Auckland District Health Board

General Practitioner, Dr C

A Report by the

Health and Disability Commissioner

(Case 15HDC00661)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mrs A's daughter, Baby A, was born in 2014, at a public hospital. The Ministry of Health Well Child/Tamariki Ora (WCTO) Programme Practitioner Handbook states that red eye reflex screening (the accepted screening test for early detection of significant eye abnormalities) using an ophthalmoscope should be undertaken at birth or up to seven days of age, and definitely by the six-week assessment. The vision screening to be undertaken at the six-week Well Child assessment should also include red eye reflex screening.

2. Baby A's red eye reflex was not checked during her time at the public hospital. She was discharged when she was six days old, and her care was then provided by Registered Midwife (RM) RM B. There was no clear communication to RM B that the red eye reflex screening had not been done in hospital.

3. It was not until RM B's fourth postnatal visit with Baby A and Mrs A on 19 Month2[1], when Baby A was 33 days old, that RM B realised that Baby A's red eye reflex had not been tested. RM B then undertook this screening. RM B believed that she saw the red eye reflex and documented accordingly.

4. Dr C saw Baby A at the medical centre for her six-week check on 2 Month3. When Dr C performed the vision assessment he checked only the corneal reflexes,[2] and did not use an ophthalmoscope. Dr C documented that Baby A had passed her vision assessment.

5. Dr C saw Baby A for her three-month check on 24 Month4. Dr C checked Baby A's corneal reflexes on this occasion. However, he did not check the red eye reflex.

6. On 13 Month5, Mrs A took Baby A to see Dr C because of her concerns that Baby A was not focusing on people's faces, and that her "wandering eye" had become worse. Dr C noted that Baby A had evidence of a squint. He checked the corneal reflexes on this occasion (not the red eye reflex), and did not use an ophthalmoscope.

7. The next day, Dr C sent a referral to ADHB Ophthalmology marked urgent, and noted: "3 month old baby with significant squint and concern about vision." Dr C included notes from the consultation the previous day (including notes stating "light reflexes fine"). As the referral letter stated that Baby A's light reflexes were normal, the referral was assigned priority B.

8. Baby A was subsequently given an appointment with an ADHB ophthalmologist on 6 Month6. She was diagnosed with a cataract and underwent surgery to remove the cataract the following day.

[1] Relevant months are referred to as Months 1-6.
[2] This can be used to assess eye symmetry.

Findings

9. Staff at ADHB failed to test Baby A's red eye reflex while she was in the public hospital, and ADHB did not have adequate systems in place to communicate whether or not the testing had been carried out. ADHB did not provide services to Baby A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[3]

10. RM B missed an opportunity to review Baby A's documentation carefully and query whether the red eye reflex test had been done.

11. Dr C failed to check Baby A's red eye reflex at the six-week and three-month checks, failed to undertake a red eye reflex examination with an ophthalmoscope at the appointment of 13 Month5 when it was clinically indicated, and, accordingly, wrote an inappropriate referral. In these circumstances, Dr C did not provide services to Baby A with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

12. The Commissioner recommended that ADHB provide a written apology to Mr and Mrs A, provide HDC with a copy of the final version of the formal policy "Newborn examination — care responsibility", and provide HDC with an update on compliance with the use of the sticker for documenting red eye reflex testing in the WCTO health book, and completion of the red eye reflex field (date of test and comments) in the electronic discharge summary document.

13. In the provisional opinion, the Commissioner recommended that Dr C provide a written apology to Mr and Mrs A. Dr C has undertaken to comply with this recommendation.

14. The Commissioner recommended that Dr C undertake a review of current best practice with regard to red eye reflex assessments.

15. The Commissioner recommended that the Medical Council of New Zealand consider whether a review of Dr C's competence is warranted.

16. The Commissioner noted that currently the Ministry of Health is undertaking policy work on the content and timing of the WCTO schedule, and newborn vision screening (including the red eye reflex component) will be covered as part of this work. He recommended that, as part of this work, the Ministry of Health consider working with stakeholders to achieve consensus on the timing and performance of red eye reflex testing, as well as the training and equipment requirements for red eye reflex testing.

[3] Right 4(1) of the Code states that every consumer has the right to receive services provided with reasonable care and skill.

Complaint and investigation

17. The Commissioner received a complaint from Mr and Mrs A about the services provided to their infant daughter, Baby A, by Auckland District Health Board, registered midwife RM B, and Dr C. The following issues were identified for investigation:

- *The appropriateness of the care provided to Baby A by Auckland District Health Board in 2014.*
- *The appropriateness of the care provided to Baby A by Dr C in 2015.*

18. The parties directly involved in the investigation were:

Mr and Mrs A	Complainants/consumer's parents
Auckland District Health Board	Provider
RM B	Midwife
Dr C	General practitioner
Medical centre	Provider

Also mentioned in this report:

Dr D	Paediatric registrar
Ms E	Ward clerk
Dr F	Ophthalmologist
Dr G	Ophthalmologist

19. Information was also reviewed from ACC and the Medical Council of New Zealand.

20. Independent expert advice was obtained from registered midwife Suzanne Miller (**Appendix A**) and in-house clinical advisor general practitioner Dr David Maplesden (**Appendix B**).

Information gathered during investigation

Background

21. In 2014, Mrs A was pregnant with her second child. Mrs A had her maternity care provided through the public hospital's (Auckland District Health Board (ADHB)) midwifery clinics. Baby A was born by elective Caesarean section on 17 Month1 at the public hospital. Mrs A arranged for her postnatal care to be provided by self-employed registered midwife RM B.

22. Baby A was diagnosed with a cataract[4] in her left eye on 6 Month6 and required surgery to remove it. This report relates to the care Baby A received from ADHB, RM

[4] An opacity of the lens of the eye that causes partial or total blindness.

B, and general practitioner (GP) Dr C at the medical centre in the months prior to Baby A's diagnosis.

Context

Red eye reflex

23. The accepted screening test for early detection of significant eye abnormalities in neonates is the red eye reflex test. This involves using a light source (usually an ophthalmoscope)[5] shining through the anterior eye structures (cornea and lens) to reflect off the retina. A normal eye will show the "red eye" appearance commonly seen in flash photography. If there is a significant opacity in the lens (cataract) the reflex will appear irregular.

Requirements to check red eye reflex — Ministry of Health handbook

24. The Ministry of Health Well Child/Tamariki Ora (WCTO) Programme Practitioner Handbook[6] states:

> "**Newborn baby vision and eye** … External examination of the eye and red reflex screening using an ophthalmoscope are essential aspects of the routine infant vision and eye examination … If the red reflex is absent, this means that light cannot get to and reflect back from the retina. A white reflex may indicate an intra-ocular mass … In the case of infants with congenital cataracts, which are reasonably common, surgery is recommended between *four and eight weeks* [emphasis in original] of age in order to preserve sight. It is vital therefore that this assessment is undertaken as soon as possible after birth and definitely by the six-week assessment …
>
> *Age of child*
> This component should be delivered at birth or up to seven days of age. This assessment is undertaken as part of either the neonatal or postnatal assessment. If for any reason the LMC is unable to undertake a full assessment (which includes a red reflex assessment with a direct ophthalmoscope) at either of these points, the LMC must make a referral to the infant's general practitioner for the assessment to be included in the six-week assessment …
>
> **Six-week eye examination and vision surveillance** … The vision screen at six weeks should be done by a practitioner trained to use a direct ophthalmoscope (eg by the GP as part of the six-week assessment) … at the six-week assessment, complete a physical external assessment. Physical external eye assessment covers the following questions … are the eyes of equal size? … are the media clear (normal red reflex)? … Do the eyes look straight (ie, point in the same direction)? … "

[5] An instrument for inspecting the retina and other parts of the eye.
[6] Ministry of Health. 2013. Well Child/Tamariki Ora Programme Practitioner Handbook: Supporting families and whānau to promote their child's health and development. Revised 2014. Wellington: Ministry of Health.

Documentation

25. The WCTO practitioner handbook is complementary to the parent-held WCTO health book. In most cases, practitioners will maintain documentation of visits and actions taken in the WCTO health book as well as in their own records. The WCTO health book has designated pages to be filled in at each assessment following birth (eg, at birth, at 24–48 hours, first week, 2–6 weeks, 4–6 weeks, etc) and designates who should fill in these assessments (eg, the lead maternity carer (LMC)). It also has spaces for comments and notes to be recorded.

26. The WCTO health book (relevant at the time of these events) has designated spaces to record whether the red eye reflex has been checked during the physical assessment at birth, and at 24–48 hours.

Care provided by Auckland District Health Board

27. Mrs A gave birth to Baby A at 1.49pm on 17 Month1 by Caesarean section when she was at 37 weeks' gestation.

Immediate postnatal care — 17 Month1

28. Following Baby A's birth, an ADHB midwife recorded details of Baby A's birth on the ADHB newborn record. The midwife documented in the clinical notes: "[S]kin to skin given after baby check by [paediatrics]." The midwife stated that she does not perform the red eye reflex screening in the operating theatre because of the brightness of the theatre lights.

29. Paediatric registrar Dr D examined Baby A in the first few minutes of life. Dr D told HDC that the aim of the initial newborn examination was to ensure that Baby A had transitioned well and established respirations, as well as to detect anomalies or illness that could cause problems requiring immediate attention. Dr D also stated that it is not usual practice to check the red reflex in the operating theatre. Dr D recorded in the clinical notes under the immediate postnatal history and examination section of the newborn record, "RR not checked", referring to Baby A's red eye reflex not having been checked at that time.

30. On the "Birth Assessment" page of the WCTO health book (page 41) is an entry that is unsigned. The WCTO health book states that this page is to be completed by the LMC. However, ward clerk Ms E confirmed that she transcribed the birth notes into page 41 of Baby A's WCTO health book. Above the text "eyes", Ms E documented a tick, and above the words "red reflex", Ms E documented a cross.

31. Ms E stated that the ward clerks were expected to transcribe additional information from the newborn record into the WCTO health book. Regarding the "eye" section of the documentation, Ms E said that the practice was to tick that the eyes had been checked as part of the newborn examination, and to cross (or write "not done") by the red eye reference if it was recorded as not having been done, or if nothing was recorded.

32. ADHB told HDC that the more usual approach across the service was to leave the check box blank if a red reflex test had not been performed, and to use a cross to

indicate an issue with the examination. ADHB stated that when a cross is used it is expected that the clinician will provide an explanation of what it means in the "comments/actions" area of the WCTO health book. The relevant "comments/actions" area of the WCTO health book was left blank.

33. At 5.50pm, a registered nurse (RN) recorded that Mrs A and Baby A had been transferred to the postnatal ward.

24–48 hours postnatal

34. Early on the morning of 18 Month1, Baby A was transferred to the neonatal intensive care unit (NICU) with hypoglycaemia.[7] She spent 18 hours under the care of paediatricians and was treated for hypoglycaemia. She was discharged back to the postnatal ward later that day, after her blood glucose had stabilised.

35. On page 43 of the WCTO health book under the heading "24–48 hours assessment", all spaces are left blank, including the space next to "eyes: red reflex". At the top of this page it states: "To be completed by your Lead Maternity Carer."

