Waikato District Health Board

A Report by the
Health and Disability Commissioner

(Case 17HDC02291)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. This report concerns the neonatal care provided to a baby in 2017 at a public hospital. The baby had two conditions — perinatal hypoxic-ischaemic encephalopathy and neonatal sepsis. The baby's condition deteriorated, and she died from an overwhelming infection.

Findings

2. The Commissioner found the district health board (DHB) in breach of Right 4(1) of the Code. The Commissioner was critical of inadequate staffing levels overnight, and that DHB staff: (a) showed a lack of critical thinking; (b) delayed antibiotic treatment; (c) delayed aEEG monitoring for hypoxic ischaemic encephalopathy; (d) did not undertake an adequate assessment of the baby; and (e) did not document adequate medical records. As a consequence, treatment for both of the baby's conditions was delayed.

Recommendations

3. The Commissioner recommended that the DHB provide a formal apology to the whānau of the baby.

4. The Commissioner also recommended that the DHB: (a) introduce an education programme for all NICU staff about the signs of possible infection, and about handover and documentation; (b) analyse the number of cot-side EEG monitoring units required; (c) review the staffing levels in the NICU; and (d) review its procedure for "Early Onset Neonatal Infection Prevention".

Complaint and investigation

5. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided to her granddaughter.[1] The following issue was identified for investigation.

- *Whether Waikato District Health Board provided Baby A with an appropriate standard of care in 2017.*

6. The parties directly involved in the investigation were:

Ms A	Consumer's mother
Ms B	Consumer's grandmother
Waikato DHB	Provider
Provider/lead maternity carer	

[1] The baby's mother supported the complaint.

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Also mentioned in this report:

Dr C	Neonatal paediatrician
RN D	Registered nurse
CNS E	Clinical Nurse Specialist
Dr F	Paediatrician

7. Further information was received from the birthing clinic and the Coroner.

8. Independent expert advice was obtained from a neonatologist, Professor Frank Bloomfield (Appendix A).

Information gathered during investigation

Background

9. In 2017, Ms A, then aged in her late teens, was in her first pregnancy.

10. On Day 1[2] at 3.33pm, Ms A delivered a female baby weighing 3,118 grams. Baby A was placed skin to skin with Ms A, but the baby appeared floppy, unresponsive, and blanched. There was no response to manual stimulation.

11. This opinion considers the subsequent care of Baby A at the public hospital.

Admission to public hospital

12. At around 3.56pm (23 minutes of age), an ambulance arrived to transport Baby A to the public hospital. Ventilation was continued en route, and Baby A's oxygen saturations were 88%.

13. On arrival at the public hospital at around 4pm, Baby A was transferred to the Neonatal Intensive Care Unit (NICU). She was pale and floppy, and CPAP ventilation was continued. A blood culture was taken and an umbilical venous catheter was inserted. Insertion of an umbilical arterial catheter was attempted but was unsuccessful. The plan recorded by the admitting nurse included: "Consider BRAINZ[3] monitoring."

14. Neonatal paediatrician Dr C was on duty until 4pm and on call overnight. He stated that Baby A's heart rate was normal and her oxygenation satisfactory on the level of support provided. However, she was found to have "serious acid levels in her blood (pH 6.98)" and so therapeutic cooling was commenced, and by 5.30pm a temperature of 33.5°C had been

[2] Relevant dates are referred to as Days 1–5 to protect privacy.

[3] The BrainZ monitor is a two-channel electroencephalograph (EEG) that monitors electrical signals from each hemisphere of the brain. The BrainZ monitor is used as a screening device and not a diagnostic tool. A formal 12-lead EEG and MRI are used for formal diagnostic measures and to assist with prognosis.

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achieved. The records state that the baby became agitated and tense following cooling, and morphine was administered with good effect.

15. Antibiotic therapy with amoxicillin and cefotaxime was commenced at 5.40pm and continued until Day 3 at 5.15pm. A chest X-ray showed that the baby had a small right-sided pneumothorax[4] but it was not of sufficient size to warrant drainage.

16. At 7.45am on Day 2, aEEG[5] monitoring was commenced owing to bradycardia[6] and a possible seizure, and the baby was administered phenobarbitone,[7] following which her heart rate dropped to the 90s. At 3pm, a paediatric registrar reviewed the baby and recorded that her heart rate was then 130bpm. He noted that the pneumothorax was not clinically significant and that there had been no significant seizure activity that day.

