Fulford Radiology Services Limited

Radiologist, Dr B

A Report by the

Health and Disability Commissioner

(Case 15HDC01413)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In 2015, Ms A became pregnant and was directed to Fulford Radiology Services Limited (FRSL) for a transabdominal ultrasound scan. On 10 Month1[1], Ms A attended her appointment with sonographer Ms D at FRSL. This was Ms D's second day working at FRSL.

2. Ms D performed the transabdominal scan and a colour Doppler scan. During this scan, Ms D was unable to detect a fetal heartbeat. Ms D documented that there was no obvious fetal heart, and that the colour Doppler scan had shown a flash of colour adjacent to the yolk sac. Ms D did not offer Ms A a transvaginal scan during this appointment.

3. Radiologist Dr B reported on the ultrasound scan from Ms D's worksheet and images. Dr B reported the scan after Ms A had left the department. This was Dr B's first day undertaking clinical work at FRSL. Dr B reviewed the images Ms D had taken and the findings she had documented in her sonographer report, and recorded them in his radiology report. Dr B documented that there was "no obvious fetal heartbeat seen" and "no evidence of viability".

4. On 11 Month1, social worker Ms G reviewed the radiology scan report. Ms G told HDC that she discussed the report with Miscarriage Clinic Lead Dr H at the public hospital, and then contacted Ms A to inform her of the results of the report.

5. On 19 Month1, Ms A attended an appointment with Dr H. Dr H gave Ms A misoprostol to assist with miscarriage.

6. On 23 Month3, Ms A consulted with Dr J at a medical centre with concerns that she was yet to have her menstrual cycle since her miscarriage. Dr J reviewed her and arranged for an urgent ultrasound.

7. On 24 Month3, Ms A attended an appointment with FRSL for a transabdominal ultrasound scan. Radiologist Dr K documented that Ms A had a viable pregnancy, and the fetus was at "approximately 17 weeks 3 days plus or minus 10 days" gestation.

Findings

8. Sonographer Ms D should have offered Ms A a transvaginal scan at the time of Ms A's appointment. Adverse comment is made in relation to Ms D's failure to do so.

9. By failing to obtain a second sonographer opinion, or recommend that a transvaginal scan should be performed, or recommend that Ms A's β-hCG levels should be monitored, or organise a review scan in one week's time, and by reporting that there was no fetal viability, Dr B did not provide services to Ms A with reasonable care and

[1] Relevant months are referred to as Months 1-5.

skill and, therefore, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[2]

10. FRSL had access to information regarding Dr B's training, qualifications, work history, and references; however, it did not identify Dr B's inexperience in the area of obstetric ultrasound scans prior to allowing him to report on obstetric ultrasounds at FRSL. In addition, FRSL did not allow Ms D sufficient time to familiarise herself with the department and protocols in place at FRSL prior to giving her a full case load, and did not record which protocols were provided to her. Furthermore, the protocols in place at FRSL in Month1 were outdated and did not provide adequate guidance for clinicians. Accordingly, Fulford Radiology Services Limited did not provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

11. The Commissioner recommended that Dr B:

a) Arrange for a clinical peer review of the standard of his radiology reporting on obstetric ultrasounds.

b) Undertake an audit of obstetric scans he has performed in the last six months in order to identify any patients who require follow-up and have not received it.

c) Provide a written apology to Ms A for his breach of the Code.

12. The Commissioner recommended that Fulford Radiology Services Limited:

a) Over a two-month period, audit compliance with the changes it has made to its ultrasound protocols to include a requirement for transvaginal ultrasound scans to be performed when there is a question regarding fetal viability.

b) Use this case as an anonymised case study for education for future medical staff employed by, or contracted to, Fulford Radiology Services Limited.

Complaint and investigation

13. The Commissioner received a complaint from Ms A about the services provided to her by Fulford Radiology Services Limited. The following issues were identified for investigation:

- *Whether Fulford Radiology Services Limited provided Ms A with an appropriate standard of care between Month1 and Month4.*

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

- *Whether Dr B provided Ms A with an appropriate standard of care between Month1 and Month4.*

14. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Radiologist/provider
Fulford Radiology Services Limited	Radiology service/provider

15. Information was reviewed from:

Dr C	Radiologist/provider
Ms D	Sonographer/provider
Ms E	Sonographer/provider
Mr F	Fulford Radiology Services Limited Service Manager
Ms G	Social worker/provider
Dr H	Miscarriage Clinic Lead
District Health Board	

Also mentioned in this report:

Dr J	General practitioner
Dr K	Radiologist

16. Independent expert advice was obtained from a sonographer, Ms Naomi Rasmussen (**Appendix A**), and a radiologist, Dr Robert Sim (**Appendix B**).

Information gathered during investigation

Background

17. In 2015, Ms A consulted with a general practitioner (GP) at a medical centre. Ms A told the GP that she was pregnant and that she wanted a termination of her pregnancy. It was confirmed that Ms A was pregnant, and the GP referred Ms A to the New Zealand Family Planning Association (NZFPA).

18. A doctor at the NZFPA reviewed Ms A and, during the same appointment, discussed Ms A's options for termination and future contraception. The doctor referred Ms A to Fulford Radiology Services Limited (FRSL) for a transabdominal ultrasound scan[3] to establish the gestational age of her pregnancy. The doctor also referred Ms A to the Sexual Health Clinic at the district health board (DHB). The Sexual Health Clinic at

[3] A small handheld instrument called a transducer is passed back and forth over the pelvic area to provide images of the abdomen.

the DHB performs medical[4] and surgical[5] termination of pregnancy procedures. Ms G was appointed as Ms A's social worker.

19. In New Zealand, termination of pregnancy can be carried out only until 20 weeks' gestation. Medical terminations are available only until nine weeks' gestation. Surgical terminations are available until 20 weeks' gestation and involve the manual removal of the fetus.

Fulford Radiology Services Limited (FRSL)

20. FRSL operated out of the public hospital and was a privately owned company at the time of these events.[6]

Sonographer care

21. On 10 Month1, Ms A attended her appointment with sonographer Ms D at FRSL for a transabdominal ultrasound scan. Ms D was employed by FRSL on a fixed-term contract. This was Ms D's second day working at FRSL.[7]

22. Ms D told HDC that on her first day at FRSL her training had been limited to being shown around the department, and she was not orientated to FRSL protocols. She said that on her first day at FRSL she "had an entire day of patients to scan which was about 15 in a day". Ms D stated that, particularly in the first few days, she felt she was under "such time constraints" that she did not get her breaks and "barely had time to have her lunch".

