District Health Board

Pacific Radiology Group Limited

Obstetrician & Gynaecologist, Dr D

Radiologist, Dr B

A Report by the

Deputy Health and Disability Commissioner

(Case 16HDC01486)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. Ms A had an ultrasound scan at a radiology service[1] when she was 19 weeks pregnant. On the hard-copy sonographer worksheet, sonographer Ms E noted that the placenta was anterior. However, she did not comment that the placenta appeared to be low lying. Radiologist Dr B then reviewed Ms E's worksheet and the sonography images. Dr B completed a written report of the scan, which states: "Placenta: anterior, not low lying." The default position for placental position in the ultrasound report template was "not low lying", ie, if nothing abnormal was noted in the sonographer's worksheet at the time of the scan, or if nothing was noticed on the images provided at the time of the radiologist's review, the radiologist could leave the placental position as the default.

2. At 35 weeks + 6 days' gestation, Ms A was taken to the public hospital by ambulance. Initially, Ms A thought that she had had a spontaneous rupture of membranes, but she found that she had substantial vaginal bleeding. The ambulance records note that Ms A was experiencing severe intermittent pain.

3. Ms A was seen at 6.45pm by consultant obstetrician Dr D. Dr D said that as the placenta was not low lying (according to the 19-week ultrasound scan) and the presenting part was engaged, she ruled out placenta praevia,[2] which had been her initial suspicion. Her provisional diagnosis was that Ms A had a mild abruption,[3] and she made a plan to manage Ms A in line with this diagnosis.

4. At 11pm Ms A was seen by an obstetric registrar, who discussed Ms A's presentation with Dr D. The registrar then inserted Cervidil[4] to induce labour. Ms A continued to report vaginal bleeding overnight.

5. The following morning, Ms A was seen by consultant obstetrician Dr F. Dr F said that the information she had at the time fitted with the diagnosis of mild placental abruption, and she planned to continue with Cervidil for up to 24 hours.

6. At 10.45am, Ms A experienced further vaginal bleeding of about 200ml. She was reviewed by an obstetric registrar and Dr F, and a digital vaginal examination revealed that the edge of the placenta could be felt. Dr F undertook an ultrasound scan using a portable scanner, and found that the placenta was low and anterior, and the fetal heart rate was low. Ms A then underwent an urgent Caesarean section. The procedure was complicated by difficulty delivering the placenta, which was abnormally adherent (placenta accreta) and low lying (placenta praevia).

7. The district health board's (DHB) policy on placenta praevia and placenta accreta states that clinical suspicion of placenta praevia should be raised in any woman with vaginal

[1] Owned and operated by Pacific Radiology Group Ltd (Pacific Radiology).
[2] When the placenta partially or totally covers the mother's cervix.
[3] Early separation of the placenta from the uterus.
[4] A slow-release prostaglandin preparation.

bleeding after 20 weeks of gestation, with a high presenting part or an abnormal lie, and painless and unprovoked bleeding, irrespective of previous imaging results.

Findings

8. The Deputy Commissioner was critical that the sonographer worksheet and electronic ultrasound report template did not reflect the requirements of the Australasian Society for Ultrasound Medicine standard. In addition, the paper-based system of documentation that was used to summarise and report scans in 2015 was fallible, and the default for placental position in the electronic ultrasound report template, to be completed by the radiologist, was "not low lying". This left the reports open to the type of human error that occurred in relation to the 19-week anatomy scan. For this reason, it was found that Pacific Radiology did not provide services to Ms A with reasonable care, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[5]

9. Because Dr B concluded in his report that Ms A's placenta was not low lying, when in fact it was, it was found that Dr B breached Right 4(1) of the Code.

10. The Deputy Commissioner was concerned that Ms E apparently recognised that the placenta was low, but forgot to return to look at this at the end of the scan. The Deputy Commissioner was critical that the appropriate placental position was not documented on the sonographer worksheet.

11. The Deputy Commissioner considered that there was a missed opportunity for Dr D to confirm Ms A's diagnosis with an ultrasound scan before undertaking a digital examination and inducing labour.

12. The Deputy Commissioner found that the DHB did not breach the Code.

Recommendations

13. The Deputy Commissioner recommended that the DHB (a) provide a training session for obstetric staff on placenta praevia and placenta accreta; (b) update its policy on antepartum haemorrhage to reflect more clearly the need to be suspicious of the accuracy of radiological reports and include a definition of mild abruption; and (c) provide HDC with a copy of its updated policy on placenta praevia and placenta accreta.

14. The Deputy Commissioner also recommended that Pacific Radiology Group and Dr B provide written apologies to Ms A.

[5] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

15. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by the DHB and Pacific Radiology Group Ltd. The following issues were identified for investigation:

- *Whether Pacific Radiology Group Limited provided Ms A with an appropriate standard of care in 2015.*
- *Whether Dr B provided Ms A with an appropriate standard of care in 2015.*
- *Whether the DHB provided Ms A with an appropriate standard of care in 2015.*
- *Whether Dr D provided Ms A with an appropriate standard of care in 2015.*

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

17. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Pacific Radiology Group Ltd	Provider
District health board	Provider
Dr B	Radiologist
Dr D	Obstetrician and gynaecologist

18. Further information was received from:

RM C	Lead maternity carer
Ms E	Sonographer
Dr F	Obstetrician and gynaecologist

Also mentioned in this report:

Dr G	Obstetric registrar
Dr H	Obstetric registrar
Dr I	Obstetrician and gynaecologist

19. Independent expert advice was obtained from a radiologist, Dr Diane Sommerville (included as Appendix A); a sonographer, Naomi Rasmussen (included as Appendix B); and an obstetrician, Dr David Bailey (included as Appendix C).

Information gathered during investigation

Background

20. Ms A, aged 36 years at the time of these events, booked with a self-employed registered midwife (RM), RM C, for primary maternity care. Ms A was expecting her third baby.

21. RM C and Ms A made arrangements for Ms A's baby to be born at the public hospital in the event that she laboured prior to 37 weeks' gestation, or at a rural primary unit closer to Ms A's home if she laboured after that. Ms A had a scan at 10 weeks' gestation to estimate her expected due date.

Anatomy scan 19 weeks' gestation

22. Ms A had an ultrasound scan at the radiology service when she was at 19 weeks' gestation.

23. Sonographer Ms E commenced the scan at 10.59am, and completed it at 11.31am. On the hard-copy sonographer worksheet, Ms E noted that the placenta was anterior. However, she did not comment that the placenta appeared to be low lying, and did not complete the sentence on the worksheet that read: "[Placenta] low lying __ mm from internal os."[6]

24. Ms E told HDC that her normal procedure when completing an anatomy scan is to start by looking at the cervix and placental location. She said that if the placenta appears to be low, she would normally go back to re-check this later in the scan. Ms E stated:

> "In hindsight, I believe I had looked at the start of this scan, thought it might be low, with the intention of going back at the end of the scan to confirm the placental edge location. This obviously did not occur. Looking at my images, I most likely forgot to go back and look at it as the rest of the scan was so normal."

25. Radiologist Dr B then reviewed Ms E's worksheet and the images. He stated:

> "Having reviewed the images again following [Ms A's] complaint, on one of the images, the lower margin of the placenta is very close to the internal os. This image was not annotated (e.g. with an arrow on the placental margin) by the sonographer and there were no concerns expressed, with the placental position being recorded as satisfactory on the sonographer's worksheet."

26. Dr B completed a written report of the scan, which states: "Placenta: anterior, not low lying." Dr B apologised for not noting that the lower part of the placenta was very close to the internal os. He stated: "I reported the examination as per the worksheet and did not appreciate the possible low-lying placenta on the first image, and that further views had not been obtained."

27. Pacific Radiology conducted an internal review and found that a multifactorial error had been made during the scan. It summarised:

[6] The cervical os is the small hole at the centre of the cervix.

> "Human factors have resulted in a potential low lying placenta not being documented in the sonographer worksheet. An error of observation has been made at the time of reporting."

28. The scan report was sent to RM C. RM C told HDC that as the report was normal, there was no clinical concern for an obstetric referral.

Admission to the public hospital

29. Ms A was taken to the public hospital by ambulance following a 111-emergency call. At this time, she was 35 weeks + 6 days' gestation. Initially she thought that she had had a spontaneous rupture of membranes, but she found that she had vaginal bleeding.

30. The ambulance crew documented that Ms A had vaginal bleeding, with "frank dark red gushing blood running down leg on standing" and "severe intermittent pain". The paramedics documented that her heart rate was 120 beats per minute, her blood pressure was 110/90mmHg, and her respiratory rate was 16 breaths per minute, and that she had a normal level of consciousness. An intravenous cannula was inserted and an infusion of normal saline was commenced. By the time Ms A arrived at the hospital at 6.40pm, her heart rate had fallen to 95 beats per minute.