17. On Day 3, the paediatric registrar recorded that the cooling was to stop on Day 4 at 5.30pm, and that the morphine was to be reduced. The antibiotics were also to stop, and extubation[8] was planned for Day 5.

18. On Day 4, the baby's pCO2 level rose,[9] and at 3.23am she was intubated on SIMV.[10] During that day the baby remained relatively stable on SIMV. At 2.17pm, the paediatric registrar reviewed the baby and did not record any specific concerns.

Deterioration

19. Overnight on Day 5, Baby A's condition changed. The pCO2 monitor showed a high pH level of 8–10. There was a sudden increase in her oxygen requirements, and at 3.20am she required 50% oxygen. By 6am, her heart rate had risen above 200bpm, and her blood pressure had dropped from 52–55mmHg to 38mmHg. RN D recorded that she informed the resident Clinical Nurse Specialist (CNS), CNS E, about this. CNS E ordered a chest X-ray, which showed a right upper lobe consolidation. CNS E made no clinical records.

20. CNS E stated that she reported back to the nursing staff that there was upper lobe collapse, and that she had requested chest physiotherapy and positioning in order to assist with re-inflation of the collapsed areas. She said that by the time the nursing notes were written by RN D at 6.29am, the baby's transcutaneous CO_2 and oxygen requirement had

[4] A pneumothorax occurs when air gets in between the lung and the chest wall, causing the lung to collapse.
[5] Amplitude integrated electroencephalography (aEEG) is a technique for monitoring brain function in intensive care settings over longer periods of time than the traditional EEG, which typically is used for hours to days.
[6] Slow heart rate.
[7] The recommended drug for the treatment of seizures in term neonates. It is also given to neonates who are being treated with curare-like muscle relaxants and whose EEG shows paroxysmal activity.
[8] Removal of assisted ventilation apparatus.
[9] Respiratory acidosis occurs when the pCO2 is abnormally high (pCO2 ≥ 50mmHg, pH < 7.35).
[10] Synchronised Intermittent Mechanical Ventilation (SIMV) is a method of providing mechanical breaths to a patient. The patient is allowed to take additional breaths in between the mechanical breaths. The patient's own breaths are called "spontaneous breaths". The ventilator detects the patient's spontaneous breathing, and waits until the patient exhales before delivering another mechanical breath. This "synchronises" the ventilator to the spontaneous breathing.

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both reduced. CNS E said that she handed over care of the NICU to the daytime team at 8am, "with details of [Baby A's] condition, investigations and responses overnight". There is no written record of the information provided in the handover.

21. The paediatrician on duty that day, Dr F, told the Coroner: "When the infant was seen on the ward round at 08.55hrs on 2/9/17 she looked well and it was planned to proceed with the extubation once the oxygen requirement had fallen."

22. Over the morning of Day 5, the baby continued to have increased oxygen requirements and her respiratory function deteriorated. At 10am she was changed to high frequency ventilation, and by 11am she appeared unwell with mottled skin. She developed a profound lactic acidosis, which did not respond to sodium bicarbonate therapy. Dr F noted his impression of "probable sepsis".

23. At midday, a chest X-ray showed diffuse bilateral lung changes, suggesting an infection or haemorrhage. At 12.00pm, a repeat blood culture was taken and antibiotics (gentamicin and amikacin) were commenced. At 1pm the baby became hypotensive.[11]

24. With regard to communication with the family, Dr F recorded that he discussed the probable sepsis with a relative who was visiting from another region, and he spoke to the baby's parents by telephone. He noted that at 12.40pm he met with the parents and whānau and updated them that the baby was seriously unwell and had a "50/50" chance of surviving.

25. At 1.45pm, Baby A had an episode of profound bradycardia, and required full resuscitation for five minutes. Her blood pressure remained low, despite maximum inotropic support[12] and rising lactate.[13] A full blood count that had been taken at 8.55am was reported at 2pm, and showed significant neutropenia.[14] At 2pm, Dr F recorded: "[F]amily updated as to gravity of situation."

26. At 2.36pm, Baby A had a further profound bradycardia, and there was no response to full resuscitation. Tragically, she was declared deceased at 3.16pm on Day 5.

27. The blood culture taken at 12.35pm on Day 5 subsequently showed growth of *Pseudomonas aeruginosa*.[15]

[11] Low blood pressure.
[12] An inotrope is an agent that alters the force or energy of muscular contractions. Inotropic support refers to the use of various drugs that affect the strength of contraction of the heart muscle.
[13] The blood lactate level is an important marker in the diagnosis of sepsis and septic shock, and is useful in evaluating response to fluid resuscitation.
[14] Insufficient neutrophils (a type of white blood cell). Neutrophils are important for fighting certain infections, especially those caused by bacteria.
[15] A Gram-negative bacterium that may cause disease in vulnerable individuals such as infants in whom the immune system is not yet developed.