36. ADHB told HDC that although there would have been an opportunity to perform red eye reflex testing during the admission to NICU:

> "[I]t was not then and is not currently, normal practice for paediatricians to complete a well-child examination for babies who are admitted to NICU to manage a short term specific problem such as hypoglycaemia. Normal practice would be to document that the well child exam was not completed and to transfer responsibility back to the LMC."

37. ADHB stated that once Baby A was discharged back to the postnatal ward, responsibility for completing the red eye reflex testing returned to the maternity team.

Discharge — 22 Month1 — 6 days old

38. On 22 Month1, Mrs A and Baby A were discharged from the public hospital into the care of RM B. On the ADHB "Labour and Birth Summary" discharge document, the space next to "Red eye reflex" is left blank. This document was completed by an ADHB RN.

39. In the ADHB root cause analysis (discussed further below), ADHB found that the handover practice in situations where red eye reflex is not done in the inpatient setting was "inconsistent and not robust across Labour and Birthing Suite, the wards and NICU". ADHB stated: "Handover would normally take place via the health software system discharge summary, the [WCTO health book] and the inpatient clinical notes. In this case, the discharge summary was blank and the [WCTO handbook] also had issues."

[7] Low blood glucose level.

Care provided by RM B

40. RM B has many years' experience as a health practitioner, including 20 years' experience as a midwife. At the time of these events, RM B had recently become self-employed and was contracted to private obstetricians to provide postnatal care. Mrs A was the first postnatal care case that RM B had received from a hospital. RM B told HDC that it had been agreed between Mrs A, the hospital and herself, that she (RM B) would not be involved in Mrs A's care until Mrs A was discharged from hospital after delivery. ADHB told HDC that RM B was employed by ADHB under a contract to provide midwifery postnatal services to women who had elected to receive such services from ADHB.

Visit 1 — 7 days old

41. On 23 Month1, RM B first visited Mrs A and Baby A at their home. RM B assessed Baby A and recorded her assessment in the WCTO health book on page 47 under the "first week assessment". The box next to "physical examination — eyes" is ticked, and the "Pass" box next to "Vision assessment" is ticked. On the page referring to "24–48 hours assessment" under "Indicators at birth for vision or eye problems", RM B has ticked "none of the above".

Visit 2 — 14 days old and Visit 3 — 21 days old

42. On 30 Month1, and again on 6 Month2, RM B visited Mrs A and Baby A. The notes recorded in the WCTO health book are related to feeding.

Visit 4 — 33 days old

43. On 19 Month2, RM B visited Mrs A's home for Baby A's 2–6 week LMC assessment. RM B undertook a red eye reflex test on Baby A at this appointment. RM B stated: "[At this time] it first became apparent to me that this test may not have been carried out while [Baby A] was in hospital." RM B said that she had mistakenly assumed it had been done at the hospital, and that she "went back over [her] care and realised it had been missed".

44. RM B told HDC:

> "At the time of this incident many of my other patients had a large sticky label on the front of the [WCTO health book] alerting me to the fact the red eye reflex had not been done. [Baby A's] did not have the label and I mistakenly assumed it had been done at the hospital."

45. Regarding the test, RM B told HDC that she used a pocket ophthalmoscope. She stated:

> "I picked up the right eye easily but struggled to pick up the left eye as [Baby A] started to cry, close her eyes and move her head backwards and forwards. [Baby A] was on her mother's knee also making the angle I was checking from difficult. After some time moving backwards and forwards with [Baby A], I was confident I had picked up the red eye reflex on her left eye."

46. RM B ticked the "Pass" box next to "vision assessment" on the 2–6 weeks LMC final assessment page of the WCTO health book. RM B also documented on that page that the red eye reflex test was completed that day, and ticked the box next to "eyes", indicating that these were "OK".

47. According to Mrs A, during RM B's assessment of Baby A, RM B struggled to find Baby A's red eye reflex, but said that "it must be there". RM B told HDC: "I do not recall saying 'It must be there' [and] I confirm categorically that I would never knowingly record an assessment incorrectly."

48. RM B documented in her postnatal notes: "Final assessment done on [Baby A]. Red eye reflex done as noted not done at birth. R eye ✓ L eye ✓." RM B's final comments recorded in the WCTO health book were: "Alert active baby girl. Gaining weight well. Has reflux but not effecting [sic] weight gain. To visit GP for reflux."

Visit 5 — 41 days old

49. On 27 Month2, RM B had her last visit with Mrs A and Baby A. RM B noted that Baby A was feeding well and had settled, and discharged Mrs A and Baby A to GP care.

Care provided by GP — Dr C at the medical centre

50. The medical centre is a partnership that provides support services for the doctors that work there, and charges the doctors for those services. The medical centre's general manager advised that Dr C practises medicine independently and is not an employee of the medical centre.

Six-week check — 2 Month3[8]

51. Mr and Mrs A noticed that Baby A appeared to have a "severe lazy eye", so they took her to see Dr C at the medical centre on 2 Month3. Mrs A told HDC that Dr C said that Baby A's eyes were just starting to develop, and to "allow her up to 6 months".

52. Dr C assessed Baby A and recorded: "[E]yes normal … eyes straight." The red eye reflex is not referred to specifically in the notes. However, Dr C told HDC:

> "I did initially see [Baby A] for her 6 week check and I normally check the eyes carefully at this time and again at 3 months. There was no squint at the time and the light reflexes were equal. I did not see a cataract but not always easy to see in a baby at this stage and I always recheck this …"

53. Dr C clarified that he checked only the corneal reflexes[9] (ie, not the red eye reflex), and did not use an ophthalmoscope. He stated: "I usually use an ophthalmoscope to test the red reflexes but to be honest I did not do this and obtained false reassurance about her eyes."

[8] Baby A had one earlier GP visit on 19 Month2, where she was seen by a GP for reflux, noisy breathing, and a small cyst in her mouth. There is no mention of concerns regarding vision in the clinical notes.
[9] This can be used to assess eye symmetry.

54. Dr C ticked the "Pass" box next to "vision assessment" on the 4–6 weeks assessment page in the WCTO health book.[10]

Three-month check — 24 Month4

55. On 24 Month4 Dr C undertook a three-month assessment of Baby A.[11] The notes for this assessment state: "… [E]yes normal …" There is no further documentation regarding the extent of the eye examination. Dr C told HDC that he checked Baby A's corneal reflexes on this occasion.

GP visit — 13 Month5

56. Around this time, Mr and Mrs A noticed that Baby A was not focusing on people's faces, and said that her "wandering eye" had become worse. On 13 Month5, Mrs A took Baby A back to see Dr C regarding these concerns, and requested a referral to a specialist. Dr C recorded in the clinical notes:

> "[C]oncern re vision, mum does not think she is seeing well, 'always cross-eyed'. Mum thinks she is not focussing and tracking well. Seems OK today, light reflexes fine, tracking light fine, Mum and dad and friends thinks there is something wrong with her eyes. Probably OK but will refer for formal testing."

57. In his response to HDC, Dr C stated that "[d]uring the examination her left eye did drift and she had evidence of a squint". He further clarified that he checked only the corneal reflexes on this occasion (not the red eye reflex), and did not use an ophthalmoscope.

58. On 14 Month5, Dr C generated an electronic referral to ADHB ophthalmology; this was marked "URGENT" and noted: "3 month old baby with significant squint and concern about vision." Dr C included notes from the consultation the previous day, and the comment: "3 months old now and significant concerns from parents and family and does have quite a marked squint."

ADHB — Ophthalmology

59. On 15 Month5, the referral was graded by ADHB Ophthalmology — Paediatrics as priority B (to be seen within six weeks). Ophthalmologist Dr F from ADHB told HDC that referrals that indicate an abnormality in the red reflex are given priority A, with the infant being seen within days. However, as the referral letter stated that Baby A's light reflexes were normal, the referral was assigned priority B. ADHB advised that this referral was triaged appropriately. Baby A was given an appointment for 6 Month6.

Ophthalmology appointment — 6 Month6

60. Baby A attended her appointment and was seen by ophthalmologist Dr G. Dr G noted that Baby A's left corneal diameter was smaller than the right, and a dense brown

[10] On 5 Month4 Baby A saw a GP because of a one-week history of a cold. There is no mention of concerns regarding vision or the appearance of Baby A's eyes in the clinical notes.
[11] In the clinical notes this is recorded as the six-week check.

opacity (a cataract) was present behind the left pupil. Dr G referred Baby A to Dr F for surgery.

Surgery

61. The following day, on 7 Month6, Dr F examined Baby A's left eye under general anaesthetic and removed the cataract from her eye. Dr F told HDC that the surgery was straightforward.

62. Mrs A told HDC that Baby A's "eye ball was not growing as stuff behind the eye was restricting the growth". Dr F stated that the type of cataract Baby A had is related to "persistent foetal vasculature" within the eye, which typically produces a cataract in utero that is present at birth, and that the affected eye is almost always smaller than the other. He stated that early or late surgery does not change the growth of the eye, but that "the earlier the surgery, the better the potential for a good visual outcome".

Further information

The family

63. Mrs A told HDC:

> "[Baby A's] left eye is much smaller as well as the surrounding lids meaning cosmetically she will always look different. She is legally blind in that eye now. The specialists told us if it was picked up on a check by 6 weeks they could have operated immediately and maybe saved her sight."

ADHB

64. ADHB told HDC:

> "ADHB accepts that it failed to ensure that [Baby A] received red eye reflex screening during her hospital stay of 6 days despite receiving care from numerous clinicians with the skills to perform this important eye check. The documentation of the newborn examination was ambiguous with respect to whether red eye reflex testing had been performed and the comments section which was the opportunity to clarify what had occurred was left blank. It is likely this occurred because the responsibility for completing the well child book had been delegated to a non-clinical person (ward clerk).
>
> We deeply regret our contribution to this tragic outcome and accept responsibility for our part in this. We have taken this outcome very seriously … we have ensured that other DHBs and professional groups have had an opportunity to share our learning."

65. ADHB told HDC that its investigation of this case revealed a number of failures in its process at the time of Baby A's birth, including:

> "• A lack of clarity around timing and responsibility for red eye reflex testing.
>
> • A knowledge/skill gap was identified in the ability of our staff to correctly perform testing and interpret results. The practice of most midwives was found

to be out of date. Most had been taught to examine each eye separately and to position the ophthalmoscope immediately in front of one eye and then the other. Agreed best practice is to hold the ophthalmoscope close to the examiner's eye 18 inches from the infant's eye in a darkened room and visualise both eyes simultaneously. An online survey by ADHB showed almost a third of the responders (LMCs) were not confident with the red reflex test and over two thirds felt they had not had formal training for performing the red reflex test.

- Limited access to ophthalmoscopes of appropriate quality in all areas caring for newborns.

- Issues with the documentation of assessments, in that the previous [WCTO handbook] provided a tick-box to indicate that an eye check has been performed but does not specifically provide a place to comment on red eye reflex test results."