31. Ms A was seen at 6.45pm by consultant obstetrician Dr D. Dr D told HDC that she had reviewed Ms A's obstetric record and anatomy scan, noting that the report stated that the placenta was not low lying. Dr D recorded that Ms A had had a spontaneous rupture of membranes at 5.40pm and that these were "blood stained +++" and that the baby's head was 4/5 palpable. Dr D documented that on examination, Ms A's abdomen was soft and non-tender, and that the baby's presentation was cephalic (head down).

32. Dr D said that as the placenta was not low lying and the presenting part was engaged, she ruled out placenta praevia, which had been her initial suspicion. Her provisional diagnosis was that Ms A had mild abruption. Dr D then performed a digital vaginal examination, which showed bleeding and a closed cervix, and made the following plan: steroid injections to promote fetal lung maturity, continuous fetal heart rate monitoring, blood tests, and consideration of induction of labour in the event of further bleeding.

33. Dr D said that she would have opted for a Caesarean section if the bleeding had been sufficiently significant to cause fetal or maternal compromise, but on the information she had at that time, these circumstances did not apply. She noted that by the time Ms A arrived at the hospital her bleeding had settled, but as there was the potential for her to bleed significantly, Dr D monitored her closely in the birthing suite.

34. At 11pm, Ms A was reviewed by obstetric registrar Dr G, who noted a normal fetal heart rate pattern, uterine tightenings, and continued vaginal bleeding. Dr G queried whether spontaneous rupture of membranes had occurred. Dr G performed a bedside ultrasound scan and recorded that there was a "reasonable amount of pockets of amniotic fluid". After discussion with Dr D, Dr G performed a digital vaginal examination and inserted

Cervidil to induce labour. Dr G's plan was to review Ms A in 12 hours' time if she was not in labour.

35. Ms A was cared for overnight by the hospital midwifery staff and had reassuring electronic fetal heart rate monitoring. She reported further episodes of bleeding "like a heavy period" during the night.

36. At 7.36am Dr G performed another digital vaginal examination and found the cervix unchanged, and that Ms A was not having contractions.

37. Around this time there was a change of medical team. Ms A was reviewed at 9am by consultant obstetrician Dr F. Dr F told HDC that Ms A's history, examination findings, and anatomy scan had been reviewed by the admitting team, which had clearly documented the placenta to be anterior and not low lying, and therefore a clinical diagnosis of mild abruption had been made. Dr F said that the information she had at the time — "painful bleeding with a presenting part fixed in the pelvis and a formal [ultrasound] documenting the placenta not to be low lying in a clinically stable mum and baby" — fitted with the diagnosis of mild placental abruption. Dr F noted at the time of her review that Ms A was not experiencing bleeding or contractions, and continuous fetal heart rate monitoring was discontinued, as it was normal. The plan at this stage was to continue with Cervidil for up to 24 hours.

38. At 10.45am, Ms A experienced further vaginal bleeding of about 200ml in the toilet. She was attended by Dr F and an obstetric registrar, Dr H, who performed a further digital vaginal examination and reported that the cervix was effaced (shortened) and was 2cm dilated, that the membranes felt intact, and that the edge of the placenta could be felt. Dr F repeated the vaginal examination and agreed with the findings. Dr F requested that a portable ultrasound scan machine be brought to the room. When this arrived, she scanned Ms A and found that the fetal heart rate was low and the placenta was low and anterior. Ms A was moved urgently to the operating theatre for delivery by Caesarean section.

39. The operation was performed as a category 1 case (the most urgent), with Dr H operating and Dr F assisting. The operation commenced at 11am and was performed under general anaesthesia, incising through the placenta to reach the baby. The procedure was complicated by difficulty delivering the placenta, which was abnormally adherent and low lying. Some portions of the placenta could not be removed from the uterine cavity, and bleeding was controlled by over-sewing with sutures and insertion of a Bakri balloon to exert pressure inside the uterine cavity. The estimated blood loss during the operation was at least two litres. It was documented that Ms A had undiagnosed anterior placenta praevia and placenta accreta.[7] Dr F also told HDC that there was evidence of a blood clot within the uterine cavity, confirming the additional clinical diagnosis of placental abruption.

40. Ms A's recovery was complicated by anaemia, for which she required a blood transfusion, and her baby required admission to the neonatal unit for nine days. In response to the

[7] When the placenta attaches too deeply into the wall of the uterus.

provisional opinion, the DHB noted that all preterm babies born in its hospital are taken to this unit to manage the usual effects of early term delivery.

Further information —DHB

41. The DHB undertook a review of Ms A's case and found that its staff had trusted the findings of the scan from 19 weeks' gestation. It stated that had the scan been correct, the clinical obstetric management of Ms A would have been correct. The DHB said that if a low-lying placenta had been documented, then a follow-up scan would have been arranged to ascertain whether the placenta remained low in the third trimester. It considered that had this happened, the placenta praevia would have been identified, and this would have influenced Ms A's clinical management when she presented with antepartum haemorrhage — ie, induction of labour would not have been attempted.

42. The DHB stated that Ms A's management was consistent with its clinical guideline on antepartum haemorrhage. The DHB acknowledged that a further ultrasound scan prior to commencing an induction of labour would have diagnosed placenta praevia, but based on Ms A's clinical presentation and the availability of what appeared to be a conclusive previous ultrasound scan report, a further scan was not considered necessary. In response to the provisional opinion, the DHB stated:

> "[T]he ultrasound report in front of the clinicians was a clear report by a Specialist Radiologist with no ambiguities which would be expected to be highly reliable with nothing to highlight to the treating team that it was incorrect."

43. The DHB sought an opinion from Dr I, an obstetrician and gynaecologist, who advised:

> "This is a case where it is easy in retrospect to be critical. However, although the guidelines could be interpreted as not being followed it is in my view somewhat harsh to say that this represents a major departure from acceptable safe practice. [Ms A] presented in the evening with a vaginal bleed. On admission she was haemodynamically stable, the CTG was reassuring a 20 week scan had stated that the anterior placenta was not low lying, and although the head was 4/5 palpable, this would not be unusual in someone having their third baby.
>
> A diagnosis of Abruption or a placenta edge bleed would not be unreasonable. In the face of continuing bleeding the decision to induce labour is also reasonable, particularly in light of two previous normal deliveries at 37 and 34 weeks.
>
> The real crux of the problem is whether the decision not to get an urgent scan in the middle of the night was justified, and whether it would have changed the management plan.
>
> In my view, faced with this dilemma, and a normal 20 week scan, it would not be unusual for a clinician to initiate the treatment plan that [Dr D] did."

44. Dr I considered that the timing of the Caesarean section in Ms A's case was appropriate. He said that even if a minor degree of placenta praevia had been known about, he is not

sure that the management plan would have changed. In Dr I's opinion, if there was a departure from accepted practice, "it would be minor rather than a major departure from acceptable safe practice".

DHB policies

45. The policy "Placenta Praevia and Placenta Accreta" states:

> "While clinical acumen remains vitally important in suspecting and managing placenta praevia, the definitive diagnoses of most low-lying placentas is now achieved with ultrasound imaging. Clinical suspicion should, however, be raised in any woman with vaginal bleeding after 20 weeks of gestation. A high presenting part or an abnormal lie, painless and unprovoked bleeding should raise the suspicion of placenta praevia irrespective of previous imaging results."

46. This policy also states: "Sterile speculum examination is appropriate to assess the source of bleeding, extent of the bleed and the possibility of rupture of membranes. Digital examination should not be undertaken."

47. The policy "Antepartum Haemorrhage" states that at 35+6 weeks' gestation, conservative management can be considered for minor abruptions. It states that at 36 weeks' gestation, delivery would be recommended owing to the risk of further bleeding, and that vaginal birth can be attempted if the CTG is normal and the mother is stable. This policy was formally issued after Ms A's care. However, the DHB advised that the policy content had been circulated, and staff were aware of it and "it reflected accepted practice".