23. The "[Ultrasound] First Trimester Obstetric" protocol in place at the time at FRSL required the sonographer to "scan the entire lower abdomen observing uterus, uterine content, both ovaries and surrounding anatomy". It stated:

> "In the event of any difficulty in delineating any organ or foetus, or in the case of [suspected] ectopic[8] pregnancy examination, a transvaginal approach should be adopted — in addition to the transabdominal examination."

24. Ms D told HDC that she was not told about the "[Ultrasound] First Trimester Obstetric" protocol prior to Ms A's ultrasound scan.

25. FRSL Transition Manager Mr F told HDC that, prior to Ms D commencing work at FRSL, she was provided with FRSL's "most common" protocols to read and familiarise herself with; however, there is no record of which protocols these were. Mr F also told HDC:

> "On her first day of work, the roster indicates she had a short 30 minute introduction session with another sonographer before commencing scanning. We

[4] Whereby medication is given in clinic to bring on a miscarriage, causing the body to expel the embryo or fetus.
[5] Whereby a surgical procedure is carried out to remove the embryo or fetus.
[6] The shareholders were the DHB and a radiology company.
[7] Ms D was employed by FRSL as a locum sonographer. Ms D qualified as a sonographer overseas.
[8] Where the fetus develops outside the uterus.

presume she was advised and happy to liaise with the other sonographers with any questions/queries."

26. Ms D performed Ms A's transabdominal scan. During the scan, Ms D was unable to detect a fetal heartbeat. Ms D documented:

> "[Fetal heartbeat] = not seen …? bleed surrounding [gestational] sac? [crown rump length][9] seen, [no] obvious [fetal heart] colour/power Doppler flow seen [adjacent] to [yolk sac]. 15 [minute] allotted scan — if [transvaginal scan] needed suggest [follow up] [patient] having no bleeding or pain."

27. Ms D told HDC that she was not fully confident that she was seeing the embryo well, which is why she thought that what she was seeing might be the crown rump length (CRL).

28. Ms D then performed a colour Doppler[10] scan and, again, no fetal heartbeat was detected, although the colour Doppler did show a flash of colour outside the embryo. Ms D told HDC:

> "There was colour Doppler documented which should have raised concern that this could be a viable pregnancy and while no definite heartbeat was seen it should have been reassessed in a few days."

29. Ms D stated that she did consider performing a transvaginal scan, but her colleague (sonographer Ms E)[11] told her that she had used the time period allotted for Ms A performing the transabdominal scan. Ms D also told HDC that her colleague stated that instead she could suggest a transvaginal scan be performed if necessary. Ms D said that she could not recall the name of her colleague.

30. Ms E told HDC that she cannot recall the specifics of Ms A's case, including whether she provided any advice to Ms D.

31. Ms D told HDC: "Looking back now I should have just done the transvaginal scan at the time even with the time constraints."

Radiologist care

32. Radiologist Dr B was the supervising radiologist for Ms A's ultrasound scan. Dr B was employed by a radiology company who provided radiologists to FRSL under a contract for services. Under that contract, on providing a radiologist to FRSL, the radiology company was required to provide FRSL with "full details of the radiologists training, qualifications, work history and references and any other information which the [radiology company] reasonably requires to make an informed assessment of the person".

[9] The measurement of a fetus from the head to the bottom of the torso.
[10] A technique that allows the sonographer to observe blood flow. The colours shown display the speed and direction of blood flow within the abdomen.
[11] Mr F told HDC that based on who was rostered on that day, the colleague referred to would have been sonographer Ms E.

33. The radiology company told HDC that FRSL had access to information regarding Dr B's training, qualifications, work history, and references.[12]

34. Radiologist Dr C told HDC that on Dr B's first day at FRSL, he acted as an observer, and accompanied her while she carried out her work. On 10 Month1, Dr B commenced his clinical work with FRSL. Dr B was trained overseas, and this was his first time working in New Zealand.

35. Dr B told HDC:

> "I was open and honest with my employers and informed them of what I could do, my skills, and what I could not do. When I commenced work at FRSL, there were people working in the department, but my supervisor was away and no one present specifically assigned to supervise me."

36. Mr F told HDC:

> "… Clinical protocols would have been available electronically via the FRSL intranet. His further induction, orientation and supervision fell under the responsibility of [the radiology company] …"[13]

37. Dr C told HDC that, in accordance with the Medical Council of New Zealand's approved supervision plan in place for Dr B, "several radiologists were immediately available to him for advice, second opinion and guidance as he required".

38. Dr B reported on the ultrasound scan from Ms D's worksheet and images.

39. Dr B told HDC that he was not present during Ms A's ultrasound scan, and reported the scan only after Ms A had left the department. Dr B reviewed the images Ms D had taken and the findings she had documented in her sonographer report, and recorded them in his radiology report. In addition, Dr B documented:

> "There was suggestion of a bleed seen surrounding the gestational sac. Some increased colour and power Doppler flow is seen adjacent to the Yolk sac … If transvaginal scanning is required this could be performed upon request … Eight week gestation. No evidence of viability."

40. Dr B told HDC:

> "The colour Doppler showed a flash of colour outside the embryo adjacent to the yolk sack, but the cause at the time was unknown as there was no cardiac activity.

[12] The radiology company provided HDC with a copy of this information.

[13] Under the contract for services, the radiology company was responsible for: induction training, including training on tasks that the radiologist had to perform, and relevant FRSL procedures and standards; and for ensuring the radiologists held appropriate qualifications, and were competent to perform the services.[13]

> I considered the colour Doppler flow adjacent to the yolk sac to be possible artefact[14] on the weight of an absent fetal heart."

41. Dr B told HDC:

> "My experience of obstetric scanning was limited mainly to first trimester obstetric emergencies such as ectopic pregnancy detection because the practice [overseas] is such that other obstetric scanning is done in obstetric departments rather than in radiology."

