Radiologist, Dr B
Radiology Service

A Report by the
Health and Disability Commissioner

(Case 16HDC01852)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report considers the adequacy of the services provided by a sonographer and a radiologist.

2. A woman in her thirties was expecting her second child. At 19 weeks' gestation, she was referred to the radiology service for a second trimester ultrasound obstetric anatomy scan. The first scan was undertaken and a sonographer and a radiologist reported that the cardiac anatomy was not well visualised and the scan was incomplete.

3. The sonographer performed a follow-up ultrasound scan and recorded in her worksheet that no abnormality had been detected in the heart. The radiologist reviewed the images and the sonographer's worksheet. His report stated: "No abnormality found in the heart" and "No abnormality detected".

4. The baby was born with congenital heart disease, and died as a result.

Findings

5. The Commissioner was critical that the images taken by the sonographer were not sufficient to confirm normality, and that the sonographer then incorrectly reported to the radiologist that no abnormalities had been detected.

6. The Commissioner considered that the radiologist should have reported that the images presented for review were not adequate to confirm normality, and therefore should have recommended a referral to secondary care for further evaluation. The Commissioner also considered that based on the images it was not possible for the radiologist to conclude that no abnormality had been detected. Accordingly, the Commissioner found that the radiologist breached Right 4(1) of the Code.

7. The Commissioner considered that the policies and procedures at the radiology service were acceptable in general, but that some aspects of its services were concerning and warranted further attention.

Recommendations

8. The Commissioner recommended that both the sonographer and the radiologist apologise to the woman and her family, and provide evidence of training in fetal cardiac imaging.

9. The Commissioner recommended that the radiology service audit the radiologist's workload and the sonographer's imaging and reporting of second trimester scans; review all of its anatomy scan templates to ensure that appropriate biometry is captured; and reflect on the quality of its communication with the woman.

10. In response to the Commissioner's provisional opinion, the radiology service reviewed its second trimester anatomy ultrasound protocol and worksheets, including the appropriateness of the default settings, and made changes as appropriate.

Complaint and investigation

11. The Health and Disability Commissioner (HDC) received a complaint from Mrs A[1] about the services provided by the radiology service. The following issues were identified for investigation:

- *Whether Dr B provided care of an appropriate standard to Mrs A.*
- *Whether the radiology service provided care of an appropriate standard to Mrs A.*

12. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	Radiologist
Radiology service	Provider

13. Further information was received from:

Ms C	Sonographer
RM D	Lead Maternity Carer/registered midwife
Dr E	Consultant paediatrician
Dr F	Radiologist
Coroner	

Also mentioned in this report:

Ms G	Sonographer
Dr H	Radiologist

14. Independent expert advice was obtained from a radiologist, Dr Richard Lees (Appendix A) and a sonographer, Carol Bagnall (Appendix B).

Information gathered during investigation

15. Mrs A, aged in her thirties at the time of these events, was expecting her second child. Mrs A booked with registered midwife (RM) RM D and completed the requisite blood tests. Mrs A had an ultrasound scan to establish her due date and check fetal nuchal translucency.[2]

16. At 19 weeks' gestation, RM D provided Mrs A with a referral for a fetal anatomy scan.

[1] Mrs A originally made her complaint to the Coroner. The complaint was subsequently transferred to HDC, with Mrs A's consent.

[2] Fetal nuchal translucency is a measure of the thickness of fluid behind the baby's neck to detect chromosomal abnormalities.

17. This report concerns the care and services provided to Mrs A at her anatomy scan appointments on 13 Month1[3] and 4 Month2.

Procedures for anatomy scans

18. The radiology service is a private radiology provider with multiple branches. Its services include community-based ultrasound and X-ray services.

19. The radiology service told HDC that its processes are efficient, and stated:

> "[Our] radiologists are supported by extensive automated processes that help increase productivity and efficiencies. These processes have been carefully designed and evolved over many years to reduce the cognitive effort required to report community examinations and enable high quality efficient work."

20. The radiology service offers fetal anatomy scans. It told HDC:

> "The fetal anatomy scan is a screening test, and screening for fetal congenital heart disease is the most challenging component of the scan. The objective of the scan is to prove normality by obtaining the 'standard views' of the fetal heart. If we are unable to obtain these standard views then there is a presumption of abnormality and the mother is referred to secondary care. The reasons for inability to obtain the standard views include the abnormal heart, as well as a technically difficult scan for other reasons such as persistent unfavourable fetal position, and acoustic factors such as maternal and fetal size. The objective of a community cardiac anatomy scan is not to diagnose a specific congenital cardiac condition but to identify a fetus where normality cannot be confirmed. Referral is made if two scans in the community have failed to prove normality."

21. D-TGA (transposition of the great arteries) is a congenital heart disease where the two main blood vessels coming off the left and right sides of the heart are inverted. It is a life-threatening condition and is often, but not always, recognised antenatally through scanning.[4]

22. The radiology service told HDC:

> "The standard views [images] that exclude D-TGA are the views demonstrating that the aorta and pulmonary artery (LVOT[5] and the RVOT[6]) are at right angles to each other."

23. The radiology service provided HDC with an overview of its workflow, which is summarised as follows. Sonographers are responsible for taking images and preparing electronic

[3] Relevant months are referred to as Months 1-5 to protect privacy.
[4] Dr E's report to the Coroner.
[5] Left ventricular outflow tract.
[6] Right ventricular outflow tract.

worksheets that document the sonographer's findings. This information is saved[7] and sent to the radiologist electronically. Radiologists are responsible for reviewing the referral form, the electronic images, and the electronic worksheet, and ensuring that all the relevant findings are recorded. If the worksheet is accurate, the radiologist authorises the worksheet as a final report for distribution. If any changes to the electronic worksheet are required, the radiologist makes the changes directly and then converts the worksheet to a report ready for distribution. The radiologist is the author of the final document, and is responsible for its accuracy, and sonographers are electronically blocked from authorising reports. A version of this workflow system is used in many other New Zealand radiology practices.

24. The radiology service's protocol states that the minimum documentation required for a second trimester anatomy scan must include:

"• Cervical canal assessment.

- Placental localisation — site and relation to the internal os.[8] If the placenta is close to the internal os (less than 2cm), a repeat scan at 32 weeks is required. Colour Doppler is also placed over the internal os to rule out vasa praevia.[9]
- BPD, HC, AC and FL.[10]
- Nuchal thickness.
- Ventricles with choroid (normal measurement <10mm — 10 to 12mm borderline)/ Cerebellum/Cisterna Magna (normal measurement 4–10 mm), Falx, Cavum Septum Pellucidum, Skull bones.[11]
- Face — Orbits/Lips and nose/profile/alveolar ridge (this is the bit we see behind the top lip; the palate is usually very poorly seen on ultrasound). Jaw, Profile.
- Spine ossification centres in sagittal, axial, and coronal planes with skin line.
- Arms/Legs — Long bones and hands/digits/feet/toes — Position of joint.
- Heart — Position/Axis/4 chambers/Introventricular septum/Foramen Ovale/Mitral valve/Tricuspid valve/RVOT/LVOT/Aorta/Ductal arch/3 vessel view.
- Diaphragm left and right (preferably in sagittal plane)/stomach.
- Cord insertion (umbilicus and placental) and 3 vessel cord/colour view of 2 arteries entering abdomen.
- Kidneys — right and left/bladder. A colour view of the fetal renal arteries.

[7] The worksheets are stored in the radiology service's information system, and the images are stored in the radiology service's digital image archive system called PACS.
[8] The opening of the cervix into the body of the uterus.
[9] A condition in which blood vessels cross the internal opening of the cervix.
[10] Growth parameters.
[11] Head anatomy.

- Stomach/Situs/Abdominal wall.
- Liquor volume is assessed as a qualitative evaluation."

25. This reflects ASUM[12] requirements for documentation for second trimester anatomy scans.

26. The radiology service has a suite of electronic worksheets, all designed for different types of scan. The electronic worksheet for the initial second trimester ultrasound obstetric anatomy scan is used when a previous dating scan has been undertaken. This scan includes a combination of both default settings and placeholder "nonsense" settings. The default settings include the phrase, "No anatomical abnormality detected", and this phrase remains on the report unless the sonographer or the radiologist changes it. The placeholder settings must be completed. One of the placeholder settings is, "The anatomy scan appears **ZZSZ**". This setting could be completed as, "The anatomy scan appears normal", or, "The anatomy scan is incomplete".