Dr D

48. Dr D told HDC:

> "I was very aware of the [DHB] Guideline on Placenta Praevia and Placenta Accreta … However, because there was not a high presenting part (the presenting part was in the pelvis) and, from the scan there was not an abnormal lie (the scan report was clear that the placenta was not low lying), the only risk factor present for placenta praevia was vaginal bleeding after 20 weeks. Therefore whilst I did initially consider and suspect placenta praevia, because the other risk factors identified by the [DHB] Guideline were not present (no abnormal lie and no high presenting part), I ruled placenta praevia out from her earlier scan. A further formal scan was not therefore necessary to rule out placenta praevia.
>
> Further, [Ms A] was admitted out of hours, when it is more difficult to obtain a formal scan. If there had been any additional risk factors to indicate placenta praevia, I would have ordered a scan and would not have proceeded with a digital examination. However, as there were no additional risk factors, I acted on the clinical information I had and I consider my plan and actions to have been appropriate based on this information. Further, according to the Royal College of Obstetricians & Gynaecologists' Guidelines on Antepartum haemorrhage (Green-top guideline No 63 2011), women presenting with antepartum haemorrhage should have an ultrasound performed to confirm or exclude placenta praevia if the placental site is not already

known. In this case, the placental site was already known from the anatomy scan. I therefore managed [Ms A] in line with abruption."

Changes to service

49. The DHB advised that as a result of this incident, the following occurred:

a) Ms A's case was reviewed at a multidisciplinary team radiology and obstetric meeting, during which awareness was raised of the need to consider the diagnosis of placenta praevia in the context of an antepartum haemorrhage.

b) Its clinical guideline on antepartum haemorrhage is to be amended to reflect more clearly the need to be suspicious of the accuracy of radiological reports.

c) PROMPT obstetric emergency courses now include training on skills to ensure a culture where clinicians of all roles and levels of seniority can speak up.

d) A perinatal education session on human factors in the birthing suite took place in June 2018, and was attended by obstetric and neonatal consultants, registrars, house officers, and midwives.

Further information —radiology service

50. Pacific Radiology stated that the paper-based system of documentation that was used to summarise and report scans in 2015 was fallible and open to the type of error that occurred in relation to the 19-week anatomy scan. It noted that the default for placental position in the ultrasound report template was "not low lying", ie, if nothing abnormal was noted in the sonographer's worksheet at the time of the scan, or if nothing abnormal was noticed on the images provided at the time of the radiologist's review, the radiologist could leave the placental position as the default.

51. Pacific Radiology stated:

"We must share the blame for allowing this error to have occurred in our system. This error can no longer occur and we are working hard to ensure other potential reporting anomalies are identified."

52. Pacific Radiology now uses Kailo sonography software for all obstetric ultrasound scans. The placental position has been set as a "hard stop", so that the sonographer worksheet cannot be sent to the radiologist for reporting unless the placental location, including whether or not it is low lying, and measurement of it from the os if it is, is recorded. Pacific Radiology stated that this was specifically put in because of Ms A's case, and noted that this was introduced before the HDC complaint was made, as risks with information flow and human error had been identified. Pacific Radiology stated that the system is structured around the latest International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) updates and requirements from the Ministry of Health and leading world experts, including the Australasian Society for Ultrasound Medicine (ASUM).

53. The radiology service uses the DHB's obstetric guidelines for definition and follow-up of placenta praevia as follows:

> "Placenta Praevia Definition …
>
> — Complete praevia — placenta covers the internal cervical os.
>
> — Marginal praevia.
>
> — Low lying placenta — 2cm or less from the cervical os.
>
> Reporting Recommendations
>
> If a low lying placenta and/or placenta praevia is found at the anatomy scan, the Radiologist is to recommend follow-up re-assessment at approximately 32 weeks gestation which may require a transvaginal scan.
>
> Report distance of the lower placental margin from the internal os on the [transvaginal] scan."

Responses to provisional opinion

54. Relevant sections of the provisional opinion were sent to Pacific Radiology, Dr B, Ms E, the DHB, Dr D, Dr F, and Ms A, and they were given the opportunity to comment. Where appropriate, changes have been incorporated into other sections of this report.

Pacific Radiology

55. Pacific Radiology stated that at the time of the scan, the radiology service was performing ultrasound services consistent with Australasian best practice, with reliance on handwritten pro forma documents and human-to-human information transfer. It stated that the DHB and the radiology service were using the ISUOG guidelines in 2015. However, it acknowledged that in hindsight the default placental position of "not low lying" on the sonographer worksheet and radiologist report was a flaw, for which it accepts full responsibility.

56. Pacific Radiology stated that to date and to its knowledge, it has had no further episodes of undiagnosed placenta praevia, and has reduced its minor error report to less than 1%. It stated that Ms A's case has led to a significant improvement in ultrasound accuracy in regions where Pacific Radiology has a footprint. Pacific Radiology said that it has initiated a regional obstetrics and gynaecology ultrasound forum which meets quarterly, with the goal of sharing information and improving ultrasound quality.

57. Pacific Radiology noted that Dr B apologised to Ms A and discussed her case with her in 2015.

DHB

58. The DHB acknowledged that Ms A's birth experience was traumatic for her and her family, and apologised. It stated:

> "Although in hindsight we are sorry that the placenta praevia was not diagnosed earlier, [the DHB] and our staff remain of the view that the care provided to [Ms A] was reasonable based on all of the information available at the time … We believe that the majority of obstetricians and gynaecologists throughout New Zealand and Australia under the umbrella of RANZCOG would share our view that [Ms A's] care was reasonable."

59. The DHB acknowledged that it would have been helpful if its guideline on placenta praevia and placenta accreta had clarified whether a single indicator was sufficient to warrant further investigation of placenta praevia, or whether all indicators (ie, a high presenting part or abnormal lie, or painless or unprovoked bleeding) needed to be present to justify that action. The DHB noted that Dr D did consider placenta praevia, and that this was her "initial suspicion", but she ruled it out based on the information available, as the only factor present was an unprovoked bleed.

60. The DHB said that based on Ms A's clinical presentation, she did not have any of the other listed risk factors required to raise clinical suspicion of a placenta praevia, so there was no reason to discount the previous imaging. It noted that the ambulance officer had documented that Ms A had experienced "severe intermittent pain". The DHB maintains that Dr D's assessment of the baby's head as being 4/5 palpable, and Dr G's assessment of the baby's head as being 3/5 palpable, would not be considered to indicate a high presenting part in a multiparous woman at 36 weeks' gestation. The DHB also stated that its clinicians took into account that Ms A did not have any other relevant risk factors for placenta praevia.

61. The DHB submitted that only one factor, being an unprovoked bleed, was present. In view of this, it considers that the presumed clinical diagnosis of a mild abruption was reasonable in a multiparous patient with a history of unprovoked bleeding and pain, no history of a uterine scar, a cephalic presenting part over the pelvis, and a prior anatomy scan indicating that the placenta was not low lying. Accordingly, it submitted that the decision to induce labour was reasonable, and noted that Dr F and Dr H exercised their own clinical judgement about what was appropriate treatment when they continued with Dr D's diagnosis and management plan. the DHB stated:

> "Our position is that our staff did not fail to take our policy on placenta praevia into account when assessing [Ms A's] clinical presentation but rather that our staff reasonably did not consider the policy, in light of [Ms A's] presentation, was applicable or triggered given she only presented with one factor being an unprovoked bleed. Staff involved however did review and check the scan report for placental position taking this into overall consideration but, did not consider that the risk factors were so strongly in favour to raise the suspicion of placenta praevia so that the scan report needed to be negated."

62. The DHB submitted that the working diagnosis of antepartum haemorrhage, and the information available to the clinicians at the time, warranted the undertaking of digital vaginal examinations.

Policy update

63. The DHB advised that it would review its policy on placenta praevia and placenta accreta to give greater clarity on when and why previous imaging should be disregarded. As part of this review, it would consider changing its policy to align with new classifications of low-lying placenta.

Ms A

64. Ms A said that she stated numerous times that she did not feel right in herself, and had a gut feeling that something was wrong. She said that she asked for a Caesarean section but was told repeatedly that she was going to progress with a normal pregnancy. Ms A told HDC: "As a patient I was not heard or taken seriously." Ms A is concerned that she was not offered an ultrasound scan overnight because she was admitted after hours.

65. Ms A stated: "It still seems like yesterday this nightmare had occurred and has in the end resulted in me having a full hysterectomy due to the continuous heavy bleeding and pain since [the] delivery."

Opinion: Ms E — adverse comment

66. Ms E performed the anatomy scan for Ms A at 19 weeks' gestation. Ms E documented on the sonographer worksheet that the placenta was anterior. However, she did not comment that the placenta appeared to be low lying, and did not complete the sentence on the worksheet that read: "[Placenta] low lying __ mm from internal os."

67. Ms E said that, in hindsight, she believes that she looked at the placenta at the start of the scan and thought it might be low, and intended to go back at the end of the scan to confirm the placental edge location. She stated that she most likely forgot to go back and look at it, as the rest of the scan was so normal.