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Further information — Waikato DHB

28. Dr C stated that Baby A had two separate conditions:

> "The first was perinatal hypoxic-ischaemic encephalopathy for which treatment proceeded normally and with good expectations of a successful outcome. The second was neonatal sepsis, which started probably on the 4th day and is the reason for her death."

29. Waikato DHB said that the commencement of aEEG monitoring was delayed for approximately 15 hours. Dr C stated:

> "It is our usual practice to use aEEG monitoring in all cooled babies, and I do not have a ready explanation for why it was not started promptly after the admission. A possible reason is that the machine was in use with another baby, but I am unable to confirm that now."

30. Dr C noted that at the time of admission, the admitting nurse practitioner recorded "consider BRAINZ monitoring", but it was not commenced until the following morning.

31. Dr C said that the baby received antibiotics from Day 1 at 5.40pm until Day 3 at 5.15am. He said that those antibiotics were not relevant to the baby's later deterioration.

32. Dr C stated that the initial clinical indication that the baby was septic was at 1am on Day 5. He said that the baby's observations indicated that antibiotics should have been started at that time. He noted that a CRP test[16] the previous evening had been ordered at 9.10pm and reported at 10.17pm and acknowledged at 10.57pm. The result of 57.8mg/L suggested an infection, and that information could have been added to the findings later in the shift when the baby's oxygen requirements started to increase.

33. Dr C said that the next major opportunity to commence antibiotics was the 8am ward round, and "[f]or some reason, the antibiotics were not started then either". He said that the baby's lactate level was increasing, and the haematology test result at 8.20am was also "very suggestive of infection", although the full white cell results were not available until 2.20pm (after the antibiotics had been started).

34. Dr C stated that on Day 5, the night shift comprised one resident plus 15–16 nurses. The NICU was at full capacity with 41 babies, but that was not particularly unusual, and there was no requirement for extra nurses.

35. With regard to the resident, Dr C said that this person may be a paediatric registrar, a neonatal nurse practitioner, or a clinical nurse specialist. With regard to CNS E, Dr C said: "[A]ny actions or consequences from her decisions are the responsibility of the senior medical staff of the NICU." Dr C said that it was not satisfactory that CNS E wrote no notes about the baby's deterioration or the indication for the X-ray that she ordered.

[16] A C-reactive protein (CRP) blood test is used to check for acute inflammation or infection in the body.

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36. Waikato DHB stated that the source of the overwhelming *Pseudomonas aeruginosa* sepsis that caused the death of Baby A is unknown. Dr F stated that *Pseudomonas aeruginosa* is an unusual cause of neonatal sepsis, and that in 33 years Waikato DHB has diagnosed 11 cases, and five of the infants died from the infection.

37. Waikato DHB stated that it has made changes to the services it provides, and is in the process of developing others, including:

- The introduction of formal writing/documentation of ward round decisions for each baby every day.
- A new standard of documentation, to be included in a Standard Operating Procedure Manual wherein there is a specific expectation that every deviation in clinical care is written up in the clinical records.
- The extension of ward rounds to include considerable additional time for teaching and coaching of junior staff in decision-making.
- Increased resident staff numbers to enable two residents to be present in the NICU on night duty.

38. Dr C stated:

> "I agree that the delay in starting antibiotics was not consistent with good practice, and we will ensure that [the HDC expert] Prof Bloomfield's comments are shared with our medical and resident team in an open education session, for the learning of all."

Further information — CNS E

39. CNS E told HDC that at the time of these events she was employed as a CNS practising under delegated orders from the NICU consultants. She stated that she was the resident on duty from Day 4 at 8pm until 8am on Day 5. She said that the midlevel resident roster is covered by a combination of medical registrars, nurse practitioners, clinical nurses, and clinical nurse specialists. She stated: "It is normal practice in NICU at [Waikato DHB], for there to be only one resident to be rostered overnight."

40. CNS E stated that she does not recall the night in question or her management of Baby A. She said that on that night there were 41 babies in the NICU and 18 in Intensive Care and, in addition, she was required to attend three deliveries, although the babies in those cases were not admitted to the NICU.