42. Dr B told HDC that, based on his previous radiologist experience overseas, he "incorrectly assumed that an obstetrician would decide if a transvaginal scan was necessary".

43. The DHB's Child and Maternal Health Service Manager Ms I[15] told HDC:

> "A transvaginal ultrasound (TVS) scan was not undertaken for [Ms A] because it is not considered standard procedure in a case such as this. [Ms A's] abdominal ultrasound result showed a non viable pregnancy of a fetus with a crown rump length (CRL) of greater than 10–11 mm and no fetal heart rate (FHR) is seen."

44. Ms A was not told the results of the ultrasound scan during her appointment.

Consultation with social worker Ms G

45. Following her appointment at FRSL, Ms A consulted with social worker Ms G at the public hospital to discuss her options in relation to the termination of pregnancy. Ms G told HDC that, at time of this discussion, the radiology report was not yet available, and Ms A was unaware of how far along she was with her pregnancy, although Ms A did believe she would be over nine weeks' gestation.

46. Ms G told HDC that she explained the available termination of pregnancy procedures to Ms A. Ms G said that she advised Ms A that, if she were over nine weeks' gestation, she would need to wait until 24 Month1 for a surgical termination of pregnancy, as this was the next available date in the clinic for the procedure.

Provision of results of scan report

47. On 11 Month1, Ms G had the opportunity to review the radiology scan report, which stated that there was "no obvious fetal heartbeat seen" and "no evidence of viability". Ms G told HDC that she discussed the report with Miscarriage Clinic Lead Dr H at the public hospital, and then contacted Ms A to inform her of the results of the report.

Miscarriage procedure

48. On 19 Month1, Ms A attended an appointment with Miscarriage Clinic Lead Dr H.

[14] Misleading data or observations resulting from flaws in technique or equipment.
[15] The DHB responded to HDC, as the DHB has since acquired 100% ownership of FRSL.

49. Ms A told HDC that, when she attended the appointment, she was under the impression that she would be undergoing a surgical procedure to remove the fetus she had miscarried.

50. Ms A told HDC that Dr H informed her that as she had recently undergone a Caesarean section, a non-surgical procedure would be safer, and Dr H recommended either rods[16] or misoprostol tablets[17] inserted vaginally to induce evacuation of the fetal tissue.

51. Ms A opted to receive the misoprostol tablets, and they were inserted at the hospital.

52. Dr H documented that she discussed the options available with Ms A and gave her the standard dosage of 800mcg misoprostol. Dr H also documented that Ms A wanted a Jadelle[18] inserted, and that she told Ms A that she could bring it to the clinic for insertion following her miscarriage.

53. Ms A told HDC that she asked Dr H what to expect, and was told to return to hospital if there was any severe pain or cramping. Ms A said that she started bleeding heavily the same day and was sick, and the bleeding continued for at least a week.

54. Ms A did not attend her appointment to have a Jadelle inserted.

Appointment at the medical centre

55. Ms A told HDC that seven to eight weeks after the bleeding she still had not had her menstrual cycle, so she decided to get a pregnancy test to be sure. The pregnancy test came back positive. On 23 Month3, Ms A consulted with Dr J at the medical centre. Ms A told HDC that Dr J used a machine to see if they could hear a heartbeat, and was told that if they could hear the heartbeat, the baby would be over 11 weeks' gestation. Dr J was able to hear a heartbeat.

56. Dr J arranged for an urgent ultrasound, and documented: "Requires URGENT ultrasound for dating considering termination. Please do transvaginal ultrasound if needed."

Second transabdominal scan

57. On 24 Month3, Ms A attended an appointment with FRSL for a transabdominal ultrasound scan. Radiologist Dr K documented: "There is a single, live, moving intrauterine gestation identified … Gestational age approximately 17 weeks 3 days plus or minus 10 days."

Termination procedure

58. As Ms A was going to be just over 18 weeks' gestation, and because there were no appointments for termination procedures available within the required time frame at the DHB, Ms G contacted an Obstetrician and Gynaecologist (O&G) from a

[16] Rods that are inserted to dilate the cervix.
[17] A medication that induces the evacuation of the fetus.
[18] A contraceptive implant used to prevent pregnancy.

termination of pregnancy clinic in a main centre to see whether he could perform the surgical procedure prior to 20 weeks' gestation. The O&G confirmed that he could. Ms G then arranged for Ms A to travel for the procedure. The DHB provided Ms A with money for accommodation and petrol vouchers.

59. On 28 Month3, Ms G completed an "out of town referral" and counselling session report.

60. On 30 Month3, the O&G performed the surgical termination procedure for Ms A.

Further information from FRSL

61. The DHB, who has taken over ownership of FRSL since the events, obtained an opinion on the events from an external radiologist, who stated that, in his opinion:

> "It would be quite correct for the radiologist to draw the conclusion that the embryo was not viable if a correctly performed transabdominal scan did not show a fetal heart beat when the CRL is 15.8mm. [Transvaginal] scan is not required for confirmation in this situation.
>
> A colour/power Doppler scan is not part of the standard protocol to prove non viability, but one was performed and showed activity inside the gestational sac. There should be no activity in the sac if the embryo is truly non viable. This activity was mentioned in the report and it should have alerted the radiologist that something atypical was occurring, and that further investigation was required."

Changes to practice

62. Mr F told HDC that when the DHB took over ownership of FRSL:

> "[A] new management structure was put in place and [the DHB's] human resource policies and protocols relating to recruitment, credentialing, induction and orientation have been adopted. As a result, a far more comprehensive orientation plan has been introduced to FRSL to sit alongside the New Zealand Medical Council (NZMC) supervision plan for medical staff practicing under vocational supervision."

63. Mr F also told HDC:

> "As a result of this case, we have revised our [Ultrasound] First Trimester Obstetric protocol further to require a [transvaginal] scan diagnosis and a repeat scan in 7–10 days to confirm non-viability of a pregnancy."

64. The new protocol states: "In the case of suspected foetal demise: If no heartbeat is seen prior to 12 weeks (or with an embryo of greater than 7mm CRL) — a [transvaginal] scan must be performed to confirm viability …"

65. Dr B told HDC that he has reviewed his practice and now recommends a follow-up scan in 7–10 days' time, and correlation with serum hCG.[19]

66. Ms D told HDC: "I have learned from this and put it into my current practice to always do a transvaginal scan if I have any doubts or questions about what I am seeing."

