her clinical assessment, she was not expecting a particularly difficult delivery, which is why she made the decision to proceed with the ventouse delivery in the delivery room. Dr D told HDC:

> "Most instrumental deliveries have some level of difficulty that is anticipated. As I was able to manually rotate the fetal head, and taking into account the descent and other factors, I was confident that an instrumental delivery was safely achievable. I did not expect it would take a further 2 pulls once the episiotomy[29] was cut; delivery over the perineum was more difficult than usual."

52. Waikato DHB said that Mrs A had been pushing since 12.35pm, and that for a first-time mother with an epidural, it was acceptable to have two hours of passive head descent, and that active pushing for up to two hours was acceptable.

Delivery

53. Core midwife RM C retrospectively recorded that she was asked to attend because RM B was the only midwife caring for Mrs A. At about 2.40pm, senior paediatric house officer[30] Dr E was also called to the birthing unit. He stated that he had two trainee interns with him in an observing capacity, and that he was present for approximately one hour prior to the delivery.

54. At 3.06pm, decelerations were noted on the CTG. At that stage, Dr D was examining Mrs A. Waikato DHB stated that the decelerations "provided further reason for the decision for an instrumental delivery". In response to the provisional opinion, Mr and Mrs A said that they were never told about the decelerations, and that fact creates doubt about whether Dr D discussed with them the option of further pushing. They said that no alternatives and risks were discussed with them prior to Dr D deciding the delivery method.

55. At 3.15pm, between contractions, Dr D applied a posterior ventouse cup over the flexion point.[31] The ventouse suction pressure was increased to 20kPa, and it was confirmed that

[29] A surgical incision of the perineum and posterior vaginal wall performed to enlarge the opening for the baby to pass through.
[30] Dr E told HDC that at the time of these events he was two months into a three-month rotation in paediatrics. He said that he had no training in obstetrics.
[31] The aim of correct ventouse cup placement is to be able to flex the head into the optimal position (so that the smallest diameter of the head is presenting) as well as apply traction. The flexion point is a crucial landmark, as optimal flexion is achieved when the centre of the cup is applied over the flexion point.

no maternal tissue was trapped in the ventouse cup. The pressure was then increased to 80kPa (600mmHg).[32]

56. Dr D began the instrumental delivery. She said that following the first pull, the required descent and rotation was achieved, and she cut an episiotomy during the fourth contraction. The head had descended and rotated to an occipito-anterior (OA) position. At that stage, she considered that delivery was imminent, so she did not call the consultant.

57. Mr and Mrs A told HDC: "At [one] stage of using the ventouse [Dr D] lost her grip and fell backwards from the pulling force applied." In response to the provisional opinion, Mr and Mrs A said that the struggling, excessive pulling, and Dr D having fallen backwards were witnessed by Dr E and RM C. However, Waikato DHB stated that "both the registrar [Dr D] and the LMC [RM B] confirm that at no time during the delivery did the registrar fall backwards". Waikato DHB gave HDC a statement from Dr E that does not refer to Dr D having fallen.

58. RM C recorded retrospectively:

> "[At approximately 3.25pm, it] became very apparent that ventouse was difficult, but peeps of head seen. Myself & LMC pushed legs back into a semi-McRobert's[33] position which enabled [Mrs A] to push more effectively."

59. RM C recorded that at 3.30pm Dr D was "continuing to struggle with delivery of head, but [was] confident progress [was] being made", and that at 3.35pm the fetal heart rate was tachycardic (rapid), and the head was delivered with obvious difficulty. As no progress was made with delivery of the shoulders, the bed was laid flat, and Mrs A was put in a more vigorous McRobert's position. RM C noted that "very firm downward traction [was] required" to deliver the shoulders.

60. At 4.25pm, Dr D recorded that following the episiotomy, two further pulls were required, and a total of six pulls were needed to deliver the baby's head. She noted that there was no cup detachment, but that it was a "difficult delivery, tight shoulders but no shoulder dystocia". Dr E stated that he observed the application of the ventouse cup to the baby's head, and his recollection is that 7–8 individual pulls were performed. He said that there was some progress following the first 3–4 pulls and, from the fifth pull, there seemed to be more progress, with the baby advancing down the birth canal a small distance with each subsequent pull. He stated that he "did not witness any moment when the Ventouse suddenly lost suction".

61. Waikato DHB stated that the ventouse cup was applied during six contractions, for a total time of 20 minutes.

[32] The RANZCOG guideline "Instrumental Vaginal Delivery" (March 2016) states: "Vacuum suction pressures of 500–600mmHg are recommended, and establishment of negative pressure without delay reduces procedure time without compromising effectiveness or safety."

[33] The McRobert's manoeuvre is used to assist in childbirth. It involves hyperflexing the mother's legs tightly to her abdomen.

62. RM B recorded: "[B]aby delivered over ~ 6 pulls/contractions." She told HDC that the baby's head advanced with each contraction, but it was not a simple lift-out in which you would see the fetal head advance rapidly. She stated that she has witnessed hundreds of ventouse procedures, and while this delivery was "a bit longer and a bit slower than is usual", she had no particular cause for concern. She said that the procedure was slow but steady, and she would not describe Dr D as "struggling".

63. At 3.37pm, Baby A was born. RM C recorded that Baby A was extremely white and floppy. The cord was clamped, and Baby A was handed to Dr E. At 3.39pm, RM B rang the staff bell for resuscitation assistance, because Baby A was not making respiratory effort. Baby A's subsequent care is outlined in detail later in this report.

64. RM C recorded that at 3.40pm, she administered "Oxytocin" to Mrs A intramuscularly. The placenta did not show signs of separating after birth and, after 30 minutes, Dr D diagnosed a retained placenta. Dr D decided to transfer Mrs A to theatre for further analgesia and manual removal of the placenta with repair of the episiotomy. Waikato DHB stated that the on-call consultant was informed of Mrs A's transfer to theatre.

Waikato DHB — further information

65. Waikato DHB stated that Dr D was credentialled to undertake instrumental deliveries independently. In response to the provisional opinion, it noted that in 2016 she was a very experienced registrar and became a fellow of RANZCOG a few months after these events.

66. With regard to the reason why a Caesarean section was not considered, Waikato DHB stated that on detailed review of the second stage of labour, a vaginal delivery was deemed achievable, with no indication for a Caesarean section. In response to the provisional opinion, it stated that it does not think that a Caesarean section should have been discussed with Mrs A or offered to her because it would not recommend a Caesarean section in these circumstances. Waikato DHB said: "Expecting that a clinician offers a procedure he/she believes is not a recommended option will likely put patients at risk and cause more harm."

67. Waikato DHB said that according to Dr D, descent of the fetal head was noted with each contraction. After the third pull, there was significant evidence of descent, and so Dr D felt that the delivery was imminent and did not call the consultant or change the management. Waikato DHB noted that with the presenting part so low in the birth canal, and given the presentation after three pulls, a Caesarean section would have had extreme difficulties and complications, and at that point a forceps delivery would also have been extremely difficult.

68. The Clinical Director of Obstetrics, Dr I, stated that normally, assisted instrumental deliveries are performed in the birthing rooms if the presentation is below the level of the spines and there are no expected difficulties, and where there is an appropriate level of anaesthesia. As Dr D was credentialled and experienced in instrumental deliveries, there was no requirement for her to inform the on-call consultant that she was undertaking the delivery in the birthing room. Dr I stated:

> "After considering all the facts, we believe that the situation turned out to be much more difficult than what [Dr D] had expected. We agreed with [Dr D's] decision to undertake a ventouse delivery, as opposed to offering a caesarean delivery — taking into account the station at which the presentation was at."

69. Dr I also said:

> "With the benefit of hindsight, and knowing that the birth was unexpectedly difficult in the later stages, it would have been more appropriate for [the delivery] to have been carried out in theatre."

70. Dr I stated that on the day of Baby A's delivery Dr D discussed the case with the Clinical Unit Leader. Following these events, the Clinical Director for Obstetrics undertook an internal investigation, and provided feedback to all of the clinicians involved in Baby A's birth and post-care. Dr I said that she and the Clinical Unit Leader also discussed the case with Dr D, for peer review and advice.

71. Dr I told HDC that Waikato DHB is developing a guideline to support staff with adverse events, in order to undertake the appropriate review, debrief of the event, and follow-up actions.

72. Waikato DHB stated that the women's service has created a new guideline on assisted vaginal delivery, and the Women's Health Service holds twice-yearly instrumental workshops where midwives, registrars, and SMOs review the indications for an instrumental birth, the informed consent process, and the practicalities of the techniques.

73. Waikato DHB said that it has also developed a protocol on "When to call the SMO", which highlights that all registrars will call for support for all instrumental rotational deliveries. However, at the time of these events, this was not a requirement if the registrar was credentialled.

Further information — Dr D

74. Dr D said that following Baby A's delivery, all instrumental deliveries she performed were supervised. No concerns were noted regarding her decision-making or technique, and she returned to independent practice.

75. Dr D stated that whenever she seeks parental consent for ventouse delivery, she now also includes information regarding the uncommon (1:300) risk of a subgaleal haemorrhage. She stated:

> "To so advise is unusual and objectively is not considered necessary because of the extremely low risk of such occurring; however, this event and the trauma felt by [the family] has necessarily increased my sensitivity to providing this advice."

76. Dr D said that similarly, when obtaining consent for mid-cavity rotational ventouse deliveries, she mentions the alternative of a Caesarean section.

RANZCOG Guideline "Instrumental vaginal birth"

77. The RANZCOG guideline "Instrumental vaginal birth" (March 2016) states that safe instrumental vaginal birth requires a careful assessment of the clinical situation and clear communication with the mother. Instrumental births should be performed by, or in the presence of, an operator with expertise in the chosen procedure and the management of any complications that may arise. The guideline notes that in many cases, the decision to perform an instrumental delivery will represent a balance between the potential risks of leaving the fetus undelivered, and the additional risks of performing a Caesarean section in the second stage of labour.

78. The guideline notes:

> "The condition of the fetus needs to be assessed. The fetus that has suffered significant hypoxic insult (either prolonged, or acute and severe) may be at greater risk of trauma during an attempted instrumental vaginal birth. In these settings the fetus may be at increased risk of trauma due to reduced tone and engorgement of the cerebral vessels. However, despite the potential risks of instrumental birth in this situation, it may remain the safest option in the prevailing clinical circumstances."

79. In relation to consent, the guideline states:

> "Women should be informed about instrumental vaginal birth, and when it may be required, during antenatal care. The time spent obtaining consent for instrumental birth during labour may be determined by the urgency of the situation. Verbal consent should be obtained and the discussion documented in the clinical record. Effective communication with the patient and her support person/persons is required to ensure that there is clear understanding of the management plan. Written consent should generally be obtained prior to an instrumental vaginal birth in an operating theatre setting, and women made aware of the possibility that attempts at instrumental delivery may need to be abandoned and caesarean section performed."

80. Recommendation three of the guideline states:

> "When there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible."

81. The guideline notes that a back-up plan should be in place in case of a failure to deliver, and states under "Prerequisites for instrumental vaginal birth":

> "When conducting mid-cavity births, theatre staff should be immediately available to allow a caesarean section to be performed without delay (less than 30 minutes).
>
> A senior obstetrician competent in performing mid-cavity births should be present if a junior trainee is performing the birth.

Anticipation of complications that may arise (e.g. shoulder dystocia, postpartum haemorrhage)

Personnel present that are trained in neonatal resuscitation."

82. The guideline also states that recognition of when it is appropriate to abandon the procedure and consider an alternative method of birth is vital. It notes that traction should not be unduly prolonged, but that at present there is no consensus on the maximum time allowable, the number of pulls, and the number of allowable cup detachments. However, the guideline states that VACCA[34] recommends an upper limit of 20 minutes from the first application of the cup, and, where birth is not imminent after 15 minutes, operators should evaluate whether further traction is warranted and consider recourse to Caesarean section.[35] The guideline states that many experienced operators suggest a maximum of three pulls without descent of the skull (not scalp), although more pulls may be acceptable if the head has descended to the level of the pelvic floor or perineum, especially if birth is attempted without episiotomy.

Treatment — Baby A

83. This section considers the care provided to Baby A, in particular the management of her subgaleal haemorrhage.

84. Dr E stated that upon delivery, Baby A was placed skin to skin with Mrs A. The cord was clamped and cut, and Baby A was stimulated by rubbing her with a towel. Dr E said that within the first 30 seconds after delivery, he grew concerned because of Baby A's lack of respiratory effort, pale mottled skin colour, and low tone.

85. Dr E said it seemed that Baby A was stunned from the prolonged delivery, and he asked staff to place her on the resuscitaire, to continue stimulation by rubbing her body with warm towels, and to provide continuous positive airway pressure (CPAP). He said that when she was about one minute of age, he checked her heart rate and found it to be greater that 100bpm. He noticed that she had a superficial scalp laceration approximately 6cm in length, and a soft swelling of her scalp approximately 1.5cm in height under the location where he presumed the cup had been applied. He recorded:[36] "? Subgaleal.[37]"

86. Dr E told HDC that Baby A had no spontaneous respiration, so he applied five inflation breaths of CPAP, at which time there were gasps from Baby A, but no significant respiratory effort.

[34] Vacca A. Handbook of vacuum delivery in obstetric practice, Vacca Research Brisbane Australia. 2003.
[35] The guidelines note that Caesarean section following an attempted instrumental delivery is often complex with the fetal head deep within the pelvis. These operations are associated with an increase in maternal and fetal morbidity, including fetal intracranial haemorrhage.
[36] Paediatric consultant Dr F told HDC that this note was written once the baby was in the NICU, and was a record of Dr H's observations.
[37] Subgaleal haemorrhage is a rare but potentially lethal condition found in newborns. It is caused by rupture of veins between the scalp and the skull, and can lead to severe loss of blood.

87. Dr E then gave Baby A intermittent positive pressure ventilation at 20cm/5cm H_2O, and requested help from the on-call neonatal registrar, Dr H.[38]

88. Dr H said that Dr E called him between 3.37pm and 3.42pm requesting an immediate senior presence for a neonate just born in the Delivery Suite and, when he arrived, the Apgar timer read "5 minutes", and at that stage Baby A was breathing spontaneously, but with rapid breathing and increased breathing effort. He stated: "Soft tissue swelling of the scalp was seen, and given the history of a difficult Ventouse delivery I was suspicious of the possibility of a subgaleal haemorrhage." He said that a hat was placed on Baby A, and her head was measured over the hat, giving a head circumference of about 37cm.