41. CNS E stated that she completed a blood form during the evening handover round and she acknowledged the results. In response to the baby's increasing oxygen requirement and transcutaneous CO_2,[17] she ordered a chest X-ray, which was performed at 4.50am. She stated that by 6.30am, she had reported back to the nursing staff that the baby had upper lobe collapse and she had requested chest physiotherapy and positioning to assist re-inflation of the collapsed areas, and the transcutaneous CO_2 and oxygen requirement had

[17] Transcutaneous carbon dioxide monitoring is a non-invasive alternative to arterial blood sampling.

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both reduced by that time. She said that she handed over the baby's care to the day team at 8am on Day 5.

42. With regard to the absence of documentation of the care she provided, CNS E stated:

> "I recognise that documentation is an important part of patient care, but unfortunately it did not occur in this case. When solely responsible for the entire NICU, attending assisted deliveries in delivery suite, and dealing with other issues that arise with neonates in the Post Natal Ward or delivery suite, leading to constant interruption, which affects prompt and satisfactory documentation. I therefore did not complete the documentation to a satisfactory standard, in lieu of dealing with an imminent clinical situation."

Autopsy

43. A coronial autopsy of Baby A found the cause of death to be *Pseudomonas aeruginosa* sepsis with a significant contributing condition of perinatal asphyxia.

Responses to provisional opinion

44. Ms B was given an opportunity to respond to the "information gathered" section of the provisional opinion, and reiterated the impact these events have had on her.

45. Waikato DHB was given an opportunity to respond to the provisional opinion, and accepted the findings and recommendations.

46. Dr F and CNS E were given an opportunity to respond to the provisional opinion, and they had no further comments.

47. Dr C was given an opportunity to respond to the provisional opinion. Where appropriate, his comments have been incorporated into the report.

48. Dr C commented that the staffing level of "one" person at registrar level had been a consistent standard at Waikato DHB and continued to be until very recently. In this regard, Dr C says that it is no different from other NICUs in New Zealand. However, in recognition of increasing workload, he acknowledges that recent enhancements to the roster numbers at Waikato DHB have made those earlier standards appear to have been inadequate, but he says that they were the necessary standards of the time. Dr C also provided HDC with analysis on how demand for the NICU has progressed over the last ten years, and commented that in his opinion, a strong push for increased resources prior to 2017 would not have been successful.

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Opinion: Waikato DHB — breach

Introduction

49. DHBs are responsible for the operation of the clinical services they provide, including any service failures.[18] 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. It is particularly important that staff working in NICUs have sufficient support to be able to perform their functions adequately and be able to escalate any concerns appropriately.

50. Baby A was born at around 3.30pm. She had no respiratory effort or response to stimulation, so an ambulance was called and she was transferred to the public hospital NICU. I consider that aspects of the care provided to Baby A by staff at Waikato DHB were suboptimal, as discussed below.

Treatment for encephalopathy

51. My expert advisor, neonatologist Professor Francis (Frank) Bloomfield, advised that the essentials of Baby A's treatment for hypoxic-ischaemic encephalopathy were consistent with standard practice. He noted that therapeutic hypothermia was instituted promptly and continued for the standard 72 hours. He stated that the majority of babies receiving therapeutic hypothermia would receive assisted ventilation via an endotracheal tube, but the baby's initial management via CPAP was a variation in practice rather than a deviation from accepted best practice.

52. The commencement of aEEG monitoring was delayed for approximately 15 hours after admission. Professor Bloomfield was critical of the delay. He stated that generally aEEG monitoring would be commenced early in babies with suspected or confirmed hypoxic ischaemic encephalopathy, as it is well recognised that there may be electrical seizures that are not detected clinically. Professor Bloomfield stated:

> "Most neonatologists in tertiary centres would commence cot side EEG monitoring in babies receiving therapeutic hypothermia for suspected or confirmed hypoxic ischaemic encephalopathy as soon as possible."

53. I accept this advice and note that Dr C stated that it was the usual practice at Waikato DHB to use aEEG monitoring on all cooled babies, and he was unable to explain why it was not started promptly in this case.

Deterioration

54. Baby A died from an overwhelming infection with *Pseudomonas aeruginosa*. Her medical records indicate that she began to deteriorate after midnight on Day 4, with her requirements for oxygen increasing rapidly, her heart rate increasing, and her blood pressure dropping.

[18] See Opinions 14HDC01187, 16HDC01010, and 17HDC00690. Available at www.hdc.org.nz.