66. ADHB noted that there was an inconsistent practice of attaching a white sticker (flag) to the WCTO health book to indicate that the red eye reflex had not been checked within 24 hours of birth and, in this case, the white sticker was not attached to the book. In this respect, ward clerk Ms E stated: "We were never required to put a sticker on the book to flag that the red eye reflex had not been carried out." ADHB stated that the sticker not being on the book contributed to the failure of the postnatal midwife to appreciate immediately that testing had not occurred prior to discharge.

67. ADHB told HDC that as an extremely serious event, this was designated a severity assessment code (SAC) "1" (most serious), and reported to the Health Quality and Safety Commission (HQSC). ADHB conducted a Root Cause Analysis (RCA), which was completed in February 2016. The root cause identified by ADHB was: "Lack of a robust system to ensure proper assessment and documentation of red eye reflex."

68. The following 13 recommendations were made in the RCA:

"1. Escalate the risk to the organisation to level 2 clinical governance.
2. Ensure appropriate quality ophthalmoscopes are available in all clinical areas where new-borns are cared for.
3. Inform NZCOM, NZ Midwifery Council, National Screening Unit and Ministry of Health of current challenges around ensuring competence for red reflex screening.
4. All midwifery educators retrained as expert red eye reflex screeners.
5. Update the health software system to reflect changes in red eye reflex screening made as a result of this review.
6. DHB–GP liaison to communicate best practice to primary health organisations.
7. Women's Health implement immediately the practice of only clinicians (not administrative staff) to document in the WCTO health book.

8. Cease practice of attaching white sticker to show 'unchecked red reflex'. Red eye reflex to be written as 'checked' or 'not checked' in the postnatal discharge summary.
9. RCA report to be shared with Ministry of Health, National Screening Unit and other DHBs to share learning.
10. New policy developed for red eye reflex checks. The test must be performed, documented and signed off by one responsible clinician (LMC) once between birth and 6 weeks. Optimal time is within first week and preferably before discharge from in-patient services.
11. Consider developing and running a training course for red eye reflex testing for all DHB staff involved in baby checks.
12. ADHB to suggest to Ministry of Health that second red eye reflex check should be specified as mandatory for the six-week GP check in the new policy/Ministry of Health guidelines.
13. ADHB to suggest to the Ministry of Health that the Well Child Book be revised to reflect unequivocal documentation for red reflex in both eyes."

69. ADHB advised that all of the above recommendations have now been implemented. ADHB told HDC that the Ministry of Health has modified the timing (in the new WCTO handbook, revised in August 2016) of the full physical examination of a newborn baby, including the red eye reflex test, until 24–48 hours of age. It believes that this is a positive change from requiring the test to be completed at birth. At birth it is not ideal timing because bright lights in the operating theatre after Caesarean section or swelling around eyes after vaginal birth can preclude a reliable examination occurring.

70. In collaboration with the Department of Ophthalmology, ADHB developed a training programme for clinicians providing care at ADHB. All midwifery educators were retrained as expert red reflex screeners and have taken responsibility to ensure that all Women's Health clinical staff are trained progressively. A training video is also available on the ADHB website.

71. Despite efforts put into training, ADHB is concerned about the reliability of red eye reflex testing as prescribed by the Ministry of Health. ADHB stated:

> "Although the red eye reflex testing is viewed by many as simple and something any appropriately trained practitioner can perform reliably our investigation leads us to believe this is not the case."

72. Accordingly, ADHB communicated with the Midwifery Council of New Zealand regarding its concerns about overall competence with respect to red eye reflex testing, and, following discussion, a link to the ADHB training video was provided to the Midwifery Council to assist with the development/maintenance of red eye reflex testing. ADHB also contacted the Ministry of Health, the New Zealand College of Midwives, and the Royal Australasian College of Physicians (Paediatrics & Child Health) regarding its concern, and said that the matter has generated considerable debate amongst professional groups who have an interest or responsibility in relation to red eye reflex testing.

73. ADHB's focus on training and skills development for red eye reflex testing has meant that there has been a substantive increase in referrals to primary care and to the ADHB ophthalmology clinic. To manage this, ADHB has agreed a local approach with the Department of Ophthalmology.

74. Following completion of ADHB's investigation into Baby A's case, it worked with HQSC to develop an Open Book report to ensure that the learning from the case was widely disseminated. Open Book reports aim to alert providers to the key findings of adverse event reviews. The reports emphasise the changes implemented to stop the event happening again. The case "Red reflex assessment in newborns" was published on the HQSC website on 16 June 2016.[12]

75. ADHB stated that the issues uncovered by this case were presented at the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) facilitated Clinical Directors forum on several occasions, and to the combined national Clinical Directors and National Midwifery forum on 15 August 2016.

76. ADHB is in the process of developing a formal policy ("Newborn examination — care responsibility") to ensure better clarity of responsibility in regard to the newborn examination, including red eye reflex testing.

77. ADHB said that it has developed a new sticker to go into the WCTO health book to assist in accurately recording red eye reflex screening, and that a mandatory field for red eye reflex (date of test and comments) has been added to the electronic discharge summary document.

78. ADHB acknowledged that there were some errors in the information contained on Baby A's discharge summary. For example, on the Labour and Birth summary it states the time of birth as 1549, with the placenta therefore being born almost two hours prior to Baby A (at 1353), and the Guthrie test,[13] normally completed 48 hours after birth, having been obtained three days prior to Baby A's birth (on 14 Month1). It also suggests that Baby A had received only breastmilk from birth, when she had been artificially fed during her time in NICU. ADHB noted that some of these errors would have been corrected as part of regular end-of-year data cleaning, and said that staff will be reminded of the importance of vigilance in their data entry.

79. ADHB stated:

> "On behalf of all the staff involved in [Baby A's] care, please convey our sincere apologies to [the family] for the distress and worry that this experience has caused them. We fully accept our contribution to [Baby A's] loss of vision and deeply regret that we have let this family down.

[12] http://www.hqsc.govt.nz/publications-and-resources/publication/2552/
[13] A routine blood test carried out on babies a few days after birth to detect the condition phenylketonuria (an inherited metabolic disorder).

> We believe we have responded to the gap in care this case has revealed and have worked collaboratively with our stakeholders to draw attention to the risk and find sustainable solutions that will minimize the likelihood that what happened to [Baby A] happens to other babies under our care and to babies cared for across New Zealand."

RM B

80. RM B told HDC that, as a result of these events, she has made the following changes to her practice:

- She has reviewed her practice to ensure that her method is in accordance with the procedures set out in the WCTO practitioner handbook.
- She now ensures that she carries out the red eye reflex test with the baby on her knee, rather than the mother's, and that the mother assists in holding the baby's head still.
- She has attended a study day to learn the updated best practice (regarding red eye reflex testing).
- She has replaced her small pocket ophthalmoscope with a better quality one.
- She is vigilant in checking whether tests that should have been carried out have in fact been carried out.
- She has spent time with a consultant paediatrician to practise her technique.

81. RM B said that she is continuing discussions with the charge midwife at the public hospital and making recommendations about areas of documentation not being left blank, and how to improve the communication between LMCs and the hospital.

82. RM B stated: "I unconditionally apologise if any omission on my part contributed to [Baby A's] eye problems."

Dr C

83. Dr C told HDC:

> "I believe as [Baby A's] primary caregiver and one who is experienced in all aspects of neonatal examination … this should have been picked up. I do not wish to offer any excuse for this as it is my responsibility to pick this up and I do not want to justify it in any way at all. Unfortunately the outcome cannot be changed but I am very sure that it will not happen again and I have put measures in place to make sure of this."

84. Dr C said that he is now "absolutely vigilant" about checking the red eye reflexes and recording this in the notes and Plunket (Well Child) book. The new Plunket book has a space to record this part of the examination.

85. Dr C stated that if he is not totally sure that the red eye reflexes are normal, he re-examines the child in a few days' time or asks a colleague. If there is still uncertainty, he will refer the child, but he noted that as yet he has not had to do this.

86. Dr C's colleagues at the medical centre are aware of what happened and remain vigilant in checking the red eye reflexes of all infants they examine. Dr C stated:

> "We have put in place 2 appointments for the 6 week check so as to lessen any pressure on time. One of our Partners suggested if red reflexes were not seen then the mother could take a flash photo to try and demonstrate this and bring it to an early repeat check as previously mentioned."

Ministry of Health

87. The WCTO health book was revised in August 2016. The revised version includes a dedicated checkbox on the "4–6 week assessment" page for "Eyes: Red reflex".

88. Currently the Ministry of Health is undertaking policy work on the content and timing of the WCTO schedule, and newborn vision screening (including the red reflex component) will be covered as part of that work. The Ministry of Health told HDC that it anticipates that consultation with relevant stakeholders will be an essential component of this work, and undertook to keep HDC updated as this work progresses.

ADHB policy

89. ADHB's policy "Admission — Postnatal" (first published October 2010)[14] states:

> "4. Admission of a Baby to the postnatal ward
>
> Assessment of the baby following admission should include the following checks (by Nurse/Midwife): …
>
> Assess if baby has been reviewed by paediatric care: implement the appropriate management plan. Ascertain whether heart, lung, hip check, red eye reflex and any relevant follow up have been completed."

Responses to provisional opinion

90. Mr and Mrs A advised that they had no comments in response to the "information gathered" section of my provisional opinion.

91. RM B confirmed that she agreed with the sections of my provisional opinion that related to her.

92. Dr C reiterated that he has put in place procedures to prevent a similar incident occurring again and has been vigilant in maintaining these. He also noted that the whole practice at the medical centre is fully aware of this incident and maintains the clinical procedures as set out above.

93. In response to the provisional opinion, ADHB stated:

> "All involved at ADHB regret the distress and ongoing eye problems [Baby A] continues to suffer, and have taken the complaint very seriously. ADHB accepts that while [Baby A] was in hospital, a [red eye reflex screen] should have occurred

[14] ADHB confirmed that this policy was relevant at the time of the events complained about.

and that information should have been clearly documented in the Well Child book and in the discharge summary."

94. ADHB undertook to comply with the recommendations made in the provisional opinion.

95. ADHB told HDC that its work on the issue since the complaint has highlighted that best practice in relation to red eye reflex screening is not clear, and it is likely that the screening is not being well performed consistently. ADHB provided HDC with two recent papers on the difficulties of performing the red eye reflex test, one of which was published in the *New Zealand Medical Journal*[15] as part of ADHB's effort to identify potential issues and improve outcomes when addressing this complaint. The paper explains the findings of a survey of practices and attitudes towards red eye reflex screening in the Auckland region.

96. ADHB stated that red eye reflex testing is a screening test and not a diagnostic test, and noted that only one out of nearly 20 paediatric cataracts in patients referred to ADHB during a 12-month period was identified correctly from red reflex screening by an experienced paediatrician. ADHB also stated that the incidence of cataracts in newborns is very uncommon (between 1 and 4.5 per 10,000 births), thus it is unusual for a practitioner to have a true positive test.

97. ADHB submitted that, other than the failure to perform the red eye reflex testing in hospital, all other tests in the WCTO health book were undertaken in a timely fashion and that, overall, the care that Baby A received at the public hospital was exemplary.