89. Dr E said that CPAP was continued for approximately 15–20 minutes in the Delivery Suite birthing room, before he and Dr H decided to take Baby A to the Neonatal Intensive Care Unit (NICU) for ongoing respiratory support. At 3.46pm, a venous cord blood gas[39] was performed in the delivery suite. It showed a baseline haemoglobin of 145g/L[40] and mild acidosis,[41] with an elevated lactate level.[42]

NICU

90. Dr H said that Baby A was wrapped warmly for the transfer, and on arrival at NICU her temperature was 37.9°C. He said that he was concerned that Baby A might have suffered birth asphyxia.

91. Dr E stated that on arrival at NICU, Baby A was transferred to a NICU CPAP machine and, although there was a mild improvement in her colour and tone, she had increased rate and effort of breathing. He noticed that Baby A had some movements, which he documented as "posturing". Dr E stated that Baby A's care was handed over to clinical nurse specialist (CNS) RN G, and his involvement with Baby A's care ended.

92. The time of Baby A's arrival in NICU on Day 8 is not documented. Dr H said that Baby A was admitted at 4.00pm, which was the time of the afternoon ward round. He said that it was decided to undertake the ward round and return to Baby A as quickly as possible, with priority given to obtaining vascular access. He said that at that stage, Baby A did not show evidence of hypovolaemic shock,[43] her heart rate was in the normal range, and she was not hypothermic.[44]

[38] The DHB told HDC that at the time of events, Dr H was a basic trainee in general paediatrics.
[39] The pH, base excess, and pCO_2 (acid-base status) of arterial blood flowing through the umbilical cord provides evidence of the metabolic condition of neonates at the moment of birth.
[40] Normal newborn haemoglobin is 140 to 240g/L.
[41] Metabolic acidosis in a newborn infant is most often secondary to disorders resulting in hypoxia or poor tissue perfusion, and will be corrected by the appropriate treatment for these conditions.
[42] Measurement of blood or plasma lactate concentrations gives an indication of the adequacy of recent or current oxygen delivery to tissues.
[43] Hypovolaemic shock is an emergency condition in which severe blood or fluid loss makes the heart unable to pump enough blood to the body. Losing about one-fifth or more of the normal amount of blood in the body causes hypovolaemic shock.
[44] Subnormal body temperature.

93. The time of Dr H's handover to RN G is not documented, but Dr H stated that it would have occurred between 4.00pm and 4.30pm. He said that immediately after the ward round he documented a brief note of his work with Baby A, and that his recorded plan to "continue management in NICU" represents that at that time his role was to hand over to RN G. He said that he remained on duty until 8.50pm, and assisted by providing care to the other neonates in NICU. He was on duty again on Day 9, and was involved in Baby A's care over the next six days.

94. Paediatric consultant Dr F told HDC that he became involved in Baby A's care "at around 16.30". He said that at the initial stage, HIE[45]/asphyxia was considered in the differential diagnosis, rather than being the focus of care. Baby A was not actively warmed following arrival in NICU, and fluids were restricted to 40ml/kg/day. Dr F stated that it was apparent immediately that there was a subgaleal bleed.

95. Dr F stated that there was no delay in recognising the subgaleal haemorrhage or of consultant input. He said: [T]he clinical picture was an evolving one, with acceleration of the impacts of progressive subgaleal bleeding manifesting over the first hours of life." He said that the first focus was managing Baby A's respiratory status, but that following handover, the significance of the evolving subgaleal haemorrhage was clear. He said that there was a delay in documentation because of the "frenetic action undertaken around the baby".

96. RN G retrospectively documented at 9.30pm that handover to her occurred at 4.30pm following the ward round. She noted that Baby A was "[p]ale, hypotonic muted response with handling, Gentle palpation of head identified small subgaleal bleed", and that this was reported to Dr F. She documented that she was unable to obtain capillary blood gas[46] and was unable to site a peripheral IV[47] owing to Baby A's poor perfusion.

97. Dr F documented in his retrospective notes at 10.19pm that a large subgaleal haemorrhage had been identified early. He told HDC that his intention was to document that the subgaleal haemorrhage was diagnosed early, and that by the time the note was written it was large, not necessarily that it was large at the time of diagnosis. Dr F stated:

> "There is no doubt in my mind that the subgaleal haemorrhage was clinically significant at my first inspection at 16:30. As to its size at that time, I don't think it was small. Clearly this was an evolving situation and the critical point is not where on the spectrum from small to large this lay (a subjective assessment at best), but that this was a high risk situation that required intervention and active surveillance."

[45] Hypoxic-ischaemic encephalopathy (HIE) is a brain injury caused by oxygen deprivation (asphyxia).
[46] Capillary blood gas (CBG) samples may be used in place of samples from arterial punctures or indwelling arterial catheters to estimate acid-base balance (pH) and adequacy of ventilation ($PaCO_2$). A puncture or small incision is made with a lancet or similar device into the cutaneous layer of the skin at a highly vascularised area (heel, finger, toe).
[47] A peripheral venous catheter (PVC), peripheral venous line, or peripheral venous access catheter is a small, flexible tube that is placed into a peripheral vein for intravenous therapy.

98. Dr F said that at 4.30pm there was a very real and clear focus that Baby A was poorly perfused, and urgent action with vascular access and volume support was required. He said that vascular access and further blood sampling proved difficult, and took time, as attempts at a peripheral IV were unsuccessful. Dr F stated that the placement of a short umbilical venous catheter (UVC) should have been straightforward and rapid, but in Baby A's case the umbilical vein was resistant to catheterisation, which resulted in a delay. Dr F considers that there was no delay in recognising the diagnosis or its significance. He said that the delays in achieving vascular access were not through negligence or incompetence, but were "a reflection of the real difficulties faced in neonatal care".

99. A UVC was placed at 5.30pm, and a normal saline bolus was administered. Dr F said that it is standard practice to titrate the volume of fluid resuscitation to the clinical response, and frequent small boluses of 10ml/kg are standard care. A venous gas was processed at 5.31pm.

100. Dr F said that half of Baby A's circulating volume was replaced in the course of the following 66 minutes, and between 5.00pm and 6.00pm, her heart rate[48] dropped from just below 170bpm to 130bpm. He stated that reduction in heart rate is a "very sensitive guide" to the adequacy of haemodynamic response to volume expansion in hypovolaemia.

101. Dr F stated that between 5.30pm and 6.00pm, blood gas assessments were not undertaken because the focus was on insertion of the catheters. By 6.04pm, umbilical, venous, and arterial catheters were in place, which secured reliable vascular access and blood sampling. Blood gas tests showed a severe metabolic acidosis, secondary to hypovolaemia.

102. Dr F stated that Baby A's haemodynamic response to the saline boluses was good, as was shown by the improvement in her heart rate, which improved further once vascular access was established. He said that the improvement in the acid-base status took longer, as was expected, and that what was more difficult to manage was the ongoing bleeding and the associated consumptive coagulopathy.[49]

103. Dr F stated that at 6.00pm, O negative blood was requested from the blood bank, and administration was under way by 6.18pm. Baby A was administered 20mL/kg of O negative uncrossmatched blood followed by 10mL/kg of cryoprecipitate,[50] and then further blood products during the evening. He said that the use of uncrossmatched O negative blood indicated awareness of the gravity of the situation. He said that Baby A's breathing had been stabilised on CPAP, and she was not intubated until there was a change in her clinical status (transient bradycardia and the development of an oxygen requirement).

[48] A normal heart rate in the newborn period is 120 to 160 beats per minute.
[49] A disorder in which the proteins in the blood involved in clotting become overactive. Small clots form in small blood vessels throughout the body, which can disrupt blood flow to organs such as the kidneys and liver and lead to organ failure.
[50] Cryoprecipitate contains clotting proteins, fibrinogen in particular. It is most commonly used as part of a substantial transfusion in which large numbers of blood components are required to assist with clotting.

104. A NICU registrar recorded that overnight Baby A had ongoing coagulopathy. She received 20ml/kg red blood cells, 10ml/kg platelets, 15ml/kg fresh frozen plasma, and 10ml/kg cryopreciptate.

105. Dr F stated that there were two further drops in Baby A's haemoglobin level within the first 48 hours, which represented ongoing bleeding. He said that it was necessary to adopt a two-pronged approach to manage the ongoing bleeding — trying to normalise the coagulation profile, and limiting the available space into which blood could escape. He said that Vitamin K had been administered at birth, and was repeated at 30 hours of age.

106. Dr F stated that in addition to the initial head circumference measurement, he requested serial measurements of Baby A's head circumference and head length. Clinical photographs were also taken to allow comparison of the size of her head. He fashioned a customised compression helmet by taping a plastic beanbag around Baby A's head and extracting air to create a firm compression.

107. Dr H said:

> "In total, more than three and half times [Baby A's] total blood volume was given in the form of various blood products following a massive transfusion protocol-type approach — red cells, fresh frozen plasma, cryoprecipitate and platelets."

108. Baby A had evidence of renal impairment. She was reviewed by a renal physician, who noted that end-stage renal failure was likely to occur during her first year. Priorities included optimising Baby A's nutrition and improving her blood pressure control.

109. Baby A's weight gain improved, and she was discharged.

Subsequent development

110. Dr F said that Baby A's head circumference reduced during the first four weeks after birth, which was likely to have been because of the resolution of the subgaleal haemorrhage. He said that her subsequent head measurements were reassuring.

111. Dr H stated that on 20 January 2017, Baby A underwent a general movement assessment. The assessment was normal, indicating that she had a low risk of cerebral palsy. On 23 August 2018, a paediatrician reviewed Baby A and found that she is growing and developing well, and there are no concerns about her development.

112. In response to the provisional opinion, Mr and Mrs A said that they want to bring to light what all of this has done to their daughter. They stated:

> "She may not ever have the healthy life she deserved. We live in constant fear that her kidney health might deteriorate and will affect her overall health. We administer her blood pressure medication twice a day and have recently had to increase the dosage to mitigate non-ideal [blood pressure] rates. We are constantly monitoring her diet and she can't have a normal life. The birthing event along [with] the ongoing care has

taken an emotional toll on us as parents. We feel like the WDHB is playing down the impact of this event on our daughter."

ACC

113. Baby A's parents applied for ACC cover for the subgaleal haemorrhage associated with hypovolaemia and subsequent renal impairment, and the impaired brain perfusion causing cortical laminar necrosis[51] following the ventouse delivery.

114. ACC obtained expert advice from neonatal paediatrician Dr J, who noted that the NICU nurse was unable to take capillary gas owing to extremely poor perfusion, and that venous access was difficult, probably because of hypovolaemia. Dr J stated:

> "It is likely that the already rapidly evolving subgaleal [haemorrhage] was mistakenly assessed as small, whereas in fact there was likely already a significant degree of hypovolaemia by 17:00. Colditz et al have recently emphasised the importance of early recognition of subgaleal bleeds and associated shock and the importance of aggressive fluid resuscitation."

115. Dr J advised that it would have been more appropriate to have initiated rapid fluid resuscitation, ideally with whole blood, by 5.00pm, without waiting for haemodilution[52] to lower the measured haemoglobin value. He said that by the time red blood cells were given, Baby A had profound metabolic acidosis due to exsanguination (blood loss).

116. Dr J stated: "The red blood cell transfusion given at this point was of too low a volume and was given more slowly than required." He noted that further subgaleal bleeding occurred over the first night, and there was an avoidable delay in recognising that, and thus a delay in providing further blood transfusions. He said that the haemoglobin level was clearly dropping by 4.30am.

117. Dr J concluded that there was a clinically relevant delay in neonatal treatment, which contributed to organ hypoperfusion[53] and increased the risk of organ injury.

Responses to provisional opinion

118. Responses to the provisional opinion have been incorporated into the report as appropriate. In addition, the following submissions were received:

Mr and Mrs A

119. Mr and Mrs A stated that they strongly believe that Baby A's injury and her subsequent lifelong condition could have been avoided if there had been better communication with them by Dr D and RM B. Mr and Mrs A said: "We also believe better understanding of the full situation while identifying risks and putting in place mitigants would have helped."

[51] The death of brain cells, usually caused by reduced blood flow to the brain.
[52] The decreased concentration of cells and solids in the blood resulting from gain of fluid.
[53] Hypoperfusion (shock) is the inadequate delivery of vital oxygen and nutrients to body tissues, which, left unchecked, will result in organ system failure and death.

120. Mr and Mrs A consider that Dr D did not take adequate action when her decision to use the ventouse became inappropriate during the delivery. They said: "All we wanted was the safe delivery of our child and [that] was communicated repeatedly to the professionals."

Dr D

121. Dr D noted that there was a severe but recognised complication with Baby A's delivery. However, she said that as is stated in the notes, there was no head palpable abdominally, and the presenting part was at +1 not caput. She reiterated that she did not call the consultant as she was confident in her decision-making, and although the delivery was difficult at times, at no time did she think it was not achievable.

122. Dr D said that twice she obtained verbal consent for the ventouse procedure from Mrs A, without coercion. Dr D stated that she did not discuss the option of a Caesarian section because "it is not recommended best practice with the above findings and certainly not without significant risk". She said that she discussed the options that she was prepared to recommend and undertake.

123. Dr D stated that she arranged to attend the annual Obstetric Malpractice Conference in August 2019, and has arranged to attend an assisted birth and vaginal breech workshop in October 2019.

Waikato DHB

124. Waikato DHB stated: "There are well known difficulties of consenting women whilst in labour, and documentation around the consenting process." It said that "it seemed unrealistic to expect that [Dr D] would have discussed all the risks, and pros and cons of all the alternatives in treatment".

125. With regard to Baby A's treatment, Waikato DHB stated:

> "
> - There was no significant delay in recognising the diagnosis of subgaleal haemorrhage
> - There was no delay in recognising the severity of the subgaleal haemorrhage
> - The difficulties in obtaining vascular access related to the challenging clinical presentation
> - There was no delay in involving consultant care
> - There was considerable expertise and clinical dedication directed towards saving this baby's life and minimising the long term negative outcomes"

126. Waikato DHB said that the ACC advice from Dr J is for a different purpose, and he did not have access to the NICU observation charts, so his opinion should be disregarded.

127. Waikato DHB does not consider that Dr D requires further training in instrumental births.

128. Waikato DHB has introduced the "Speaking up for Safety" programme and holds PROMPT courses for obstetric emergencies in the Delivery Suite four times per year.

129. The Women's Health Service has developed a pathway to follow in serious events with adverse patient outcomes.

Opinion: introduction

130. As this Office has emphasised in previous cases, DHBs are responsible for the operation of the clinical services they provide, including any service failures.[54] It is incumbent on all DHBs to support their staff with systems that guide and support good decision-making and promote a culture of safety.