68. My expert advisor, sonographer Naomi Rasmussen, advised that the scan images taken were adequate, and that the scan was not rushed. Ms Rasmussen noted that the first image shows the cervix and the probable low-lying placenta. She advised that the placenta should have been documented on the worksheet as low lying, but that the failure to do so, in her view, was a minimal departure from accepted practice.

69. Ms Rasmussen stated: "The correct images have been taken but the low lying placenta was not documented on the work sheet. This would be viewed as an oversight by [Ms E's] peers."

70. I accept Ms Rasmussen's advice and I am satisfied that the images obtained during the scan were appropriate. However, I am concerned that Ms E apparently recognised that the placenta was low, but forgot to return to look at this at the end of the scan. I am also critical that the appropriate placental position was not documented on the sonographer worksheet. While I am critical of these oversights, I accept Ms Rasmussen's explanation that, in her view, it was a minimal departure from accepted practice. I also note that the

images and worksheet were then passed on to a radiologist, who had a responsibility to report appropriately on the images obtained.

Opinion: Dr B — breach

71. Radiologist Dr B reviewed sonographer Ms E's worksheet and the images of the 19 week anatomy scan. Dr B's written report of the scan states: "Placenta: anterior, not low lying."

72. Dr B acknowledged in hindsight that one of the scan images shows the lower margin of the placenta very close to the internal os. However, he commented that the image was not annotated (eg, with an arrow on the placental margin) by the sonographer, and there were no concerns expressed, with the placental position being recorded as satisfactory on the sonographer's worksheet. Dr B stated that he reported the scan in accordance with the worksheet and did not appreciate the possible low-lying placenta on the first image, and that further views had not been obtained.

73. My expert advisor, radiologist Dr Diane Sommerville, explained that the standard of care for a mid-trimester obstetric scan (an anatomy scan) is based on ASUM and Royal Australian and New Zealand College of Radiologists (RANZCR) standards of practice. She provided an excerpt from the relevant ASUM standard, with respect to placental assessment, stating that this should be performed and completed at all mid-trimester obstetric scans:

> "6. Placenta — Site ( )
>
> — Distance from internal os ( ) cm
>
> — Placental myometrial interface clearly defined ( )
>
> Placental Localisation.
>
> The relationship between the lower margin of the placenta and the internal os should be determined. This is most accurately assessed with vaginal imaging. If the relationship between placental position and the internal os is still uncertain at the end of the scan, then a repeat scan at 34 weeks, or earlier if clinically indicated should be considered. Repeat scans should only be necessary in about 5% of all cases."

74. Dr Sommerville noted that there are no images documenting the placenta to internal cervical os distance, in accordance with the above standard, and as the placental distance from the cervical os is unknown, the examination is incomplete. She advised that in her view this was a significant departure from the standard of care or accepted practice.

75. Dr Sommerville stated:

> "[Dr B's] conclusion in his radiology report [19 weeks' gestation] in respect to the placenta was not appropriate. On the scan performed it was not possible to conclude the placenta was 'not low lying' …
>
> Despite the Sonographer writing a 'normal' [on the] completed worksheet it is the Radiologist's job to review the images to ensure this is correct and nothing has been missed. If the Radiologist is concerned about any aspects of the scan they would normally discuss this with the Sonographer and ask them to get the patient back for a further scan if necessary. Unfortunately it appears that the Radiologist has failed to notice that there was no placental-cervical os image and the scan has been interpreted inappropriately as normal."

76. I accept Dr Sommerville's advice. I am concerned that the placental distance from the internal os was not determined in this case, in accordance with the ASUM standard. Accordingly, I am also critical that Dr B concluded in his report of the scan that the placenta was not low lying. I acknowledge that the placenta was not flagged by the sonographer as being low lying, and that this may have falsely reassured Dr B that it was not. However, as the radiologist reporting on the scan, it was Dr B's responsibility to review the images carefully, irrespective of what was written on the worksheet, to satisfy himself of the findings and report appropriately on the images obtained.

77. Dr B had a responsibility to provide Ms A services with reasonable care and skill. Because Dr B concluded in his report that Ms A's placenta was not low lying, when in fact it was, I find that Dr B breached Right 4(1) of the Code.

Opinion: Pacific Radiology Group Ltd — breach

78. Pacific Radiology is responsible for the operation of the clinical services it provides, and is responsible for service failures. It has a responsibility to have in place robust systems to provide an appropriate standard of care to consumers.

79. Pacific Radiology stated that the paper-based system of documentation that was used to summarise and report scans in 2015 was fallible and open to the type of error that occurred in relation to the 19-week anatomy scan. It noted that the default position for placental position in the electronic ultrasound report template, to be completed by the radiologist, was "not low lying". Pacific Radiology stated: "We must share the blame for allowing this error to have occurred in our system."

80. I note that the ASUM standard states that the following should be recorded for all mid-trimester obstetric scans:

> "6. Placenta — Site ( )
>
> — Distance from internal os ( ) cm …"

81. I am concerned that the sonographer worksheet and the electronic ultrasound report template in use at Pacific Radiology at the time of these events did not require the distance of the placenta from the internal os to be recorded on all mid-trimester obstetric scans.

82. While there were human errors by Ms E and Dr B, Pacific Radiology did not have a system in place at the time of these events to protect against those errors — the paper worksheet did not have a required field in relation to the cervical-placental distance, and the default position for the placenta in the ultrasound report was "not low lying". I am critical that these errors were able to occur within Pacific Radiology's system, and I consider that had these requirements been in place, these errors would not have occurred.

83. I acknowledge that Dr Sommerville advised that Pacific Radiology's standard operating procedures and policies were in keeping with expected standards. Similarly, my expert advisor, sonographer Naomi Rasmussen, advised that the protocols provided by Pacific Radiology for anatomy scanning were correct and complete, especially with regard to documenting a low-lying placenta.

84. I note Dr Sommerville's recommendation that the sonographer worksheet be changed so that the cervical-placental distance is documented for all mid-trimester anatomy scans, to serve as an extra check for sonographers and radiologists. I consider that had these requirements been in place, in line with the ASUM standard, these errors would not have occurred.

85. Notwithstanding my advisors' comments regarding the procedures and policies at Pacific Radiology being appropriate, I am critical that the sonographer worksheet and electronic ultrasound report template did not reflect the requirements of the ASUM standard. In addition, the paper-based system of documentation that was used to summarise and report scans in 2015 was fallible, and the default for placental position in the electronic ultrasound report template, to be completed by the radiologist, was "not low lying". This left the reports open to the type of human error that occurred in relation to the 19-week anatomy scan. For this reason I do not consider that Pacific Radiology provided services to Ms A with reasonable care. Accordingly, I find that Pacific Radiology breached Right 4(1) of the Code.

Other comment

86. I note that Pacific Radiology now uses a different software system, and the placental position has been set as a "hard stop", so that the sonographer worksheet cannot be sent to the radiologist for reporting unless the placental location, including whether or not it is low lying, and measurement of it from the os if it is, is recorded. I consider this change to be appropriate in the circumstances, and believe it will go some way to preventing a similar error in future.

Opinion: Dr D — adverse comment

87. Dr D was the consultant obstetrician responsible for Ms A's care when she was admitted to the public hospital at 6.45pm.

88. Dr D noted that Ms A had had a spontaneous "blood stained +++" rupture of membranes, and that the baby's head was 4/5 palpable in a cephalic position. The ambulance notes stated that Ms A had "frank dark red gushing blood running down leg on standing" and "severe intermittent pain". Dr D confirmed that she had reviewed Ms A's anatomy scan, which stated that the placenta was not low lying. Dr D told HDC that as the placenta was not low lying and the presenting part was engaged, she ruled out placenta praevia, which had been her initial suspicion. She made a provisional diagnosis of mild abruption. Dr D performed a digital vaginal examination and planned to consider induction of labour if there was further bleeding. Later that evening, Ms A experienced further bleeding. After discussion with Dr D, Dr D's registrar, Dr G, performed a digital vaginal examination and inserted Cervidil to induce labour. Dr D noted that her management was in line with the policy on antepartum haemorrhage.

89. The policy on placenta praevia states that "clinical suspicion should be raised in any woman with vaginal bleeding after 20 weeks of gestation. A high presenting part or an abnormal lie, painless and unprovoked bleeding should raise the suspicion of placenta praevia irrespective of previous imaging results."

90. My independent advisor, obstetrician Dr Bailey, advised that until placenta praevia had been excluded, digital examination and induction of labour were contraindicated, as there was a risk these could precipitate life-threatening haemorrhage.