27. Likewise, the electronic worksheet for the "follow-up" second trimester ultrasound anatomy scan is also a combination of default settings and placeholder settings. This worksheet is used when the initial scan has not been completed successfully and some data has already been obtained. The settings on this worksheet differ from those on the initial worksheet, and include a placeholder setting of, "No abnormality found in the **ZZSZ**", and a default setting of, "**COMMENT**. No abnormality detected".

28. The electronic worksheet also had placeholder settings for biometry. Biometry is the measurement of various segments of the anatomy of the fetus.

Anatomy scan 13 Month1

29. On 13 Month1, Mrs A attended the radiology service for an initial second trimester anatomy scan.

30. Ms G was the sonographer who performed the scan. Ms G was not able to obtain clear images of the fetal heart, and she did not obtain a standard "3 vessel view[13]".

31. Ms G completed one of the placeholder settings on the electronic worksheet to read: "The anatomy scan is incomplete. Cardiac anatomy not well visualised." She also deleted the default setting that read, "No abnormality detected", and noted that a follow-up appointment had been booked.

32. The radiology service told HDC:

> "Note was made [by Ms G] of the difficulty imaging the fetal heart. There is no record of why the images could not be obtained. In general, anatomy scans can sometimes be not completed due to the position of the baby. In that case, a follow up anatomy

[12] Australasian Society for Ultrasound in Medicine.
[13] The 3-vessel view is a transverse view of the anterior mediastinum (space in the chest) and great vessels (of the heart) just above the level of the fetal heart.

(FA) scan is required. Here, the sonographer exercised her professional judgement to recall the patient for an FA scan."

33. On the same day, Dr H, a radiologist at the radiology service, reviewed the images and the worksheet and authorised the final report. The report, which essentially confirmed Ms G's worksheet, stated that the anatomy scan was incomplete, that the cardiac anatomy was not well visualised, and that a follow-up scan had been booked.

34. Dr H authorised reports on 308 scans on 13 Month1.

35. Mrs A told HDC that she was advised that they were unable to get a clear image of Baby A's heart and that she would need to attend another ultrasound for this to be completed.

36. Mrs A booked a follow-up appointment for the next week at a local centre. She told HDC that when she presented at Hospital 1 for the scan, she was advised that the appointment had been made for her at the radiology service in the main centre. She rescheduled her appointment for the following week at Hospital 1.

37. Mrs A told HDC that she attended her scheduled appointment, and the Hospital 1 staff advised her that the sonographer was away sick. Mrs A then contacted the radiology service and was booked for the following week.

Anatomy scan 4 Month2

38. On 4 Month2, Mrs A attended her appointment with the local radiology service. She was 25 weeks' gestation. Ms C was the sonographer.

39. Mrs A told HDC:

> "[Ms C] called me into the Radiography room and asked why I was there for. [Ms C] asked for a referral form which I did not know I required as I had been advised at my original appointment that a follow up scan was needed. I proceeded to advise [Ms C] that the original sonographer was unable to see [Baby A's] heart properly and had referred me to this appointment."

40. Ms C performed the ultrasound scan.

41. The radiology service stated:

> "The scan was conducted with good equipment, correctly set up. This was a difficult scan in unfavourable conditions … The images of the heart that are stored in [the radiology service's electronic] PACS system are incomplete and show a view that looks like a normal RVOT [right ventricular outflow tract], but there is no corresponding view to show that the LVOT [left ventricular outflow tract] is at right angles to the RVOT, and no '3 vessel view'. So they are not sufficient to prove normality and exclude D-TGA. Therefore this fetus should have been flagged by both the sonographer and the radiologist as 'unable to prove normality' after two community scans and referred on to secondary care."

42. Ms C completed the "follow-up" second trimester anatomy scan worksheet. The setting that stated, "No abnormality found in the **ZSZZ**" was completed as, "No abnormality found in the heart". The default setting of, "No abnormality detected" was not deleted, and appeared on the worksheet she sent to the radiologist.

43. The radiology service told HDC that the stored images are "not sufficient to document normality", and that Ms C has reviewed the stored images and agrees with this assessment.

44. Ms C said that her assessment of the fetal heart was not typical of her usual standard. She stated: "I don't know why this was so but this was my second day back at work after nine days of sick leave."

45. Mrs A told HDC:

> "During the scan I felt [Ms C's] professionalism was disengaged towards me. I queried if everything was alright where [Ms C] advised me that everything looked ok to her. I left [the radiology service], disappointed in the treatment that I received from [Ms C] but overjoyed that my soon to be born son was healthy."

46. The radiologist, Dr B, told HDC:

> "I reviewed the referral form, the images, and the sonographer's digital worksheet. Having satisfied myself as to the accuracy of the scans, the images and the content of the digital worksheet I authorised them as the final reports for distribution."

47. Dr B said: "[T]he report is incorrect in stating that that fetus was normal and that a serious error has been made." He also stated: "[T]he scan and my image review had not been adequate to exclude [D-TGA]. And I had failed to realise that deficiency and arrange for a formal fetal echocardiogram[14]."

48. Dr B made no changes to the sonographer's worksheet, and authorised the final report at 10.17pm. The report stated, "No abnormality found in the heart" and, "No abnormality detected". Dr B authorised reports on 462[15] scans on 5 Month2.[16]

49. The radiology service told HDC:

> "The radiologist should have recognised that the images presented for review were inadequate, reported the scan as incomplete and recommended referral to secondary care for further evaluation. It is not clear why he did not. It was not lack of knowledge, skill or experience. It may have been momentary inattention. Alternatively, the radiologist may have assumed that the experienced sonographer was relying on her real time assessment of the heart when she said on her worksheet that no

[14] A scan to check the fetal heart.
[15] The radiology service's letter to HDC states that Dr B's workload for 4 Month2 was 344 reports. However, the information in the letter from Dr B assumes a workload of 462 reports authorised on 5 Month2.
[16] The reports were authorised the day after the scan was performed.

> abnormality was detected, but she did not explicitly state that she was relying on a real time assessment. So this would have been an invalid assumption by the radiologist. He should not have accepted the sonographer statement that there was no abnormality, and should have referred [Mrs A] on to secondary care."

50. RM D stated: "The follow up scan reported no abnormality found in the heart. The findings were shared with [Mrs A] and a copy attached to her notes."

Subsequent events

51. RM D told HDC:

> "[Mrs A] was offered all the usual antenatal visits and tests. She attended our regular arranged appointments and all antenatal visits were recorded in her midwifery notes."

52. On 11 Month5, Mrs A went into labour. At 11.04am she delivered her son at the local birthing unit. RM D recorded that Baby A was an alert and healthy baby.

53. At approximately 10pm that evening, Baby A's condition began to deteriorate. The Hospital 2 Neonatal Retrieval Team was called, and arrived at the birthing unit at 11.55pm. Baby A was transferred to Hospital 2 by helicopter. During the flight, Baby A's heart rate dropped and resuscitation was initiated.

54. Full resuscitation measures continued at Hospital 2, but Baby A continued to deteriorate.

55. Mrs A told HDC: "He was not stable enough to be transported [elsewhere]. It was decided to stop treatment to allow us to hold him in our arms to pass away."

56. On 12 Month5, Baby A died as a result of transposition of the great arteries.

Further information from the radiology service

57. In respect of the radiologist's workload, the radiology service stated:

> "At the relevant time, the radiology service relied on its radiologists to manage their own workloads. That was a reasonable approach for it to take given that they are highly trained medical professionals. Nevertheless, the radiology service no longer takes that approach. Since [these events], their workloads have been closely monitored by [the radiology service's Managing Director]."