131. It is also essential that clinicians think critically and recognise if a patient's response indicates that adherence to a protocol or treatment plan is inappropriate. I consider that the care provided to Mrs A and Baby A by staff at Waikato DHB was suboptimal, as discussed below.

Opinion: Waikato District Health Board — breach

Care of Mrs A

Introduction

132. On Day 8, at around midnight, Mrs A had an ARM performed and, at 2.30am, an oxytocin infusion was commenced. By 5.30am, her cervix was 7cm dilated, and the baby's head was at the level of her ischial spines.

133. At 11.45am, Dr D reviewed Mrs A and increased the oxytocin to 8ml per hour. Mr and Mrs A told HDC:

> "We believe a thorough assessment done at that time could have identified the cluster of risk factors that were present which would have elevated this birth into the 'High Risk' category. Alternatives such as a caesarean were not considered or offered to us despite the risks."

134. By 1.30pm, Mrs A was fully dilated, and she commenced pushing at 1.40pm. There was no further descent of the baby's head, and at 2.35pm Dr D was informed of the lack of progress. At 3.06pm, Dr D conducted a VE and found that the baby's position was ROT/ROP and central caput and mild moulding were present.

135. Dr D discussed with Mr and Mrs A the options of an attempted rotation of the fetal head and continued pushing, or an instrumental delivery. Mrs A verbally consented to the

[54] Opinion 14HDC01187 (30 June 2016). See also Opinion 16HDC01010 (12 March 2018).

manual rotation of the fetal head. However, the attempted rotation was unsuccessful as the head rotated back to its original position.

Warning signs of difficult delivery/discussion with consultant

136. My expert advisor, obstetrician and gynaecologist Dr Cynthia Farquhar, advised that the decision for an instrumental vaginal birth was appropriate and reasonable.

137. However, Dr Farquhar also stated that, in her opinion, Mrs A's presentation was consistent with deep transverse arrest in the mid cavity, and there were adverse clinical features in Mrs A's presentation that could be regarded as "warning signs". These were the lack of descent below the ischial spines (station 0), the failure of the fetal head to rotate to the OA position after nearly three hours at full dilatation, and pushing for 90 minutes. While Dr D recorded that the station was "+1 with pushing", Dr Farquhar said that she interpreted that as station 0 when not pushing. Dr Farquhar noted that when the position is ROP and there is moulding and caput, the station may appear to be +1 when in fact it is more likely to be station 0. She advised that the station was only one factor, and other warning signs that it would be a difficult delivery were the caput and malposition. However, in response to the provisional opinion, Dr D reiterated that there was no head palpable abdominally and the presenting part was at +1, not caput.

138. Waikato DHB did not have a policy in place requiring registrars to involve a consultant in instrumental deliveries. Dr Farquhar advised that as Dr D was credentialled to perform ventouse deliveries and was a senior registrar, she was not required to inform the consultant unless she thought the delivery would be difficult. With regard to the anticipated level of difficulty of the delivery, Dr D told Waikato DHB that she was not expecting a difficult delivery, which was why she made the decision to proceed with the ventouse delivery in the delivery room rather than in an operating theatre. Dr D told HDC:

> "Most instrumental deliveries have some level of difficulty that is anticipated. As I was able to manually rotate the fetal head, and taking into account the descent and other factors, I was confident that an instrumental delivery was safely achievable. I did not expect it would take a further 2 pulls once the episiotomy was cut; delivery over the perineum was more difficult than usual."

139. Dr Farquhar advised that in her view Dr D underestimated the severity of the warning signs. Dr Farquhar considered that Dr D's failure to anticipate the level of difficulty at the time of delivery and to call the consultant to assist was probably an important departure, as it is likely that a more senior colleague would have taken into account the warning signs.

140. The RANZCOG Guideline "Instrumental Vaginal Birth" (2015) states in recommendation 3:

> "When there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible."

141. Dr Farquhar advised that in her view the warning signs were sufficient to require the procedure to be performed in theatre.

142. I accept Dr Farquhar's advice. I am concerned that in all the circumstances Dr D did not contact the consultant. In addition, while acknowledging that this may not have had any impact on the outcome, I am also concerned that Dr D did not arrange to perform the instrumental delivery in an operating theatre. I acknowledge that Waikato DHB's practice was that assisted instrumental deliveries were normally performed in the birthing rooms if the presentation was below the level of the ischial spines, there were no expected difficulties, and there was an appropriate level of anaesthesia. The issue here is what constitutes "expected difficulties".

143. In my view, Dr D's decisions relate in part to not recognising the potential level of difficulty in performing the ventouse delivery, but also to Waikato DHB's view at the time that registrars could proceed to carry out mid-cavity rotational deliveries without first discussing the decision with a consultant. I note that Waikato DHB has now developed a protocol on "When to call the SMO", which highlights that all registrars are to call for support for all instrumental rotational deliveries.

Performance of ventouse delivery

Number of pulls

144. Dr D recorded that there were six pulls over 22 minutes. The RANZCOG Guideline recommends an upper limit of 20 minutes from the first application of the cup and, if birth is not imminent after 15 minutes, operators should evaluate whether further traction is warranted and consider recourse to Caesarean section.

145. RM B retrospectively recorded: "[B]aby delivered over ~ 6 pulls/contractions." Although Dr E recollected that there were 7–8 individual pulls, I accept RM B's and Dr D's evidence in this regard, including Dr D's documentation.

146. Dr D's notes state that there was minimal descent with the first pull, then there was significant subsequent descent with the next two pulls. Dr D performed an episiotomy with the fourth pull, and then two more pulls were required to deliver Baby A's head. Dr D recorded that there was no cup detachment. Dr Farquhar advised that the pressures used were appropriate and the pulls were achieving the desired descent and movement of the fetal head, although the number of pulls was on the upper limit. She noted that with a ventouse delivery, there is a point of no return, as Caesarean birth is not easily or safely achieved when the fetal head is far into the birth canal. I accept this advice.

Degree of force

147. Mr and Mrs A stated that at one stage, Dr D lost her grip and fell backwards from the pulling force applied. However, according to Waikato DHB, both Dr D and RM B said that Dr D did not fall backwards at any time during the delivery. Given the conflicting accounts, I am unable to make a finding as to whether this event occurred.

148. Dr Farquhar advised that the strength of the pulls or the amount of traction is difficult to assess from the notes. She said that if the cup popped off, that would often indicate use of

excessive force. However, it does not appear that the cup came off during the ventouse delivery.

149. Dr Farquhar noted that it would seem that there was some degree of force given the subgaleal haemorrhage and the 2–3cm tear on Baby A's scalp. In the circumstances, I am unable to determine the extent of the pulling force or whether it was appropriate.

Failure to contact consultant when difficulty encountered

150. As stated above, Dr D's notes record that there was minimal descent with the first pull, then significant subsequent descent with the next two pulls.

151. RM B recorded: "Vertex advanced slowly." She later told HDC that the baby's head advanced with each contraction. She said that the delivery was "a bit longer and a bit slower than is usual" but progress was steady, and she would not describe Dr D as "struggling".

152. RM C's midwifery notes indicate that in her view the ventouse was difficult. At 3.25pm she recorded, "1525 approx, became very apparent that ventouse was difficult", and at 3.30pm she recorded that Dr D was continuing to struggle with the delivery of the head.

153. Dr Farquhar advised:

> "If I was to take [Dr D's] notes as the sole source of information, I would say that there was no indication for C-section as she describes 'significant descent'. If we consider the midwifery notes then there appears to be an indication for considering C-section …"

154. Dr Farquhar stated: "I consider that [Dr D] should have called the on call consultant when she was encountering difficulties — probably around the 3–4th pull around 15.25–15.30hrs."

155. Dr Farquhar advised:

> "In my view, it is a good practice and a good principle for all clinical care by any health professional regardless of their level of training and expertise to call for assistance if they encounter difficulties in clinical care."

156. I agree with this advice. In my view, by 3.25pm Dr D should have recognised the difficulty and sought assistance from the consultant.

Care of Baby A

157. Baby A was born at 3.37pm. Following delivery, she had a lack of respiratory effort, pale mottled skin, and low tone. She had a superficial scalp laceration approximately 6cm in length, and a soft swelling of her scalp approximately 1.5cm in height.

158. House officer Dr E called for assistance, and registrar Dr H attended when Baby A was around five minutes of age. Dr H said that he suspected a subgaleal haemorrhage.

159. CPAP was continued for approximately 15–20 minutes in the delivery/birthing room before Dr H transferred Baby A to NICU for ongoing respiratory support. Baby A was admitted to NICU at around 4pm, and it was decided to undertake a ward round and return to her as quickly as possible.

160. After the ward round, care was handed over to RN G, who recorded retrospectively that Baby A was "[p]ale, hypotonic muted response with handling, Gentle palpation of head identified [a] small subgaleal bleed", and that this was reported to Dr F. RN G documented that she was unable to obtain capillary blood gas[55] and was unable to site a peripheral IV owing to Baby A's poor perfusion.

161. Dr F stated that when he carried out his first assessment of Baby A at 4.30pm it was immediately apparent that there was a subgaleal bleed and, by the time he completed his records at 10.19pm, that there was a large subgaleal haemorrhage. He said that his intention was to document that the subgaleal haemorrhage was diagnosed early and was large by the time the note was written, not necessarily that it was large at the time of diagnosis.

162. Vascular access and further blood sampling was difficult, which caused a delay. Attempts at siting a peripheral IV were unsuccessful, and at 5.30pm a short UVC was placed, and a bolus of 10ml/kg normal saline was administered. Half of Baby A's circulating volume was replaced over the course of the next 66 minutes. By 6.04pm, umbilical, venous, and arterial catheters were in place.

163. My expert advisor, paediatrician Dr Thorsten Stanley, noted that despite the very poor blood gas results, a saline bolus of only 10ml/kg was given at 6pm. He stated that Baby A's arterial blood gas results at 5.31pm strongly suggested that the bolus was inadequate. He advised that the normally recommended volume in this setting would be 20ml/kg, repeated frequently until blood products are available, to allow possible reversal of metabolic acidosis, especially when there is a concern regarding active continuing blood loss. In contrast, Dr F said that it is standard practice to titrate the volume of fluid resuscitation to the clinical response, and that frequent small boluses of 10ml/kg are standard care.

164. Dr Stanley considered that consideration should have been given to intubating and ventilating Baby A at 5.30pm, to reduce the risk of cardiac or respiratory failure or collapse. However, Dr F said that Baby A's breathing had been stabilised on CPAP, and she was not intubated until there was a change in her clinical status (transient bradycardia and the development of an oxygen requirement).

165. At 6.05pm, O negative blood was issued from the blood bank, and given at 6.18pm at the rate of 20ml/kg. Dr Stanley advised that O negative blood should have been available on a

[55] Capillary blood gas (CBG) samples may be used in place of samples from arterial punctures or indwelling arterial catheters to estimate acid-base balance (pH) and adequacy of ventilation ($PaCO_2$). A puncture or small incision is made with a lancet or similar device into the cutaneous layer of the skin at a highly vascularised area (heel, finger, toe).

continuous basis in a matter of minutes, and should have been administered as soon as it was clear that Baby A had a significant subgaleal bleed compromising her circulation. Dr Stanley was also critical that coagulation factors[56] were not given until two hours after birth. He noted that a large subgaleal bleed leads to consumption of clotting factors if the bleeding is not controlled rapidly, which prevents easy correction of the coagulopathy.

166. Dr Stanley advised that in his view, there was significant and serious delay in the diagnosis and management of Baby A's subgaleal haemorrhage. He also considered that there was a significant delay in achieving effective vascular access, and a delay in prompt correction of her hypovolaemia, anaemia, and coagulopathy. He stated that blood sampling to assess response to treatment was less frequent than expected, given the severity of Baby A's metabolic and haematological disturbance. I accept this advice.

167. Dr J advised ACC that in his view, the subgaleal haemorrhage was mistakenly assessed as small, whereas there was a significant degree of hypovolaemia by 5.00pm. Dr J advised that it would have been more appropriate to initiate rapid fluid resuscitation, ideally with whole blood, by 5.00pm, and that by the time red blood cells were given, Baby A had profound metabolic acidosis due to exsanguination. Dr J also considered that the red blood cell transfusion was too low a volume and given more slowly than required, and that there was a delay in recognising that further subgaleal bleeding occurred over the first night, and thus a delay in providing further blood transfusions. I note that the ACC advice was obtained for different reasons and that Dr J did not have access to the NICU observation charts.

168. It is clear that these are matters on which different clinicians hold different views. Dr F considered that there was no delay in recognising the diagnosis or its significance. He said that the delays in achieving vascular access were not through negligence or incompetence, but were "a reflection of the real difficulties faced in neonatal care". However, Dr Stanley and Dr J have identified similar serious concerns, and for that reason I am inclined to accept the advice of my independent advisor, Dr Stanley, that the management was suboptimal.

Conclusions

169. At the time of these events, Waikato DHB did not have a policy in place requiring registrars to involve a consultant in instrumental rotational deliveries. In addition, the practice was to perform ventouse deliveries in the birthing room rather than in an operating theatre if the presentation was below the level of the ischial spines, no difficulties were expected, and there was an appropriate level of anaesthesia.

170. Dr D was credentialled to undertake instrumental deliveries independently, which meant that she was solely responsible to determine whether she required support and whether the delivery should take place in theatre. In the event, it appears that Dr D underestimated the likely level of difficulty of Mrs A's ventouse delivery, and consequently did not consider

[56] Plasma components (such as fibrinogen, prothrombin, thromboplastin, and factor VIII) that are involved in the clotting of blood.

it necessary to contact the consultant or carry out the delivery in theatre. In addition, when Dr D did encounter difficulties, it is concerning that she did not request support from the consultant.

171. My expert advisor, obstetrician and gynaecologist Dr Cynthia Farquhar, advised:

> "There should be education about the importance of risk assessment for potentially difficult deliveries and having a low threshold for calling the consultant even when experienced and credentialed."

172. I note that Waikato DHB's women's service has created a new guideline on assisted vaginal delivery, and that education and regular registrar teaching sessions have been implemented, with instrumental deliveries being covered extensively in the sessions.

173. I am critical that Waikato DHB's policies at the time did not provide more guidance to registrars about the "red flags" that would necessitate contact with the consultant, and, in particular, did not require a consultant review prior to rotational instrumental deliveries when such "red flags" existed. However, as noted above, Waikato DHB has created the new guideline on assisted vaginal delivery, and implemented regular education and registrar teaching sessions. Waikato DHB has also developed a protocol on "When to call the SMO", which requires that registrars call for support for all instrumental rotational deliveries. I consider these changes to be an appropriate response to the circumstances of this case.