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55. Professor Bloomfield advised that there was a significant change in the baby's condition that should have alerted clinicians to the possibility of infection. He stated that there should have been a thorough assessment of the baby, including appropriate investigations to exclude infection. However, there are no notes from the medical team over this period to indicate that the significance was recognised and acted upon. The nursing notes indicate that a chest X-ray was performed, which showed consolidation in the right lung.

56. However, CNS E said that the baby's transcutaneous CO_2 and oxygen requirement had both reduced by the time the nursing notes were written by RN D at 6.29am, and so antibiotics were not commenced. CNS E handed over care of the NICU to the daytime team at 8am.

57. There was a further opportunity to recognise the baby's condition at the time of the morning round on Day 5. The baby's lactate level was increasing, and the haematology test result at 8.20am was also "very suggestive of infection", although the full white cell results were not available until 2.20pm (after the antibiotics had been started).

58. Dr F appears not to have been aware of the overnight deterioration. He told the Coroner:

> "When the infant was seen on the ward round at 08.55hrs on 2/9/17 she looked well and it was planned to proceed with the extubation once the oxygen requirement had fallen."

59. Professor Bloomfield stated that the progression of the baby's deterioration from being relatively stable at 11pm on Day 4, to her death 13 hours later, indicates overwhelming sepsis with a highly virulent organism. Professor Bloomfield also noted that in his view it was doubtful that earlier initiation of antibiotics would have changed the outcome, but it was impossible to be certain. Professor Bloomfield stated:

> "I believe that most of my peers would have expected sepsis to be high on the list of differential diagnoses to explain the deterioration, particularly in light of an abnormal chest radiograph, and antibiotics to have been commenced earlier. I believe that most would consider that initiation of appropriate therapy was delayed and that this delay would be met with moderate disapproval."

60. I accept this advice. I note that CNS E was the resident on duty overnight and she failed to recognise the need to escalate the baby's care and did not contact the consultant. In my view, as a clinical nurse specialist and the sole resident on duty, it was essential that there be a low threshold for seeking assistance. Dr C noted that the next major opportunity to commence antibiotics was on the morning ward round, and I am critical that Dr F failed to recognise the signs of a developing infection and begin antibiotic treatment.

Staff levels and record-keeping

61. No medical documentation was made between 2.17pm on Day 4 and 12.30pm on Day 5, during which period the baby deteriorated. CNS E stated that she made no records overnight as a consequence of the pressure of work, as she prioritised dealing with

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imminent clinical situations. Professor Bloomfield advised that the lack of medical documentation would be met with serious disapproval.

62. I note that Dr C stated that "any actions or consequences from CNS' decisions, are the responsibility of the senior medical staff of the NICU". In my view, it was suboptimal that CNS E wrote no clinical records; however, this appears to have been a consequence of pressure of work. CNS E said that she was solely responsible for the entire NICU, attending assisted deliveries in delivery suite, and dealing with other issues that arose with neonates in the post-natal ward or delivery suite. She stated that the constant interruptions affected her ability to complete the documentation. In my view, if CNS E's failure to document was a consequence of work pressure, then she should have been better supported. Professor Bloomfield advised that in a NICU with 41 cots, in his view it was seriously inadequate to have just one member of staff (a clinical nurse specialist or a paediatrician) who was also responsible for covering the delivery suite and postnatal wards. He stated:

> "I agree entirely that this arrangement is likely to lead to constant interruptions and, I would contend, is not a safe level of staffing for a tertiary neonatal intensive care unit. There should be a member of the medical team (whether medical, NNP or CNS) on site on the unit at all times, and this would not be possible if there is only one member of staff who also is being called to births on the delivery suite and, potentially, to the postnatal wards."

63. Professor Bloomfield said that the expectation would be to have a medical practitioner such as a registrar or an accredited neonatal nurse practitioner on site. However, he said that this has not always been the practice in the past (including in 2017), when neonatal nurses with advanced nursing practice qualifications (similar to a clinical nurse specialist) may have staffed a unit without a medically qualified person on site. In Professor Bloomfield's view, the workload overnight on Day 4–5 would have required a minimum of two members of staff, and the staffing level may well have affected the ability to document in a timely manner overnight.

64. There are also no records of the handover of the baby's care to the day team at 8am on Day 5, or of the morning round. Professor Bloomfield advised that the absence of medical documentation between 2.17pm on Day 4 and 12.30pm on Day 5 is seriously deficient. He stated:

> "I would have expected the person on night duty to have completed retrospective documentation from the nightshift after handing over to the day team before going home and documentation from the day team prior to 12:30 given the deterioration."