58. In respect of radiologists' supervision of sonographers at the radiology service, the radiology service stated:

> "[Direct supervision by a radiologist of a sonographer] has long been superseded and it is now universal practice for a sonographer to undertake an ultrasound on their own. It is common practice in obstetric scanning in New Zealand, and indirect supervision has been accepted as appropriate by IANZ, Royal Australian and New Zealand College of Radiologists ('RANZCR') and third-party funders such as the Ministry of Health. However, radiologists are always available to the sonographers for

clarification, either physically or through electronic communication via the PAC and RIS[17] systems, Skype, telephone or instant message."

59. In respect of the processes and procedures at the radiology service, the radiology service stated that it has been accredited by IANZ since for many years continuously, and that the procedure in place at the time of these events allowed Ms C to take appropriate images and for Dr B to report on them. The radiology service stated that it followed reporting procedures that were consistent with those followed by other large radiology providers throughout New Zealand.

60. The radiology service stated:

> "In a perfect world, the content of the template/worksheet in a normal routine scan should be exactly the same as the final radiologist report. Accurate completion of templates and the correct description of abnormalities is an extremely important part of a modern sonographer's training; changes made by a radiologist indicate the sonographer has made a mistake. At the radiology service such sonographer mistakes are uncommon."

61. In respect of the error rate for reporting scans at the radiology service, the radiology service stated:

> "[The radiology service] had 540,000 cases in the last three years, with four potentially avoidable serious scan errors. Its error rate is 0.7 per 100,000 examinations. Two of the four errors were by [Dr B]."

62. The radiology service stated that it does not make videos of the scans it takes, and it is not aware of any radiology clinic in New Zealand that routinely makes a video of any scan.

63. The radiology service no longer provides services at Hospital 1.

Further information from Dr B

64. Dr B provided a detailed analysis of his workload on 5 Month2. He stated that the radiology service has a sophisticated reporting system that allows for increased radiologist output compared to traditional practices. He pointed to the development of worksheet templates and a computerised workflow system.

65. Dr B told HDC: "These work hours and workload are not excessive, and in my experience, well within the normal range of overtime worked by many medical and other professionals."

Industry standards

IANZ accreditation

66. IANZ is the industry standard accreditation body used by the public health system and many private health providers. The radiology service has had accreditation for many years. Accreditation requires compliance with the New Zealand Code of Radiology Management

[17] Research Information Systems.

Practice 2011, the Procedures and Conditions of Accreditation, and applicable technical criteria. The radiology service told HDC that as part of the accreditation process, staff must comply with ASUM (the Australasian Society for Ultrasound in Medicine).

ASUM

67. ASUM Standards of Practice state:

> "Some structures [of the anatomy] may not be demonstrated because of maternal size, fetal position and other factors. Repositioning or rebooking the woman may be necessary to complete the examination. If the assessment of the fetal anatomy is limited, for whatever reason, this should be recorded."

68. ASUM guidelines also state that each practice should decide its own policy on the archiving of images and making hard copy images available to the referring doctor and patient.

Responses to provisional opinion

Mrs A

69. Mrs A was given an opportunity to comment on the "information gathered" section of the provisional opinion. Mrs A did not provide any further comment.

Dr B

70. Dr B was given an opportunity to respond to the provisional opinion, as it relates to him. Where relevant, his response has been incorporated into the "information gathered" section above.

71. Dr B submitted that routine "hard copy" imaging onto film was superseded by digital records more than twenty years ago. He provided HDC with an opinion from Dr F, a senior radiologist, in support of that submission. Dr F stated that at the time of these events, hard copy images of anatomy scans were not routine or expected, and that most referrers asked not to receive any hard copy images.

72. Dr B also submitted that his workload and reporting times were not excessive, and within normal acceptable limits. He referred to Dr F's opinion in support, who stated that at his practice, review of obstetric anatomy scans usually takes two minutes or less, but can take up to five minutes if a sonographer's mistakes need to be corrected.

73. Dr B told HDC that since these events he has completed a review of the technique and interpretation of fetal heart scans, and that he continues to conduct ongoing reviews and to participate in in-house training. Dr B stated that a series of visual reminders have been placed into all anatomy scan and growth scan templates so that staff are reminded of what abnormal fetal heart images looks like.

74. In respect of the default settings on the "follow-up" second trimester ultrasound anatomy scan electronic worksheet anatomy scan, Dr B stated:

> "Thank you very much for bringing this to our attention. [I] addressed that immediately on receipt of the provisional report."

The radiology service

75. The radiology service was given an opportunity to respond to the provisional opinion, as it relates to the radiology service.

76. In respect of whether the default settings in the electronic worksheets have the potential to cause error, the radiology service stated:

> "There is no way that this practice could cause error. [The radiology service] amended the default text in the comments section immediately following receipt of the Provisional Report so that its sonographers and radiologists are now required to write 'normal' in the comments box. This must be done deliberately; it is literally impossible for it to be 'overlooked' as suggested [in] the Provisional Report."

77. In respect of whether [the radiology service] has an adequate policy for making a hard copy of the images available to a radiologist, [the radiology service] stated that it has decided its own policy as required by the ASUM guidelines. [The radiology service] said that it uses PACS to allow radiologists, sonographers, and appropriately credentialled referrers to view scans without the need for hard copies. [The radiology service] stated: "This is in line with commonly accepted practices used across New Zealand and all radiology practices use PACS technology."

78. In respect of the oversight of sonographers and radiologists, the radiology service stated that a lead sonographer monitors the sonographers' workload on a daily basis, and the Managing Director monitors the radiologists' workloads daily. The radiologists also supervise the sonographers as required.

79. In respect of its communication with consumers, the radiology service stated that its communication practices have been IANZ approved and are the benchmark for the industry.

Ms C

80. Ms C was given an opportunity to respond to the provisional opinion, as it relates to her.

81. Ms C stated that at the radiology service's remote site at Hospital 1, she had little administrative support, worked long hours, and the scanning room was isolated, and this made the working conditions difficult.

82. Ms C said that her recollection is that on 4 Month2 she was unable to access Mrs A's previous report on the electronic system because the system was down, and she had to ask Mrs A what needed to be scanned. Ms C stated:

> "I have never denied that the images I took that day were inadequate and didn't understand why I would accept them and the tragic outcome has always been of deep regret to me. In retrospect I feel I was simply overwhelmed by events."

Opinion: Dr B

Scan interpretation and reporting — breach

83. ASUM recognises that sometimes it may not be possible for sonographers to obtain adequate images, and said that in that event, the fact that the assessment is limited must be recorded in the worksheet.

84. Dr B reviewed the sonographer's worksheet and the images taken on 4 Month2. Dr B then authorised the radiology report, which stated, "No abnormality found in the heart" and, "No abnormality detected".

85. Dr B told HDC that the report that the fetus was normal was incorrect. He said that the scan and the images were not adequate to exclude D-TGA, and that he failed to realise the deficiency and arrange for a formal fetal echocardiogram.

86. My expert advisor, Dr Richard Lees, stated:

> "There is no way that with the images that were provided anyone could determine whether the heart was normal or abnormal. All that anyone could do was confirm that there is a heart present.
>
> This would not be acceptable to our peers who practise obstetric ultrasound. This is a marked [severe] departure from acceptable standard of practice."

87. I accept Dr Lees' advice and am satisfied that the images obtained during the scan were not adequate to confirm normality. Two of the images taken were unclear and did not show the LVOT and the RVOT at right angles to each other. There was no "3 vessel view".

88. A radiologist's role is to ensure that appropriate data and images are obtained, and then to report the images and data accurately. I am critical that Dr B did not report that the images were inadequate to confirm normality, and recommend a referral to secondary care for further evaluation.

89. Dr B had a responsibility to provide Mrs A with services with reasonable care and skill. Dr B concluded in his report of 5 Month2 that no abnormality had been detected in the ultrasound images, when it was not possible to draw this conclusion based on the images available. Accordingly, I find that Dr B breached Right 4(1) of the Code.

Workload — other comment

90. On 5 Month2, Dr B reported on 462 scans. At the time of these events, Dr B was responsible for managing his own workload.

91. Dr Lees advised: "This is an impractically huge workload. It would not allow professional attention for any of these cases."

92. Dr B said that there is no consensus on the accepted workload for a radiologist in private practice.

93. Dr B referred to an opinion from his peer, Dr F, who considered that an obstetric anatomy scan will usually take two minutes or less but can take up to five minutes per scan.