91. Dr Bailey raised concern that Dr D diagnosed mild abruption, despite the ambulance describing blood running down Ms A's legs. He noted that this usually signifies significant bleeding. Dr Bailey disputed that Ms A's presenting part was engaged, and stated: "Engagement is defined as the passage of at least half of the fetal head into the pelvis, but on admission most of the head (4/5) was palpable above the pelvis, so the head was not engaged." In light of these factors, Dr Bailey stated that he believes Dr D did not make an appropriate assessment when Ms A was admitted, and did not consider the possibility of placenta praevia in line with policy, "as a result of which a course of treatment was commenced which could have been life-threatening".

92. Dr Bailey advised that the appropriate management when Ms A initially presented was expectant (ie, closely watching Ms A's condition but not giving treatment unless her symptoms worsened). He stated: "While the bleeding was settling and fetal heart rate monitoring was reassuring it was appropriate to wait, as in many cases the bleeding will stop and preterm birth can be avoided."

93. Dr Bailey advised that regardless of the results of previous imaging, placenta praevia should have been considered as a possible diagnosis, as indicated in the DHB's guideline. He stated:

> "Therefore, I believe a formal scan should have been requested. Whether this was required out-of-hours, or could wait until morning, was a clinical decision. However, such a scan should have been performed before considering induction of labour."

94. In response to the provisional opinion, Dr D confirmed that she turned her mind to placenta praevia as her initial suspicion, but she ruled it out because based on the information available to her, the only factor present from the policy on placenta praevia was an unprovoked bleed. Further, she noted that in her view Ms A did not have any other risk factors to raise clinical suspicion of a placenta praevia, so she considered that there was no reason to discount the previous imaging.

95. I note that the DHB's advisor, Dr I, stated that although the baby's head was 4/5 palpable, this would not be unusual in someone having her third baby, and that the diagnosis of abruption would not be unreasonable. He commented: "In my view, faced with this dilemma, and a normal 20 week scan, it would not be unusual for a clinician to initiate the treatment plan that [Dr D] did."

96. Dr Bailey reviewed Dr I's opinion, and acknowledged that other obstetricians may differ regarding the degree of departure from accepted practice. However, he maintained his view that Dr D failed to provide appropriate care.

97. I note Dr Bailey's advice that the baby's head being 4/5 palpable was not consistent with Dr D's description of the presenting part being engaged. However, I also note Dr I's advice that this would not be unusual for a woman having her third baby, which may also have supported Dr D's decision not to take steps to rule out placenta praevia.

98. I appreciate that there are differences of opinion between my expert advisor, Dr Bailey, and Dr I and Dr D. Clearly with the benefit of hindsight, Ms A's case should have been managed differently. In my opinion, Ms A's presentation of an unprovoked bleed, which had been described by the ambulance staff as "gushing blood running down leg on standing" and by Dr D as "blood stained +++", should have prompted Dr D to undertake an ultrasound scan to satisfy herself that the diagnosis of placenta praevia could be excluded, before undertaking a digital examination and inducing labour. In my view, this was a missed opportunity for Dr D to confirm Ms A's diagnosis. However, I acknowledge Dr D's explanation that Ms A was admitted out of hours, when it is more difficult to obtain a formal scan, and that if there had been any additional risk factors to indicate placenta praevia, she would have ordered a scan and not proceeded with a digital examination.

99. I acknowledge that there are other mitigating factors in this case — most importantly, the anatomy scan result that clearly stated that Ms A's placenta was not low lying. I accept that this was falsely reassuring and led Dr D to consider a diagnosis of mild abruption rather than placenta praevia, and to provide treatment in accordance with the policy on antepartum haemorrhage.

Opinion: DHB — no breach

100. District health boards are responsible for the operation of the clinical services they provide, and are responsible for service failures. They have a responsibility to have in place robust systems to provide an appropriate standard of care to consumers.

101. Individual clinicians were involved in making and executing the treatment plan for Ms A, and the anatomy scan available was falsely reassuring. The policy on placenta praevia specifically states that clinical suspicion of placenta praevia should be raised in any woman with vaginal bleeding after 20 weeks of gestation, with a high presenting part or an abnormal lie, and painless and unprovoked bleeding, irrespective of previous imaging results. It also specifies that digital examinations should not be undertaken.

102. My expert advisor, consultant obstetrician Dr David Bailey, advised:

> "It is my opinion that the care provided to [Ms A] represented a major departure from acceptable safe practice. I believe this would be the opinion of the majority of my peers. There were clear clinical grounds for considering a diagnosis of placenta praevia. Two Consultant Obstetricians and two Registrars proceeded with digital examinations and induction of labour with Cervidil, which could have precipitated life-threatening haemorrhage. The [DHB] guidance on Placenta Praevia and Placenta Accreta was not followed."

103. The DHB and its staff have provided clear explanations for their rationale to treat Ms A in line with its policy on antepartum haemorrhage, rather than its policy on placenta praevia. In particular, the DHB considered that the only factor exhibited by Ms A that was referred to in the policy on placenta praevia was unprovoked bleeding after 20 weeks. It noted that the ambulance records state that Ms A had experienced severe intermittent pain; the position of the presenting part would not be unusual in someone having her third baby; and Ms A did not have other relevant risk factors for placenta praevia. The DHB stated:

> "Our position is that our staff did not fail to take our policy on placenta praevia into account when assessing [Ms A's] clinical presentation but rather that our staff reasonably did not consider the policy, in light of [Ms A's] presentation, was applicable or triggered given she only presented with one factor being an unprovoked bleed. Staff involved however did review and check the scan report for placental position taking this into overall consideration but, did not consider that the risk factors were so strongly in favour to raise the suspicion of placenta praevia so that the scan report needed to be negated."

104. While I acknowledge my expert's advice, in all of the circumstances I am unable to conclude that the overall care provided by the DHB was unreasonable in the circumstances. Clearly with the benefit of hindsight, Ms A's case should have been managed differently, and in my view, there was a missed opportunity for Dr D to confirm Ms A's diagnosis with an ultrasound scan. However, the DHB has provided clear explanations for why its obstetric staff managed Ms A in line with the diagnosis of antepartum haemorrhage rather than placenta praevia, and I accept these. I note in

particular the influence the incorrect anatomy scan result (stating that the placenta was not low lying) would have had on the treating clinicians' decision-making.

Recommendations

105. I recommend that the DHB:

a) Provide a training session for obstetric staff on placenta praevia and placenta accreta, including its policy. Evidence that the training has been scheduled should be sent to HDC within three months of the date of this report.

b) Update its policy on antepartum haemorrhage to reflect more clearly the need to be suspicious of the accuracy of radiological reports, and to include a definition of "mild abruption". A copy of the updated policy should be sent to HDC within three months of the date of this report.

c) Provide HDC with a copy of its updated policy on placenta praevia and placenta accreta once this has been finalised.

106. I recommend that Pacific Radiology Group Ltd provide a written apology to Ms A for the failings outlined in this report. The apology should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

107. I recommend that Dr B provide a written apology to Ms A for the failings outlined in this report. The apology should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

Follow-up actions

108. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Pacific Radiology Group Limited, will be sent to the Medical Council of New Zealand, and it will be advised of the names of Dr B and Dr D.

109. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Pacific Radiology Group Limited, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australian and New Zealand College of Radiologists, and the Medical Radiation Technologists Board.

110. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Pacific Radiology Group Limited, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from radiologist Dr Diane Somerville:

> "Please find my opinion regarding the complaint by [Ms A] against [the radiology service] re her care [at 19 weeks' gestation].
>
> I have read and agreed to follow the Commissioner's guidelines for independent advisors.
>
> I have been a vocationally registered Diagnostic Radiologist since 1998. I have worked at Waikato Hospital (1997–2007) and in private practice (1998–current). I have been involved in the reporting of secondary level Obstetric Imaging since 1998 and tertiary level imaging during my hospital tenure. My qualifications are MB, CHB 1990, Otago University and FRANZCR 1997. My referral instructions from the Commissioner are to provide expert advice as follows:
>
> Please comment on:
>
> 1. Based on the sonographer's scans and findings [at 19 weeks], were [Dr B's] conclusions in his radiology report appropriate?
> 2. What checks would you expect to be in place to ensure the scans performed were adequate?
> 3. Given the information available to [Dr B], were his subsequent actions appropriate?
> 4. Had a low lying placenta been identified at the 19 week scan, would a subsequent follow-up scan have been planned and within what timeframe?
> 5. Whether [the radiology service's] Incident Review report and conclusions adequately identify any errors or omissions in the scan [at 19 weeks].
> 6. The adequacy of [the radiology service's] standard operating procedures and policies both as at [the 19 week scan] and currently.
> 7. Any other comments you may wish to make about [the radiology service] that were provided to [Ms A].
>
> For each question, please advise:
>
> a. What is the standard of care/accepted practice?
> b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
> c. How would it be viewed by your peers?
> d. Recommendations for improvement that may help to prevent a similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b). Please limit your advice to radiology services. The Commissioner may opt to obtain sonography advice from a sonography expert at a later date.