98. ADHB acknowledged that the system of recording the red eye reflex test was not sufficiently clear.

Opinion: Introduction

99. There were numerous providers involved in Baby A's care, all of whom had some responsibility to ensure that her red eye reflex was tested. Multiple opportunities were missed to check Baby A's red eye reflex and, as a result, surgery to remove the cataract was performed outside of the optimal timeframe.

100. It should be noted that the cataract may or may not have been visible at birth, and may or may not have developed over the first four months of Baby A's life.

101. This case serves as a timely reminder to providers to ensure that they carefully review the care that has been provided prior to their involvement with a consumer.

[15] Raoof, N. and Dai, S. Red Reflex Screening in New Zealand: a large survey of practices and attitudes in the Auckland region. *NZMJ* 15 July 2016, Vol 129 No. 1438.

Opinion: Auckland District Health Board — breach

102. District health boards are responsible for the operation of clinical services within hospitals, and can be held responsible for any service failures.[16] ADHB had an organisational duty to ensure that care was provided to Baby A with reasonable care and skill.

103. Baby A was born on 17 Month1 in the public hospital by Caesarean section. In Baby A's second day of life she spent 18 hours under the care of paediatricians in NICU, where she was treated for hypoglycaemia then discharged from NICU back to the postnatal ward. Baby A was discharged from the public hospital on 22 Month1, when she was six days old, into the care of LMC RM B. At no time during Baby A's admission was her red eye reflex tested.

104. The WCTO Programme Practitioner Handbook states that the external examination of the eye and red reflex screening using an ophthalmoscope should be performed at birth or up to seven days of age. It also states that if for any reason the LMC is unable to undertake this assessment at either the neonatal or postnatal assessment, the LMC "must make a referral to the infant's general practitioner for the assessment to be included in the six-week assessment".

105. ADHB's "Admission — Postnatal" policy requires the postnatal ward to assess the baby once the baby is admitted to the ward. This assessment includes ascertaining whether the red eye reflex has been tested.

106. Dr D examined Baby A in the first few minutes of life, but did not examine her red eye reflex. Dr D recorded, "RR not checked", on the newborn record. ADHB noted that it is not usual practice to check the red eye reflex in the operating theatre, as the bright lights can preclude a reliable examination occurring. My expert advisor, RM Suzanne Miller, agrees. I therefore consider that it was appropriate for Baby A's red eye reflex not to have been checked at that time.

107. Baby A's red eye reflex was not tested while she was in NICU. ADHB said that it is not normal practice for paediatricians to complete a Well Child examination for babies who are admitted to NICU to manage a short-term specific problem such as hypoglycaemia. ADHB stated that normal practice would be to document that the examination was still to be completed, and transfer responsibility back to the LMC. However, the "24–28 hours assessment" page of the WCTO health book was not completed. In my view, it was acceptable that the red eye reflex test was not performed in NICU, but this was a missed opportunity for staff to acknowledge that the test had not been done and to communicate this to the postnatal ward. ADHB stated that once Baby A was discharged back to the postnatal ward, responsibility for completing the red eye reflex testing returned to the maternity team. However, during her stay in the postnatal ward, no one tested Baby A's red eye reflex.

[16] See, for example, opinion 13HDC00343, available at www.hdc.org.nz.

108. ADHB accepts that it failed to ensure that Baby A received red eye reflex screening during her hospital stay, "despite receiving care from numerous clinicians with the skills to perform this important eye check". ADHB stated: "We deeply regret our contribution to this tragic outcome and accept responsibility for our part in this."

109. RM Miller advised:

> "[A]ll care prior to discharge was the responsibility of the ADHB staff. It is surprising and concerning that a baby who had been admitted to NICU, and who was assessed by multiple practitioners, both medical and midwifery, during her six day postnatal stay had not had this basic check completed."

110. While there were occasions during Baby A's admission when it was appropriate that the red eye reflex was not tested, overall ADHB had a responsibility to ensure that the test was completed by its staff while Baby A was in hospital. There were a series of missed opportunities to check whether the test had been performed, communicate whether or not it had been performed, and in fact carry out the test.

111. ADHB told HDC that its investigation of this case revealed a number of failures in its process at the time of Baby A's birth, including a lack of clarity around timing and responsibility for red eye reflex testing. I agree. In my view, ADHB did not have adequate systems in place to communicate whether or not the testing had been carried out. There were a number of factors that I consider were suboptimal in this case:

a) The documentation on the "Birth Assessment" page of Baby A's WCTO health book completed by Ms E (a tick above the text "eyes" and a cross above the words "red reflex") was ambiguous and open to misinterpretation.

b) There was an inconsistent approach to the documentation on the "Birth Assessment" page. Ms E said that the practice was to tick that the eyes had been checked as part of the newborn examination, and to cross (or write "not done") by the red eye reference if it was recorded as not having been done, or if nothing was recorded. ADHB said that the more usual approach across the service was to leave the checkbox blank if a red eye reflex test had not been performed, and to use a cross to indicate an issue with the examination. A cross would then require further explanation in the "comments/actions" area of the WCTO health book.

c) There was an inconsistent practice of attaching a white sticker to the front of the WCTO health book to indicate that the red eye reflex test had not been checked within 24 hours of birth. Baby A's WCTO health book did not have a white sticker attached to it, which meant that RM B did not realise immediately that testing had not occurred.

d) On the labour and birth summary discharge document, the space next to "red eye reflex" is left blank, which does not confirm whether the test had been done or not.

112. RM Miller advised:

> "Despite written documentation that everyone involved in [Baby A's] care had access to, there were a number of moments of missed opportunity; at [Baby A's] initial handover to the postnatal ward, at the handover to NICU, during the NICU admission, at the handover back from NICU to [the postnatal] Ward, and at discharge from hospital when vigilant communication might have triggered the appropriate assessment to be completed."

113. There were multiple missed opportunities during Baby A's admission for someone to query whether the assessment had been completed, and I am critical that this did not occur.

114. Baby A was discharged from hospital into the care of RM B. The handover occurred via the ADHB clinical records and documentation in the WCTO health book. The systems issues at ADHB outlined above meant that there was also no clear communication with RM B about the red eye reflex test. In my view, other than Dr D's note on the newborn record stating, "RR not checked", the documentation completed by ADHB staff (in the ADHB records and the WCTO health book) was ambiguous as to whether Baby A's red eye reflex had been checked. I note RM Miller's advice that it would be optimal that the discharging midwife or nurse verbally hand over to the new LMC.

Conclusion

115. Staff at ADHB failed to test Baby A's red eye reflex while she was in the public hospital, and ADHB is responsible for that failing. In addition, ADHB did not have adequate systems in place to communicate whether or not the testing had been carried out. I consider that ADHB did not provide services to Baby A with reasonable care and skill, and breached Right 4(1) of the Code.

Other comment — actions taken as a result of these events

116. ADHB has implemented numerous initiatives to minimise the risk of a similar event occurring in future. ADHB has been involved in sharing the learnings from this event widely, and has engaged in discussions about suggestions for change across the wider health sector. These actions are commendable.

Opinion: RM B — adverse comment

Review of care

117. Baby A was discharged from the public hospital when she was six days old, into the care of LMC RM B. Baby A's red eye reflex had not been checked while she was in hospital.

118. ADHB stated that handover to the LMC would normally take place via the discharge summary, the WCTO health book, and the inpatient clinical notes. Dr D noted, shortly after Baby A's birth, "RR not checked", on the newborn record. In the WCTO health book, on the birth assessment page, above the text "eyes" a tick is documented, and

above the words "red reflex" a cross is documented, without any further explanation. The 24–48 hours assessment in the WCTO health book was not filled in. On Baby A's discharge summary, the space next to "red eye reflex" was left blank.

119. RM B said that at the time of this incident many of her other patients had a large sticky label on the front of the WCTO health book alerting her to the fact that the red eye reflex had not been done. She stated: "[Baby A's] did not have the label and I mistakenly assumed it had been done at the hospital." ADHB said that there was an inconsistent practice of attaching a white sticker (flag) to the WCTO health book to indicate that the red eye reflex had not been checked within 24 hours of birth. There was no white sticker attached to the front of Baby A's WCTO health book.

120. It was not until RM B's fourth postnatal visit with Baby A and Mrs A on 19 Month2, when Baby A was 33 days old, that RM B realised that Baby A's red eye reflex had not been tested. RM B then undertook this screening.

121. My expert midwifery advisor, RM Suzanne Miller, advised:

> "Since the sticker was 'normal practice' at the time as a mechanism for communicating non-completion, and in the context of [Baby A] having already spent six days in hospital (including time spent in NICU) it was therefore a reasonable assumption for [RM B] to make that the red reflex had already been completed … it was reasonable under the circumstances that [RM B] assumed the screening had been done, therefore there was no departure from accepted care."

122. While RM Miller has relied on the white sticker as being normal practice in making her comments, ADHB has said that this was an inconsistent practice, and the ward clerk was not aware of this system. Given that RM B said that many of her former patients had the label attached to the WCTO health books, I accept that the white sticker was sometimes used to communicate that the red reflex had not been checked.

123. I accept RM B's explanation that she mistakenly assumed that the red eye reflex had been done at the hospital, owing to the absence of the white sticker. However, in my view, RM B also had a responsibility to carefully review the care that had already been provided to Baby A. In this regard, RM Miller advised:

> "[RM B] as the new LMC for [Mrs A] and [Baby A] had a responsibility to thoroughly assess any documentation provided to her by the ADHB staff, via [Mrs A], in order to develop a care plan in discussion with her that reflected her wishes and was responsive to any previous issues identified during the care to date."

124. I consider that the documentation in the ADHB records and WCTO health book was ambiguous as to whether the test had been completed. RM B missed an opportunity to review this documentation carefully and query whether the red eye reflex test had been done.

Red eye reflex test

125. RM B examined Baby A's red eye reflex on 19 Month2. RM B stated:

> "I picked up the right eye easily but struggled to pick up the left eye as [Baby A] started to cry, close her eyes and move her head backwards and forwards. [Baby A] was on her mother's knee also making the angle I was checking from difficult. After some time moving backwards and forwards with [Baby A], I was confident I had picked up the red eye reflex on her left eye."

126. According to Mrs A, during RM B's assessment of Baby A, RM B struggled to find Baby A's red eye reflex, but said that "it must be there". RM B told HDC: "I do not recall saying 'It must be there' [and] I confirm categorically that I would never knowingly record an assessment incorrectly."

127. RM Miller advised me:

> "If, as [RM B] asserts, she experienced some difficulty with [Baby A's] left eye, but did go on to obtain a clear result and documented this accordingly, then there was no departure from standard care, and given an apparently normal result, no referral was required."

128. Given the circumstances of this case, it is not possible to determine the extent to which Baby A's cataract was detectable at the appointment with RM B on 19 Month2. RM B said that she was confident that she picked up the red eye reflex; Mrs A stated that RM B told her that "it must be there". Both agree that the checking process was difficult. While there are some questions arising about RM B's testing technique arising from this consultation, I accept that RM B believed that she saw the red eye reflex, and documented accordingly. As the result was apparently normal, no referral was required.