94. I am not aware of a national or international consensus on the number of scans that a radiologist in a community practice may safely report on in a standard eight-hour day. Dr Lees does not provide data on the acceptable workload for a radiologist in a community practice, but his impression is that a workload of 462 reports is too high. It is possible that his view is influenced by the specific requirements of the Australian system, and may not take account of the low complexity, highly automated environment at the radiology service. There is no consensus on a radiologist's workload, and I am unable to make a finding as to whether Dr B's workload on 5 Month2 was too high. However, the larger the radiologist's workload in a standard eight-hour day, the greater the potential for error. For this reason, Dr B's current workload should be audited by a peer to determine whether it is appropriate.

Opinion: The radiology service —adverse comment

95. The radiology service provided detailed information on its work practices. I have obtained expert advice from a sonographer and a radiologist on these work practices.

Electronic worksheets

Biometry

96. Biometry is the measurement of anatomic segments of the fetus by ultrasound. ASUM and the radiology service's protocols require that a range of biometry is to be obtained for second trimester anatomy scans. Not all of this biometry is included in the radiology service's initial anatomy scan and the follow-up scan templates, but it may be that the outstanding biometry is included in one of the other electronic worksheets. The focus in this report is on the initial anatomy scan and the follow-up anatomy scan worksheets only.

97. Dr Lees expressed concern about whether sufficient biometric detail was included in the initial anatomy scan worksheet.

98. Ms Bagnall, on the other hand, stated in respect of both the initial and the follow-anatomy scan worksheets: "The report issued is clear with all relevant referrer and patient details. Appropriate biometry is included."

99. The radiology service stated that all of the biometry that Dr Lees stated was necessary in a worksheet was included in either the initial anatomy scan worksheet or the follow-up anatomy scan worksheet.

100. Ms Bagnall is an expert in the biometry that is to be obtained by sonographers in New Zealand, and I accept her advice that the biometry required in the initial anatomy scan worksheet and the follow-up anatomy scan worksheet was appropriate.

101. In response to my provisional opinion, the radiology service provided evidence that some, but not all, of the templates have been reviewed to ensure that appropriate biometry is included.

Default settings

102. The default setting was adjusted correctly by both the sonographer and the radiologist on the 13 Month1 worksheet and report. The default setting that stated "No abnormality detected" was deleted to reflect the fact that the images were incomplete and it was not possible to confirm normality.

103. On 4 Month2, the default setting that stated "No abnormality detected" was not altered or deleted by either the sonographer or the radiologist despite the fact that inadequate and incomplete images had been taken and it was not possible to confirm normality.

104. I have some concerns about a system that entrenches clinical findings in default settings. There is a risk in these circumstances that a default setting may be overlooked and result in an incorrect report. However, the critical error on 4 Month2 was not that the default setting was overlooked, but that the images were not sufficient to establish normality, and neither the sonographer nor the radiologist recognised this. In this case, there is no evidence that the default settings contributed to the critical error or to the incorrect report.

105. In response to my provisional opinion, the radiology service provided evidence that this issue has been reviewed and that changes have been made to the default settings.

Policies and procedures

106. Dr Lees stated: "These [policies and procedures] are comprehensive and professional."

107. Ms Bagnall stated: "The policies and procedures for sonographers are comprehensive and details carefully the expectations of requirements to fulfil protocol."

108. However, Dr Lees raised concerns about the following issues:

- A sonographer should provide a "hard copy of everything".

  I note that the ASUM guidelines state that each practice should decide its own policy on archiving of images and making hard copy images available to the referring doctor and patient.

  I also note that Dr B, with support from his peer Dr F, submitted that at the time of these events, hard copy images of anatomy scans were not routine or expected and that the radiology service has decided its own policy in respect of hard copy images.

- A radiologist should have direct supervision of a sonographer.

  I accept that indirect supervision may be the industry standard, but appropriate oversight is still required.

In response to my provisional opinion, the radiology service stated that radiologists supervise sonographers as required. The radiology service also advised that the lead sonographer monitors the sonographers' workload on a daily basis.

- A radiologist's final report appeared to be the sonographer's worksheet and not the radiologist's professional opinion.

  I accept that the radiologist's report is authored by the radiologist and represents the radiologist's professional opinion.

- A referral to secondary care should have occurred when the first scan was inconclusive.

  I accept Ms Bagnall's advice that referral in these circumstances is warranted after two or three attempts have been made to obtain the appropriate images.

- The scan should have taken place in the main centre and not the local centre.

  I note that at the time of these events the local site was IANZ accredited, and I find that it was therefore appropriate for the scan to be conducted there.

109. I accept my experts' advice that, in general, the policies and procedures are adequate. The concerns raised by Dr Lees may represent a variance between the work practices in New Zealand and work practices in Australia.

Supervision of radiologists' workload

110. At the time of these events, radiologists at the radiology service managed their own workloads with no oversight by the radiology service. This lack of oversight is concerning because of the potential for excessive workloads to develop, and for this to result in avoidable errors being made by the radiologists.

111. I note that radiologists' workloads are now monitored by the Managing Director at the radiology service, and I commend this change in practice.

Communication with Mrs A

112. Mrs A stated that multiple appointments were rescheduled without notice, that on 4 Month2 the sonographer appeared to have a poor understanding of the service that was required, and that the sonographer's manner was disengaged.

113. Mrs A was clearly unhappy with the radiology service's communication with her, and I agree that it appears to have been suboptimal. This is an opportunity for the radiology service to reflect on the quality of its communication with consumers, and to consider how it may be improved.

Conclusion

114. In my provisional report I stated that although the policies and procedures at the radiology service were acceptable in general, some aspects of the services it provided were concerning, and warranted the radiology service's further attention. As outlined above, these were:

- Whether all the requisite biometry is captured in the templates.

- Whether the default settings have the potential to cause errors.
- Whether there is an adequate policy for making a "hard copy" of the images available to a radiologist.
- Whether sonographers and radiologists are receiving appropriate oversight, especially in relation to workload.
- Whether communication with the consumer could be improved.

115. As outlined above, and in response to the provisional opinion, the radiology service provided evidence that these issues have been considered, and that where appropriate, changes have been made.

Opinion: Ms C — adverse comment

116. The role of a sonographer is to acquire the appropriate images and biometry, to complete a worksheet detailing patient information and biometry, and then to record normal and abnormal findings. This information is sent to the radiologist, and the radiologist has ultimate responsibility for reporting the images and data accurately.

117. The images that Ms C obtained were incomplete. There was no clear standard view to show the position of the LVOT in relation to the RVOT, and the "3 vessel view" was absent.

118. Ms Bagnall reviewed the images taken by Ms C and stated:

> "The standard of imaging does not meet the normal standard of care expected as evidenced by the practice protocol, ISUOG[18] and ASUM guidelines … This would be considered to be a moderate departure from the accepted standard of care."

119. Having taken the images and recorded the biometry, Ms C sent her worksheet to the radiologist. Her worksheet stated: "No abnormality found in the heart" and "No abnormality detected".

120. Ms Bagnall stated: "The sonographer on 4 [Month2] misinterpreted the findings as normal."

121. I agree with my expert that the images taken by Ms C were not sufficient to confirm normality. In addition, I am critical that Ms C failed to recognise that the images were inadequate and then incorrectly reported to the radiologist that no abnormalities had been detected.

[18] International Society of Ultrasound in Obstetrics and Gynecology.

Recommendations

122. I recommend that Dr B:

a) Provide a written apology to Mrs A and her family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

b) Provide HDC with evidence of fetal cardiac imaging training, within three months of the date of this report.

123. I recommend that the radiology service:

a) Undertake an audit of Dr B's workload and error rate for the last three months, to be conducted by an independent peer.

b) Undertake an audit of Ms C's imaging and reporting of second trimester scans for the last three months, to be conducted by an independent peer.

d) Review all anatomy templates to ensure that all appropriate biometry is captured.

e) Reflect on the quality of communication with consumers at the time of these events, and consider how it may be improved. The radiology service is to provide HDC with evidence of compliance with these recommendations within three months of the date of this report.