Further responses

67. Dr B told HDC:

> "I would like to take this opportunity to convey my sincere apologies to [Ms A] and her family for the upset and stress caused. I have always endeavoured to attain the highest standards of practice and I have no hesitation in apologising for the deficiencies identified regarding my care."

68. Dr B also told HDC that he has since obtained a lot of experience in New Zealand and has taken part in continuing medical education.

69. Mr F told HDC that Dr B has also requested, and obtained approval, to attend a symposium in which the focus is on musculoskeletal, and obstetrics and gynaecology continuing education.

70. Ms D told HDC: "I am very sorry to [Ms A] and apologise sincerely that she had to go through all of this."

Responses to provisional opinion

71. The parties were given an opportunity to comment on the relevant sections of the provisional report. The responses have been incorporated into the report where appropriate. Further responses are outlined below.

72. Dr B told HDC: "I was not aware … that [Ms D] was a locum on her first day and was not familiar with some of the systems in the department." He also stated:

> "I am a conscientious and competent radiologist. I have worked hard to improve radiology services for the people of [the region]. I participate in CPD activity, including local peer review and audit. […] and I have introduced interventional radiology to the region. This unfortunate episode does not indicate wider deficiencies in my practice."

73. Ms D told HDC that she has learned from her shortcomings in this case.

74. Mr F told HDC:

> "[W]e accept the findings of [Dr Robert Sim] and have acted to address all of the issues which we believe contributed to this failure to diagnose a viable pregnancy with quite devastating consequences for [Ms A]. As a result of this case, we have put in place revised protocols that are consistent with current best practice and will

[19] A test to determine the levels of hormone human chorionic gonadotropin (hCG), which is produced during pregnancy. The levels of hCG change depending on the gestation.

eliminate the potential for any repeat occurrence. We have also participated in a meeting with [Ms A] to discuss the radiological circumstances of the case and to provide our apologies directly to her."

Opinion: Ms D — adverse comment

75. On 10 Month1, sonographer Ms D performed a transabdominal ultrasound scan and colour Doppler scan on Ms A. The colour Doppler scan showed a flash of colour adjacent to the embryo.

76. Ms D documented that there was no obvious fetal heartbeat, and that a colour power Doppler flow was seen. She suggested follow-up if a transvaginal scan was needed.

77. Ms D told HDC: "I was not fully confident that I was seeing the embryo well which is why I questioned it as being the CRL."

78. Ms D stated that she did consider undertaking a transvaginal scan, but after discussing the case with a colleague she was advised that as Ms A was booked in for only a 15-minute appointment, she could suggest a follow-up transvaginal scan if needed. Ms D told HDC that she could not recall the name of the sonographer colleague who provided her this advice. She told HDC: "Looking back now I should have just done the transvaginal scan at the time even with the time constraints."

79. Mr F told HDC that based on the 10 Month1 roster, the "ultrasound colleague" referred to by Ms D would have been sonographer Ms E. However, Ms E told HDC that she cannot recall the specifics of the case, including whether she provided any advice to Ms D. I am unable to make a finding as to whom Ms D spoke with on 10 Month1 regarding Ms A's scan, or the nature of that conversation.

80. My expert advisor, sonographer Ms Naomi Rasmussen, advised that if there is any doubt regarding the viability of a fetus, a transvaginal scan should be offered. Ms Rasmussen stated that the flash of colour on the colour Doppler scan, and the query regarding the CRL, suggested that there was some doubt, and, accordingly, Ms D should have offered Ms A a transvaginal scan at the time of the appointment, even if there was time pressure. Ms Rasmussen advised that the failure to do so would amount to a mild departure from an accepted standard of care.

81. I accept Ms Rasmussen's advice, and am critical that Ms D did not offer Ms A a transvaginal scan. However, I also accept that Ms D recorded her findings in her report accurately. Furthermore, Ms D appropriately recorded her doubt as to what she was seeing, and noted the possibility of a transvaginal scan, and she did not record that it was a non-viable pregnancy. I also note that Ms D has learned from this case, and it is her current practice always to do a transvaginal scan when she has any doubt about what she is seeing.

Opinion: Dr B — breach

82. Under Right 4(1) of the Code, Ms A had the right to have services provided with reasonable care and skill by the staff involved in her care.

83. Dr B was the radiologist who reported on Ms A's transabdominal ultrasound scan and colour Doppler scan, which was undertaken on 10 Month1. Dr B reviewed the images of the scans undertaken. He recorded Ms D's findings in his radiology report and documented that there was a suggestion of a bleed seen surrounding the gestational sac, and some increased colour and power Doppler flow adjacent to the yolk sac. He noted that if transvaginal scanning was required, this could be performed upon request. Dr B concluded that there was no evidence of viability.

84. Dr B documented in his report that a transvaginal scan could be requested if required. He did not implement any follow-up actions or document any recommendations in his report.

85. It was Dr B's second day working at FRSL, and his first day undertaking clinical duties. It was Dr B's first time working in New Zealand. Dr B told HDC that he had limited experience in obstetric ultrasound scans, and that, in his country of training, the obstetrician involved would be the one to request a transvaginal scan be performed if he or she believed it to be necessary.

86. Although it was Dr B's first day undertaking clinical duties as a radiologist in New Zealand, I am of the view that, in accordance with his supervision plan signed off by the Medical Council of New Zealand, he had access to three other radiologists, and would have been able to discuss with his colleagues what the next appropriate course of action would be.

87. My expert advisor, radiologist Dr Robert Sim, reviewed the images of the scans taken by Ms D, and Dr B's report. Dr Sim advised that "the images provided for reporting should have signalled uncertainty regarding pregnancy failure and the diagnosis of miscarriage to the reporting radiologist". Dr Sim advised that Ms D also indicated her uncertainty by recording "?CRL" to question whether what she was seeing on the images was the CRL.

88. Dr Sim also advised that the presence of the colour flow on the Doppler scan suggested either fetal cardiac activity or blood flow within the umbilical cord. He advised that this activity would not occur within a fetus or cord of a failed pregnancy.