174. With regard to the care provided to Baby A, I acknowledge that efforts were made to treat the subgaleal haemorrhage and minimise the harm Baby A suffered. However, I remain of the view that a number of Waikato DHB staff failed to act sufficiently promptly and effectively to what was an evolving emergency situation. Baby A had a severe subgaleal haemorrhage, and management was inadequate in that treatment was delayed. Baby A was born at 3.37pm, but it took until 5.30pm to site a short UVC, and until 6.04pm to put in place umbilical, venous, and arterial catheters so that effective fluid resuscitation and blood transfusion could commence. When fluids were initiated, the volumes were inadequate.

175. I consider that Waikato DHB failed to provide adequate guidance to staff in relation to seeking consultant support when undertaking potentially difficult deliveries, and that a number of staff failed to respond sufficiently promptly and effectively to Baby A's subgaleal haemorrhage. I therefore find that Waikato DHB failed to provide services to Mrs A and Baby A with reasonable care and skill, and breached Right 4(1) of the Code.

Opinion: Dr D — adverse comment

Ventouse delivery

176. Dr Farquhar stated that in her opinion Mrs A's presentation was consistent with deep transverse arrest in the mid cavity, and there were adverse clinical features that could be regarded as "warning signs". These were the lack of descent below the ischial spines (station 0), the failure of the fetal head to rotate to the OA position after nearly three hours at full dilatation, and pushing for 90 minutes. Dr D recorded that the station was "+1 with pushing", and Dr Farquhar said that she interpreted that as station 0 when not pushing. She noted that when the position is ROP and there is moulding and caput, the station may appear to be +1 when in fact it is more likely to be station 0. However, I note that in response to the provisional opinion Dr D reiterated that there was no head palpable abdominally and the presenting part was at +1, not caput.

177. Dr Farquhar advised that the station was only one factor, and that other warning signs that it would be a difficult delivery were the caput and malposition.

178. As Dr D was credentialled to perform ventouse deliveries and was a senior registrar, she was not required to inform the consultant unless she thought the delivery would be difficult.

179. Dr D was not expecting a difficult delivery, so she decided to proceed with the ventouse delivery in the birthing room rather than in an operating theatre. The Waikato DHB practice was to perform ventouse deliveries in the birthing room rather than in an operating theatre if the presentation was below the level of the ischial spines, no difficulties were expected, and there was an appropriate level of anaesthesia.

180. In my view, Dr D underestimated the likely level of difficulty of the ventouse delivery, and consequently did not contact the consultant or arrange to perform the ventouse delivery in an operating theatre. I am critical of these failings, but accept that Waikato DHB did not have in place a policy that required registrars to involve a consultant in all instrumental deliveries. I note that subsequently Waikato DHB developed a protocol on "When to call the SMO", which highlights that all registrars are to call for support for all instrumental rotational deliveries.

Informed consent

181. On Day 8 at 11.45am, Dr D reviewed Mrs A. Mrs A appeared exhausted, but was comfortable with an effective epidural block. The CTG was reassuring, and no fetal head was palpable abdominally. The records state that the VE showed full dilatation, ROT/ROP, central caput, and mild moulding, and the presenting part was 1cm below the level of the maternal ischial spines at station +1. The oxytocin was increased to 8ml per hour.

182. Mr and Mrs A told HDC:

> "We believe a thorough assessment done at that time could have identified the cluster of risk factors that were present which would have elevated this birth into the

> 'High Risk' category. Alternatives such as a caesarean were not considered or offered to us despite the risks."

183. By 2.10pm, there had been no further descent of the baby's head, and Dr D was informed of the lack of progress.

184. Dr D examined Mrs A. No fetal head was palpable abdominally, and a VE found that Mrs A was fully dilated and the baby's position was ROT/ROP, with central caput[57] and mild moulding[58] present, and the station was +1. Dr D said that she discussed the findings with Mr and Mrs A and explained the clinical situation. Dr D stated that the options discussed were either an attempted rotation of the fetal head and continued pushing, or an instrumental delivery. Mrs A verbally consented to manual rotation of the fetal head, which was attempted, but was unsuccessful.

185. Dr D recorded:

> "d/w [discussed with] [Mr and Mrs A] further pushing for half hour v/s [versus] assisted delivery [with] ventouse given positioning & slow progress — elected & consented to ventouse."

186. Dr D said that she explained the risk of bruising and swelling to the baby's head from an instrumental delivery, and that Mrs A said, "do what you think is best" on two occasions. In response to the provisional opinion, Mr and Mrs A said that it is untrue to say that Mrs A elected and consented to a ventouse delivery, and "the only discussion had at that time was [Dr D's] decision to use the ventouse and [Mrs A] agreeing due to trust that this was the safest method of delivery".

187. Dr D said that she obtained verbal consent for the ventouse procedure twice. She stated that she did not discuss the option of a Caesarean section because "it is not recommended best practice with the above findings and certainly not without significant risk". She said that she discussed only the options that she was prepared to recommend and to undertake.

188. The RANZCOG Guideline states that a clear explanation should be given and consent obtained appropriate to the clinical situation. Dr Farquhar noted that the guidelines do not say whether or not women should be offered the option of a Caesarean section at the time of decision-making about a ventouse delivery. She noted that accepted practice is likely to be varied, and that any discussion or recommendation would usually include a discussion of alternatives. However, Dr Farquhar advised that although a Caesarean section was an option, there was no reason to recommend it, as the baby's head was at station 0 and the CTG was normal.

189. Dr Farquhar noted: "This does not mean that [a Caesarean section] should not have been discussed with [Mr and Mrs A]." Dr Farquhar advised that it would have been reasonable

[57] A diffuse swelling of the scalp caused by the pressure of the scalp against the dilating cervix during labour.
[58] The bones of the fetal head move closer together or overlap to help the head to fit through the pelvis.

to tell Mrs A that a Caesarean section was one option, and then provide reasons why a ventouse was the preferred option. I agree.

190. Dr Farquhar said that the possible fetal adverse events with the ventouse should have been mentioned, such as swelling around the placement of the cup, and cephalohaematoma,[59] which occurs in 10% of births following ventouse delivery. Dr Farquhar advised that as a subgaleal haemorrhage is rare — occurring in 1 in 300 ventouse deliveries — it would not need to be mentioned specifically.

191. Waikato DHB stated in response to the provisional opinion that "it seemed unrealistic to expect that [Dr D] would have discussed all the risks, and pros and cons of all the alternatives in treatment". The DHB stated that it does not think a Caesarean section should have been discussed with, or offered to, Mrs A because it would not recommend a Caesarean section in these circumstances. It submitted: "Expecting that a clinician offers a procedure he/she believes is not a recommended option will likely put patients at risk and cause more harm."

192. Right 6 of the Code states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. That information includes an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option. The Code does not state that a clinician should discuss only the options he or she is recommending.

193. I remain of the view that Dr D did not fully discuss with Mrs A the risks of an instrumental delivery, and should have discussed the option of a Caesarean delivery. While I accept my expert's advice that there was no reason to recommend a Caesarean section, it was important that Mrs A understood the reasons for recommending a vaginal delivery with ventouse as the preferred option, and I am critical that this discussion did not take place.

Other comment

194. I am concerned by Mr and Mrs A's statements that it would be untrue to say that Mrs A elected and consented to a ventouse delivery, and at the responses by the DHB and Dr D to the informed consent matters raised in my provisional opinion.

195. Recently, the Commissioner and I met with representatives from RANZCOG[60] to discuss (among other matters) our concerns about the adequacy of the information provided to women about mid-cavity rotational instrumental deliveries, and were advised that the following information would be provided to clinical directors and members of Te Kāhui

[59] A cephalohaematoma is a collection of blood between a baby's scalp and the skull. Blood vessels damaged during labour and delivery release the blood, and the blood pools into a mass under the skin of the scalp.
[60] The meeting took place on 20 September 2019.

Oranga ō Nuku (formally the New Zealand Committee) prior to further discussion at upcoming RANZCOG meetings:

> "When booking at a hospital for birth it may be beneficial to provide information about the specialist care provided within the facility, even though a primary birth is expected. Such information is not explicit in NZ antenatal education courses. Patient Information along the lines of both RANZCOG's and RCOG's 'Assisted Vaginal Birth' may help explain what may occur if labour and delivery does not follow an expected primary birth pathway. Such information may help women's understanding of the Obstetrician's role when this is unexpectedly needed during labour and delivery.
>
> Fellows and trainees are encouraged to weigh the risks of adverse perinatal and maternal outcomes when mid cavity rotation assisted deliveries are considered, particularly when there are already fetal concerns. It is appreciated that timely access to theatre, especially after hours, cannot be guaranteed in many units. Consequently, given the time critical nature of some evolving situations, practitioners should consider providing adequate early information about potential delivery options wherever possible.
>
> Informed consent should be clearly documented for significant labour interventions, with the reason for the planned intervention and clear explanations of attendant risks and benefits. When an assisted vaginal delivery is planned, this should also include information about any potential Caesarean Section delivery and if in theatre written consent is advised.
>
> Practitioners should be aware of the recent BJOG August 21st Canadian paper 'Perinatal & maternal morbidity and mortality among singletons following midcavity operative vaginal delivery versus Cesarean Section' by Muraca et al. This paper explores serious perinatal and maternal outcomes in relation to midcavity assisted delivery compared with Cesarean Section at full dilation and conclusions may eventually, if confirmed, supersede previous recommendations."[61]

196. In addition, HDC was advised that it is anticipated that the RANZCOG 2016 guideline on instrumental deliveries will be updated; the 2020 ASM Committee will be requested to arrange a debate about "Midcavity Assisted Delivery or Cesarean Section in 2020?"; and that at the RANZCOG annual Obstetric Skills Day in Wellington for new trainees in November, alongside the practical skills workshops, there will be a virtual scenario of an attempted assisted delivery that fails, with the need to manage the subsequent emergencies.

[61] Per Chair RANZCOG Dr Celia Devenish.

Recommendations

197. I recommend that within three months of the date of this report, Dr D arrange refresher training on informed consent, and provide evidence to HDC of having arranged the training and the content of the training.

198. Waikato DHB has agreed to undertake the following:

a) Review the "Practice Recommendation on the Management of Neonatal Subgaleal Haemorrhage" with a view to adopting the guideline or preparing a guideline specific to Waikato DHB, and report the outcome to HDC.

b) Review the implementation of the protocol "When to call the SMO", to ascertain whether registrars do call for support from consultants for all instrumental rotational deliveries.

c) Include in the SMO and RMO "Responsibilities and the limits of delegation of responsibilities to RMOs" policy a statement about what to do if any concerns arise while undertaking procedures, when the policy is renewed in November 2019.

199. I recommend that within three months of the date of this report, Waikato DHB review the effectiveness of its "Speaking up for Safety" programme and the pathway to follow in serious events with adverse patient outcomes, and report back to HDC on the outcome of the review.

200. I recommend that within three weeks of the date of this report, Waikato DHB provide a written apology to Mr and Mrs A for the failings identified in this report. The apology is to be sent to HDC for forwarding.

Follow-up actions

201. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waikato DHB, will be sent to the Medical Council of New Zealand, and it will be advised of Dr D's name.

202. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waikato DHB, will be sent to RANZCOG, the Royal Australasian College of Physicians (Paediatrics and Child Health Division), the Midwifery Council of New Zealand, the New Zealand College of Midwives, and HQSC, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

203. I intend to continue discussions with RANZCOG on how and when information can be provided to women about assisted deliveries, and also to raise this with the Midwifery Council of New Zealand and the New Zealand College of Midwives.

Appendix A: Independent Paediatric advice to the Commissioner

The following expert advice was obtained from paediatrician Dr Thorsten Stanley:

"**COMPLAINT: WAIKATO DISTRICT HEALTH BOARD**
Your Reference: C18HDC01259

Thank you for asking me to provide an opinion regarding the management of [Baby A], date of birth [Day 8]. Thank you for providing background regarding this case. I note that I have not been provided with details of her long-term outcome (she must be now almost two years of age), however, I have grave concerns that her outcome will not be good.

The only longitudinal data I have is in the form of a head circumference chart which plots her reducing head size up to the age of four weeks. This would suggest that an event has occurred that has led to a reduction in the size of her brain. It is my presumption from the description of the case made available to me that [Baby A] will in fact have significant brain injury. This is consistent with her [MRI scan] which showed intracranial subdural blood and cortical changes likely due to cortical laminar necrosis (significant death of brain cells). I note that when seen in clinic at two months of age she was said to be smiling (it is not clear whether this was responsive smiling or reflex smiling) and cooing. She is also said to be turning her head to a voice. At two months of age turning her head to a voice would be rather advanced unless it is measured in a supine position.

The issue at hand is the acute management of a baby who has experienced a subaponeurotic (subgaleal) haemorrhage. Whilst [Baby A] suffered later complications (ie acute renal failure, a commonly-associated problem) her renal failure was the longer-term outcome of the event that occurred within the first day of life. I will therefore concentrate my comments on her management from the time of birth onwards.

[Baby A] was her mother's first pregnancy. It had been uncomplicated up until the time of delivery. She was delivered at 40 weeks gestation. Towards the end of pregnancy abnormal Dopplers were noted and as a result labour was induced.

Thin meconium staining was noted at the time of delivery and a Ventouse extraction was performed. This was described as a *very difficult* extraction. The newborn record (summary of prenatal history and delivery) does not give details of intrapartum fetal monitoring but notes the presence of thin meconium. Cord pH is not documented. A malformation of the placenta is described but no further detail provided on this form. First stage is documented at 8 hours and 45 minutes and the second stage at 4 hours 24 minutes.

Delivery was on [Day 8] at 3.37pm. Expected date of delivery was [Day 5]. On this form, (Page 2) Apgar score is delineated at 4, 6 and 8 at one, five and 10 minutes. First feed is documented at 60 minutes and skin to skin at 60 minutes. Birth weight is 3.458

kilos (normal), **length and head circumference are not documented**. The Neonatal sheet describes induction of labour because of abnormal Dopplers. No pregnancy complications are described. No medication was provided during pregnancy prior to delivery and labour was as a result of induction. Nitrous oxide analgesia is described but no other analgesia.

Delivery was by Ventouse as described. The one minute Apgar scores were 2 for heart rate, 1 for respiratory effort, 0 for tone, 1 for reflex irritability, 0 for colour. By five minutes 2 for heart rate and 1 for each of the other parameters, reaching 2 for heart rate, 2 for respiratory rate and 2 for reflex irritability by 10 minutes with 1 for muscle tone and colour. CPAP using an air puff was used for resuscitation. The form was signed by [Dr E]. The examination was described on [Day 8] at 1615 hours 45 minutes after birth. There is no other examination of the baby described on this form.