124. In the provisional report I recommended that the radiology service review the second trimester anatomy ultrasound protocol and worksheets, including the appropriateness of the default settings. The radiology service has reviewed the documents and made changes as appropriate.

125. I recommend that Ms C:

a) Provide a written apology to Mrs A and her family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

b) Provide HDC with evidence of fetal cardiac imaging training, within three months of the date of this report.

Follow-up actions

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

127. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, RANZCR, and the Medical Radiation Technologists Board, and they will be advised of Dr B's name.

128. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be 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 a radiologist, Dr Lees:

> "Thank you for instructing me to give my advice to the Health and Disability Commissioner concerning the above matter.
>
> I confirm that I do not have a personal or professional conflict in this case and confirm that I have never previously heard of the radiology service. I have signed your confidentiality agreement and am bound by it.
>
> I confirm that I am a practising radiologist and nuclear medicine specialist, having completed my specialist training with what is now known as the Royal Australian and New Zealand College of Radiologists in 1975. I also have a Fellowship of the Royal College of Radiologists (UK) and am certified, by examination, by the American Board of Radiology (USA). I hold a Diploma of Diagnostic Ultrasound and am a Fellow of the Faculty of the Australasian Musculoskeletal Medicine (FAMM).
>
> I have read the following multiple times:
>
> Letter of complaint dated […].
>
> [The radiology service's] responses […].
>
> Clinical records from [the radiology service] covering the period [five months to Month2].
>
> Information from [the radiology service] about radiologists' workload on 13 [Month1] and 5 [Month2].
>
> At my request, you have provided me with a large bundle of documents that was provided by [the radiology service] concerning the circumstances leading to the complaint, subsequent to it and from the practice concerning their protocols and procedures.
>
> I have read the following documents provided by you in an attachment to your letter […]. These consisted of:
>
> Letter of complaint dated […].
>
> There was also a protocol of radiographers' anatomy scan template and the one for follow up anatomy scans to be used on recall if the original scan resulted in the need for further examination. Other templates have not been provided, which is not inappropriate.
>
> I have also been provided with a CD of the imaging of the relevant scans. They contain static images of the anatomy scans of [Mrs A] on 13 [Month1] and 04 [Month2].
>
> My responses to your specific questions are:

The standard of reporting by the radiologist on 13 [Month1].

This was adequate and, in particular, he did state that the examination in respect of the heart was incomplete.

The standard of reporting by the radiologist on 4 [Month2].

This was inadequate, incorrect and represents a major departure from accepted standards of practice. I will comment further on both of these reports later in this letter.

The adequacy of the policies and procedures in place at [the radiology service] (these documents will be provided in due course).

These are comprehensive and professional. Whether they have been adhered to is for others to investigate. I will comment further.

The appropriateness of the radiologist's workload.

I assume that you mean [Dr B], not the others.

The information that has been provided is slightly inconsistent in respect of the relevant days.

The workload of [Dr B] is clearly excessive. In the first bundle of documents, a radiologist was reported as having produced 308 reports, all of them ultrasounds. It has not been indicated whether this is [Dr B's] workload or that of [Dr H] who reported the first incomplete anatomy scan. Whichever doctor it was allowed only an average of 1.56 minutes per examination to supervise, examine the imaging and worksheets, report, then check and finally sign off on the typed reports. It would allow no time to discuss the cases with the technicians, examine the difficult cases personally, (if indeed the radiologist was located at the place of examination, which would have been the exception), for eating and drinking, telephone conversations with referring doctors or others, supervision of staff and other administrative or personal matters. In reality, in an eight-hour day, each examination would have been allocated less than one minute at most, hardly adequate for professional attention to the needs of any of the patients, let alone properly to confirm normality or detect any problem.

On 15 [Month2], [Dr B] has been reported as having reported 163 ultrasound examinations, 66 immigration examinations, presumably chest x-rays but possibly more complex examinations and 233 examinations, which are described as 'general'. This is a total of 462 examinations in a day. This is 1.04 minutes per examination in an 8 hour day but in reality would have to have been much less. This is an impractically huge workload. It would not allow professional attention for any of these cases. This in any jurisdiction would be a major departure from acceptable professional standards.

Any other matters you consider warrant comment in this case.

Hard copy print outs of anatomy scan templates and templates for recalls in under two weeks were included in the second bundle of documents.

These are not worksheets. Proper worksheets have all of the biometry itemised. These should list clinical history and/or indication for the examination, additional history given by the patient, the last known menstrual period with the predicted gestational age and EDD (expected date of delivery).

The anatomy (morphology) worksheet should itemise everything on the attached document with hard copy recording of each item so that the reporting doctor has corroboration and also so that they can be reviewed later if necessary. The **attached** worksheet is a good example of an anatomy worksheet.

The images provided are incomplete, as admitted, and therefore could not help. If this is typical, it is not acceptable, as they could not be used to determine whether a foetus is morphologically normal. They could not be used with confidence to confirm or alter the other features of the pregnancy.

The sonographer's opinion that the morphology scan was normal was a technical, not a professional one.

What is the standard of care/accepted practice?

These are grossly inadequate reports. The radiologist should be provided with complete biometry and hard copy documentary of the images and prepare his/her report using them. Ideally, a video, particularly of the moving parts such as the heart, body and limb movements should have been available and for the permanent record. The reports should be of the complete examination including the documentation.

The standard depends on the country and the location within that country. There cannot be a universally accepted gold standard.

Access to larger, well-equipped facilities with well-trained technicians and professionals is desirable and recommended, if available, particularly if travel is feasible.

Provision of service in normal environments for people living in non-urban areas is sometimes difficult because of the time required and difficulty of travel. […] [Mrs A] lives, or did live, [nearby]. It is worth noting that the [local] ultrasound facility has since been closed.

I do not consider that the particular incidents would meet the acceptable standard of care or practice in Australia where distances are, in many cases, much greater than those in New Zealand, particularly considering where this lady lived.

It would appear that the sonographer has filled in the template with little or no corroborative evidence provided for the radiologist including a proper worksheet and hard copy of everything. It is only the sonographer's opinion as to whether the foetus is normal or abnormal. There is inadequate documentary evidence and no possibility, with remote reporting, for the radiologist to personally have intervened in this or other problematic or difficult cases.

In summary, this appears to be a technician's report with little or no professional input. This is unacceptable as the work is not that of a specialist medical practitioner.

Hard copy imaging is inadequate, particularly in respect of the abnormal heart in this case. This was admitted and confirmed by both the sonographer and the radiologist. There is no way that with the images that were provided anyone could determine whether the heart was normal or abnormal. All that anyone could do was confirm that there is a heart present.

This would not be acceptable to our peers who practise obstetric ultrasound. This is a marked [severe] departure from acceptable standard of practice.

There is a large of number of locations for this practice and a small number of radiologists, including [Dr B]. They personally reported an enormous number of cases on the days for which information was provided. [Dr B] would have been working remotely from all but one of the practices and possibly all of them. This means that he was not available to directly supervise or interact with the technicians (sonographers and radiographers).

Local investigation could determine whether [Dr B] and/or the others were working in bunkers with video screens and no, or almost no, interaction in a real time with any of the technical staff.

The antenatal diagnosis of congenital heart disease in an anatomy scan at approximately 20 weeks' gestation is very difficult. There is extensive literature in peer-reviewed journals about this. Articles were provided in the response prepared by [the radiology service]. These articles are of good quality and there are many more available.

The ability to detect transposition of the great vessels in-utero has been reported from the low 20% of cases to the order of 70%. The higher figures are recent and include clinics and hospitals that are centres of excellence and for special referral of difficult or high risk patients.

[Mrs A] was examined in a small town by a sonographer who appears to have been well qualified but was provided with limited clinical information. She was also supposedly recovering from a reasonably long period of illness and according to her statement may not have fully recovered. This raises the question as to whether paramedical practitioners should be working in a remote location, unsupervised, when they have grave clinical responsibilities and are not well. I do not consider that the particular incidents would meet the acceptable standard of care or practice in Australia where distances are, in many cases, much greater than those in New Zealand, particularly considering where this patient lived.

If required, I can assist you to prepare a list of peer reviewed articles on the topics.