I have been provided with the following supporting information:

1. Letter of complaint [including a letter to [Ms A] from [the public hospital] and [the radiology service].
2. [Pacific] Radiology Limited's response to HDC dated 24 October 2016.
3. [Radiology service] clinical records and scan for [19 weeks] along with a report by [Dr B].
4. [Radiology service] standard operating procedures/policy relating to a routine anatomy ultrasound scan at 19 weeks.

Note: [Pacific] Radiology has advised that the current policy was in place in 2015.

A summary of events has been provided to me by the Commissioner's Office.

My Opinion is as follows:

1. Based on the sonographer's scans and findings [at 19 weeks' gestation], were [Dr B's] conclusions in his radiology report appropriate?

The report states: Placenta: anterior, not low lying.

[Dr B's] conclusion in his radiology report of [19 weeks] in respect to the placenta was not appropriate. On the scan performed it was not possible to conclude the placenta was 'not low lying'.

(a) What is the standard of care/accepted practice?

In NZ the standard of care/expected practice for a Mid trimester Obstetric scan (Anatomy scan) is based on ASUM and RANZCR Standards of practice (enclosed copy of ASUM standards). ASUM and RANZCR are our Professional bodies. Below is an excerpt from the relevant ASUM standard, with respect to placental assessment. This should be performed and completed at all mid trimester Obstetric scans.

6. Placenta — Site ( )
— Distance from internal os ( ) cm
— Placental myometrial interface clearly defined ( )

Placental Localisation.

The relationship between the lower margin of the placenta and the internal os should be determined. This is most accurately assessed with vaginal imaging. If the

relationship between placental position and the internal os is still uncertain at the end of the scan, then a repeat scan at 34 weeks, or earlier if clinically indicated should be considered. Repeat scans should only be necessary in about 5% of all cases.

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

I have reviewed the scan performed [at 19 weeks]. There are several images at the start of the scan showing an anterior placenta. On one of these images the placenta appears close to the cervix, but its exact position is unable to be confirmed. There are no images documenting the placenta to internal cervical os distance, as per the standard above. As the placental distance from the cervical os is unknown, the examination is incomplete. This is a significant departure from the standard of care or accepted practice.

With respect to possible placenta accreta I do not see any definite signs or features suggestive of this on the scan performed, with a normal hypoechoic myometrial interface between the placenta and the bladder. However, this is a difficult sonographic diagnosis and requires vigilant assessment of the myometrial placenta interface in a patient with placenta praevia/low lying placenta and previous Caesarean section/uterine surgery. This is often a tertiary (hospital) level diagnosis. Placenta accreta would hopefully have been diagnosed in this patient at later scans in pregnancy, had these been performed for follow up of the low lying placenta.

(c) How would it be viewed by your peers?

My peers would confer with my opinion above. The case illustrates that all points of the scanning protocols are there for a reason.

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

It is my recommendation that [the radiology service's] Ultrasound pregnancy data sheet/Worksheet be changed so that the cervical-placental distance is documented for all Anatomy scans. Currently it appears to read that the distance only needs to be documented if the placenta is noted to be low lying. This serves as an extra check for the Sonographer and reporting Radiologist. If at the end of the scan the Sonographer cannot write in the distance on the worksheet (such as when the check has been forgotten) the patient will be asked to return so the scan can be completed.

2. What checks would you expect to be in place to ensure the scans performed were adequate?

(a) What is the standard of care/accepted practice?

The Sonographer performs the scan covering all the examination checklist as above. For every point on the examination checklist an image is taken and saved, for the Radiologist to later review and for medico-legal purposes. The examination images are then checked by a Radiologist before reporting. If any of the checks are unable to be

completed or are incomplete/inadequate the patient is rebooked within 1–2 weeks to complete the scan checks. The checks in place are therefore 2 fold, at the time of the sonographer performing the scan and filling in a checklist and at the time of reporting — when the Radiologist checks all imaging is adequate/present and normal/abnormal.

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

There has been an error made by both the Sonographer and reporting Radiologist with an incomplete scan and failure to diagnose a low lying placenta. Both have failed to realise that the placental distance from the internal cervical os has not been checked.

(c) How would it be viewed by your peers?

As discussed above.

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

As discussed above.

3. Given the information available to [Dr B], were his subsequent actions appropriate?

Despite the Sonographer writing a 'normal' and completed worksheet it is the Radiologist's job to review the images to ensure this is correct and nothing has been missed. If the Radiologist is concerned about any aspects of the scan they would normally discuss this with the Sonographer and ask them to get the patient back for a further scan if necessary. Unfortunately it appears that the Radiologist has failed to notice that there was no placental-cervical os image and the scan has been interpreted inappropriately as normal.

4. Had a low lying placenta been identified at the 19 week scan, would a subsequent follow-up scan have been planned and within what timeframe?

If the placenta is shown to be low lying at the 19 week scan a follow up scan is recommended between 32–34 weeks gestational age to recheck the placental position (as the position will often become normal as the pregnancy progresses). If the placenta is still low lying at 32–34 weeks a Specialist Obstetric referral is recommended as the patient may ultimately need to deliver by Caesarean section. At this stage further scans will normally be performed at a Hospital/tertiary level. If the patient becomes symptomatic (ie: with bleeding) the patient should be reimaged ASAP.

5. Whether [the radiology service's] Incident Review report and conclusions adequately identify any errors or omissions in the scan [at 19 weeks].

[The radiology service's] Incident Review report and conclusions adequately identify the errors/omissions in the [19 week scan]. Their conclusion that an error of observation has been made at the time of the scan reporting is correct in my opinion.

6. The adequacy of [the radiology service's] standard operating procedures and policies both [at the time of these events] and currently.

[The radiology service's] standard operating procedures and policies (as provided) are in keeping with expected standards. However, as above, it is my recommendation that the Sonographer worksheet be changed so that the cervical-placental distance is documented for all Mid trimester/anatomy scans. Currently the distance is only required if the placenta is noted to be low lying. This serves as an extra check for the Sonographer and reporting Radiologist. If the Sonographer has forgotten to perform that check they will be unable to write in the distance and will realise the scan is incomplete.

7. Any other comments you may wish to make about the radiology services that were provided to [Ms A].

I have not been given any information about the bedside 'informal' scan performed at the public hospital, but it is unclear why a 'formal' scan was not performed (including placental assessment) given the patient's acute presentation with bleeding.

Summary:

Based on the information provided, [Ms A] received care below the expected standard for her 19 week scan performed at [the radiology service]. The determination of whether the placenta is low lying is an expected 'standard of care' at this scan. Unfortunately the placental position was not adequately assessed by the Sonographer at the time of scanning and the Radiologist failed to pick up this error at the time of reporting.

Yours sincerely,

Dr Diane Sommerville"

Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from sonographer Naomi Rasmussen:

"I have visited [the radiology service] 3 or 4 times as an examiner of sonographers completing their DMU practical assessment for ASUM.

I may have met [Ms E] or [Dr B] during this process but have no recollection of having met them.

I have always found the standard of training and caliber of students and sonographers at [the radiology service] high.

Were the scans performed by the sonographer at 19 weeks adequate?

Yes they were adequate. The scan was not rushed taking 24 minutes with a further 2–3 minute scan presumably after the baby had changed position. Good quality images of the fetal anatomy were documented.

The first image labelled cervix shows the cervix and the probable low lying placenta.

No departure from accepted practice.

This would be viewed as a normal documentation of an Anatomy scan by our peers.

As with all missed diagnosis and mistakes, review of the case with peers is recommended.

Were there sufficient checks in place to ensure all the appropriate scans were performed?

The images taken were accepted practice. The work sheet was completed and signed. The CRG protocol for an Anatomy scan including assessment of a low lying placenta *and* Placenta Accreta are correct.

No departure from standard practice.

Normal practice by peers.

No recommendation.

Whether, if there were any unusual features on the scans performed, a senior sonographer should have recognized that further investigation was required.

The placenta should have been documented on the worksheet as low lying.

Assessment of the myometrium for Placenta Accreta was not indicated as the patient had not had a previous caesarian section. Assessment of patients at risk of Placenta Accreta is usually done at a later gestation.

Minimal departure from accepted practice. The correct images have been taken but the low lying placenta was not documented on the work sheet. This would be viewed as an oversight by her peers.