[Dr E] (Paediatric SHO) was actually present at delivery and his first note documented at 1430 hours prior to the birth of [Baby A]. He was asked to attend the instrumental delivery of [Baby A] who was documented on this note (clinical notes) as being at 40 weeks and three days. He describes the labour as being difficult. There was a two-hour delay to full dilatation and a decision was made to use Ventouse. He then describes the baby's condition at birth. The time of delivery is not documented in his notes. I presume that the other descriptions (1537) are correct.

At birth he noticed the presence of a small scalp laceration, thought to be secondary to the Ventouse. He also notes the presence of what he describes as a large cephalhaematoma and he raises the question of a **possible subgaleal bleed**. Saturations are 100% in room air. He said the baby was delivered stunned with poor respiratory effort although the heart rate was over 100 and there was poor tone. The baby responded to injections. The colour remained pale. (It is hard to see how an Apgar score of 1 for colour was achieved when baby was pale — as that should score 0.) He notes that the antibody test is negative, that the mother is Rubella immune and the VDRL, Hepatitis B and HIV tests are all negative. He notes the baby is given CPAP at 15 minutes and is transferred to Neonatal Intensive Care. He feels that the airway and breathing and air entry are adequate. He asks the registrar [Dr H] to assist. **Moderate work of breathing is noted with intercostal and subcostal recession,** 1mg of Vitamin K is given.

He writes: Impression:

1) Stunned baby.

2) Breathing spontaneously with adequate saturations, thin meconium exposure and

3) Plan to continue in Neonatal Intensive Care and do capillary gas in one hour.

There is then a registrar's note (which is untimed) on [Day 8]. The registrar ([Dr H]) describes on her/his arrival before five minutes of age the heart rate was more than 100, there was spontaneous respirations but there is tachypnea (rapid breathing) with increased effort. CPAP of 5cms of water is being given and is being appropriately

applied, the baby requiring only room air. The baby is described as being **pale with no spontaneous movement and reduced tone**. Her pallor was not in keeping with her heart rate of over 100. Unfortunately this important clinical sign was not recognised for its significance. A pale baby with a reasonable heart rate usually has suffered a volume loss and is anaemic. This is commonly seen after babies such as where there is a rupture of the infant vessels because of an abnormal insertion into the placenta for example.

However, [Baby A] appears to have been managed on the basis that she was asphyxiated even though her Apgar score at 10 minutes was 8 which would be usual for a baby with significant asphyxia. First cry is at seven minutes with some spontaneous movements and increased tone by five minutes. Saturations are 100% in room air at seven minutes. CPAP is continued and a decision is made to transfer to Neonatal Intensive Care. Significant soft tissue swelling of the scalp is noted, epidermal injury with dermis exposed. **S/He also queries a subgaleal haemorrhage.** The baby is noted to be posturing abnormally, with extensor movements on arrival in Neonatal Intensive Care. The maternal history is reviewed. S/He wonders whether the baby might be stunned, whether it might have hypoxic ischemic encephalopathy or whether there might be a subgaleal haemorrhage. The plan is made to simply continue the same management (respiratory support). There is **no further documentation in the notes until 2130 hours**.

Unfortunately, [Dr E] has not acted on the probable subgaleal that he or she has recognised in the newborn period. A capillary gas is planned to be done at one hour. No head circumference is documented.

Mum's relatively straight forward perinatal history is again documented. [Dr H] writes s/he thinks that this baby is either 'stunned' or has the baby got a hypoxic ischaemic encephalopathy (asphyxia) (which I think is the possibly same thing!) or does the baby have a subgaleal haemorrhage.

[Dr H's] plan is simply to continue management in Neonatal Intensive Care. In my opinion this represents inadequate management of a baby who appears to be suffering from shock. Capillary refill time is not described. A cord gas appears not to have been taken which is in my opinion suboptimal assessment if asphyxia is being considered. An early cord lactate can be very helpful in planning subsequent care.

The next note is not until 2130 hours and written in retrospect. This note is written by [RN G] who I think is a Neonatal Nurse Practitioner or Clinical Nurse Specialist. She describes (written in retrospect) a handover at 1630 hours. The baby is already now an hour of age. Apart from CPAP support there appears to have been no invasive management of this baby who has by description poor circulation and features to suggest severe anaemia. The baby is in room air with saturations of 100%. This should also strongly suggest the baby's respiratory distress is not due to significant lung disease given the baby is not requiring more than room air. The baby is described as pale, hypotonic (next word illegible), response with handling. Gentle palpation of the

head identifies **a 'small' subgaleal bleed**, as reported by [Dr F] when he was in attendance later. A capillary gas is attempted but is unsuccessful. Attempts are now made to put peripheral intravenous lines into this baby but because of poor perfusion this fails.

This suggests to me the subgaleal bleed is **massive, not small**. Umbilical arterial and venous lines are subsequently inserted with a little difficulty. At this stage the baby's condition is deteriorating rapidly with reduced response to handling, and reduced peripheral perfusion. Normal saline 35 mls (10 mls/kg) is given at 1700 hrs.

(This is a manifestly inadequate volume in a baby with significant hypovolaemia and suggests a lack of understanding of the urgency and severity of the situation that can arise after a subgaleal bleed.)

A cross match is done, coagulations are taken and a blood culture. [Dr F] is called to be in attendance (timing of call, timing of arrival not documented) due to concerns.

Unfortunately, the first gases taken on this baby's umbilical line samples show the baby is **severely acidotic** with a pH of 6.55 and a base excess of –30.6 and a lactate of 20. The pCO_2 level is not elevated, confirming the acidosis is entirely due to hypovolaemic shock. There is no documentation of the clinical response to the first saline bolus.

AN HOUR subsequently the baby is given further saline 10 mls/kg, 15 minutes later uncross-matched O negative red blood cells and 30 minutes later subsequently cryoprecipitate.

Unfortunately, a 'long gap ECG pattern' is recognised and chest compressions are started (timing of the chest compressions in relation to the recognition of severe shock is not documented). Sodium bicarbonate is given and the baby is now electively intubated (with ease) to secure the airway. Calcium gluconate is given intravenously, chest x-rays and abdominal x-rays are taken.

A repeat arterial blood gas shows a pH of 6.9, a base excess of –26 and a lactate still of 22. Cross matched O negative blood is now given at 20mls per kilo. Repeat coagulation studies are taken. [Dr F] discusses the grave concerns regarding the baby's condition with parents and in particular both short and long term prognosis.

[Dr F's] note is documented at 2219 hours. He confirms the presence of a large subgaleal haemorrhage which he says is 'identified early'.

Unfortunately, I cannot find any documentation of this fact — early notes only describe a possible small subgaleal.

He describes how there is a struggle to maintain normovolaemia (adequate blood volume) and that there is severe metabolic acidosis. He doesn't feel the baby has any respiratory disease and that the baby is hyperventilating to mitigate a metabolic

acidosis. He describes a degree of coagulopathy with some difficulty initially getting transfusion service access to fresh frozen plasma, but cryoprecipitate is given. He describes significant red cell support with 20mls per kilo, subsequently 10mls per kilo, 6mls per kilo and 10mls per kilo, (i.e. >half a circulating blood volume) in addition to clotting factors. A decision is now made not to actually cool this baby. Although not documented in the notes, in fact passive cooling *was* started in the immediate period after the baby was born.

There is subsequently a note from […] PM (signature illegible but presumably a pm shift nurse specialist). In this is described, 'Received [Baby A] from Delivery Suite at 1600 hours (ie half an hour after birth), placed on 6cm CPAP initially and 40% oxygen but weaned to room air. Tachypnoeic on arrival with a heart rate initially of 140 to 160 which is then noted to be dropping and unable to take a capillary gas due to **extremely poor perfusion and a pale baby++**. The baby then started to drop the heart rate and respiratory rate and the head was noted to have a subgaleal bleed, less responsive. Lines were inserted by [RN G], Neonatal Nurse Practitioner at 1700 hours to get blood samples. UVC gas noted to be even worse with a pH of 6.46 and a PCO_2 of 10.3, the arterial gas being 6.56 and PCO_2 of 3.35 (kilopascals). Her condition continued to deteriorate with little to no response to handling. There were two boluses of normal saline as documented. Coagulations and a cross match were taken by [RN G], [Dr F] was in attendance and O negative red cells were given. Heart rate unfortunately remained in the low 110s to 120s. O negative red cells were given 1818 hours. There was further deterioration in the heart rate. Chest compression was given at 1635 hours as the heart rate dropped into the 60s. A narrow complex tachycardia was noted. Cryoprecipitate was given 1841 hours, intubation occurred at 1846 hours, calcium gluconate at 1835 hours, sodium bicarbonate subsequently and multiple red cell transfusions given as documented.

I have found a sheet which I think represents the fluid management of this baby. Initially as mentioned there was no line inserted. The first documented intravenous fluid was at 1700 hours in the form of a normal saline bolus (35mls). A further 35mls was given at 1800 hours one hour later. The first red blood cells are not given until 1818 hours. This is almost three hours after baby's birth and **is far too late**. Red cells (70mls or 20mls per kilo) are given at 1818 hours and a further 35mls (10mls per kilo) is given subsequent to that. Cryoprecipitate is given 35mls at 1839 hours slowly. Red cells are then subsequently given at 1923 hours.

The total blood given to this baby prior to stabilisation is 380mls. This exceeds the baby's whole blood volume, which is normally recognised to be 80mls per kilo.

Unfortunately, I think the staff involved markedly underestimated the degree of hypovolemia this baby was experiencing.

Serial measurements of head circumference have been described as one way of defining the degree of blood loss (each cm equals 40 mls of blood loss, Up To Date

2018). Unfortunately, no initial head circumference was measured and as a result this valuable information was never acquired.

In my opinion, by the time this baby suffered her severe metabolic acidosis (with the first sample at 1731 hours showing a pH of 6.46 venous, 6.56 arterial) the 'writing was on the wall'. It would be highly unusual for a baby with this degree of acidosis to survive without suffering significant injury. In fact, [Baby A] suffered injury both to her kidneys and her brain. The conclusion from the renal team from [a children's hospital] is that she would require a renal transplant probably within the first year of life (if my understanding is correct). Certainly, although she was described in the discharge summary as having a 'reassuring MRI scan' this is **far from the case**. The Radiology report (paragraph 3) describes changes in the cortex demonstrated in a few gyri related to the posterior superior left temporal lobe and insula cortex are likely due to the effects of **cortical laminar necrosis**; the more typical effects of significant hypoxic ischaemic injury involving the basal ganglia, peri Rolandic cortex and hippocampi are not seen. I suspect the last part of the paragraph reassured staff that in fact brain injury had not occurred but cortical laminar necrosis has a very poor prognosis. (see reference: van der Knaap MS et al. Neuropediatrics 1993; 24(3) 143–148)

This MRI scan was performed relatively early in [Baby A's life]. She was only 13 days old at that time and I suspect that a further MRI at a later point would have better delineated injuries that have occurred essentially postnatally.

The MRI request also suggests that she was not significantly encephalopathic. However, her grossly abnormal posturing in the first few hours of life and her subsequent seizure would suggest this is not the case. Furthermore, there is no record of her having had an EEG monitoring. It is possible that was elected not to be carried out because of her coagulopathy as these days this is carried out with subcutaneous needles. There is of course a potential to apply electrodes with adhesive but this is technically more challenging.

Her initial blood gas, soon after birth was not normal. She had a capillary sample taken at 1546 hours on [Day 8]. This showed an elevated lactate of 5, low normal haemoglobin of 145, bicarbonate of 18.45, a base excess of –6.4 and a pH of 7.3. This gas shows a degree of metabolic acidosis but not severe. It will certainly not be consistent with a baby with severe perinatal asphyxia.

Had the subgaleal haemorrhage been recognised to be potentially life threatening, her management would have no doubt been different. Umbilical arterial and venous lines would have been placed immediately in the newborn period allowing access for transfusion. Coagulation factors and haemoglobin would have been measured on an immediate postnatal sample. Serial measurements would have been considered. Serial head circumferences would have confirmed that in fact she was developing a large subgaleal bleed. The management of a significant subgaleal bleed is immediate replacement with blood and coagulation factors. She did not receive anything except normal saline for two hours after her lines were first inserted. This in spite of her

arterial blood gas at 1804 hours showing a haemoglobin of 77. I suspect by the time those gases were taken it was too late to save her. However, it is not clear whether O negative uncrossed match blood is immediately available for rapid treatment in Waikato. Such blood is necessary to save the lives of babies who also have bleeding from their umbilical vessels (as I described earlier). A delay of an hour can sometimes be enough to convert a baby from a full recovery to one with irreparable brain damage.

I see the problem here is a failure to recognise the seriousness of ANY subgaleal bleed in the immediate postnatal period.

Extracting information from these notes has been a challenge; at present each tertiary unit uses their own notes. Hopefully the widespread adoption of a unifying database (Badgernet) will allow more rapid and accurate data access.

Similarly, I was not provided with the obstetric or perinatal notes. I presume an obstetric/maternity expert has been asked to provide feedback on [Baby A's] earlier management which led to the subgaleal bleed in the first place.

It appears staff responded slowly to worrisome clinical features in [Baby A].

Management of infants and children in children's wards has been revolutionised by the development of paediatric early warning system vital signs (PEWS) charts. These make it easier for staff to recognise when an infant is requiring an escalation of care, including the potential for consultants and intensivists to be called to a child (by nursing staff) even when junior staff are not worried.

It is possible that similar charts should be developed for infants especially in units that deal with infants of many different gestations. Normative values are very different in term babies versus very preterm ones.

The intensive care charts forwarded to me from Waikato are difficult to read in a black and white copy as they have the different components in different colours. The NICU respirator support chart from [Baby A's] first day of life demonstrate a pulse rate of 170 at 1600 and 1700 hours. In a full-term baby this would be regarded as tachycardia; there was associated tachypnoea at 70/min. There was a rapid drop in pulse at 1800 hours to 120/min which coincides with fluid resuscitation. Of note the initial temperature is documented at 1600 hours at only 31.9 degrees C. This temperature is measured by the axillary route. This predates the use of cooling, with the radiant warmer set at 36 degrees C. I believe this represents significant hypovolaemic shock.

We also experienced a baby with a severe subaponeurotic haemorrhage [this year]. This baby also had been delivered by Ventouse, a well-recognised risk factor for subaponeurotic haemorrhages. It is recommended all babies delivered by Ventouse should have a careful evaluation for the development of such a complication. The subgaleal haemorrhage was noted in Wellington over the first hour and was managed

with replacement O negative blood, fresh frozen plasma and an initial bolus of saline. This baby received replacement of 98% of its circulating blood volume with red cells over the first four hours as well as multiple boluses of cryoprecipitate to rapidly normalise the coagulation markers. The baby made a full recovery.