129. I note that RM B has undertaken further training to ensure that her red eye reflex testing technique is up to date. I consider that this is appropriate in the circumstances.

Opinion: Dr C — breach

Six-week check

130. Dr C saw Baby A at the medical centre for her six-week check on 2 Month3. The WCTO Programme Practitioner Handbook states that the vision screen at six weeks should be done by a practitioner trained to use a direct ophthalmoscope, and that the physical external eye assessment should assess whether the red eye reflex is normal.

131. Dr C clarified that when he performed the vision assessment he checked only the corneal reflexes, and did not use an ophthalmoscope. Dr C told HDC that usually he would use an ophthalmoscope to test the red reflexes, but he did not do this, and obtained false reassurance about Baby A's eyes.

132. Dr C ticked the "Pass" box next to "vision assessment' on the 4–6 weeks assessment page in the WCTO health book, and documented in the clinical notes: "[E]yes normal … eyes straight."

133. My in-house clinical advisor, Dr David Maplesden, advised that he is moderately critical that Dr C did not undertake an appropriate red reflex check at the six-week check.

134. I accept Dr Maplesden's advice, and I am critical that Dr C failed to undertake the expected clinical examination (red eye reflex test) at Baby A's six-week check.

Three-month check

135. Dr C saw Baby A for her three-month check on 24 Month4. Dr C told HDC that he checked Baby A's corneal reflexes on this occasion. However, he did not check the red eye reflex. He documented in the clinical notes: "[E]yes normal."

136. Regarding the failure to undertake red eye reflex testing, Dr Maplesden stated: "I am mild to moderately critical that he [Dr C] did not perform this examination at the three-month check."

137. I accept this advice, and consider that Dr C should have undertaken the red eye reflex test at this examination, especially because he had not performed it at the six-week check.

138. While I have some concerns about Dr C's care at the six-week and three-month checks, there are mitigating factors to these criticisms. These are that Baby A's red eye reflex was apparently normal when checked by RM B on 19 Month2, there were no concerns documented in the medical centre's notes regarding Baby A's vision prior to these checks, and there was no dedicated area of the WCTO health book related to red eye reflex testing for the six-week and three-month checks. I also note Dr Maplesden's advice that, historically, the red eye reflex assessment is done poorly in primary care.

GP visit 13 Month5 and referral to ADHB Ophthalmology

139. On 13 Month5, Mrs A took Baby A to see Dr C because of her concerns that Baby A was not focusing on people's faces, and that her "wandering eye" had become worse. Dr C stated that "[d]uring the examination her left eye did drift and she had evidence of a squint". He further clarified that he checked only the corneal reflexes on this occasion (not the red eye reflex), and did not use an ophthalmoscope.

140. On 14 Month5, Dr C sent a referral to ADHB Ophthalmology marked "URGENT", and noted: "3 month old baby with significant squint and concern about vision." Dr C included notes from the consultation the previous day (including notes stating "light reflexes fine"). Baby A was given an ophthalmology appointment for 6 Month6, and subsequently underwent surgery to remove a cataract from her left eye.

141. Dr Maplesden advised: "I would be moderately to severely critical if [Dr C] did not perform a formal assessment of red reflex using an ophthalmoscope on 13 [Month5]

when [Baby A's] parents presented concerns regarding her vision." I agree, and am very concerned that Dr C did not undertake a red eye reflex examination with an ophthalmoscope at this appointment when it was clinically indicated.

142. Dr C stated:

> "I believe as [Baby A's] primary caregiver and one who is experienced in all aspects of neonatal examination … this should have been picked up. I do not wish to offer any excuse for this as it is my responsibility to pick this up and I do not want to justify it in any way at all. Unfortunately the outcome cannot be changed but I am very sure that it will not happen again and I have put measures in place to make sure of this."

143. ADHB told HDC that referrals that indicate an abnormality in the red reflex are given priority A, with the infant being seen within days. However, as the referral letter stated that Baby A's light reflexes were normal, the referral was assigned priority B. Dr Maplesden advised that the comment in the referral by Dr C, "light reflexes fine", could be perceived as being clinically misleading. I agree, and am critical because ADHB interpreted this comment to mean that Baby A's red eye reflexes were fine.

Conclusion

144. Baby A had the right to have the services she received from Dr C provided with reasonable care and skill. Dr C failed to check Baby A's red eye reflex at the six-week and three-month checks, failed to undertake a red eye reflex examination with an ophthalmoscope at the appointment of 13 Month5 when it was clinically indicated, and, accordingly, wrote an inappropriate referral. In these circumstances, I consider that Dr C did not provide services to Baby A with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

145. I recommend that ADHB:

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

b) Within three months of the date of this report, provide HDC with a copy of the final version of the formal policy "Newborn examination — care responsibility".

c) Within three months of the date of this report, provide HDC with an update on compliance with the use of the sticker for documenting red reflex testing in the WCTO health book, and completion of the red eye reflex field (date of test and comments) in the electronic discharge summary document.

146. In the provisional opinion, I recommended that Dr C provide a written apology to HDC for forwarding to Mr and Mrs A within three weeks of the date of this report. Dr C has undertaken to comply with this recommendation.

147. I recommend that Dr C undertake a review of current best practice with regard to red eye reflex assessments, and report back to HDC within three months of the date of this report to confirm that he has done this.

148. I recommend that the Medical Council of New Zealand consider whether a review of Dr C's competence is warranted, and report back to HDC within three months of the date of this report with the details of any action taken as a result of this recommendation.

149. I note that currently the Ministry of Health is undertaking policy work on the content and timing of the WCTO schedule, and newborn vision screening (including the red reflex component) will be covered as part of this work. I recommend that, as part of this work, the Ministry of Health consider working with stakeholders to achieve consensus on the timing and performance of red eye reflex testing, as well as the training and equipment requirements for red eye reflex testing. I would appreciate a report back from the Ministry of Health within three months of the date of this report on the progress of this recommendation.

Follow-up actions

150. A copy of this report with details identifying the parties removed, except ADHB and the experts who advised on this case, will be sent to the Medical Council of New Zealand and the Royal Australasian College of General Practitioners, and they will be advised of Dr C's name in covering correspondence.

151. A copy of this report with details identifying the parties removed, except ADHB and the experts who advised on this case, will be sent to HQSC, the New Zealand College of Midwives, and the Ministry of Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent midwifery advice to the Commissioner

The following expert advice was obtained from registered midwife Suzanne Miller:

"You have requested my advice concerning care provided to [Baby A] by Auckland District Health Board (ADHB), ADHB midwifery staff, and midwife [RM B] between [Month1] and [Month6]. I have read the Commissioner's Guidelines for Independent Advisors (July, 2014 version), and can confirm that I have no personal or professional conflict which prevents me from providing an opinion on this case.

My name is Suzanne Miller. The following identifies my qualifications to provide this opinion:

My qualifications are Registered Midwife 1991, Registered Comprehensive Nurse 1988 and Master of Midwifery (Distinction) 2008 from Victoria University of Wellington. I have been practising midwifery continuously since 1991, firstly as a hospital-based midwife at Kenepuru Maternity Unit, and subsequently as an LMC midwife in both Auckland and Wellington.

Since 2010 I have been employed as a Senior Lecturer at the Otago Polytechnic School of Midwifery, where I teach across both the undergraduate and postgraduate midwifery programmes. I continue to maintain a small midwifery caseload alongside my full-time employment.

I am a member of the New Zealand College of Midwives (Wellington Region) and have held office both as treasurer (Auckland, Wellington) and Core Committee member (Wellington). I was a Midwifery Standards Review midwifery reviewer for six years, a Midwifery First Year of Practice reviewer for two years, and currently mentor graduate midwives via the Midwifery First Year of Practice Programme. I hold a Ministerial appointment (nominated by NZCOM) to the Neonatal Encephalopathy Working Group of the Perinatal and Maternity Mortality Review Committee. I am an NZCOM-ratified expert midwifery advisor, and have been appointed as a panel member for the Midwifery Council of New Zealand Professional Conduct Committee.

I have received and reviewed the following documents:

Package from HDC including list of enclosures, summary of facts, advice sought. **NB** HDC expert advisor guidelines were not included amongst enclosures, but I have access to a copy of the 2014 version of these Guidelines.

Letter dated [2015] from [Dr F] ADHB Ophthalmologist

Letter dated [2015] from [RM B], midwife.

Extracts from the Tamariki Ora Well Child Programme Practitioner Handbook

Clinical records pertaining to [Baby A's] care.

ADHB Policy Documents: Admission–Postnatal and Access Holders in Women's Health.

I subsequently requested copies of the following pages from [Baby A's] Well Child Tamariki Ora Health Book: pp. 42, 43 and 47. These and pages 46, 48, 55, 57, 59 and 63 were also provided.

You have requested that I provide an opinion as to whether the clinical care provided to [Baby A] was appropriate in the following respects:

1) **Care by ADHB and ADHB midwifery staff** including whether assessments by midwifery staff following [Baby A's] birth were appropriate, whether these assessments were undertaken adequately and in a timely manner, and whether the assessment noted in [Baby A's] Well Child Tamariki Ora Health Book (WCTOHB) on 17 [Month1] indicating 'needs comment/action' should have been escalated.

2) **Care by [RM B]** including whether [RM B] should have been aware of the above noted comments in the WCTOHB and/or should have followed up on this assessment, whether appropriate assessments were performed on [Baby A] on 23 [Month1], whether assessments performed by [RM B] on 19 [Month2] were performed adequately and in a timely manner, and whether [RM B] should have referred [Baby A] for further testing.

3) **ADHB —** you have asked me to comment on the appropriateness of relevant midwifery policies in place at the time of these events.

4) You have asked that I comment on other aspects of the care provided to [Baby A] that I consider relevant.

5) For each question above — what is the standard of care/accepted practice, if a departure from standard care has occurred, how significant a departure do I consider it to be, and how would my midwifery peers view the care provided?

Background to [Baby A's]case

[Baby A] was born by Caesarean section on 17 [Month1]. She was examined at birth by a paediatric registrar, and no red reflex check[1] was performed at this time. [Baby A] was then admitted to [the postnatal ward] along with her mother [Mrs A]. It was noted (by addition of an 'x' on page 41 of [Baby A's] WCTOHB) that the red reflex check had not been performed, but it is unclear who completed this page of the documentation. This check is normally documented over two pages in the book (pp 41 and 42) and page 42 was left blank apart from a tick (√) to indicate that IM Vitamin K had ben administered, so I cannot discern who

[1] The red eye reflex test is conducted with an ophthalmoscope to confirm the clarity of the lens and the presence of the retina. An absent red eye reflex may be associated with the presence of congenital cataracts. The red eye reflex test should ideally be conducted in the first week of life, because early diagnosis of visual anomalies and timely referral for further assessment and corrective surgery prior to six weeks has been shown to improve long term visual outcomes (Fry & Wilson, 2005; Gunn & Davies, 2015)

completed this documentation, though it is likely this would have been a staff nurse or midwife who admitted [Baby A] onto the postnatal ward, based on documentation received from the Newborn Record (Immediate postnatal history and examination) completed by the paediatric registrar who examined [Baby A] at birth.