Case review with peers as a reminder of how easy a mistake can be made.

Had a low lying placenta been identified at the 19 week scan, would a subsequent follow-up scan have been planned and within what timeframe.

Standard practice when a low lying placenta is identified is to recommend rescanning the patient at 32–34 weeks to assess the exact relationship of the inferior margin of the placenta to the internal os of the cervix. Usually an internal/trans vaginal scan is performed at this stage.

Whether [the radiology service's] Incident Review report and conclusions adequately identify any errors or omissions in [the 19 week scan].

After reading the information provided I would agree with the incident review report and that it accurately identifies the error that was made in the [19 week scan].

The adequacy of [the radiology service's] standard operating procedures and policies.

The protocols provided from CRG for an Anatomy scan are correct and complete especially with regard to documenting a low lying placenta.

No recommendation for improvement.

Any other comments you may wish to make about the sonography services that were provided to [Ms A].

I feel in this case that a human error was made by not documenting the low lying placenta. Having said that, care has been taken obtaining good quality images of the fetal Anatomy. The scan has not been rushed as approximately 25 minutes was spent scanning the patient.

Peers would feel that a mistake was made but would probably worry that they could make a similar mistake."

Appendix C: Independent advice to the Commissioner

The following expert advice was obtained from obstetrician Dr David Bailey:

"I have been asked to provide expert advice to the Health and Disability Commissioner regarding the care provided by [the DHB] to [Ms A] around the time of the birth of her third baby. I have read the Guidelines for Independent Advisors provided by your office and agree to follow these guidelines.

I am a Consultant in Obstetrics & Gynaecology at Northland District Health Board. I graduated in Medicine from London University in 1985 and trained in Obstetrics & Gynaecology in New Zealand and the United Kingdom, with advanced training in Maternal Medicine and Fetal Medicine. I became a Member of the Royal College of Obstetricians and Gynaecologists in 1999 and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in 2005. I also have a Diploma in Advanced Obstetric Ultrasound from the Royal College of Obstetricians and Gynaecologists. My main interest is in quality improvement in maternity care.

I have been asked to review the records of the care provided to [Ms A] and to comment on the following:

The appropriateness and timeliness of the plan of care and interventions undertaken when [Ms A] presented [at 35 weeks + 6 days' gestation].

Whether [Ms A's] symptoms indicated the need for a further scan.

Whether a caesarean section should have been considered earlier.

Any other matters in this case that I consider warrant comment.

In providing this advice I have relied on the following documents and resources:

The letter of complaint from [Ms A] and subsequent correspondence between the Office of the Health and Disability Commissioner and the Chief Executive of [the DHB].

The clinical notes from [the DHB] provided by the Commission.

The 19-week ultrasound scan report from [the radiologist service].

References as listed at the end of this report.

Background

[Ms A] booked with a self-employed midwife for primary maternity care and arrangements were made for her baby to be born at [the public hospital]. She was expecting her third baby. Her Maternity Booking Form indicated that she had a body-mass index of 23.9 (which is normal) and that she was a smoker. She had a history of treatment for cervical dysplasia and of two vaginal births […] and she was 36 years old. She had an early scan at 10 weeks' gestation, giving her an expected due date of

[…]. An anatomy scan at 19 weeks' gestation was reported to show normal fetal development and an anterior placenta which was not low-lying.

[In the evening Ms A] was brought to the public hospital by ambulance following a 111-emergency call. At this time, she was 35 weeks + 6 days gestation. She initially thought she had spontaneous rupture of membranes but found she had vaginal bleeding. The ambulance crew reported that she had vaginal bleeding, with blood running down her legs, and had a heart rate 120 beats per minute, blood pressure 110/90 mmHg, respiratory rate 16/minute and normal level of consciousness. An intravenous cannula was inserted and an infusion of normal saline was commenced. By the time she arrived at the hospital at 18.40 her heart rate had fallen to 95 beats per minute. [Ms A] was seen at 18.45 by a Senior Medical Officer (Consultant), [Dr D], who diagnosed spontaneous rupture of membranes and 'mild abruption'. Abdominal examination was reported to show a soft non-tender uterus with the baby's presentation cephalic (head down) and the presenting part not engaged. [Dr D] then performed a vaginal examination which showed bleeding and a closed cervix; it is not stated whether this was a speculum or a digital examination. [Dr D] made the following plan: steroid injections to promote fetal lung maturity, continuous fetal heart rate monitoring, blood tests and induction of labour if there was further bleeding.

At 23.00 [Ms A] was reviewed by a Registrar, [Dr G], who noted a normal fetal heart rate pattern, uterine tightenings and continued vaginal bleeding. It appears that the diagnosis of spontaneous rupture of membranes was uncertain. [Dr G] performed a bedside ultrasound scan and reported a 'reasonable amount of pockets of amniotic fluid', but did not report any measurements or comment on placental localization. After discussion with [Dr D], [Dr G] performed a digital vaginal examination and inserted Cervidil, a slow-release prostaglandin preparation, to induce labour. [Dr G's] plan was to review in 12 hours if [Ms A] was not in labour.

[Ms A] was cared for overnight by the hospital midwifery staff and had reassuring electronic fetal heart rate monitoring. She reported further episodes of bleeding 'like a heavy period' during the night. [At 07.36am] [Dr G] performed another digital vaginal examination and found the cervix unchanged.

Around this time there was a change of medical team and [Ms A] was reviewed at 09.00 by another Consultant Obstetrician, [Dr F]. There were no bleeding or contractions at this time and continuous fetal heart rate monitoring was discontinued. The plan at this stage was to continue with Cervidil for up to 24 hours. However, at 10.45 [Ms A] experienced further vaginal bleeding of about 200 mL in the toilet. She was attended by [Dr F] and by a Registrar, [Dr H], who performed a further digital vaginal examination and reported that the cervix was effaced (shortened) and was 2 cm dilated, that the membranes felt intact and that the edge of the placenta could be felt. [Dr F] repeated the vaginal examination and confirmed these findings and [Ms A] was moved urgently to the operating theatre for delivery by caesarean section. The operation was performed as a category 1 case (the most urgent) with [Dr H] operating

and [Dr F] assisting. The operation was performed under general anaesthesia, incising through the placenta to reach the baby, and was complicated by difficulty delivering the placenta, which appeared to be abnormally adherent. Some portions of the placenta could not be removed from the uterine cavity; bleeding was controlled by over-sewing with sutures and by insertion of a Bakri balloon to exert pressure inside the uterine cavity. The estimated blood loss during the operation was at least two litres, in addition to the blood loss before surgery, which was not specified.

[Ms A's] recovery was complicated by anaemia requiring a blood transfusion. Analysis of cord blood samples indicated hypoxic acidosis and the baby was admitted to the Neonatal Unit for nine days. Apgar scores were 6 at 1 minute and 8 at 5 minutes.

It is evident from the hospital records that this was an extremely distressing experience for [Ms A] and although she was visited several days after the birth by [Dr F] and given a detailed explanation of the events it appears she remained anxious and dissatisfied with the care she had received.

Advice

This advice is given following review of the clinical records and the references listed at the end of the report, including local Obstetric guidelines from [the DHB], national guidelines from the Ministry of Health and from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), and internationally recognized guidelines from the Royal College of Obstetricians and Gynaecologists (RCOG).

Were the plan of care and interventions undertaken when [Ms A] presented [at 35 weeks + 6 days' gestation] appropriate and timely?

When [Ms A] presented to hospital [at 35 weeks + 6 days' gestation] with antepartum haemorrhage she was seen very quickly by a Consultant Obstetrician. However, I do not consider that the plan adopted was appropriate, for the following reasons:

I believe that it is likely [Dr D] did not appreciate the amount of bleeding [Ms A] had experienced. The ambulance crew described 'dark red gushing blood running down her leg' and recorded a maternal tachycardia of 120/minute, both suggestive of a major antepartum haemorrhage. By the time [Ms A] arrived at hospital she had received intravenous fluid resuscitation and her heart rate had improved, which may have given a misleading impression of her blood loss. A diagnosis of spontaneous rupture of membranes appears to have been assumed, though the examination did not confirm this. It can be very difficult to distinguish blood from blood-stained liquor, however in this situation it is usually safer to overestimate, rather than underestimate, blood loss.