It is *possible* [Baby A] may well have been a much worse case than ours. It is certainly possible that she would not have responded to treatment even if she had been managed aggressively from the start. There remains a mortality with sub aponeurotic (subgaleal) haemorrhage today although it is not clear whether this mortality also reflects delayed diagnosis.

I noted that [Baby A] was later managed with bean bag compression of her head. There is only a little evidence to suggest this is useful management and is often used at a later stage. Prime treatment (see references) involves rapid replacement with blood and coagulation factors. Early on after massive bleeds into the subgaleal space there is compensated hypovolaemic shock; initially the baby's heart rate and blood pressure may be normal but there is pallor and mottling which goes on to hypothermia and slow capillary refill (not documented in this case), whereas subsequently with a failure of compensatory mechanisms the baby then develops secondary hypotension tachycardia, decreased cardiac output and decreased urinary output and development of a secondary disseminated vascular coagulation. The early coagulation problems are related to consumption within the subgaleal bleed which can completely deplete the baby's blood of the capacity to clot. These babies may require massive volumes of coagulation factors to correct such consumption, on occasion necessitating exchange transfusion. This requires very frequent sampling.

I note there was some early confusion that her parents might both have a coagulation disorder. The interpretation of the coagulation disturbances in the affected infant can be very challenging especially as the disease progresses if it is not aggressively managed early on.

Other risk factors apart from the use of vacuum extraction include a prolonged second stage, repeated or prolonged use of the vacuum and of course primigravida mothers such as this one. Coagulopathy is only seen in babies with severe subgaleal haemorrhage and therefore an early coagulation screen on the cord blood would have helped to delineate this baby's difficulties.

There appear to be no easily accessible guidelines to management of this condition but a paper in an obstetric journal by Swanson A et al (Subgaleal hemorrhage: Risk factors and outcomes. Acta Obstetrica et Gynecologica Scandinavica Feb 2012 260–263 and an older article by Julie Reid ('Neonatal Subgaleal Hemorrhage'. Neonatal Network Vol 26 (4) July 2007 219–227) and also Davis DJ Neonatal subgaleal hemorrhage: diagnosis and management. CMAJ 2001; 164 (10) 1452–1463 provide reasonable detail. The Australasian Advanced Paediatric Life Support course does not cover management at present which is unfortunate as this condition may occur in any unit, not just level 3 NICU's.

I am delighted to learn the Australasian Neonatal Network is putting together detailed management guidelines which may go some way towards improving outcomes

I note [Baby A] was said to have a normal neurological examination (Dubowitz) at discharge. Unfortunately, as far as I can tell the examiner presumed her to be newborn whereas in fact when she was examined she was already 4 weeks old.

SUMMARY

To respond to your questions:

1 I believe there was significant delay in confirming the diagnosis of severe subgaleal bleeds and subsequent hypovolaemia and consumptive coagulopathy.

I believe this delay potentially led to serious kidney damage and brain injury as yet not fully defined.

This delay in effective treatment was a **significant departure from recommended practice**, bearing in mind clinicians are not well supported by official guidelines on recommended treatment although there is good literature and Up to Date confirms urgency of diagnosis and treatment.

2 The management of this condition requires considerable experience on the part of the treating physician and should in my opinion have consultant involvement from the time of diagnosis. It remains unclear when the diagnosis of subgaleal haemorrhage was finally entertained but significant hypovolaemia, cause uncertain would allow instigation of valuable treatment whether this be due to massive fetomaternal haemorrhage, ruptured fetal vessels or whatever. It is unclear at what stage after birth the consultant was called — he certainly was not present in the first hours of life and mention of his involvement only follows after [Baby A] had her cardiac arrest/cardiopulmonary resuscitation.

The documentation of communication with senior staff early in [Baby A's] life, if it occurred, is not of an acceptable standard and **represents a significant departure from standard practice.**

3 Similarly documentation of medical and nursing review and management of this very sick baby in the first hours of life is also inadequate and is at **a level that is a significant departure from standard practice.**

It is uncertain if the complications [Baby A] experienced could have been avoided even with optimal care as I cannot be certain how rapidly she bled into her subgaleal space but *timely management* would undoubtedly have limited these complications and might have prevented them altogether.

4 All infants at increased risk of subgaleal haemorrhage should have repeated clinical review, early vascular line insertion and frequently repeated blood count and coagulation screen as indicated, as well as serial head circumference measurements.

Head circumference is an easy and accurate measurement in the newborn period. It is my impression it is often omitted, (also in my region of practice).

There is a need for a readily available locally produced management guideline for this condition with bullet points on which babies are at risk, how to recognise signs of subgaleal bleeds, how to recognise severe bleeds and how to manage them effectively. I believe this is being prepared this year."

Addendum 24 February 2019

"Thank you for providing the replies from [Dr F] and [Dr H]. I note also the NZ Newborn Clinical Network has recently published a Practice Recommendation on the Management of Neonatal Subgaleal Haemorrhage although this was not available at the time of [Baby A's] birth. I will refer to this document as a reference (reference A) as it contains much useful information, and the references contained in this document *were* all available at the time of her presentation.

I am grateful for the provision of further information by [Dr F] and [Dr H] which I was unable to extract from the notes as provided to me. I will comment on [Dr F's] responses as he has presented them.

Paragraph 1.

I am delighted to learn [Baby A] appears to be making very good developmental progress at 2 years of age, in spite of her early life experiences. I hope her progress continues to be normal for age, as she reaches an age where cognitive milestones can more accurately be assessed (i.e. 5–10 years). (references available)

Paragraph 2.

My assessment of her brain injury is not speculative, but based on definite changes on her MRI scan. I accept a reduction in head growth percentile would be expected as the blood products are reabsorbed from her subgaleal haemorrhage. She appears to be following on the 50th percentile for head growth. This is the expected trajectory if her parents also have (individually or averaged) heads on the 50th percentile.

Paragraphs 3,4,5. No comments required.

Paragraph 6.

I am grateful to [Dr F] for pointing out the location in the notes of a record of [Baby A's] first head circumference measurement, at 37 cm, shortly after birth. **A measurement of 37 cm is very abnormal in this setting, especially if head growth in utero has been normal (35 cm is an average head circumference at 40 weeks)** and should have immediately raised suspicions of a subgaleal haemorrhage, especially in an infant of normal birth weight ([Baby A's] weight was approximately on the 50th percentile).

I note [Dr H] expressed uncertainty as to [Baby A's] actual head circumference as it was measured with a bonnet over the head. A subgaleal haemorrhage is the result of the scalp being forcefully pulled off the underlying tissues as part of the birthing process: it is extremely painful and applying a bonnet may have been very unpleasant for [Baby A]. In a setting of possible subgaleal haemorrhage this should have been avoided, using alternative methods to secure nasal prongs if these were necessary, and certainly the bonnet should have been removed to allow accurate serial measurement of head circumference and observation of the size of the subgaleal collection.

Paragraph 7.

I do not accept the circumstances prevailing at the time of her birth and later precluded an appropriate examination of [Baby A].

Paragraphs 8,9,10. noted

Paragraph 11. I do not agree infants who have been asphyxiated and are successfully resuscitated have persistent pallor.

I accept a haemoglobin of 145 g/L is in the normal range for a newborn; (Waikato lab quotes a very wide range of 135–225 g/L). However, [Dr H] does not appear to be aware the haemoglobin can be spuriously high if measured early in a setting of acute blood loss, and under these circumstances a haemoglobin of 145 g/L would raise concerns that the true haemoglobin is actually significantly lower. Ref. A recommends red blood cell transfusion if the haemoglobin is <140 g/L, which reflects this situation.

Paragraph 12, 13 and 14. Capillary refill *should* be part of the assessment of a pale infant, as a valuable measure of hypovolaemia, and especially in a setting of possible ongoing blood loss (see also Ref A).

Paragraph 16. [Dr F] agrees this was a significant subgaleal bleed, and as such urgent management was necessary.

Paragraph 17,18, 19.

[Dr F] assessed [Baby A] at 1630. However vascular access (both for urgent blood sampling and fluid resuscitation) was not achieved until an hour later, at 1730.

I believe once the diagnosis of subgaleal haemorrhage was entertained (shortly after birth) appropriate vascular access should have been immediately obtained, suitable for infusing significant volumes of blood and blood products. This is also recommended in Ref A. Ref A suggests two intravenous cannulae or an umbilical venous catheter (UVC).

In the setting of an infant born in a Level 3 unit like [the public hospital], the placement of a UVC should be straightforward and rapid.

UVCs are commonly inserted immediately at birth in a setting of massive blood loss from the placenta/cord.

UVCs also allow easy blood sampling, as would have been repeatedly necessary in this setting. It is unclear why time was lost attempting peripheral venous access in this emergency setting, especially with a senior medical officer available on site.

This does suggest the seriousness of the situation was perhaps not fully recognised. Subgaleal bleeds are a **clinical emergency**. A valuable hour of fluid resuscitation was lost.

I am unclear if the decision to insert the umbilical arterial line delayed the establishment of effective vascular access. Umbilical arterial line insertion, although of potential benefit, was not urgent in this case, once the umbilical venous line was placed.

Paragraph 20. I note the drop in the heart rate after 35 mls (10ml/kg) of Normal saline. However, I would regard a bolus of 10 ml/kg as being insufficient (the normally recommended volume in this setting would be 20 ml/kg, frequently repeated, until blood products are available, to allow possible reversal of metabolic acidosis), especially where there is a concern regarding active continuing blood loss. [Baby A's] arterial blood gas at 1731h, the time of the UVC/UAC insertion, showed a pH of 6.46 (base excess –29,) and when repeated at 1804h it had only risen to pH 6.56 with a worse base excess of –30. This strongly suggests the bolus was inadequate (see also Ref A). These blood gas results, especially taken from an arterial line, are commonly associated with subsequent infant demise.

I note at 1800h a further bolus of only 10ml/Kg was given in spite of the very poor blood gas results.

O negative blood was only issued from the blood bank at 1805 hrs and finally given at 1818 hrs at 20 ml/kg.

Severe haemorrhage can occur in an infant at birth as a result of umbilical cord or placental blood loss and NZ level 3 units should have O negative blood available on a continuous basis *in a matter of minutes* for this and other emergencies where rapid administration of blood can be life-saving. Such O negative blood should have been rapidly available for [Baby A] and should have been administered as soon as it was clear she had a significant subgaleal bleed compromising her circulation.

Similarly, coagulation factors were not given until 2 hours after birth (see recommendation, Ref A).

Paragraphs 21, 23,25,27–29.

I have covered this in part already in my response to Paragraph 20. The later the effective correction of hypovolaemia and coagulopathy the poorer the outcome.

There is indeed a 'golden hour' in the management of blood loss, as subsequently there is secondary organ damage (such as kidneys, liver, and heart) which leads to a failure of homeostasis by the body. The liver's capacity to produce clotting factors is compromised, and the heart's capacity to effectively provide circulation to the vital organs such as the liver and kidneys is limited, requiring the need for inotrope support. There is at this point also risk of brain damage due to inadequate cardiac output. Similarly, a large subgaleal bleed leads to consumption of clotting factors if the bleeding is not rapidly controlled, which prevents easy correction of the coagulopathy (as discussed in my previous report).

NB I can see no discussion in the clinical notes whether [Baby A] had received Vitamin K at birth, and whether further vitamin K was administered as part of her resuscitation (Ref A).

[Baby A's] recovery from her severe metabolic acidosis was slow, with persistent severely elevated lactates. Consideration should have been given to giving her early inotropic support, even with a normal blood pressure, given her continuing extremely poor blood gases. There should have also been consideration to organising an urgent echocardiogram, which would have aided in this decision. It is possible such cardiovascular support might have mitigated her subsequent acute renal failure.

Intubation and ventilation should have been considered once the severity of her acidosis was recognised at 1730 hrs, to allow for optimal cardiorespiratory support and reduce the risk of heart failure.

I believe the frequency of blood sampling to assess response to treatment was less than expected, given the severity of her metabolic and haematological disturbances.

Paragraphs 22, 24 and 26.

Comments noted.

Paragraph 30.

Measurement of serial head circumference, carefully performed using pre-marked cutaneous guides to tape placement, is in my experience very useful in this setting, especially early on, before the scalp has reached the limits of its capacity to expand. I accept they represent a two-dimensional measurement of a three-dimensional abnormality but this is the best available and if anything will tend to under-estimate blood loss. However, I accept normalisation of blood results would make accurate knowledge of head growth acutely less important.

Paragraphs 31, 32 and 51.

Contents noted. [Baby A] has sustained significant kidney damage with long-term implications, details of which are outside my area of expertise.

Paragraph 33.

I note there is uncertainty whether [Baby A's] early neurological state was normal or not.

Paragraphs 34–36, 37, 39, 40, 41 and 42.

Noted. I am pleased her temperature was 37.9 Deg. C not 31.9 Deg. C

Paragraph 43–44.

I included details of a local case to illustrate differences in management of [Baby A] and another case that appeared somewhat similar. This was more to confirm such management is practically possible. I accept each case must be treated on its specific needs.

Paragraph 45, 46.

Contents noted.

Paragraph 47.

Coagulopathy is the result of consumption of coagulation factors — its presence confirms a significant bleed. Early measurement of coagulation factors is an important part of the management of subgaleal bleeds (see e.g. Ref A).

Report summary: comments

1. There was indeed significant and serious delay in the diagnosis and in particular, the management of [Baby A's] subgaleal haemorrhage.
2. I note the consultant paediatrician was present from early in [Baby A's] life. This was not clear from the documentation.
3. The fact standard of documentation often falls below recommendations does not justify it. The time at which a note is written or an event occurs is essential information.

Conclusions

1. There was considerable delay in reaching a diagnosis as to the presence and severity of the subgaleal haemorrhage in [Baby A].
2. There was significant delay in achieving effective vascular access when such access should be readily and rapidly available.
3. There was delay in prompt correction of her hypovolaemia, anaemia and coagulopathy. Such delay has been associated with a poorer response to treatment and is likely to have played a part in the injuries she has sustained.
4. Frequency of blood sampling to assess response to treatment was in my opinion less than expected, given the severity of her metabolic and haematological disturbance.
5. Consideration should have been given to intubate and ventilate [Baby A], in particular when the severity of her blood gas derangement was recognised at 1730h, to reduce the risk of cardiac or respiratory failure/collapse. She was clearly hyperventilating to try to blow off CO_2 in an attempt to compensate for her

severe metabolic acidosis. It is likely her hyperventilation would have been clinically visible prior to this time.