89. Dr Sim advised:

> "Sufficient doubts existed based on the archived images regarding pregnancy failure for the reporting radiologist to require consideration of these options:
>
> a. Second sonographer opinion
> b. Transvaginal ultrasound
> c. Review scan in one week

d. Recommend monitoring of serial βhcg levels."

90. I accept Dr Sim's advice, and consider that Dr B failed to consider the flash of colour on the colour Doppler scan properly, and the uncertainties flagged by Ms D. Consequently, he incorrectly reported that Ms A's pregnancy was not viable. By failing to obtain a second sonographer opinion, or recommend that a transvaginal scan should be performed, or recommend that Ms A's β-hCG levels should be monitored, or organise a review scan in one week's time, and by reporting that there was no fetal viability, Dr B did not provide services to Ms A with reasonable care and skill and, therefore, breached Right 4(1) of the Code.

91. I note that Dr B has since participated in continuing medical education to increase his knowledge base, and will be attending a symposium with a focus on obstetrics and gynaecology.

Opinion: Fulford Radiology Services Limited — breach

92. FRSL had a responsibility for ensuring that Ms A received an appropriate standard of care. It needed to have adequate systems and procedures in place to support staff, in order to facilitate consumers receiving an appropriate standard of care.

93. At the time of these events, Dr B was a sub-contractor for FRSL, and Ms D was an employee of FRSL. Accordingly, I am satisfied that FRSL is a healthcare provider and an employing authority for the purposes of the Health and Disability Commissioner Act 1994. As such, FRSL may be held directly liable for the care provided to Ms A, and it may be held vicariously liable for any actions or omissions of its employees and/or agents.

Radiologist Dr B

94. [Dr C] told HDC that, in accordance with the Medical Council of New Zealand's approved supervision plan in place for Dr B, "several radiologists were immediately available to him for advice, second opinion and guidance as he required".

95. Dr Sim advised that the supervision plan in place for Dr B was adequate, and that Dr B had access to three radiologists at the time of the care provided to Ms A. I agree that had Dr B possessed the necessary qualifications and experience for the role he was to undertake, that the supervision plan would have been appropriate. Dr B also had access to support available to him through his colleagues.

96. However, it is clear that Dr B did not possess the necessary qualifications and experience for the role he was to undertake. I am critical that, while FRSL had access to information regarding Dr B's training, qualifications, work history, and references, it did not have an understanding of the level of experience Dr B had in the area of obstetric ultrasound scans. I am of the opinion that, given Dr B had been trained overseas and had not practised in New Zealand previously, FRSL should have

enquired further into Dr B's understanding of obstetric ultrasound scans and his understanding of his role as a supervising radiologist, prior to allowing him to act in that role.

97. It is unacceptable that FRSL did not identify Dr B's inexperience in the area of obstetric ultrasound scans prior to allowing him to report on obstetric ultrasounds at FRSL.

Sonographer Ms D

98. Mr F told HDC that, prior to Ms D commencing work at FRSL, she was provided FRSL's most common protocols to read and familiarise herself with. Mr F told HDC:

> "On her first day of work, the roster indicates she had a short 30 minute introduction session with another sonographer before commencing scanning. We presume she was advised and happy to liaise with the other sonographers with any questions/queries."

99. Ms D also told HDC that she felt as though she did not receive any training at FRSL and was not told about all of the proper protocols. Ms D said that she felt she was under "such time constraints" that she did not get to have her breaks, and barely had time to have her lunch. She also stated that she was given a full case load of 15 ultrasound scans a day on her first day of work as a locum sonographer at FRSL.

100. Mr F told HDC that Ms D was provided with the relevant protocols, but he was unable to locate any record of which protocols she was given. Accordingly, I am unable to determine which protocols Ms D was provided with.

101. My expert advisor, sonographer Ms Naomi Rasmussen, advised that she would not expect FRSL to provide any training to Ms D in regard to her scanning technique, but that she should have been given time to familiarise herself with the department. Ms Rasmussen told HDC that usual practice would be for the sonographer to be given a week to become familiar with the department before being given a full list of patients.

102. I am critical that FRSL did not allow Ms D sufficient time to familiarise herself with the department and protocols in place at FRSL prior to giving her a full case load, and did not record which protocols were provided to her.

Protocols in place at the time of events

103. My expert advisor, radiologist Dr Robert Sim, advised that the protocols in place at FRSL in Month1 were "cursory and outdated". Dr Sim advised that a radiologist or sonographer approaching the "Ultrasound First Trimester Obstetric" protocol for guidance would be disappointed.

104. Dr Sim advised that although the "Ultrasound First Trimester Obstetric" protocol references the use of transvaginal ultrasound (TVUS) in the event of any difficulty in delineating any organ or fetus and ectopic pregnancy, the accompanying worksheet did not require the sonographer to record that a transvaginal scan had been performed, agreed to, or declined by the woman.

105. The protocol in place during the period of care provided to Ms A had deficiencies in that it did not provide for important information to be discussed with the patient and recorded on the sonographer's worksheet. This was unacceptable.

106. Following this incident, FRSL amended its protocols to require a transvaginal scan to be performed, with a repeat scan in 7–10 days' time, to confirm non-viability of a pregnancy. Dr Sim has advised that the FRSL protocols are now of an acceptable standard.

Conclusion

107. FRSL had access to information regarding Dr B's training, qualifications, work history, and references; however, it did not identify Dr B's inexperience in the area of obstetric ultrasound scans prior to allowing him to report on obstetric ultrasounds at FRSL. In addition, FRSL did not allow Ms D sufficient time to familiarise herself with the department and protocols in place at FRSL prior to giving her a full case load, and did not record which protocols were provided to her. Furthermore, the protocols in place at FRSL in Month1 were outdated and did not provide adequate guidance for clinicians.

108. Accordingly, I consider that Fulford Radiology Services Limited did not provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

109. This case is a salutary reminder of the need to ensure that the assessment, induction, and oversight of new staff occur professionally and appropriately. New Zealand has a high proportion of internationally trained doctors (42%). An assessment was made that ought not to have been, and, while the radiologist should have conferred with readily accessible colleagues, the employing authority needs to ensure that expectations and protocols — the way we do things — are made clear.