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

As this patient was within reasonable distance of larger centres with more adequate staff and opportunity for secondary and tertiary referrals consideration should have been given to refer her to one of these. This is because the foetal heart was not seen at the first morphology examination.

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

Objectively, none of my well qualified and ethical peers would regard this as in any way an adequate management of an anatomy (in Australia known as a morphology) scan particularly as the first scan was inconclusive.

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

Radiologists (and obstetricians practising ultrasound) should be prevented from undertaking excessive workloads, which result in inadequate supervision of staff and patients. They should be available to interact with the technicians and patients personally, particularly if there is any difficulty or risk. Professionals should not sign off on technicians' reports and so called worksheets. The ones provided are not worksheets at all. They are reports of a technician's opinion about normality or abnormality and of minimal biometry.

I trust this report has been of assistance."

The following further advice was provided on 7 July 2019:

"1. The role of the sonographer (technician) is to provide a complete, high quality, set of measurements with hard copy (printed or video) of these and of imaging of sufficient quality and resolution to allow verification and interpretation by the reporting clinician. In obstetric cases this is usually a radiologist or obstetrician. It is not the role of the technician to interpret and report the studies but to record all of the data and morphology so that they can be interpreted and reported by a suitably trained clinician.

   The work sheets of [the radiology service] are deficient in that they allow the technician to largely usurp the role of the trained clinician and misrepresent the report as a professional rather than a technical one. This is a serious departure from acceptable professional standards. It can result in unfortunate or even tragic consequences, as it did in [this case].

2. As described in para 1, the role of the technician is to document a full set of biometry and anatomical images so that they can be properly interpreted and reported by an appropriately trained specialist, clinician. The role of the technician is not one of reporting, rather one of documentation.

3. As already stated, the documentation should be fastidious. If the technician is concerned about a possible abnormality this should be communicated to the responsible medical specialist and arrangements made to recall the patient to the original or another site, depending on geography or other circumstances, as soon as is practicable. If there is serious concern she should be referred to a specialist obstetric service that is equipped to investigate and manage high risk pregnancies. I understand that these services are available in New Zealand.

4. The hard copy imaging is inadequate. This was confirmed by [Ms C], the sonographer in her statement that appears to be undated. She also wrote '… working remotely was probably not ideal …' and that she had returned to work after nine days of sickness having cancelled scans and '… felt considerable pressure not to let my patients down'.

5. The radiologist should have realised that the imaging and other documentation was inadequate if he had allowed enough time to systematically work through them.

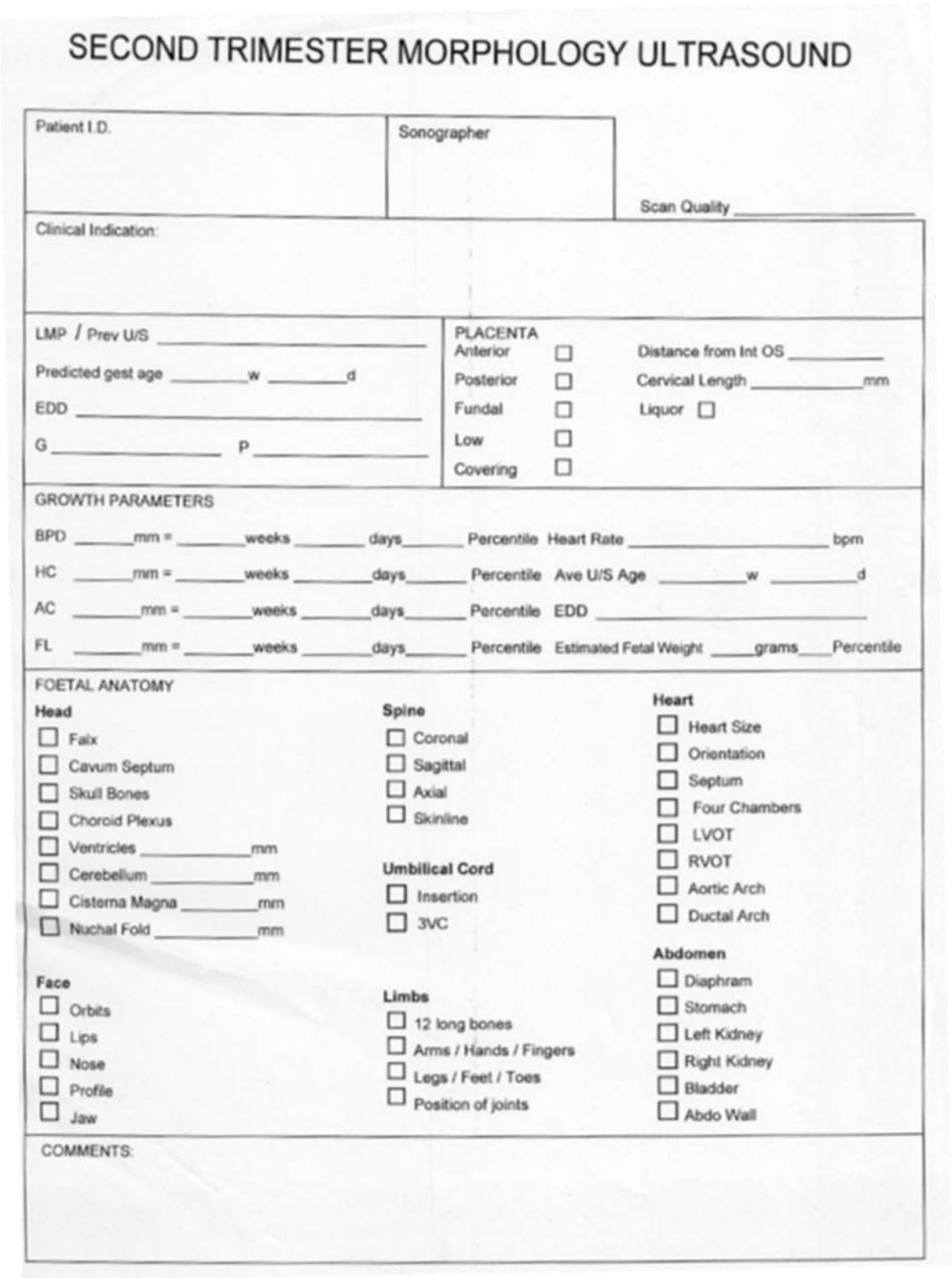
Comment Page 5: The report that was issued is basically a copy of the sonographer's work sheet. That is not a professional interpretation of the biometry and images. The documentation was incomplete and would have been recognised as such by a specialist radiologist or obstetrician diligently fulfilling his or her duty of care.

Page 6. This is a severe departure from acceptable standards of medical practice in my opinion.

Kind regards,

Richard Lees

Attachment: Sonographers Work Sheet"



SECOND TRIMESTER MORPHOLOGY ULTRASOUND

Patient I.D.

Sonographer

Scan Quality _____

Clinical Indication:

LMP / Prev U/S _____

Predicted gest age _____w _____d

EDD _____

G _____ P _____

PLACENTA

Anterior ☐ Posterior ☐ Fundal ☐ Low ☐ Covering ☐

Distance from Int OS _____

Cervical Length _____mm

Liquor ☐

GROWTH PARAMETERS

BPD _____mm = _____weeks _____days_____ Percentile Heart Rate _____ bpm

HC _____mm = _____weeks _____days_____ Percentile Ave U/S Age _____w _____d

AC _____mm = _____weeks _____days_____ Percentile EDD _____

FL _____mm = _____weeks _____days_____ Percentile Estimated Fetal Weight _____grams____Percentile

FOETAL ANATOMY

Head

☐ Falx
☐ Cavum Septum
☐ Skull Bones
☐ Choroid Plexus
☐ Ventricles _____mm
☐ Cerebellum _____mm
☐ Cisterna Magna _____mm
☐ Nuchal Fold _____mm

Face

☐ Orbits
☐ Lips
☐ Nose
☐ Profile
☐ Jaw

Spine

☐ Coronal
☐ Sagittal
☐ Axial
☐ Skinline

Umbilical Cord

☐ Insertion
☐ 3VC

Limbs

☐ 12 long bones
☐ Arms / Hands / Fingers
☐ Legs / Feet / Toes
☐ Position of joints

Heart

☐ Heart Size
☐ Orientation
☐ Septum
☐ Four Chambers
☐ LVOT
☐ RVOT
☐ Aortic Arch
☐ Ductal Arch

Abdomen

☐ Diaphram
☐ Stomach
☐ Left Kidney
☐ Right Kidney
☐ Bladder
☐ Abdo Wall

COMMENTS:

Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from a sonographer, Carol Bagnall:

"My name is Carol Bagnall and I have been asked to investigate and provide an opinion on the complaint 16HDC01852.