65. I agree. I am critical of the standard of documentation, but acknowledge that this may have been a consequence of inadequate staffing overnight. However, I would have expected CNS E to make the notes later. I am also critical that no medical records were made by the day staff until 12.30pm, for which Dr F was responsible.

66. This Office has continually stressed the importance of clear and accurate documentation. As set out in the Health and Disability Services (Core) Standards, consumer information

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must be accurately recorded, current, and accessible when required. In my view, the documentation in this case was seriously sub-optimal.

Conclusions

67. In my view, Waikato DHB failed to provide Baby A with services with reasonable care and skill, in that:

- The commencement of aEEG monitoring was delayed for approximately 15 hours.
- There were clinical indications that the baby was becoming septic by 1am on Day 5, but there was insufficient assessment of the baby, and antibiotics were not commenced until 12.00pm.
- The medical/CNS staffing level overnight was inadequate.
- There were inadequate medical records made overnight on Day 4–5 and during the morning shift on Day 5.

68. Waikato DHB staff displayed a concerning lack of critical thinking when Baby A's condition deteriorated. The failure to recognise the baby's worsening condition meant that antibiotics were not commenced until midday on Day 5.

69. Overall, I find that Waikato DHB failed to respond adequately to a deteriorating situation and, accordingly, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights.

Other comment

70. As part of her complaint, Ms B expressed concerns about the manner in which staff at Waikato DHB NICU communicated with her. The clinical records suggest that there was considerable communication with the family, particularly when the baby's condition deteriorated. However, I note that it would be expected that communication would be with the parents of the baby and, in this case, Ms B was a grandparent. It was the parents' right to decide the extent to which they wished to have information shared with the wider whānau.

71. Ms B was also concerned about communication with the family following the baby's death, and the facilities available at the morgue. I note that Waikato DHB stated that it is undertaking a project with the Quality and Patient Service to review and improve aspects of the mortuary service.

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Recommendations

72. In the provisional opinion, I recommended that within three months of the date of this opinion, Waikato DHB carry out the following steps and report back to HDC:

a) Introduce an education programme for all NICU staff about the signs of possible infection, clarity of handover between teams, and the importance of clear and full documentation.

Waikato DHB advised that since this event in 2017 the following changes have come into effect:

- A weekly education session has been introduced.
- A specific sepsis management bundle of care has been developed, which all staff complete.
- Significant changes in the handover process have been implemented. Formal handover from the night staff to the incoming day staff now occurs.
- The requirements for documentation is near completion, having been trialled and refined over 2019, and a draft document provided to HDC.

I accept that Waikato DHB has now met this recommendation.

b) Carry out an analysis of the number of cot-side EEG monitoring units it requires, to ensure that it has sufficient equipment to provide appropriate care to all babies.

Dr C commented that the NICU has two cot-side aEEG monitors, and only very occasionally (perhaps twice in ten years) has there been a need to ration the equipment between more than two babies. An analysis of potential need has been provided to HDC.

I accept that Waikato DHB has now met this recommendation.

c) Review the staffing levels in the NICU.

Waikato DHB advised that resident staffing levels in the NICU were reviewed in 2019, and Waikato DHB approved an increase of five full-time residents (registrars/neonatal nurse practitioners) to provide additional cover on night shifts seven days a week. In addition, from 9 December 2019, a Neonatal Fellow position was introduced to provide additional support for the NICU medical workforce. A new protocol for Neonatal Intensive Care Unit — Medical Escalation Pathway was developed in 2019 and has since been implemented. The protocol details when staff should escalate for assistance from the senior medical team.

I accept that Waikato DHB has now met this recommendation.

d) Review its procedure for "Early Onset Neonatal Infection Prevention" to determine whether it is fit for use when *Pseudomonas aeruginosa* is in the differential diagnosis.

Dr C confirmed that a review of the DHB's standard antibiotic programme was completed in February 2020, and provided HDC with a copy.

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I accept that Waikato DHB has now met this recommendation.

73. I recommend that within three weeks of the date of this opinion, Waikato DHB formally apologise to the whānau of Baby A for its breaches of the Code. The apology is to be sent to HDC for forwarding.