On 18 [Month1] [Baby A] was admitted to the Neonatal Intensive Care Unit for treatment of hypoglycaemia and was discharged back to the ward later that same day. Despite being assessed several times by paediatric staff, the red eye test was not completed during [Baby A's] NICU admission, nor on the ward in the days prior to discharge. [Baby A] was discharged home on 22 [Month1], into the care of [RM B] (midwife), who, by mutual agreement, had agreed to provide postnatal care for [Mrs A] and [Baby A] once they returned home.

[RM B] visited the family at home on five occasions, the first being within 24 hours of discharge from hospital with the second visit planned for one week's time. At the fourth visit on 19 [Month2], when [Baby A] was 4w 5d old, [RM B] realised that the red reflex check had not yet been performed, and so she performed this eye examination immediately, and documented a normal result for both [Baby A's] right and left eyes.

[Baby A] was referred to the GP and the Oral Health Service by [RM B] on 6 [Month2], and Plunket referral was declined.

According to information supplied by HDC, [Baby A] was seen by doctors on three occasions between the age of 4w 5 d and 16 weeks 'owing to concerns about her vision'. The Well Child Tamariki Ora Health Book notes an examination by (GP) [Dr C] on 02 [Month3] ([Baby A] being 6w 5d at this visit) where a tick (√) is documented for vision assessment, indicating a normal (pass) result.

On 14 [Month5] [Baby A] was referred by her GP to the Eye Clinic at ADHB for assessment, but the absence of a red reflex was not noted in the referral hence it was triaged as a Category B which required assessment within six weeks. [Baby A] was seen on 6 [Month6], and she underwent surgery that same day to remove a cataract from her left eye. Her visual prognosis appears poor for this eye.

Issues identified in the complaint:

You have asked that I express an opinion on the matters outlined above 1–5.

Care by ADHB and midwifery staff.

1) Although a red reflex test is one component of a full neonatal examination, it is not usual practice for this test to be completed at birth in the situation of a caesarean section. The attending paediatrician will more usually complete an initial assessment that establishes the neonate's successful transition to extra-uterine life, but 'other' aspects of the assessment such as measurement of head circumference, length, weight and red reflex checks are usually carried out later. This enables the baby to be more quickly returned (if well) to the parents for skin

to skin contact which is entirely appropriate, as the findings of these 'other' assessments are not going to be urgently acted upon. *Thus the fact that the attending paediatrician did not perform the test at birth does not constitute a departure from the usual standard of care.*

Upon admission to the postnatal ward, the ADHB Policy (Admission–Postnatal) suggests that the following checks should be completed by the midwife or nurse: reviewing the birth summary, mother's management plan, clinical records and 'implement and follow up on any relevant issues' — part of which includes to 'ascertain whether heart, lung, hip check, red eye reflex and any relevant follow up have been completed' (p. 4). These findings should be documented in the baby's clinical notes. The Policy does not dictate that the midwife or nurse assigned to care for the baby is required to complete these examinations, but to ascertain whether or not they have been completed and arrange follow up if necessary. While it would be within the scope of a midwife to perform the red eye test, technically the responsibility lies with the Lead Maternity Carer, in this case because [Baby A's] mother was immediately post-surgical, this would have been the medical team assigned to [Mrs A's] care. Someone noted in the Well Child book that the test had not been completed. There is otherwise no mention of the red reflex test in any of the clinical notes pertaining to [Baby A's] care, apart from on the Immediate Postnatal History and Examination page of the Newborn Record ('RR not checked') and the WCTOHB entry on page 41.

The documentation completed by [an RN] at 1750 on admission to the ward notes that TOB (time of birth) was 1349, and records gestation, weight, Apgars and that the neonatal examination was NAD (no abnormality detected). [Baby A] had not passed urine or meconium yet, and the notes describe the plan for [Baby A's] feeding and blood sugar monitoring. If [the RN] is a casual nurse seconded to the postnatal ward, but this was not her/his usual place of work, s/he may be unfamiliar with the detail of the admission policy in relation to the checks outlined above. It may have been assumed that all relevant neonatal checks had been completed either at birth, or at the assessment at 1530 by Paediatric Registrar [Dr D]. But regardless, this was a missed opportunity for ensuring there was a plan in place for getting the test completed, given that someone noted it had not been done.

The second check at 24–48 hours outlined in the Well Child Practitioner Handbook, and documented on pages 43 and 44 of the Well Child Tamariki Ora Health Book, should have been completed by ADHB staff, since [Baby A] remained in hospital and under their care. This would have provided a further opportunity to notice that the red eye check had not been completed. This check appears not to have been completed by hospital staff (page 43 is blank, and page 44 of the Well Child Health Book has been signed, but not dated, by [RM B], although [Baby A] was not yet in her care at 48 hours. This entry notes that there are no indicators at birth for vision or eye problems, but a check back to page 41 at this time of signing would have alerted [RM B] to the fact that the red eye check needed follow up.

The ADHB Policy 'Access Holders in Women's Health' outlines the responsibilities of both the ADHB staff and 'independent' practitioners in relation to the care of women and babies. As [RM B] had negotiated that care would be transferred to her *after* [Mrs A] and [Baby A] had been discharged home, all care prior to discharge was the responsibility of the ADHB staff. On discharge, their responsibilities include a handover to the 'independent' practitioner and ensuring the Well Child Tamariki Ora Health Book is completed with all relevant information for the ongoing Provider documented.

So the red eye check should ideally have been completed prior to discharge from hospital, by either the midwifery staff, or a medical person responsible for [Baby A's] care. If not, the fact that it was still needing to be done, should have been clearly communicated to [RM B], and documented in the Well Child Health Book on hospital discharge. As it was noted in the Well Child Health Book that the check had not been completed at birth, this could be construed as having been communicated to the post-discharge LMC, although it would be optimal that a verbal handover to the new LMC from the discharging midwife or nurse took place during which the need to complete the test could have been communicated verbally as well.

The last entry in the clinical notes relating to [Baby A] was on 22 [Month1], NSG 0700–1530 — this assessment included a documented weight gain of 90 grams, and [Baby A] was noted to be 'BF well'. No further details are recorded. The Labour and Birth Summary notes that [Mrs A] and [Baby A] were discharged [at 10:44] on this day, but this entry does not suggest that a full neonatal examination of [Baby A] was performed prior to discharge. The final entry was signed by [an] SN (Staff nurse) [name unclear]. I am unaware if it is within the Scope of Practice of a staff nurse to complete a full neonatal examination. The Labour and Birth summary also has the section relating to red eye check left blank, along with several other blank parameters. I do not know if a copy of this summary is given to parents or the postnatal LMC on discharge at this DHB.

(NB: This Labour and Birth summary (three pages) contains numerous other errors; for example the time of birth is noted as 1549, with the placenta therefore being born almost two hours prior to the baby (at 1353), and Guthrie test, normally completed 48 hours after birth, having apparently been obtained three days prior to the baby's birth (on 14 [Month1]). It also suggests [Baby A] had received only breastmilk from birth, when she had in fact been artificially fed during her time in NICU. This highlights the need for a) vigilant data entry on the part of the staff and b) thorough assessment by the new caregiver in discussion with the woman to ensure the veracity of the information on the printed summary form if it is made available to her.

The standard of care by ADHB staff expected for [Baby A] did not reflect the Policies in operation at the time. On admission to the postnatal ward it is expected that the admitting nurse or midwife will ascertain what care has already been provided, and initiate a care plan that ensures follow up of any aspects not yet completed. The 'x' on p 41 of the Well Child Health Book identifies that this

check still needed to be completed, yet this does not appear to have occurred. It is surprising and concerning that a baby who had been admitted to NICU, and who was assessed by multiple practitioners, both medical and midwifery, during her six day postnatal stay had not had this basic check completed. This would constitute a moderate departure from expected care, given the potential seriousness of non-referral if an anomaly was detected. Midwives would generally view the discharge from hospital at six days of age without completing this check as being below a reasonable standard of care, but ultimately the LMC (medical team in this case) holds responsibility for ensuring its completion.

Care by Midwife [RM B]

Notwithstanding any missed opportunity by the ADHB staff in respect to [Baby A's] care, at the first visit to the family home on assuming care on 23 [Month1], [RM B] as the new LMC for [Mrs A] and [Baby A] had a responsibility to thoroughly assess any documentation provided to her by the ADHB staff, via [Mrs A], in order to develop a care plan in discussion with her that reflected her wishes and was responsive to any previous issues identified during the care to date. It may be that it was at this first home visit that [RM B] signed the 24–48 hour check (page 44, WCTOHB); ideally she could have noted the *actual date* this check was completed, rather than signing for a check that should have been completed up to five days earlier by the hospital staff. The previous page (43) was blank, but this fact should also have provided another opportunity for noticing the need for a red eye check to be completed.

The First Week assessment (p. 47) is documented by [RM B] and dated 22 [Month1] on p. 47, (but 23 [Month1] on p. 46) and indicates a 'pass' for vision assessment. In a different colour pen (and therefore presumably added later) the red eye was noted as having been completed on 19 [Month2].

Professional guidance in relation to care provided in the postnatal period to the baby is covered in the 'Subsequent decision points in the postnatal period — every 24 to 48 hours until the woman feels confident in her home environment' section of the Midwives Handbook for Practice (NZCOM, 2015, p. 45). This outlines that assessments and observation of the baby are made as per the Well Child Tamariki Ora Schedule (and as required) to review the baby's health status and to discuss the outcomes of this with the mother, planning ongoing care. The Midwifery Code of Ethics also requires that midwives 'have a responsibility to ensure that no action or omission on their part places the woman or her baby at risk' (NZCOM, 2015, p. 13).

[RM B] should have identified at the first home visit that the red eye check had not yet been attended to; this remained the case until four weeks later. Whilst it is likely she assumed that this check had been completed while [Baby A] was in the postnatal ward (or NICU) it was her responsibility to check.[2] When it came to her attention when [Baby A] was four weeks old, she set about rectifying the

[2] RM Miller clarified that RM B's peers would consider this a mild departure from usual practice.

oversight. At the time, she was satisfied that she had successfully observed a red reflex present in both eyes, and documented this accordingly.

Given that she felt at the time that she had correctly performed the procedure, and had not detected any abnormality, there was no reason she would have referred [Baby A] on for further assessment at this point. The time at which this assessment *did* occur, was within the window considered acceptable for the red eye test to be conducted and still have allowed for timely referral if an anomaly had been identified, providing it was noted as an urgent referral at that point.

Regarding whether the assessment was adequately carried out on 19 [Month2], there are two accounts: if, as [Mrs A] asserts, [RM B] had difficulty obtaining a clear result for [Baby A's] left eye, but said 'it must be there' and documented a normal result, this would be a moderate departure from standard care as a definite and reliable result should have been pursued. Midwives would expect that a thorough assessment was performed, and if the result was unsure, further assessment by the same or a different practitioner would be warranted. Optimal assessment of the red reflex requires first visualising the red flare in both eyes at the same time to assess for symmetry and colour consistency, then closer examination of each eye individually to assess for any dark spots or opacities (Siderov, 2008).