It does not appear that a possible diagnosis of placenta praevia was considered, despite the presenting clinical features of unprovoked bleeding and a high presenting part. It is very concerning that several Obstetricians, including senior doctors, performed digital vaginal examinations on [Ms A] without first excluding the diagnosis

of placenta praevia. The earlier 19-week scan, which did not report a low-lying placenta, appears to have been accepted uncritically. However, [the DHB's] guideline Placenta Praevia and Placenta Accreta states:

> 'While clinical acumen remains vitally important in suspecting and managing placenta praevia, the definitive diagnoses of most low-lying placentas is now achieved with ultrasound imaging. Clinical suspicion should, however, be raised in any woman with vaginal bleeding after 20 weeks of gestation. A high presenting part or an abnormal lie, painless and unprovoked bleeding should raise the suspicion of placenta praevia irrespective of previous imaging results'.

Until placenta praevia had been excluded, digital examination and induction of labour were contraindicated, as there was a risk these could precipitate life-threatening haemorrhage. The Guideline also states:

> 'Sterile speculum examination is appropriate to assess the source of bleeding, extent of the bleed and the possibility of rupture of membranes. Digital examination should not be undertaken'.

These recommendations are similar to the advice in the RCOG Green-top Guidelines on Antepartum Haemorrhage and on Placenta Praevia, Placenta Accreta and Vasa Praevia, both of which are widely held to reflect international best practice.

Did [Ms A's] symptoms indicate the need for a further scan?

[Ms A] presented with an unprovoked antepartum haemorrhage and when she was examined she was found to have a soft, non-tender uterus and a high presenting part (4/5 palpable, unengaged). Regardless of the results of previous imaging, placenta praevia should have been considered as a possible diagnosis, as stated in [the DHB's] guideline. Therefore, I believe a formal scan should have been requested. Whether this was required out-of-hours, or could wait until morning, was a clinical decision. However, such a scan should have been performed before considering induction of labour. It is possible that this scan, performed with Doppler blood flow imaging, might also have alerted the Obstetricians to the possibility of placenta accreta.

Should a caesarean section have been considered earlier?

I believe that when [Ms A] initially presented with antepartum haemorrhage the appropriate management was expectant. While the bleeding was settling and fetal heart rate monitoring was reassuring it was appropriate to wait, as in many cases the bleeding will stop and preterm birth can be avoided. It is possible that the vaginal examinations and Cervidil treatment contributed to the continued bleeding, unplanned caesarean section and preterm delivery experienced by [Ms A].

Other matters relating to this case.

…

The images from [Ms A's] 19-week anatomy scan were reviewed following this case and it appears that a low-lying placenta had been overlooked when the scan was originally reported. Following this, it appears [the DHB] have tried to shift

responsibility for the events described above onto [the radiology service]. [The letter from the DHB's] Safety and Quality Unit to [Ms A] stated:

> 'Our review of the care you received during your admission to hospital has revealed that, given the information available to the staff at the time, all care was provided appropriately'.

Further to this, the letter dated 1 November 2016 from [the DHB] to the Commission also failed to acknowledge the inappropriate management in this case and the failure to follow [the DHB's] guideline and attempted to shift blame onto [the radiology service]. As stated earlier in this report, I do not agree that the care provided was appropriate. Had [the DHB's] guideline been followed, placenta praevia should have been considered and excluded, regardless of previous imaging reports.

Summary

Following my review of the notes and of the other documents it is my opinion that the care provided to [Ms A] represented a major departure from acceptable safe practice. I believe this would be the opinion of the majority of my peers. There were clear clinical grounds for considering a diagnosis of placenta praevia. Two Consultant Obstetricians and two Registrars proceeded with digital examinations and induction of labour with Cervidil, which could have precipitated life-threatening haemorrhage. [The DHB's] guidance on Placenta Praevia and Placenta Accreta was not followed. The anxiety provoked by antepartum haemorrhage was undoubtedly compounded by the treatment [Ms A] received, which led to a category 1 caesarean section. It is likely that [Ms A] would still have required caesarean delivery under general anaesthetic and would probably still have been at risk of major intra-operative haemorrhage, but preterm birth might have been avoided and it might have been possible to plan the delivery and avoid a stressful emergency procedure. It is concerning that the deficiencies in [Ms A's] care appear not to have been acknowledged by the DHB management.

References

[The DHB] Health Pathway. Placenta praevia and placenta accreta. (April 2011 version provided by HDC).

RCOG Green-top Guideline 63 (2011). Antepartum haemorrhage. *www.rcog.org.uk*

RCOG Green-top Guideline 27 (2011). Placenta praevia, placenta accreta and vasa praevia: Diagnosis and management. *www.rcog.org.uk*

RANZCOG position statement. Placenta accreta. Latest revision 2015. *www.ranzcog edu.au.*

Ministry of Health (2011). Guidelines for Consultation with Obstetric and Related Medical Services (Referral Guidelines)."

The following further advice was received from Dr Bailey:

> "In response to your email of 31 May 2018 I have read through my advice provided in February 2017. I apologize for the delay in responding to your request for further advice.
>
> I think the responsibility of individual practitioners is a complex issue. Within a clinical department there is reluctance to change a plan initiated by a senior colleague. In most cases best practice involves continuing with a plan once it has been started. Clinical plans always involve a degree of uncertainty because clinical skills and investigations are imperfect. However, changing plans is confusing for staff and undermines the collegiality which is essential for good teamwork. In addition, there is strong psychological pressure to conform with a plan and to find aspects of the case which support the plan, a process known as confirmation bias. The tendency of individuals working in a team to conform to a collective plan has been described as 'group-think'. In addition, in hierarchical organizations such as clinical departments, junior members of the team (in this case Registrars) may be discouraged from challenging the instructions of senior doctors.
>
> Nevertheless, individual clinicians are responsible for their own practice and all the clinicians involved in the care of [Ms A] should have been familiar with the organizational guidelines regarding a serious pregnancy complication such as antepartum haemorrhage. In my opinion, as I stated in my previous advice, I consider that [Dr D] failed to provide appropriate safe care. The possibility of placenta praevia was not considered and a dangerous plan for induction of labour was initiated. There was an opportunity to review the clinical situation and reconsider the plan at the morning handover of care, but [Dr F] appeared not to do this and therefore also carries some responsibility for the subsequent adverse outcome. The Registrars, acting under direct supervision of the Consultants, might be considered less responsible. Some junior doctors feel able to challenge the decisions of their seniors, while others do not, and the organizational culture within hospitals and departments may also play a role here. It is not possible to assess this from the information provided.
>
> In summary I consider that [Dr D's] initial assessment and actions constituted a serious departure from acceptable safe practice. I think that [Dr F] also carries some responsibility for continuing the unsafe plan. As the senior medical officers, they were responsible for the actions of their juniors to whom they delegated clinical responsibilities. There may also have been an organizational culture at [the DHB] which discourages junior medical staff and midwives challenging the plans of senior doctors."

The following further advice was received from Dr Bailey:

> "I am writing in response to your email of 20 December 2018 and regarding the supporting documents relating to this case which were forwarded to me on 16 January 2019. I apologise for the delay replying to your enquiry.

I have reviewed the documents you forwarded, including statements from the practitioners involved, a report from [Dr I] and copies of past and current guidelines from [the DHB].

I do not think that the additional information provided changes my assessment of the case or the advice I have provided. I acknowledge that other Obstetricians may differ regarding the degree of departure from accepted practice, as [Dr I] has done. However, I believe [Dr D] did not make an appropriate assessment when [Ms A] was admitted [at 35 weeks + 6 days' gestation] and did not consider the possibility of placenta praevia, as a result of which a course of treatment was commenced which could have been life-threatening. The following points should be considered:

[Dr D] diagnosed a 'mild abruption' (a term which does not have a definition in [the DHB's] Antepartum Haemorrhage guideline), despite the ambulance describing 'blood running down the legs', which usually signifies significant bleeding.

In her report [Dr D] states that the fetal head was engaged; however, this was not the case. Engagement is defined as the passage of at least half of the fetal head into the pelvis, but on admission most of the head (4/5) was palpable above the pelvis, so the head was not engaged.

The possibility of placenta praevia was not considered, despite [the DHB's] Placenta Praevia guideline stating:

> A high presenting part or an abnormal lie, painless and unprovoked bleeding should raise the suspicion of placenta praevia irrespective of previous imaging results.

As a result of the failure to consider placenta praevia, induction of labour was later commenced which could have precipitated a life-threatening haemorrhage.

While preparing my initial report I discussed this matter with my Obstetric Colleagues and they all concurred that placenta praevia was a possible diagnosis, and this needed to be excluded before considering induction of labour.

I would like to clarify a comment in my initial report. The various statements and documents your office provided clearly show that the public hospital takes the issue of relations between junior and senior medical staff very seriously and encourages a supportive and collegial work environment. My earlier speculation that hierarchical relationships might have hindered communication and prevented junior doctors questioning decisions appears unfounded."