6. Consideration should have been given to supporting her heart and circulation with the use of inotropes. Such a decision would have been aided by early echocardiography (if available, which one would expect in a Level 3 neonatal unit) to assess cardiac contractility and output."

Appendix B: Independent Obstetric advice to the Commissioner

The following expert advice was obtained from obstetrician and gynaecologist Professor Cynthia Farquhar:

"I have been asked to provide expert advice to the Commissioner.

[The] parents of [Baby A] have outstanding concerns about the following issues:

- A ventouse was used with excessive force at least five times and the reasons for its use was not communicated to them;
- The vacuum extractor was not positioned correctly; and
- Alternatives such as a caesarean section were not considered;

The Commission has asked that I review the enclosed documentation and advise whether I consider the care provided to [Baby A] and [Mrs A] by [Dr D] was reasonable in the circumstances, and why. In particular, comment on the following questions:

1. Was the use and the number of uses, of the ventouse by [Dr D] appropriate in the circumstances?
2. Should alternative delivery methods have been considered?
3. Should [Dr D] have sought support from a senior staff member when the delivery became overly complicated?
4. Should [Mrs A] have gone to theatre to deliver [Baby A] in the circumstances?

And for each question, please advise:

a. What is the standard of care/accepted practice?
b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
c. How would it be viewed by your peers?
d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Throughout this report I have drawn on the following guidelines.

1. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines of 2016 'Instrumental vaginal birth'
2. RANZCOG guidelines of 2015 'Prevention, detection, and management of subgaleal haemorrhage in the newborn'
3. Royal College of Obstetricians and Gynaecologists (RCOG) United Kingdom 2011 'Operative vaginal delivery'

Summary of the pregnancy from the medical records:

[Mrs A] was in her first pregnancy and was booked with a Lead Maternity Carer, [RM B] for her maternity care. She was referred at [39 weeks and 3 days gestation] as she had reduced fetal movements. A cardiotocograph (CTG) was arranged which was reported as normal. An ultrasound scan was arranged the following day and there was

concern about growth slowing. An induction of labour was planned for [Day 4]. Her weight was 72kg at the time of admission.

[Baby A] was born on [Day 4] following a ventouse delivery and had a large subgaleal haemorrhage (SGH) that required blood products and a lengthy recovery in hospital. [Baby A] was discharged home [55 days after birth].

The following is a summary of the care from [Days 4–11] following admission to the public hospital.

Date/Time

[Day 4] 12.30hrs	Admitted to the public hospital for IOL. The admission CTG was reported as normal. The induction was prolonged taking more than 72 hours before an artificial rupture of the membranes was performed although it would have been possible 24 hours earlier but the Delivery Suite was busy. Throughout this time six hourly CTGs were done and reported as normal. Care was provided by DHB staff (midwives and doctors) as is the policy for induction at Waikato DHB.
[Day 7] 23.15hrs	Admitted to Delivery Suite and ARM was performed by the consultant on-call. The Cervical dilatation was 2–3 cm.
[Day 8] 02.30hs	Oxytocin infusion commenced.
05.30hrs	Cervical dilatation was 7cm and baby's head was at the level of the ischial spines.
06.20hrs	Care was taken over by the LMC.
07.15hrs	Epidural block was requested by the patient. Cervical dilatation was 8cm dilated and the station was at the level of the ischial spines. A fetal scalp electrode was applied.
08.20hrs	The epidural was inserted at and administered by 08.20 hours.
08.55hrs	[The obstetric consultant] notes that at 7.15hr cervical dilatation was 8cm, the station was still at the level of the ischial spines and the position of the fetal head was not able to be described because of caput. A urinary catheter was sited.

10.30hs	Cervical dilatation was 9cm, the station was still at the level of the ischial spines, position — a ? was written.
11.30hrs	Anterior lip of the cervix was present. Examined by LMC.
11.45hrs	Reviewed by senior registrar ([Dr D]). No specific actions.
12.30hrs	Anterior lip pushed away by the LMC. Station 0. Now fully dilated.
13.40hrs	Pushing commenced. Catheter removed. Position of the head was not able to be described.
14.10hrs	[Mrs A] was placed in lithotomy to aid pushing.
14.35hrs	Senior registrar [Dr D] is called. CTG was reported as normal. Minimal descent of the head. Continue pushing.
15.06hrs	A deceleration was noted on the CTG. DS coordinator and core midwives called to assist. [Dr D] performed a VE. Fully dilated, as right occipital transverse (ROT) to right occipital posterior (ROP), station +1 with pushing, central caput, +1 moulding, no head in the abdomen. Fetal scalp electrode removed and abdominal monitoring commenced as decision for ventouse delivery made. Neonatal team informed of delivery.
15.15hrs –15.35hrs	Posterior ventouse cup applied over the flexion point between contractions. The CTG was described by [Dr D] as reassuring. Pressure starts at 0.2 and increased to 0.8 once [Dr D] is satisfied with placement of cup. There were 6 pulls over 22 minutes. There was minimal descent with the first pull, there was descent with the next two pulls, episiotomy with the 4th pull but then two more pulls required to deliver the head. No cup detachment. The pressures used were appropriate (started at 0.2 and increased to 0.8 once confident that the cup position was correct and no maternal tissues were trapped).

15.25hrs	Midwife notes 'very apparent that ventouse was difficult but peeps of head seen'. Patient is placed in semi-McRoberts position.
15.30hrs	Midwife notes 'registrar continuing to struggle with delivery of head'. The fetal heart rate was heard throughout using abdominal tocography and sounded overall reassuring.
15.35hrs	Baby's head delivered. Midwife notes fetal tachycardia and there was difficulty in delivering the head.
15.37	Baby delivered after placing in full McRoberts position to assist in the delivery of the shoulders. Baby noted to be pale and stunned at delivery. The cord was clamped. Birth weight is 3458g. Agpars were 4 at 1 min, 6 at 5 min and 8 at 10 min. Baby was taken to the Neonatal Intensive Care Unit after being resuscitated.
1610	Placenta was retained and [Mrs A] had a manual removal in theatre.
[Days 9–11]	[Mrs A] was on postnatal ward and then moved to rooming in at NBU.

The CTGs were not part of the records sent but were described as reassuring during labour and delivery except for one deceleration. The notes were not in chronological order which makes reading difficult.

1. Was the use and the number of uses, of the ventouse by [Dr D] appropriate in the circumstances?

With regard to the question of whether or not it was appropriate to use a ventouse in [Mrs A's] case I have considered the following circumstances:

[Mrs A] had had a long induction and then a long first stage with slowing of cervical dilatation towards the end of the 1st stage. The station was always 0. [Mrs A] had pushed for an hour and a half but there was no descent.

At the time of the decision for ventouse delivery the position of the head in relation to the pelvis was described as right occipital transverse (ROT) to right occipital posterior (ROP). This implies that the fetal head was tending to be somewhere between the two positions. There was no head palpated in the abdomen suggesting that descent was good and the station was described by [Dr D] at +1 with pushing. All other assessments by the midwife suggest it was station 0. Moulding of the fetal head was recorded as +1 which is not excessive. This scenario is consistent with deep transverse arrest in the midcavity. The delivery was in the delivery suite and not in theatre. The

consultant was not called. That suggests [Dr D] was confident that the vaginal delivery could be achieved.

A ventouse (also known as a vacuum extraction) delivery was recommended by [Dr D]. A metal posterior cup was chosen instead of the softer silastic cup because of the position of the fetal head (ROT to ROP). The posterior cup was placed on the posterior fontanelle in order to flex the head. Using the softer silastic cup would not be recommended with the fetal head in this position as they are more likely to come off and need reapplying and vaginal delivery is less likely to occur.

There were 6 pulls over 22 minutes. There was minimal descent with the first pull, there was descent with the next two pulls, episiotomy with the 4th pull but then two more pulls required to deliver the head. No cup detachment. The pressures used were appropriate (started at 0.2 and increased to 0.8 once confident that the cup position was correct and no maternal tissues were trapped).

Two midwives recorded their observations.

[RM C] notes the following:

15.25hrs 'Very apparent that the ventouse was difficult but peeps of the head seen.' Patient's legs pushed back into a semi-McRoberts position presumably to aid maternal effort. At 1530 the midwife records that 'Reg continuing to struggle with delivery of the head, but is confident that progress is being made.' 15.35 'Head delivered with obvious difficulty'. 15.37 Difficulty getting body out but baby is delivered.

[RM B] (LMC M/W) notes the following: Ventouse advanced slowly. Baby delivered over approximately 6 pulls/contractions.

All notes of [Dr D], [RM C] and [RM B] were written in retrospect in some cases hours later.

1.1 Was the decision to use a ventouse appropriate in the circumstances?

I have chosen to consider the question of choosing the ventouse separately from the question about the number of pulls. I consider that the decision for instrumental vaginal birth was appropriate and reasonable and in my view most obstetricians would have made a similar decision.

There were several options at this point in the labour.

1. Ventouse in order to rotate the fetal head to direct occipital anterior and delivery to follow.
2. Manual rotation where the head is manually rotated to occipital anterior was trialed by [Dr D] and failed.
3. Rotational forceps is another option but these are infrequently used now although in experienced hands is considered a safe option.
4. Caesarean section was an option but in my view there was no reason to recommend a caesarean section at this time as the head was at the spines

(Station 0) and the CTG was reported normal. This does not mean that it should not have been discussed with [Mr and Mrs A]. See below.

There are pros and cons with ventouse delivery versus forceps versus caesarean birth. Ventouse is associated with increase in failure to complete the vaginal delivery and is associated with increased likelihood of cephalohaematoma, retinal haemorrhages but less maternal perineal and vaginal trauma when compared with forceps. In the RCOG guidelines from the United Kingdom the ventouse has been advocated as the instrument of first choice since 1989 but this is not the case with the RANZCOG guidelines. In the UK RCOG guideline they note that caesarean section at the second stage of labour is associated with increased risks of major obstetric haemorrhage for the mother and increased admissions of the baby to the special care baby unit.

a. What is the standard of care/accepted practice?

According to the RANZCOG guidelines (2015) 'Instrumental vaginal birth' there are few contraindications to offering instrumental delivery (ventouse or forceps). Contraindications are fetal conditions such as an underlying bleeding disorder or increased fracture likelihood (osteogenesis imperfecta), face presentation and gestation less than 34 weeks. [Mrs A] did not have any contraindications to ventouse. But there were some adverse clinical features that could be regarded as 'warning signs'. These were the lack of descent beyond the ischial spines (station 0) and the failure of the fetal head to rotate to the occipito-anterior position after nearly 3 hours at full dilatation and pushing for 90 mins. [Dr D] described the position as between right occipito-transverse to occipito-posterior.

This table is a summary of the RANZCOG prerequisites for operative vaginal delivery which apply to both ventouse and forceps deliveries.

RANZCOG prerequisites	**My assessment if prerequisite was met**
Fetal condition should be assessed. A baby already showing signs of distress may be better delivered by caesarean section.	Yes CTG was described as reassuring.
Clear explanation should be given and consent obtained, appropriate to the clinical situation.	Unclear. Patient reports she did not feel consent was sufficient but it is recorded by [Dr D] that verbal consent was obtained.

Less than or equal to one fifth of head is palpable in the abdomen, vertex presentation, full dilatation, adequate pain relief, exact position of the head can be determined, moulding is no more than +1.	All met.
The operator should be experienced in the instrument that they choose.	[Dr D] was credentialed in ventouse delivery
Adequate facilities, back up plan, senior staff present if junior staff.	PARTLY. In my view consultant should have been informed about the plan to do a ventouse.
Operating theatre ready so that immediate caesarean section can be performed. See recommendation 3 below.	NO. RANZCOG recommends that when there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible. I consider there was an increased likelihood of problems. I interpret this recommendation to mean that the ventouse should have been undertaken in an operating theatre.
Anticipate complications such as shoulder dystocia and PPH.	Unclear. These complications did not occur but others did.
Neonatal staff present.	Yes although the neonatal staff member who was present was a senior house officer who would probably not be competent to manage such an unwell baby. A registrar arrived at 5 mins after birth.

The RANZCOG guidelines also highlight features that are more likely to be associated with failure — they are high BMI, and baby >4kg, mid cavity, and occipito-posterior position. This patient had the last two of these features.

RANZCOG Recommendation 3: When there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible.

Two prerequisites in the list above were not completely fulfilled in my view. Although [Dr D] was a senior registrar who has been credentialed in the use of ventouse since 2014, I still consider the consultant should have been informed (it was a Friday afternoon and the consultant would not have been very far away). I know that in some places this is at the discretion of the staff member and that the requirement to contact the specialist varies according to DHB. Secondly the place of delivery should have been in theatre. There should be a low threshold to doing the ventouse in an operating theatre. It is my opinion that the warning signs of station 0 and the ROT-ROP position were sufficient to firstly inform the consultant and to do the procedure in theatre.

1.2 With regard to the number of pulls?

As mentioned above there were 6 pulls over 22 minutes. [Dr D] has written (retrospectively) that were was minimal descent with the first pull, there was descent with the next two pulls, episiotomy with the 4th pull but then two more pulls required to deliver the head. There was no cup detachment which is sometimes an indication that too much traction was being applied. The pressures used were appropriate.

a. What is the standard of care/accepted practice?

According the RANZCOG guideline mentioned above,

> 'Vacca recommends an upper limit of 20 minutes from first application of the cup. Where birth is not imminent after 15 minutes, operators should evaluate whether further traction is warranted, and consider recourse to caesarean section. It should be noted that where the head is deeply engaged in the maternal pelvis (and macrosomia is not anticipated) that completion of vaginal birth by vacuum extraction or forceps may still be safer than a caesarean section.
>
> Many experienced operators suggest a maximum of three pulls without descent of the skull (not scalp) (defined as three contractions, even if there are multiple maternal "pushes" within each contraction), although more pulls may be acceptable if the head has descended to the level of the pelvic floor or perineum especially if birth is attempted without episiotomy.'

In the case of [Mrs A], the pulls were achieving the desired descent and movement of the fetal head. The number of pulls was on the upper limit as outlined above. Unfortunately with ventouse delivery, there is a point of no return as caesarean birth is not easily or safely achieved when the fetal head is so far into the birth canal. So the last two pulls (5th and 6th) were most likely needed to achieve the delivery of the head. In the RANZCOG guideline it says 'more pulls may be acceptable.' I consider that [Dr D] should have called the on call consultant when she was encountering difficulties — probably around the 3–4th pull around 15.25–15.30hrs. The RANZCOG guideline for

Instrumental Vaginal Delivery mentions that failure to abandon the procedure when there is no progress has led to litigation in the UK. From the RCOG guideline — 'the bulk of malpractice litigation results from failure to abandon the procedure at the appropriate time, particularly the failure to eschew prolonged, repeated or excessive traction efforts in the presence of poor progress.'