I have read and agree to follow the Guidelines for Independent Advisors.

I am a Sonographer. My qualifications are as follows:

1. NDMDI (National Diploma in Medical Diagnostic Imaging) 1993
2. DMU General (Diploma in Medical Ultrasound) 1997
3. I have completed the Burwin Institute course in Fetal Echocardiography. Although I hold a general ultrasound qualification, my subspecialty in ultrasound is in the field of Fetal Medicine and Fetal Echocardiography. I have worked alongside Maternal Fetal Medicine Subspecialists and Fetal Pediatric Cardiologists since 1995 when I began my ultrasound career and I took over the role of lead fetal cardiology sonographer at Auckland City Hospital in 2010 when I was appointed as Clinical Specialist of Women's Health ultrasound. I am now currently the Team Leader of Ultrasound and Clinical Director of Women's Health Ultrasound and I continue to work clinically in the field of Fetal Medicine and Fetal Echocardiography and lead the Fetal echocardiography ultrasound team.

The Commissioner has asked me to comment on the following:

1. The standard of the imaging obtained by the sonographer on the 13th [Month1]
2. The standard of imaging obtained by the sonographer on the 4th of [Month2]
3. The standard of reporting by the sonographer on the 13th of [Month1]
4. The standard of reporting by the sonographer on the 4th of [Month2]
5. The appropriateness of the sonographer's workload on both the 13th [Month1] and 4th [Month2]
6. The appropriateness of [the radiology service's] policies for sonographers.
7. Any other matters you consider warrant comment on this case.

Where appropriate, 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 (mild, moderate, significant)?
c. Recommendations for improvement that may help to prevent a similar occurrence in the future.

Information reviewed in this investigation

1. Complaint received from [Mrs A]
2. Letter of apology to [Mrs A] from [the radiology service].
3. Internal investigation into antenatal scans of [Baby A], baby of [Mrs A] at [the radiology service], and the non diagnosis of D TGA.
4. Ultrasound images from scans dated [at 9 weeks]
5. Ultrasound images from scan dated 13th [Month1]. Anatomy scan, gestational age is 22 weeks and 6 days.
6. Ultrasound images from scan dated 4th [Month2]. Follow up Anatomy scan follow up. Gestational age is 25 weeks 4 days.
7. Sonographer workload for the dates 13th [Month1] and 4th [Month2].
8. [Radiology service] ultrasound protocol for anatomy scan.
9. ISUOG (International Society Ultrasound Obstetrics and Gynaecology) ISUOG Practice Guidelines (updated): sonographic screening examination of the fetal heart Ultrasound Obstet Gynecol 2013; 41: 348–359 Published online in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/uog.12403
10. ASUM (Australasian Society Ultrasound in Medicine) The 18–20 week scan protocol. Prepared by Dr Sue Campbell Westerway. Current Protocol Fetal Heart Assessment during the 18–20 Week Anatomy scan. ASUM NZ Branch. Prepared by Martin Necas and Carol Bagnall. August 2014

Summary of events: [Mrs A], mother of [Baby A] attended [the radiology service] for ultrasound examinations.

The first scan was a dating scan on [date] and the pregnancy was assigned a gestational age of 9 weeks and 2 days.

[Mrs A] reports a Nuchal Translucency scan, details of this scan have not been provided. However it is generally accepted that in non specialist centers that review of fetal cardiac anatomy at this gestation is not routinely undertaken and so the images have not been requested.

[Mrs A] attended for an anatomy scan to the [main centre] branch of [the radiology service]. At this appointment the fetal cardiac anatomy could not be completed and a follow up appointment was scheduled.

There were complications with the scheduling of two subsequent scan appointments and [Mrs A] was then seen for the follow up anatomy scan at the [local] branch of [the radiology service] on the 4th of [Month2].

[Mrs A] did not have a referral for this appointment as she was unaware that this was a requirement. She informed Sonographer [Ms C] that the scan was to complete the views of the fetal heart and the scan was performed and reported as normal.

[Baby A] was born at 11.04am on the 11th [Month5]. At approximately 8:30pm the on duty nurse noticed there was something wrong with [Baby A]. After unsuccessful attempts at breast and syringe feeding, [Baby A] was placed on a resuscitaire where the readings were noticed to be low for approximately an hour, thought likely due to faulty equipment.

At approximately 10pm the duty nurse contacted [Mrs A's] LMC Midwife [RM D] and it was agreed that [Hospital 2] would be called for advice. A medical team were prepared and sent via helicopter to the [birthing unit].

[Baby A] was transferred to [Hospital 2] by helicopter. Cardio Pulmonary Resuscitation was initiated in the helicopter and continued until arrival in NICU (Neonatal Intensive Care Unit). [Baby A] was unable to be stabilised for transfer [elsewhere] and passed away shortly after.

1. Opinion on the standard of imaging obtained by the Sonographer on the 13th of [Month1].

The ultrasound images from the scan dated 13th [Month1] have been reviewed.

This is an anatomy scan with representative images of the examination stored. Ultrasound is a real time examination with the sonographer choosing to take images representative of the examination performed. Ultrasound practices have protocols of what images are to be stored, it is generally the Sonographer who assumes responsibility for acquiring the images and radiologist/sonologist who double reads and signs them off. The ultrasound machine used is a Philips brand. Philips ultrasound machines are widely used throughout radiology practices within New Zealand and Internationally.

It is not possible to comment of the length of the examination time as the demographic data has been removed from the ultrasound imaging. This is a background setting on the ultrasound machine and it is individual practice to determine what information is stored on the ultrasound image.

Commentary will relate to the imaging of the fetal heart only.

The C5-1 transducer has been selected.

Ultrasound transducers vary in frequency with the higher frequency giving better resolution than lower frequency. It is general practice to select the highest frequency transducer that gives adequate penetration to provide diagnostic images.

At 22 weeks it would be reasonable to use a C5-1 transducer for an anatomy scan, although with newer generation technology often a higher frequency may be used. It is not uncommon to attempt to use a higher frequency transducer, not take images and then revert back to the lower frequency during a scan if the higher frequency is not suitable for imaging the area of interest. It is not able to be determined if this occurred during this scan.

The fetus is lying in a breech position with the left side up and right side down. There are three images of the fetal heart taken.

The first image is labeled RVOT. This stands for Right Ventricular Outflow Tract and should represent the Main Pulmonary Artery demonstrating the origin artery arising from the right ventricle. The image provided is taken using a general setting, it would be expected practice to use a fetal cardiac preset when imaging the fetal heart.

The image provided does not represent a standard image of the RVOT with the vessel appearing to have incorrect orientation if it were to represent the pulmonary artery and the branch pulmonary arteries are not visualised.

Note here that a general sonographer is not necessarily trained to the level that they will observe branch pulmonary arteries in a routine scan. Colour imaging has not been performed.

The second image is labeled four chamber heart. The cardiac preset has been selected, the major difference to the imaging being that there is higher contrast, no persistence on and a resolution setting used. The image demonstrates the expected view of the four chamber heart with the apex to the left and both atria and ventricles demonstrated.

The third image is a four chamber heart view with colour/power imaging demonstrating normal flow across the atrio-ventricular valves (AV valves) and no suggestion of a ventricular septal defect (VSD).

This is an incomplete study as reflected in the report. The quality of the limited imaging is acceptable, in the technical sense. The potential for diagnosis was not recognised with the fetus in an optimal position for imaging. No reason was given as to why the cardiac imaging was incomplete as the fetus was in a left side up position which would normally enable full assessment of the fetal cardiac anatomy. There was however a request to have a follow up scan, which is appropriate if the sonographer is not confident to call the anatomy normal.