Recommendations

110. I recommend that Dr B:

a) Provide a written apology to Ms A for his breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

b) Arrange for a clinical peer review of the standard of his radiology reporting on obstetric ultrasounds, within two months of the date of this report, and report back to HDC within three months of this report being issued.

c) Undertake an audit of obstetric scans he has performed in the last six months in order to identify any patients who require follow-up and have not received it, and report back to this Office regarding the audit within two months of this report being issued.

111. I recommend that Fulford Radiology Services Limited:

a) Over a two-month period, audit compliance with the changes it has made to its ultrasound protocols to include a requirement for transvaginal ultrasound scans to be performed when there is a question regarding fetal viability. I recommend that Fulford Radiology Services Limited report back to HDC within three months of this report.

b) Use this case as an anonymised case study for education for future medical staff employed by, or contracted to, Fulford Radiology Services Limited.

Follow-up actions

112. A copy of this report with details identifying the parties removed, except Fulford Radiology Services Limited and the experts who advised on the case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

113. A copy of this report with details identifying the parties removed, except Fulford Radiology Services Limited and the experts who advised on this case, will be sent to the Royal Australian and New Zealand College of Radiologists.

114. A copy of this report with details identifying the parties removed, except Fulford Radiology Services Limited and the experts who advised on this case, will be sent to the district health board, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent radiologist advice to the Commissioner

The following expert advice was obtained from a consultant radiologist, Dr Robert Sim:

> "I have received your letter of 26 February 2016 seeking my opinion on the care provided to Ms A by [the] District Health Board.
>
> I am a Diagnostic Radiologist with subspecialty interest in women's imaging. My qualifications are MB ChB (Otago) Dip Obst (Auckland) FRANZCR. I am employed as a radiologist by Auckland District Health Board and work in the National Women's Ultrasound service and I am a partner in Auckland Radiology Group. I am a member of the Radiology Professional Advisory Committee (RADPAC) to International Accreditation New Zealand (IANZ) and an assessor for performance assessment committees of the New Zealand Medical Council (NZMC). I am also a member of the Northern Regional Alliance Maternity Imaging Quality Assurance Group and a member of the Technical Working Group, Antenatal Screening for Down Syndrome and other conditions of the National Screening Unit of the Ministry of Health.
>
> You have asked that I review the documents and provide an opinion on the following issues:
>
> 1. Should [Dr B] have recommended a transvaginal scan be undertaken?
> 2. From the sonographer's findings, were [Dr B's] conclusions in the radiology report appropriate?
> 3. Please comment on the clinical soundness of [the DHB's] responses from a radiology perspective.
> 4. Any other comments you wish to make about the radiology services provided.
>
> For each question you have asked that I advise:
>
> 1. What is the standard of care/accepted practice?
> 2. If there has been a departure from the standard care or accepted practice, how significant a departure do I consider it is?
> 3. How would it be viewed by my peers?
>
> In your letter you have summarised the background to the complaint regarding [Ms A's] ultrasound scan on 10 [Month1], and subsequent medical care, with further scan on 24 [Month3] at the public hospital.
>
> You have also noted you don't require my advice on the care provided by the sonographer.
>
> **Documentation provided:**
>
> 1. Letter of Complaint from [Ms A].
> 2. Responses from Fulford Radiology Service Ltd and [the DHB].

3. Clinical notes include request forms, sonographer worksheets and radiologist's reports for ultrasound examinations of 10 [Month1] by [Dr B] and 24 [Month3] by [Dr K].
4. Images from [the DHB] PACS for ultrasound scans of 10 [Month1] and 24 [Month3].

Review of clinical notes and images from the public hospital:

Ultrasound referral form from Family Planning [date] records clinical details as '*[…] ? dates … considering termination.*'

Review of the ultrasound images of the examination conducted on 10 [Month1] confirms transabdominal scan was performed with no transvaginal ultrasound examination. In agreement with the sonographer's worksheet the sac diameter is measured as 35mm, with a yolk sac present and the fetal CRL measured as 15mm. A single image using M mode with no demonstrated cardiac activity is labeled *'? CRL.*' A further image using colour Doppler technique, with demonstrable vascular flow adjacent and likely within fetus or umbilical cord, is also labeled '*?CRL*'. Three images in total demonstrate colour flow in this region.

The sonographer worksheet states '*? bleed surrounding gestational sac. ? CRL seen. No obvious FH* [fetal heart] *… 15 min allotted scan — If TV needed suggest f/u* [follow up*] … patient having no bleeding or pain.*'

The radiology report by [Dr B] documents the archived findings in the sonographer worksheet. It also reads:

'*A transabdominal scan was performed.*

There is a single intrauterine gestation identified with CRL 15.8mm = 8 weeks 0 days. The sac measures 55 mm x 32.7 x 18.1 mm = 9 weeks 0 days. This gives an EDD of [date].

No obvious fetal heart seen.

There was suggestion of a bleed seen surrounding the gestational sac. Some increased colour and power Doppler flow is seen adjacent to the yolk sac.

Patient mentioned no pain or bleeding.

If transvaginal scanning is required this could be performed upon request.'

It concludes:

'*Eight week gestation. No evidence of viability.*'

Review of the ultrasound images, sonographer worksheet and radiologist report by [Dr K] of 24 [Month3] confirms appropriate examination and reporting of a live fetus of 17 weeks 3 days gestational age with EDD recorded as [date].

Letter of 27 [Month4], from [the] Clinical Director of Fulford Radiology Services to [Ms A], who reviewed the examination of 10 [Month1] states:

'*This scan was performed when looking from outside your body, though it is recommended that to confirm that there has been a miscarriage, a follow-up internal or transvaginal scan is also performed. This is because the images are clearer and more accurate internally …*

[The reporting radiologist] *also said that a transvaginal scan could be performed if requested. When there is a question of a miscarriage in the early stages of pregnancy, the appointment is booked for a longer time, to enable both an external and internal scan to be performed.*

We did not receive any further request for scanning until your general practitioner, [Dr J], referred you for a trans-vaginal scan on 23 [Month3].