If, as [RM B] asserts, she experienced some difficulty with [Baby A's] left eye, but did go on to obtain a clear result and documented this accordingly, then there was no departure from standard care, and given an apparently normal result, no referral was required.

With the benefit of hindsight, it appears that a misdiagnosis occurred, with serious consequences for [Baby A]. It is pleasing that [RM B] has taken steps to improve her knowledge about neonatal care, and revised her practice systems to ensure that a similar oversight cannot occur in the future. Further, she has attempted to address concerns regarding the interface at the handover of care on discharge from the maternity facility involved, so that documentation accurately reflects care already provided. In this respect [RM B] is to be commended in that she has shown accountability as required under Standard Seven of the Midwives Standards for Practice, including that she:

> 'document[s] any misjudgements of practice and initiate[s] restorative actions'
>
> 'reflects on practice' and
>
> 'seeks to maintain and improve the policies and quality of service in the organisation or agencies in which she works' (NZCOM, 2015, p. 24).

Comment on ADHB Policies

Policy development within a DHB is typically a protracted multi-disciplinary process, so I do not feel able to comment on the 'appropriateness' of these documents that have been derived from a robust process of consultation and

collaborative effort. My only observation about the said documents would be about the confusing use of the term 'Independent' to describe LMC midwives. ALL midwives are independent and autonomous practitioners, and the term 'independent' is no longer in widespread use; midwives who work in the community as Lead Maternity Carers are called 'self-employed' midwives. This terminology could be addressed at the next policy review.

Overall comment on the care provided to [Baby A]: [Baby A's] case appears to have been an example of what can occur when communication within a fragmented care scenario in the maternity system has been sub-optimal. Despite written documentation that everyone involved in her care had access to, there were a number of moments of missed opportunity; at [Baby A's] initial handover to the postnatal ward, at the handover to NICU, during the NICU admission, at the handover back from NICU to [the postnatal ward], and at discharge from hospital when vigilant communication might have triggered the appropriate assessment to be completed. Upon receiving [Baby A] into her care, more thorough assessment of the care to date by [RM B] would have surfaced the need for the eye examination to be performed, although this was addressed once the oversight was noticed.

Yours faithfully

Suzanne Miller

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New Zealand College of Midwives (NZCOM) Inc. (2015). *Midwives handbook for practice.* Christchurch, New Zealand: NZCOM.

Siderov, J. (2008). The Newborn eye: Visual function and screening for ocular disorders. In L. Davies & S. McDonald (Eds.) *Examination of the newborn and neonatal health: A Multidimensional approach.* (pp. 183–195). Edinburgh: Churchill Livingston Elsevier."

RM Miller provided the following further advice on 28 November 2016:

"You have requested that I provide further advice in the case of [Baby A] who was born at [ADHB] on 17 [Month1]. Please refer to my previous advice for a summary of facts related to the case.

I have subsequently been sent the following information:

2016 Guidelines for Independent Advisors

A copy of my previous advice (5 of the original 7 pages)

A response from [RM B] to my previous advice

A copy of the Root Cause Analysis completed by the DHB, authored by [DHB staff].

A copy of the response from the ADHB [Chief Medical Officer].

37 Appendices which I will not itemise here but which include copies of email correspondence between a number of key stakeholders, Policy documents, ADHB Protocols, statements from staff involved in [Baby A's] care, HQS Open Book education resource and so on.

You have requested me to consider, having examined this additional information, whether I would have reason to add to or amend my earlier expert advice. Also whether I consider the changes made by [RM B] and ADHB are appropriate.

Care by LMC [RM B]

At the time I wrote my previous report I was unaware of the customary 'informal' practice at this DHB of putting a white sticker on the front of the Well Child Book in the event that the red reflex screening had not been completed prior to discharge. I accept that this is a mitigating factor in [RM B's] failure to immediately appreciate when she assumed care of [Baby A] on discharge from hospital that the screening had not been completed. Since the sticker was 'normal practice' at the time as a mechanism for communicating non-completion, and in the context of [Baby A] having already spent six days in hospital (including time spent in NICU) it was therefore a reasonable assumption for [RM B] to make that the red reflex had already been completed. Although it would be *optimal* for [RM B] to have gleaned from the documentation inside the Well Child Book that the screening was not completed, the DHB has acknowledged that the method of documentation in the Well Child Book was 'non-standard and open to misinterpretation'. In this case I wish to amend my earlier opinion of mild departure to conclude that it was reasonable under the circumstances that [RM B] assumed the screening had been done, therefore there was no departure from accepted care.

In relation to whether [RM B] provided care using reasonable skill when she realised that the red reflex check had not been completed, I have no reason to amend my previous alternate advice on this matter. Although [RM B] has acknowledged that the education she has since received has highlighted that 'best practice' is 'very different to what [she] was taught', at the time she was performing the procedure according to the teaching she had been exposed to. If she was *unsure* of her diagnosis, but documented a normal result, this would constitute a moderate departure as a repeat screening would be indicated to either confirm a normal result or elicit an offer of referral if an abnormal result was

obtained. If she was sure of her diagnosis, and adjudged the result to be normal, she need not have referred [Baby A] for further assessment and therefore reasonable care was provided.

[RM B] has taken a number of steps to ensure there is unlikely to be a repetition of her misdiagnosis of [Baby A's] red reflex as being normal. These include engaging in further education, working alongside a consultant paediatrician to practise her technique and purchasing a higher quality ophthalmoscope. She has also taken steps to improve the accuracy of her documentation and now has increased vigilance regarding her review of handover information. She has worked with the Midwifery Educator at ADHB to improve communication between Lead Maternity Carers and the DHB, and has reflected on her practice with Midwifery Standards Reviewers. These are all appropriate steps to have taken.

I agree with the comments of [the Midwifery Advisor from the Midwifery Council of New Zealand] that red reflex screening is a core competency for midwives, and constitutes one component of a full neonatal examination. All registered midwives are expected to be competent in this skill. I also agree with [the NZCOM Midwifery Advisor] and [Newborn Network Chair] that a concerted move towards a multi-disciplinary consensus about optimal practice and timing for this screening could be made, as this will enable all practitioners involved in the care of newborns to consider a more consistent approach. As [the NZCOM Midwifery Advisor] points out, this is a *screening* test, not a diagnostic one, and diagnosis remains the preserve of ophthalmologists.

Care by ADHB

Regarding the DHB response: it appears that a number of initiatives have been implemented that will minimise the risk of repeat occurrence of the omission of newborn red reflex screening while babies remain within the hospital setting. Responsibilities of employed staff and self-employed LMCs have been clarified with respect to red reflex screening. Consistent education has been made available for clinicians who practise both within the hospital and in the community. High quality equipment has been provided within the DHB, though I note that there are cost implications for community providers if the pen ophthalmoscope currently used by most providers is not supported for use. There are improved mechanisms for documenting and communicating completion or otherwise of screening. These steps taken are appropriate.

The ADHB Red Reflex Protocol (Appendix 37), as a DHB-specific response, will probably address the immediate concern relating to the increased referral of newborns to the Ophthalmology Service which has resulted from widespread education of clinicians. The Protocol is not likely to be applicable in other DHBs whose needs may be different.

It would seem that there is a lack of clinical consensus about the best time to screen, the most appropriate equipment to use considering all clinical settings (including homebirth and primary maternity units), the level of difficulty

associated with screening a newborn, and the most appropriate referral pathways, which strengthens the case for a collaborative multi-disciplinary approach to establishing such consensus.

[The Chief Medical Officer's] response outlines that it was not in 2014, nor is it now, normal practice for a baby who has been admitted to NICU to receive a full paediatric examination during their admission. I therefore respectfully accept that this is the case. I imagine that most parents would make an assumption that a full check of their baby would occur prior to discharge from paediatric care, and hope it is communicated to parents when this has not occurred.

Yours faithfully

Suzanne Miller

Midwife."

Appendix B: In-house general practitioner advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden:

> "1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her infant daughter, [Baby A], by various providers including [Dr C] of [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the information on file: complaint from [Mrs A]; response from LMC [RM B] and Well Child Book and postnatal records; response from GP [Dr C] and [medical centre] notes; response from Auckland DHB including comment from ophthalmic surgeon [Dr F]; [ADHB clinical notes].
>
> 2. [Baby A] was born at [ADHB] by emergency caesarean section on 17 [Month1]. She spent a day in NICU after experiencing neonatal hypoglycaemia. Post natal care was performed by staff midwives and [Mrs A] and [Baby A] were discharged home on 22 [Month1]. [RM B] provided post-natal care. [Mrs A] complains that [RM B] failed to detect an abnormality in [Baby A's] left eye when she performed an examination on 19 [Month2]. [Baby A] was subsequently seen by [Dr C] for a six-week check on 2 [Month3], three month check prior to immunisations on 24 [Month4], and for an eye check on 13 [Month5] — the latter because [Baby A's] parents felt there was something wrong with her eyes. Neither [RM B] nor [Dr C] expressed any particular concern regarding an eye abnormality at any of the checks undertaken. However, [Dr C] did refer [Baby A] for specialist eye review (referral marked urgent) on 13 [Month5]. [Baby A] was reviewed by an ophthalmologist on 6 [Month6] and she was identified as having a slightly smaller left eye compared with the right, and a left sided cataract described by [Dr F] in his report as *a dense brown opacity behind the left pupil.* [Dr F] comments further: *the type of cataract she has is related to 'persistent foetal vasculature' within the eye. This typically produces a cataract in utero which is present at birth. The affected eye is almost always smaller than the other. Early or late surgery does not change the growth of the eye.* Prompt removal of the cataract (usually within 6–10 weeks of birth) and meticulous follow-up is required to optimise vision in the affected eye and [Dr F] has commented that the delay in recognition and removal of the cataract, while not affecting the growth of [Baby A's] eye, is likely to have adversely affected the chance of restoring useful vision in the eye.
>
> 3. The accepted 'screening' test for early detection of significant eye abnormalities in neonates is the red reflex (red-eye reflex). This involves using a light source (usually an ophthalmoscope) shining through the anterior eye structures (cornea and lens) to reflect off the retina giving the 'red eye' appearance commonly seen in flash photography. If there is a significant opacity in the lens (cataract) the reflex will be irregular. Some retinal tumours (retinoblastoma) lead to complete

loss of the red reflex and a 'white eye' (leucocoria) which is a sinister finding. The 'red eye' reflex is different to the corneal light reflex — the latter being used to test for possible squint (strabismus) and referring to light being reflected off the corneas, such reflection being asymmetrical in the presence of squint. The picture below (From Barts Hospital, London) summarises red reflex findings.

Normal red reflex

Red reflex absent
Obvious +/- asymmetry

Red reflex abnormal

Pictures courtesy of St Barts Hospital.