The imaging was not completed to the expected standard on this day given the fetal position was optimal. The limited study was recognised by the sonographer and recall recommended and arranged which is the accepted practice.

2. Opinion on the standard of imaging obtained by the sonographer on the 4th [Month2]

The images dated 4th [Month2] have been reviewed. This is a targeted scan which includes images of the biometry and fetal heart.

The equipment used is Philips brand and the C5-1 transducer has been used with the fetal echo preset selected.

It is difficult to determine the lie of the fetus but it appears to be transverse. This can be a technically difficult position to image the fetus in. There are 10 images of the fetal heart completed in three minutes. Situs cannot be determined from these images, but has been proven to be normal on the scan dated 15th [Month1]. The fetus is therefore lying left side down.

Image 1: Is difficult to interpret and is assumed to be of the four chamber heart. The interventricular septum is not clearly visible.

Image 2: Difficult to interpret — Non diagnostic.

Image 3: Is labeled as four chamber heart view. Interventricular septum not clearly visible.

Image 4: Is labeled as four chamber heart. Non standard imaging.

Image 5: Four chamber heart view with colour imaging. Should demonstrate flow over the AV valves. The colour scale is low and the frame rate is slow at 13Hz. Imaging therefore not optimised for cardiac imaging.

Image 6: Labeled as RVOT. Non standard imaging with the main pulmonary artery not clearly visible in the expected location. With knowledge of the diagnosis, there is suspicion that the pulmonary artery can be seen centrally within the image.

Image 7: Labeled as RVOT. There is a prominent vessel which does not take the expected course of the main pulmonary artery.

Image 8: Labeled as LVOT (Left ventricular outflow tract which should represent the aorta arising from the left ventricle). The image demonstrates a vessel arising from the presumed left ventricle, but there is no length to the vessel to confirm that it is the aorta.

Image 9: Labeled as LVOT: Non standard view of the LVOT, the vessel does not take the expected course if it was to represent a normally connected aorta.

Image 10: Non diagnostic.

Image 11: This is an image taken to represent either the aortic arch or the ductal arch, presumably the aorta.

Image 12: This is also an image taken to represent the aortic or ductal arch. Presumably the duct. Color imaging has not been used which is useful in determining from which vessel the head and neck vessels arise from and therefore confirming the actual vessel being imaged. Overall opinion, is that the image acquisition was difficult due to fetal position. The standard views expected to be obtained as per practice protocol, ASUM and ISUOG guidelines were not obtained or visible and normal fetal cardiac anatomy cannot be confirmed. This is in agreement with the internal practice review.

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

The accepted practice is to follow the protocol of ASUM or ISUOG guidelines (attached) and the local practice protocol which adheres to these guidelines. The standard of imaging does not meet the normal standard of care expected as evidenced by the practice protocol, ISUOG and ASUM guidelines.

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 (mild, moderate, significant)?

This would be considered to be a moderate departure from the accepted standard of care as representative images only are taken of an examination and these cannot reflect completely the level of difficulty of the examination at the time. There are many factors that affect the ability to obtain standard views and ultimately the ultrasound examination is a real time examination.

C. How would it be viewed by your peers?

Peers would sympathise with the Sonographer on the 4th [Month2] as it is clear from the imaging that the position of the fetus made for difficult imaging, however most would recognise that the standard views were not obtained and normality could not be confirmed.

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

All sonographers who undertake obstetric ultrasound should maintain competency by ensuring continuing professional development (CPD) is inclusive of obstetrics and fetal cardiac imaging as it is recognised by most sonographers that this is the most technically challenging area to assess.

There should be regular review of imaging by peers/radiologists with any concerns regarding quality brought to the attention of the sonographer so that there is scope and support for improvement. If further support or up skilling is unable to be supported by the local practice, then the local tertiary centre could be approached for assistance.

If the standard views are unable to be obtained then the patients should be recalled. If after 2–3 attempts normality cannot be confirmed then referral to a tertiary centre should be recommended.

3. Opinion on the standard of reporting by the Sonographer on the 13th of [Month1].

The report issued is clear with all relevant referrer and patient details. Appropriate biometry is included. The report articulates well that cardiac views were incomplete, that a follow up scan was indicated and had been arranged.

4. Opinion on the standard of reporting by the Sonographer on the 4th of [Month2].

The report issued is clear with all relevant referrer and patient details. Appropriate biometry is included. The report indicates that the fetal cardiac anatomy was normal.

There are no concerns with the standard of reporting from either examination.

The concern in relation to this case is in the recognition of pathology and interpretation of the views at the time of scan in real time and therefore the interpretation of the images. The sonographer on the 13th of [Month1] failed to recognise the pathology with the fetus in optimal position. The sonographer on the 4th of [Month2] misinterpreted the findings as normal, as reported.

5. Opinion on the sonographer workload on both the 13th [Month1] and 4th [Month2].

On the days of the 13th [Month1] and 4th [Month2], both sonographers completed 19 examinations. These would be considered to be fully booked lists, assuming that the sonographer works an 8 hr shift. This would allow for approximately 25 minutes per scan. Some scans do not take this long eg: dating scan and some take longer eg: anatomy scans. Sonographers work at different speeds to complete examinations with the more confident and experienced sonographer completing examinations in a shorter space of time and often taking fewer images. Practices generally allow the sonographer to determine how long they would like for each examination as examination length can vary depending on what is to be imaged, sonographer experience and specialty. Without being able to assess the booking schedule, it does however appear as if sufficient time was allowed for appointments on both days.

6. Advise on the appropriateness of [the radiology service's] policies for sonographers.

The policies and procedures for sonographers are comprehensive and details carefully the expectations of requirements to fulfill protocol.

7. Any other matters you consider to warrant comment in this case.

It should be noted that dTGA can be a very difficult diagnosis to make on prenatal ultrasound and although one of the more common cardiac anomalies, it has been recognised globally to have a poor detection rate antenatally. The most recent literature available: Population trends in prenatal detection of transposition of great arteries: impact of obstetric screening ultrasound guidelines. Ravi P1, Mills L2, Fruitman D2, Savard Wl, Colen T1, Khoo N1, Serrano-Lomelin J1,3, Hornberger LK1,4. Ultrasound Obstet Gynecol. 2018 May;51(5):659–664. doi: 10.1002/uog.17496.

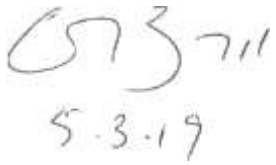
The detection rates of dTGA were quoted as follows: 2003 to 2015, 127 cases with d-TGA were encountered in Alberta, of which 47 (37%) were detected prenatally. Prenatal detection improved over the study period, from 14% in 2003–2010, to 50% in 2011–2013, and to 77% in 2014–2015.

Antenatal Detection Rates of Dextro — Transposition of the Great Arteries and Impace of Standard Fetal Heart Screening in Queensland over a 10 year period. K. Jardine, A. Lee-Tannock, b. Auld, F. Stanley, B. Anderson, H. Franco, K. Eagleston, J. Suna, J Johnson, C Ward, A Gooi. Heart, Lung and Circulation, 2018, Volume 27, Supplement 2, Page S62. The overall detection rate of dTGA from 2008–2018 was quoted as 61%.

New Zealand Detection rates of dTGA from 2012–2014 were approximately 58% (Source Dr Tom Gentles, Clinical Director Paediatric Cardiology, Starship Hospital).

The theme that is repeated throughout the available literature is that although detection rates of dTGA are improving, the actual detection rates are still considered to be low.

The ability to detect such anomalies is dependent on multiple factors and ultrasound is an imaging modality where human factors play a significant role in detection of any pathology. It would appear in this case that a combination of difficult fetal position and human factors contributed on the second occasion to the non diagnosis of the dTGA. In retrospect it is possible to review the images and acknowledge that the standard views are not visible, but at the time, the sonographer believed that the anatomy was normal.



Appendix 1 ASUM Standards of practice — Guidelines for the Performance of Second (Mid) Trimester Ultrasound Appendix 2 ISUOG Practice Guidelines — examination of the fetal heart 16HDC01852 10”