I have had the opportunity to review the scan images myself, with the sonographer who did the scans and the radiologist who reported them. They were performed satisfactorily and reported accurately. Had an earlier transvaginal scan been performed it is very likely that the clearer and more accurate images would have enabled the sonographer to see the heart beating. I would comment however, that it is usual to be able to see the heart beating at eight weeks, though not always, and that is why the radiologist mentioned that a transvaginal scan could be performed to confirm whether there is a miscarriage or a live pregnancy (as in your situation). Ultimately the decision to return for the second scan however, is made between the woman and her doctor and midwife.'

Letter of 16 [Month5], from [Ms I] to [Ms A] states:

'*Following our investigations into your events, we have found that it is best to undertake a transvaginal scan if the abdominal scan shows no heartbeat. This enables the medical staff to have a greater degree of accuracy as a transvaginal scan is more likely to indicate a heartbeat if there is one.*

As a result of the above all abdominal scans that do not have a heartbeat are followed up with a transvaginal scan.'

Further letter of 30 [Month5] from Ms I to [Ms A] reiterates the advice now in place at [the DHB]:

'*…every woman who has an abdominal scan that does not show a heart beat will automatically have a transvaginal scan to ensure this is accurate.*'

On 13 November [Ms I] wrote to the Health and Disability Commissioner.

The HDC asked for an explanation to why a transvaginal scan was not undertaken for [Ms A]. It was stated that:

'A transvaginal ultrasound (TVS) was not undertaken for [Ms A] because it is not considered standard procedure in [a] *case such as this. [Ms A's] abdominal ultrasound result showed a non-viable pregnancy of a fetus with a crown rump length (CRL) of greater than 10–11mm and no fetal heart rate (FHR) is seen.*'

An opinion solicited from [a radiologist] is cited. No supporting evidence based information or literature is provided in this opinion.

It is stated '*All women who are referred for a dating scan now have a TVS automatically if they are less than 10 weeks gestation and no FHR is found.'*

Review

The US protocols for diagnosis of failed pregnancy or missed miscarriage have been promulgated by the Australasian Society for Ultrasound in Medicine (ASUM) based on literature review and are evidence and consensus based guidelines. The ASUM guideline D11 was updated in 2014 and should be incorporated in New Zealand radiology service protocols. This reference clearly states:

'*An experienced operator using high quality transvaginal equipment may diagnose pregnancy failure under either or both of the following circumstances:*

1. *When the mean sac diameter (MSD) is >25mm with no visible fetal pole.*
2. *When there is a visible fetus with a CRL cut off >7mm but no fetal movements can be demonstrated. The area of fetal heart should be observed for a prolonged period of at least thirty (30) seconds to ensure that there is no cardiac activity.*

In situations where pregnancy failure is suspected by an operator who either does not have extensive experience in making the diagnosis or does not have access to high quality equipment or if there is any doubt about the viability of the fetus, a second opinion or a review scan in one week should be recommended in the report.'

In this instance the transabdominal measurements were of Mean Sac Diameter 35 mm and CRL of 15.8 mm.

The guideline Diagnosis of Failed Pregnancy (missed miscarriage) from Auckland District Health Board for National Women's ultrasound is appended. This protocol helpfully states:

'*Transvaginal Ultrasound should always be performed as this results in a more diagnostic study.*

In situations where pregnancy failure is suspected by an operator who either does not have extensive experience in making the diagnosis or does not have access to high quality equipment or there is any doubt about the viability of the fetus, a second opinion or review scan in one week should be recommended in the report.'

In 2012 Bourne and Bottomley wrote on the evidence behind diagnostic criteria for miscarriage:

'*If in doubt, repeating scans at an interval is emphasized. It is axiomatic that decisions about embryonic viability must not be open to doubt. So it is surprising how little evidence exists to support previous guidance. Any clinician working in*

this area knows of women being wrongly informed that their pregnancy has failed. This cannot be acceptable and guidance in this area must be "failsafe".'

Fertil Steril. 2012 Nov;98(5):1091-6. doi: 10.1016/j.fertnstert.2012.09.017.

Issues:

1. Should [Dr B] have recommended a transvaginal scan be undertaken?

The images provided for reporting should have signalled uncertainty regarding pregnancy failure and the diagnosis of miscarriage to the reporting radiologist. The images are obtained with 5.1mHz probe and the fetus is unsharp, with poor M mode placement on the fetus.

Several images were labelled '? CRL' which can only be interpreted as uncertainty by the sonographer. Uncertainty and ambiguity exist for the reporting radiologist.

The presence of colour flow documented in three images adjacent to or within what is labeled as the fetal pole indicates either fetal heart activity or umbilical cord blood flow. Menstrual dating was unknown and there was no history of either pelvic pain or bleeding which can be markers of miscarriage. Missed miscarriage can be a symptomless finding on ultrasound but justifies particular ultrasound vigilance.

Sufficient doubts existed based on the archived images regarding pregnancy failure for the reporting radiologist to require consideration of these options:

a. Second sonographer opinion
b. Transvaginal ultrasound
c. Review scan in one week
d. Recommend monitoring of serial serum Bhcg levels

The best option would have been transvaginal ultrasound at the time of the initial study. Real time radiologist supervision should have been considered.

There is nothing in the issued report to alert the referring practitioner to any uncertainty in its content. To state: '*if transvaginal ultrasound is required this could be performed upon request*' is meaningless in this context, and an unhelpful disclaimer.

A reasonable and best course of action should have been to phone the Family Planning Clinic to voice radiologist concern regarding the incomplete scan and insist that [Ms A] be recalled for interval TVUS. This should have been documented in the report he wrote. He did not recommend a review scan in one week, or indeed at all.

2. From the sonographer's findings, were [Dr B's] conclusions in the radiology report appropriate?

The conclusion that this was an 8 week pregnancy was appropriate. To state '*No evidence of viability*' is not correct.

The presence of colour flow on Doppler suggests either fetal cardiac activity or umbilical cord blood flow. It should be noted that blood flow is not seen with colour Doppler within a fetus or cord of a failed pregnancy.

Common ultrasound practice is to use colour Doppler to ascertain and map the presence of blood flow. Good practice precludes its use in early pregnancy on the grounds of potential thermal effects on the fetus, but it is frequently used if M-mode does not demonstrate cardiac activity as a second level check by experienced sonographers in early pregnancy. M mode is usually used to formally document what the sonographer has observed in real time — the absence of cardiac activity.