In the RANZCOG guideline for Subgaleal Haemorrhage (SGH) they reference Vacca 'who concludes that significant SGH is almost always preceded by a difficult vacuum extraction as evidenced by a prolonged extraction with excessive number or strength of pulls, multiple cup detachments, and/or completion of delivery with forceps.'

In [Mrs A's] case there appeared to be some progress with each of the pulls so this is not the same scenario as in the preceding paragraph. However, the RANZCOG guidelines say this 'Where birth is not imminent after 15 minutes, operators should evaluate whether further traction is warranted, and consider recourse to caesarean section.' But it appears that [Dr D] felt that the birth was achievable. And 7 mins later the baby was delivered. As stated above there might have been an opportunity for [Dr D] to seek assistance from the consultant at approximately 15.25 to 15.30hrs.

The strength of the pulls or the amount of traction is difficult to assess from the notes. There has been no mention of rocking (sometimes used to ease the head out and not recommended). The cup did not come off which often indicates excessive force. The figure provided in the report from the public hospital suggests that the posterior cup was correctly applied and the tear is just adjacent to where the cup most likely was applied. Yet it would seem that some degree of force must have occurred to result in the subgaleal haemorrhage and the 2–3 cm tear on the fetal scalp.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

There are some departures from the standard of care and accepted practice. The failure to inform the on call consultant on two occasions — once when deciding to undertake a ventouse on a woman with a mid cavity deep transverse arrest and a second time when 3–4 pulls were completed and delivery was proving difficult. This suggests that the registrar although credentialed, underestimated that this was likely to be a difficult ventouse delivery. This policy varies between DHBs and so there may be a difference of opinions about this. Having a low threshold for asking for assistance is a good strategy at any time when faced with difficulties during a birth whether junior or senior doctor.

[Mrs A] should have been transferred to an operating theatre to do the ventouse. The RANZCOG guidelines are slightly confusing on this point (see table above) but Recommendation 3 states 'When there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible.' I interpret this as meaning that the delivery should be in theatre. This is the standard of practice in many hospitals when doing a trial of operative vaginal delivery. It suggests

that [Dr D] underestimated the severity of the warning signs — in this case a woman with mid cavity deep transverse arrest. Being in a theatre would make changing from ventouse to caesarean section easier to achieve.

c. How would it be viewed by your peers?

This is speculation on my part. My peers would probably consider:

- That the decision to do a ventouse was reasonable in the first instance
- That the registrar although experienced, did not anticipate a difficult delivery although the warning signs of mid cavity and ROT-ROP position
- That the consultant should have been notified about the ventouse and [Dr D] should have asked for help after 10–15 mins of attempting the ventouse.
- That the delivery should have been in theatre because of the 'warning signs' mentioned above.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

- Encourage all staff to take into account warning signs such as mid cavity and ROT-ROP position in order to anticipate a difficult ventouse and then appropriately plan for it.
- This includes having senior staff present and undertaking difficult deliveries in theatre.

2. Should alternative delivery methods have been considered?

This question has already been covered partly in the previous question when the decision to use ventouse was made. The choice of ventouse was a reasonable option. A caesarean section was not indicated at that time although it should have been discussed.

a. What is the standard of care/accepted practice?

RANZCOG guidelines for instrumental vaginal delivery state that a 'clear explanation should be given and consent obtained, appropriate to the clinical situation.'

The guidelines do not say whether or not all patients should be offered caesarean section at the time of decision making about ventouse. Accepted practice is likely to be varied. Full informed written consent including discussion of the options would have been required if the patient had the trial of ventouse in theatre. Whenever an intervention is planned there are generally other options that are discussed.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

As there is no standard of care or accepted practice about offering caesarean section at the time of discussing ventouse then it is difficult to say there is a departure from accepted practice. Any discussion or recommendation would usually include a discussion of alternatives but in second stage it is not an easy conversation. Ideally this

delay in second stage secondary to deep transverse arrest is discussed as a possible scenario by the LMC in the third trimester. In question 1 I wrote the following:

> 'Caesarean section was an option but in my view there was no reason to recommend a caesarean section at this time as the head was at the spines (Station 0) and the CTG was reported normal. This does not mean that it should not have been discussed with [Mr and Mrs A]. [Dr D] says that she was told by [Mrs A] "do whatever you think is best". This statement by a patient who was tired does not mean that caesarean section should not have been discussed. It would have been reasonable to say that caesarean section at this time is one option and then provide the reasons why a ventouse was the preferred option. At the same time the fetal adverse events with the ventouse should have been mentioned such as swelling around the placement of the cup and cephalohaematoma (occurs in 10% of births following ventouse). SGH is rare occurring 1 in 300 ventouse deliveries and so would not need to be specifically mentioned.'

c. How would it be viewed by your peers?

Again this is speculative. As there is no standard then it is likely that there will be several differences of opinion. Some would consider that caesarean section should have been discussed as part of the decision making but that the preference was to do a ventouse. Others would say that there was not the time to go into a detailed discussion.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

All women at full dilatation should have an explanation of the options (unless an emergency precludes that) including caesarean delivery but that the preference is ventouse. Ideally discussions about the need for operative vaginal delivery at full dilatation would be undertaken in the third trimester between the LMC and the patient.

1. Should [Dr D] have sought support from a senior staff member when the delivery became overly complicated?

This question is partly covered in question 1 and 2. Apologies for repetition.

a. What is the standard of care/accepted practice?

[Dr D] was a senior registrar and was credentialed in the use of ventouse by both RANZCOG and the DHB. In spite of this, I consider that the consultant should have been informed (… the consultant would not have been very far away). The requirement to notify the specialist even when credentialed when doing an operative delivery varies according to DHB. It is often left to the discretion of the registrar to decide it they need help. Even a senior registrar who is credentialled should have a low threshold about calling the consultant in this case because of the warning signs (station 0 and the ROT-ROP position) of a possible difficult delivery. There was a

second opportunity to call the consultant when difficulty in delivery of the head was encountered about 10–15 mins after the ventouse commenced.

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

This is probably an important departure as it may have prevented the outcome of the subgaleal haemorrhage. A more senior colleague would hopefully have taken into account the warning signs and may have suggested delivery in theatre. There may have been an opportunity to change the plan once the difficult delivery was encountered and to deliver the baby by caesarean section. However, we cannot be sure of a better outcome as delivery can be difficult if the head is low in the birth canal.

c. How would it be viewed by your peers?

Again this speculation but I think my peers would consider the registrar, although experienced, underestimated the warning signs and did not call for assistance when the delivery became difficult.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

There should be education about the importance of risk assessment for potentially difficult deliveries and having a low threshold for calling the consultant even when experienced and credentialled.

2. Should [Mrs A] have gone to theatre to deliver [Baby A] in the circumstances?

Again there is some repetition.

a. What is the standard of care/accepted practice?

The warning signs of station 0 and the ROT-ROP position were sufficient to justify being delivered in theatre in my view. Recommendation 3 in the RANZCOG guideline states 'When there is an increased likelihood that attempted instrumental birth may not be successful, where feasible, the attempt should be conducted in a place where immediate recourse to caesarean section is possible.'

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

The standard of practice in many hospitals when doing a trial of operative vaginal delivery with a ROT-ROP and station 0 would be to deliver in theatre. By not doing this suggests that [Dr D] underestimated the difficulty [of the] delivery that could occur. Being in a theatre would make changing from ventouse to caesarean section easier to achieve. This is probably an important departure as it may have prevented this outcome as changing course might have been easier. However, as stated above we cannot be sure of a better outcome as delivery can be difficult if the head is low in the birth canal.

c. How would it be viewed by your peers?

Again that this speculation but I think my peers would consider that is a registrar who although experienced was not prepared for this difficult delivery.

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Education about the importance of risk assessment and looking for warning signs for difficult delivery and having a low threshold for delivery in theatre.

Summary: [Dr D's] decision to deliver [Baby A] by ventouse was reasonable in the circumstances. However, there were adverse clinical features present that signaled potential problems might occur during the delivery. It would seem that these were not anticipated as the consultant was not called and the patient was not delivered in theatre. Consent for the procedure did not consider other options such as caesarean birth.

Professor C Farquhar
University of Auckland and Auckland District Health Board"

Addendum 28 September 2017

"I write in response to the letter of 26th September 2017.

I have been asked to advise on the following issues:

1. My report mentions station 0 whereas [Dr D] states that the 'station was +1 with further descent'. The Commissioner asks if the station was +1 would that change my advice.

My response: the hand written notes of [Dr D] clearly are '+1 with pushing'. Not '+1 with further descent'. I interpret that to be station 0 when not pushing. When the position is ROP and there is moulding and caput the station may appear to be +1 when in fact the station is more likely to be station 0. Given that I consider the station was 0 then my advice doesn't change. To answer the Commissioner's question about whether station of +1 would change my opinion, I think not as station is only part of the examination and the caput and malposition were also present as warning signs of difficult delivery. I still consider that delivery in theatre and notifying the consultant were indicated and that this is a moderate departure from the standard of care.

2. The report suggests that 'despite adverse features being present, [Dr D] did not anticipate a difficult delivery'. Was this a departure from accepted standards?

My response: not anticipating difficulty at the time of delivery is a moderate departure.

3. Whether after 3–4 pulls, there was clinical indication for a C-section.

My response: Please see the bottom of page 7 and the next page of the 1st report. Giving it further thought and rereading the notes, the registrar states 'significant

subsequent descent with next two pulls' which suggests that there was no clinical indication for a C-section and imply that delivery could be expected without further difficulty. The midwifery notes by [RM C] are not in agreement on this point '1525 approx, became very apparent that ventouse was difficult' and '1530 obs reg continuing to struggle with delivery of head'. The second midwife [RM B] wrote 'vertex advanced slowly'. If I was to take [Dr D's] notes as the sole source of information I would say that there was no indication for C-section as she describes 'significant descent'. If we consider the midwifery notes then there appears to be an indication for considering C-section and this is a moderate departure from the standard of care.

4. 'the outcome of care is irrelevant' (as in page 11 question 3b) and asks 'whether the departure is still considered moderate'

My response: My apologies for not applying the principle as stated. Yes the departure is still moderate.

Professor Cynthia Farquhar
University of Auckland and Auckland District Health Board."

Addendum 20 October 2018

"I have been asked to provide advice on the following issues:

1. Does the response change any of my findings so far?
The response provided to me included the two RMOs for paediatrics ([Dr H], [Dr E]). [Dr H] arrived after the delivery so did not provide any further information). [Dr E] was present throughout and noted '7–8 pulls' which is in conflict to the other reports of staff which vary from 3–4 pulls to 6 pulls.

[RM B] was asked by [the clinical midwife director] if she felt comfortable in asking [Dr D] to stop and she advised that 'she had good working relationship with her and wouldn't hesitate to say something if she felt that the procedure should be abandoned'. She has also stated that she was not tempted to ask [Dr D] to stop the procedure. She has also stated 'I would not describe the doctor as "stuggling".'

Note: The second junior midwife had used the words 'struggling to deliver the head'.

My response: this does not change initial report. These are additional comments that speak to the relationship between the midwife and registrar which were good. There were several pulls required (varyingly described from 3–4 to as many as 7–8). Clearly this was a difficult delivery of the head as there was a 3cm laceration of the fetal scalp and a severe subgaleal haemorrhage. There were warning signs of difficult delivery (station 0 and caput, and persistent ROP). I still consider that delivery in theatre and notifying the consultant were indicated either prior to the procedure or after 10 mins of ventouse application with 3–4 pulls (1525) and that this is a moderate departure from the standard of care. I don't think I can completely ignore the midwifery notes

written by [RM C] '1525 approx, became very apparent that ventouse was difficult' and '1530 obs reg continuing to struggle with delivery of head'. The senior midwife [RM B] wrote 'vertex advanced slowly'. A call to the consultant at approximately 1525 would have been appropriate at the very least.

2. Do you consider that the policies and procedures in place at the time of the event were adequate?

I have been provided with three policies of the Waikato DHB.

- SMO and RMO Responsibilities and the limits of delegation of responsibilities to RMOs.

This document doesn't necessarily reflect the duties on a delivery unit where the progress of labour can change in a matter of minutes. It does not mention credentialling. The only item of relevance is possibly item 3 on page 3 on the 4th bullet point. 'Any patient for whom the diagnosis or management is unclear …'

[Dr D] was credentialled for ventouse and was a senior registrar. She was not required to inform her SMO unless she thought it would be difficult. I have already noted the decision for ventouse was appropriate although there were warning signs that it may be a difficult delivery and that transferring to theatre for the delivery would have been appropriate. Once the difficulties were encountered at around 1525 then I would have expected [Dr D] to call for help. In my view, it is a good practice and a good principle for all clinical care by any health professional regardless of their level of training and expertise to call for assistance if they encounter difficulties in clinical care.

- The other two policies relate to fetal monitoring and are not relevant.
- There is no policy on operative vaginal delivery however, there is mention of the RANZCOG policy.

a) If you consider that there has been a departure from expected standard, how significant a departure do you consider this to have been.

If I consider the midwifery notes of [RM C] then there appears to be an indication a call to the consultant at approximately 1525 to discuss progress and options for delivery. I see no reason to completely ignore these notes even though this midwife only had 20 months' experience. The paediatric SHO also suggests a slow delivery with 7–8 pulls. This is a moderate departure from the standard of care.

b) Do you have any recommendations for improvement.

Development of a policy for operative vaginal delivery.

Include in the SMO and RMO Responsibilities and the limits of delegation of responsibilities to RMOs policy a statement about credentialling and what to do if any concerns while undertaking procedures.

Education of all staff about calling for assistance if concerns.

Encouraging a culture where calling for assistance is not seen as a failure.

3. Would you expect the DHB to conduct an internal investigation following the event.

The notes state 'against expectations, [Baby A] has survived her severe subgaleal bleed. However, she continues to have evidence of renal impairment. … this is likely to indicate permanent renal injury … and very likely to require dialysis and then renal transplantation'.

This suggests that this baby was a near miss for a neonatal death. Clearly [Baby A] has serious renal morbidity that potentially may have been avoidable. It is my view that there should have been an internal investigation by a multidisciplinary panel in order to explore the reasons for the poor outcome for [Baby A]. I am unclear if this investigation has been undertaken as there is some mention of an informal investigation and review within the notes.

Professor Cynthia Farquhar
University of Auckland and Auckland District Health Board"