Follow-up actions

74. A copy of this report will be sent to the Coroner.

75. A copy of this report with details identifying the parties removed, except Waikato DHB and the expert who advised on this case, will be sent to the Nursing Council of New Zealand, the New Zealand Nursing Organisation, the Royal Australasian College of Physicians (Paediatrics and Child Health Division), and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Professor Frank Bloomfield:

"To whom it may concern:

Ref C17HDC02291

I have been asked to provide an opinion to the Commissioner on case number C17HDC02291; I have read and agree to follow the Commissioner's guidelines for independent advisors. My name is Francis Harry Bloomfield. I am Professor of Neonatology at the University of Auckland and consultant neonatologist at Starship Children's Hospital since 2002. I am registered with the Medical Council of New Zealand. My qualifications are BSc (Hons), MBChB, MRCP (UK), FRACP, PhD.

I submit the enclosed report as requested by the HDC regarding the treatment of [Baby A] at … [the public hospital]. I have been asked to comment on [the following] key areas: (1) The treatment [Baby A] received for perinatal hypoxic ischaemic encephalopathy; (2) The treatment [Baby A] received when she developed signs of infection, and (3) Any other matters that I consider warrant comment.

I have reviewed the documents provided (letter of complaint; Waikato DHB's response dated 19 March 2018; Clinical records from Waikato DHB from [Day 1] to [Day 5]; Labour notes for [Day 1]; Clinical records from [the birthing clinic] for [Day 1]; Statement and notes from [the ambulance service], and the post-mortem report). The following were not provided: any imaging or formal reports of said imaging; echocardiography report for [Baby A]; laboratory test reports; cotside EEG traces.

…

1. The treatment [Baby A] received for perinatal hypoxic-ischaemic encephalopathy. The essentials of [Baby A]'s treatment for hypoxic-ischaemic encephalopathy are consistent with standard practice. Therapeutic hypothermia was initiated promptly using a servo-controlled device and continued for the standard 72 hours. Whilst the majority of babies receiving therapeutic hypothermia would receive assisted ventilation via an endotracheal tube, this is not universal. [Baby A] was managed initially via CPAP, with intubation only being performed at about 36 hours of age due to rising PCO2 levels on blood gas measurements. Different approaches to use of ventilatory support during therapeutic hypothermia reflect variation in practice rather than deviations from accepted best practice.

(a) Cotside EEG monitoring was only commenced approximately 24 hours after initiation of therapeutic hypothermia. Generally, this would be commenced early in babies with suspected or confirmed hypoxic ischaemic encephalopathy as it is well recognised that there may be electrical seizures that are not detected clinically.
(b) Although this may mean that some prior seizures went undetected, given [Baby A]'s general condition over this early period, which was very good, this is unlikely

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to have impacted upon neurological outcome. Due to her untimely death prior to the possibility of neuroimaging, and partial post mortem without examination of the brain, we do not have information on the degree of brain injury. The clinical notes indicate that [Baby A] had stage 2 hypoxic ischaemic encephalopathy and the evidence available in the records supports this.

(c) Most neonatologists in tertiary centres would commence cotside EEG monitoring in babies receiving therapeutic hypothermia for suspected or confirmed hypoxic ischaemic encephalopathy as soon as possible.

2. The treatment [Baby A] received when she developed signs of infection

[Baby A] died from overwhelming infection with *Pseudomonas aeruginosa.* Of note is that there was a positive blood culture and isolation from the lungs, but other organs appeared unaffected. Antibiotics were commenced at 12:00 pm on [Day 5]. The medical records do indicate deterioration prior to this, commencing at about midnight with the fraction of inspired oxygen increasing rapidly from 0.21 (air) at 23:00 to 0.4 at 01:00. Contemporaneous with this is an increase in resting heart rate which was around 120 beats per minute between 16:00 and 20:00 on [Day 4], increasing to 140 bpm by midnight and 160 bpm at 02:00. At 03:00 the heart rate was 200 beats per minute. Blood pressure recordings were made every 6–8 hours. For most of [Day 4], the mean blood pressure was 52–55 mmHg. At 01:00 it was 43 mmHg and at 06:00 38 mmHg.

(a) These physiological changes should alert one to the possibility of infection, representing a significant change in baby's condition. The response should be a thorough assessment of the baby including appropriate investigations to exclude infection. There are no notes from the medical team over this period, with entries at 14:17 on [Day 4] not expressing any concern and then at 12:30 on [Day 5] when [Baby A] was seriously ill. The nursing notes do indicate that a chest radiograph was performed, which showed consolidation in the right lung, but I cannot identify the timing of this (although prior to 06:30 as this is when the nursing note was made) and neither the radiographs, nor a radiologist report, were available for review. Antibiotics were not commenced for a further 6 hours.