4. The Well Child/Tamariki Ora Programme Practitioner Handbook[1] recommends a full clinical examination of the neonate (including assessment of red reflex) is undertaken within 48 hours of birth. Further clinical examination (including assessment of red reflex) is recommended at the time of discharge from maternity services and at the six-week post natal check. The Handbook includes the comment: *If for any reason the LMC is unable to undertake a full assessment (which includes a red reflex assessment with a direct ophthalmoscope) at either of these time points* [at birth or up to seven days of age], *the LMC must make a referral to the infant's general practitioner for the assessment to be included in the six-week assessment.*

5. It is apparent several providers failed to detect [Baby A's] congenital cataract (assuming it was present at birth and did not evolve significantly after birth) over the first four months of her life. This needs to be considered in the context of 'common practice' which does not always represent optimum practice. A 2011

[1] http://www.wellchild.org.nz/sites/default/files/pdfs/well-child-tamariki-ora-programme-practitioner-handbook-24oct13.pdf Accessed 17 August 2015

British Medical Journal article on congenital cataract detection[2] included the following comments: *In ideal conditions, examination for the red reflex by an experienced practitioner readily identifies congenital cataract; however, its effectiveness as a screening tool has yet to be formally evaluated. A national UK study assessing all diagnoses of congenital cataract during one year found that less than half were detected at either the newborn or 6–8 week examinations (35% at the newborn examination and a further 12% at the 6–8 week examination).[3] A more recent regional study from the Republic of Ireland found that over a 10 year period, none of the 27 cases of congenital cataract was detected at the neonatal check and only 24% were detected by the general practitioner on subsequent examination.[4] Although recommendations for red reflex detection as part of the newborn and 6–8 week examinations were in place at the time of these studies, no data were available on the percentage of infants who had such testing, so whether delays in diagnosis were caused by problems performing the test or by failure to test (assuming that most cataracts were present from birth) is unclear. Red reflex examination can be difficult to perform. Eyelid swelling at birth can make eye opening difficult, especially if the infant is distressed. Examination conditions can be suboptimal, with brightly lit rooms, background noise, and interruptions. Examination of infants aged 6–8 weeks is usually easier when eyelid swelling has resolved and they are more visually alert and maintain gaze.*

6. Clinical notes summary relating to [Baby A's] eye assessments

(i) [Baby A] was born via caesarean section at 1349hrs on 17 [Month1]. On the handwritten completed 'Immediate Postnatal History and Examination' template the comment adjacent to the section relating to eye examination states *RR not checked.* The form is signed by a paediatric registrar.

(ii) On 18 [Month1] [Baby A] was admitted to NICU because of hypoglycaemia, being discharged later the same day. There is no reference to an eye examination in the NICU notes or discharge summary.

(iii) The computer generated [ADHB] labour and birth template report dated 22 [Month1] includes a section titled *Immediate Newborn Assessment Baby* completed by [a hospital midwife]. The section adjacent to *Red eye reflex* is left blank.

(iv) On the 'Birth Assessment' page of the Well Child/Tamariki Ora (WCTO) record book is an entry which is unsigned. The entry appears to refer to [Baby A's] immediate post-natal examination findings but it is unclear who completed this assessment. The assessment 'key' states: *Yes, OK√ Needs comment/action X.* Above the section 'eyes red reflex' are the symbols: √ X implying (to me) that the assessor felt the red reflex in the right eye was normal but the left eye reflex

[2] Russell H, McDougall V, Dutton G. Easily Missed? Congenital cataract. BMJ. 2011;342:d3075
[3] Rahi JS, Dezateux C. National cross sectional study of detection of congenital and infantile cataract in the United Kingdom: role of childhood screening and surveillance. BMJ. 1999;318:362–5.
[4] Sotomi O, Ryan CA, O'Connor G, Murphy BP. Have we stopped looking for a red reflex in newborn screening? 2007;100:398–400.

required further comment or action. However, I can find no elaboration on these findings in the associated clinical documentation.

(v) On 19 [Month2] [RM B] has documented in the post natal notes: *Final assessment done on [Baby A]. Red eye reflex done as noted not done at birth. R eye√ L eye√.* The appropriate area in the WCTO was completed indicating normal red reflex in both eyes.

(vi) Later on 19 [Month2] [Baby A] was assessed by [a medical centre GP]. [Mrs A] had several concerns about [Baby A] which were addressed. There was no mention of concerns regarding vision or the appearance of [Baby A's] eyes.

(vii) On 2 [Month3] [Dr C] has recorded the results of [Baby A's] six-week assessment undertaken by him. This includes *eyes normal … eyes straight.* While red reflex is not mentioned specifically, [Dr C] states in his response: *I did initially see [Baby A] for her 6 week check and I normally check the eyes carefully at this time and again at 3 months. There was no squint at the time and the light reflexes were equal. I did not see a cataract but not always easy to see in a baby at this stage and I always recheck this …* I am unable to confirm that [Dr C] did undertake an assessment of [Baby A's] red reflexes at this or subsequent assessments although it is clear he assessed her corneal light reflexes for symmetry.

(viii) On 5 [Month4] [Baby A] presented to [a medical centre GP] with a non-specific viral illness. There is no reference to parental concerns regarding [Baby A's] eyes and there is no reference to eye assessment in the clinical notes (and I would not expect such an assessment in a patient presenting with symptoms of viral infection).

(ix) On 24 [Month4] [Dr C] undertook a three month assessment of [Baby A] (erroneously identified as six week check) prior to her vaccinations. Notes include: *eyes normal* although the extent of the eye examination is not clear from the documentation.

(x) On 13 [Month5] [Dr C] assessed [Baby A] after parental concerns were expressed regarding a possible squint. Notes include: *concern re vision, mum does not think she is seeing well, 'always cross-eyed'. Mum thinks she is not focussing and tracking well. Seems OK today, light reflexes fine, tracking light fine … probably OK but will refer for formal testing.* An electronic referral was generated the next day, marked urgent, with a copy of the consultation notes incorporated and *3 month old baby with significant squint and concern about vision.*

(xi) In his response, [Dr F] states the referral was received on 14 [Month5] and triaged on 15 [Month5]. Referrals which indicate an abnormality in the red reflex are given 'A priority' with the infant being seen within days. As the referral letter stated light reflexes were normal, the referral was assigned a 'B priority' meaning an orthoptic clinic appointment was planned within six weeks.

(xii) On 22 [Month5] [Baby A] was seen by [a medical centre GP] with right eye irritation. A Hair was noted on the cornea and removed. There is no reference to any abnormality noted in the left eye.

(xiii) On 6 [Month6] [Baby A] was seen by ophthalmologist [Dr G] who noted the left corneal diameter was smaller than the right, and a dense brown opacity was present behind the left pupil. On 7 [Month6] [Baby A] underwent examination under anaesthetic and left cataract extraction performed by [Dr F].

7. Comments

[Dr C] has not specifically documented assessing [Baby A's] red reflex during his examinations of her, although he has referred to 'light reflexes' which could mean red reflex, corneal reflex or both. [Dr C] had three occasions on which [Baby A's] abnormal red reflex might have been detected, the last of these associated with parental concerns regarding her vision (ie she was symptomatic). The cataract was apparently quite obvious to [Dr G] on 6 [Month6] which was about three weeks after [Dr C's] most recent review, but 15 weeks after [RM B's] review. I would be moderately critical if [Dr C] did not assess [Baby A's] red reflex at the time of her six week check and particularly on 13 [Month5] when she presented with eye symptoms and parental concern regarding her vision. If he did assess her red reflex on both occasions, some concern might be raised at his competency in detecting red reflex abnormalities (particularly on 13 [Month5]) although without having viewed the patient myself it is not possible for me to determine how subtle or obvious the abnormality was. It would be prudent for [Dr C] to review his knowledge of red reflex assessment and abnormalities as [RM B] has done.

8. Addendum 4 July 2016

(i) I have reviewed the following additional documentation: copies of relevant sections of the WCTO record; ADHB RCA report; additional response from [Dr C] dated 26 June 2016.

(ii) The WCTO record for the 4–6 week check undertaken by [Dr C] has a dedicated area for 'Vision assessment' which has been ticked. However, there is no dedicated area for 'red reflex' in this section of the book, an oversight which has apparently been remedied in a subsequent edition. The section of the WCTP record related to LMC assessment at 2–6 weeks does have a dedicated 'red reflex' section and this has been annotated as normal by the assessing LMC (date 19 [Month2]).

(iii) The ADHB RCA identified a series of missed opportunities for [Baby A's] red reflex to have been checked including opportunities prior to discharge from hospital after birth. It is confirmed that there was no formal check of [Baby A's] red reflexes prior to her discharge from hospital after birth. I presume this aspect of [Baby A's] care will receive comment in the expert midwifery advice obtained.

(iv) [Dr C] has stated in his additional response that on the two occasions he examined [Baby A] (presumably referring to his examinations of 2 [Month3] and

24 [Month4]) only corneal reflections were performed and an ophthalmoscope was not used. [Dr C] does not comment on whether he used an ophthalmoscope in his examination of [Baby A] on 13 [Month5] following which a referral was sent for specialist review. The referral letter did not contain any reference to an abnormal red reflex — if it had, the DHB states [Baby A] would have been seen within a few days rather than the few weeks that eventuated. The comment in the referral by [Dr C] — *light reflexes fine* — could be perceived as being clinically misleading if red reflex was not done.

(v) My interpretation of the additional information provided is that [Dr C] had three opportunities to detect [Baby A's] congenital cataract but he failed on at least two of these occasions to perform the expected clinical examination (red reflex check as part of standard six-week and three month 'Well Child' examinations) and may also have failed to undertake this examination when it was clinically indicated on 13 [Month5] (or alternatively failed to detect an abnormality if the examination was undertaken on this date) at which stage [Baby A's] parents were expressing concern at her vision. Probably the most relevant of these oversights was at the six-week check at which stage detection of the cataract and appropriate surgical management would have optimised [Baby A's] chances of retaining useful vision in that eye.

(vi) [Dr C] acknowledges in his response that he should have used an ophthalmoscope and formally assessed [Baby A's] red reflexes at the six-week and three-month checks, and that he is familiar with the technique of examining for this reflex. His current practice is to use the ophthalmoscope and if the examination is difficult or equivocal, to re-examine the child in a few days and ask for collegial review if required.

(vii) Taking into account the additional information reviewed, and considering the discussion in section 5, I am moderately critical that [Dr C] did not undertake an appropriate red reflex check on [Baby A] at her six-week check and mild to moderately critical that he did not perform this examination at the three-month check. Mitigating factors are that the reflex was apparently normal when checked on 19 [Month2] by the LMC, there were no concerns expressed initially regarding [Baby A's] vision, there was no dedicated area of the WCTO book related to red reflex testing for the six-week and three-month checks at the time of the events in question, and historically this assessment is done poorly in primary care. I would be moderately to severely critical if [Dr C] did not perform a formal assessment of red reflex using an ophthalmoscope on 13 [Month5] when [Baby A's] parents presented concerns regarding her vision.

(ix) I note the Health Quality & Safety Commission have recently released a report on red reflex testing in neonates[5] and I recommend [Dr C] review this publication."

[5] https://www.hqsc.govt.nz/assets/Reportable-Events/Publications/Open-book/OB-Red-Reflex-assessment-Jun-2016.pdf Accessed 4 July 2016