(b) It is difficult to assess whether the delay in commencement of antibiotics contributed in any way to the final outcome. The progression of [Baby A's] deterioration, from relatively stable at 23:00 on [Day 4] to demise 13 hours later indicates overwhelming sepsis with a highly virulent organism. It is doubtful that earlier initiation of antibiotics would have changed the outcome but it is impossible to be certain. It is also the case that review of the notes with full knowledge of the outcome and diagnosis carries a substantial benefit of hindsight.

(c) Nevertheless, I believe that most of my peers would have expected sepsis to be high on the list of differential diagnoses to explain the deterioration, particularly in light of an abnormal chest radiograph, and antibiotics to have been commenced earlier. I believe most would consider that initiation of appropriate therapy was delayed and that this delay would be met with moderate disapproval. The lack of medical documentation over the 24 hour period when [Baby A] deteriorated would be met with serious disapproval.

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(d) It is difficult to make recommendations for improvement to prevent recurrence in the future beyond education of staff as to the importance of the signs of possible infection, clarity of hand-over between teams, and, most obviously, the importance of clear and full medical documentation.

3. Any other matters warranting comment.
Pseudomonas aeruginosa sepsis in a term infant is rare. I note [Dr C's] suggestions regarding possible sources of infection. I think there is an additional possibility. [Baby A] may have acquired *Pseudomonas aeruginosa* during the birth without this being responsible for her condition at birth. As noted by [the pathologist], *Pseudomonas aeruginosa* is commonly found in water and it is possible that the water of the birthing pool was contaminated, resulting in [Baby A] becoming infected. This, together with the initial treatment with antibiotics for 36 hours, would explain the delay between birth and onset of severe sepsis. If the infection had been responsible for [Baby A's] condition at birth, I would not have expected her to have a relatively stable course for 72 hours. Cases of *Pseudomonas aeruginosa* infection in newborns acquired from water, including a birthing pool, are reported in the literature, albeit infrequently (see below) and despite appropriate cleaning of the facilities. It may be worth [the birthing clinic] testing their birthing pools for contamination with *Pseudomonas aeruginosa*.

Vochem *et al* Sepsis in a newborn due to *Pseudomonas aeruginosa* from a contaminated bath tub. New England Journal of Medicine 2001; 345: 378–379.

Parker *et al* Pseudomonas otitis media and bacteremia following a water birth. Pediatrics 1997; 99(4): **doi:** 10.1542/peds.99.4.653a

Rawal *et al* Water birth and infection in babies. BMJ 1994; 309: 511

Byard RW and Zuccollo JM. Forensic issues in cases of water birth fatalities. Am J Forensic Med Pathol 2010; 31(3): 258–60. doi 10.1097/PAF.0b013e3181e12eb8. *Note that this is a New Zealand publication and also carries recommendations on full post mortem examination including of the placenta.*

Frank Bloomfield"

Addendum

"The nursing complement required would depend upon the acuity of the babies within those 41 cots. For comparison, the baseline nursing staff at National Women's NICU is 14 nurses when we have 36 babies, increasing up to 16 or 17 when we reach 40 or more. Additional nurses may be required if there is a very sick baby requiring 1:1 care (that is, one nurse dedicated to a sick baby). Babies receiving therapeutic hypothermia for hypoxic ischaemic encephalopathy would often, although not always, have a dedicated nurse delivering 1:1 care.

I think that one member of staff for a NICU with 41 cots who also is responsible for covering delivery suite and postnatal wards is seriously inadequate. I agree entirely that

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this arrangement is likely to lead to constant interruptions and, I would contend, is not a safe level of staffing for a tertiary neonatal intensive care unit. There should be a member of the medical team (whether medical, NNP or CNS) on site on the unit at all times, and this would not be possible if there is only one member of staff who also is being called to births on the delivery suite and, potentially, to the postnatal wards.

One would normally expect a medical practitioner (e.g. registrar) or accredited neonatal nurse practitioner to be on-site, although this has not always been the practice in the past (including in 2017) when neonatal nurses with advanced nursing practice qualifications (so probably similar to a CNS) may have staffed a unit without a medically qualified person on site. However, I would reiterate that one member of staff for the workload you describe is, in my view, seriously inadequate. This would require a minimum of two members of staff. This may well have affected the ability to provide documentation in a timely manner overnight, but the absence of documentation between 14:17 on the 1st and 12:30 on the second (with, presumably, a new complement of day-time staff commencing somewhere between 8 and 9) is seriously deficient. I would have expected the person on night duty to have completed retrospective documentation from the nightshift after handing over to the day team before going home and documentation from the day team prior to 12:30 given the deterioration."

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