3. Please comment on the clinical soundness of [the DHB's] responses from a radiology perspective.

The responses from [the DHB] contain several statements worthy of consideration. These should be examined in light of the Auckland District Health Board guideline, common ultrasound/radiology practice and the views of Bourne and Bottomley:

a. Appropriate and best care is more important than expediency based on available time. [The DHB] and radiologists cite time constraints as a reason for not performing a transvaginal study. This was a scheduled, non acute study, with images archived over a 12 minute time frame. Common and usual ultrasound practice is to extend the ultrasound examination to include a transvaginal component if it is required to obtain the required information, and particularly to confirm the presence or absence of fetal life.

b. Requiring the recipient of the report, either Family Planning Clinic clinician, general practitioner, midwife or specialist Obstetrician to determine the need for transvaginal ultrasound is inappropriate. It is a decision made by the examining sonographer or supervising radiologist. Absolute certainty in ultrasound confirmation of fetal viability is required, or in the presence of uncertainty, recommendation of the appropriate options as outlined (in 1) above.

   '*Ultimately the decision to return for the second scan however, is made between the woman and her doctor and midwife*' as stated in [the DHB's] correspondence to [Ms A] also requires robust unequivocal recommendation from the reporting radiologist.

c. '*All women who are referred for a dating scan now have a TVS automatically if they are less than 10 weeks gestation and no FHR is found.*' This is an ad hoc response which references no evidence/consensus based standards, protocols/guidelines or robust information to support this statement.

4. Any other comments you wish to make about the radiology services provided.

This is an inexplicable miss.

No reference is made to protocols, standards or guidelines which may have been be in existence within the radiology service to cover the contingencies of ultrasound examination in early pregnancy.

Supervision of Sonographers and other Medical Radiation Technologists in the conduct and performance of obstetric ultrasound examinations is a basic and required role of the radiologist. It is referenced in the Section 88 notice. It is not known if [Dr B] was the supervising radiologist on 10 [Month1] for [Ms A]. If so, he has failed to supervise appropriately. Certainly as the subsequent reporting radiologist he omitted to document that the study was uncertain and fetal viability inconclusive without TVUS. His written conclusion was wrong.

There is no record of [Dr B's] obstetric ultrasound expertise.

It is recommended that the service consider referencing the Canterbury and Auckland Heath Pathways, consider the ASUM and Auckland DHB guidelines for first trimester and early pregnancy ultrasound.

The ADHB Diagnosis of Failed Pregnancy (Missed Miscarriage) guideline should be considered as an example of what may be incorporated in the [the DHB] protocol.

Radiologist education updates may be required.

Review of radiologist CPD applicable to obstetric ultrasound is suggested.

The Radiology Department Early Pregnancy Ultrasound worksheet should be updated to require formal acknowledgement, or otherwise, that TVUS has been performed.

Based on this single case concern should exist regarding other early pregnancy ultrasound examinations in which viability is a consideration and TVUS has not been conducted and studies have been reported by [Dr B]. This may require a formal retrospective audit.

You have asked that I not provide advice on the care provided by the sonographer. It should be noted that the conduct of the examination suggests sonographer inexperience. This should have signaled an even greater need for careful radiologist supervision.

Summary:

[Dr B's] departure from the standard of care expected is highly significant with reference to both questions 1 and 2, and would be viewed as a moderate to severe departure by my peers.

Confirmation of fetal life or failure of pregnancy requires strict adherence to internationally accepted guidelines. As stated by Bourne and Bottomley guidance in this area should be 'failsafe'.

'*Transvaginal Ultrasound should always be performed as this results in a more diagnostic study,*' as recommended in the guideline Diagnosis of Failed Pregnancy (missed miscarriage) from Auckland District Health Board for National Women's ultrasound is fundamental in early pregnancy ultrasound.

Radiology peers and sonographers to whom I presented this case without identifying details, are likewise in agreement. Views were expressed unequivocally that the conduct of this early pregnancy examination was a severe departure from expected standards of practice.

Robert Sim

References

1. ASUM Policy D11 Guideline, revised August 2014 http://www.asum.com.au/files/public/SoP/D11-Guidelines-for-the-Performance-of-First-Trimester-Ultrasound.pdf
2. Diagnosis of Failed Pregnancy (Missed Miscarriage) RADUSOBSIN003 NW Ultrasound Auckland District Health Board, issued October 2011, reviewed August 2015
3. Fertil Steril. 2012 Nov;98(5):1091-6. doi:10.1016/j.fertnstert.2012.09.017."

Further expert advice was obtained from Dr Sim:

"Previous opinion was provided on 14 March 2016. This advice should be considered to follow on as an addendum.

Further documentation has been provided and advice sought on:

1. Whether the additional information received from [the DHB] (on behalf of FRSL) and radiologist [Dr B] alters my expert advice previously provided in any way, or raises new issues.
2. The adequacy of the system in place at FRSL for training new employees on 10 [Month1], including the induction policy and the supervision plan for [Dr B] which was in place at the time.
3. The adequacy of the protocols in place at FRSL on 19 [Month1].
4. The adequacy of the protocols in place at FRSL currently and those that are in draft form.
5. The adequacy of the diagnosis of first trimester failed pregnancy protocol which FRSL has informed HDC is currently in draft form.
6. Please also comment on any other aspects of the care provided to [Ms A] that I consider warrant such comment.

New documentation provided:

1. Letter from [the DHB] (on behalf of FRSL), dated 28 July 2016.
2. Letter from [Dr B], dated 21 July 2016.
3. Supervision plan for [Dr B].
4. Letter from [Dr C] regarding supervision in place for [Dr B], dated 1 September 2016.
5. Email from [the DHB] detailing the supervision in place for [Dr B] in [Month1].
6. FRSL policies in place 10 [Month1].
7. FRSL policies in place currently.
8. FRSL Fetal death protocol in place [Month1] and currently.
9. FRSL ultrasound diagnosis of first trimester failed pregnancy protocol — currently in draft form.
10. FRSL proposed US first trimester protocol.

Review of documents:

Review of the documents provided identifies salient new information regarding conduct and reporting of the obstetric US for [Ms A] on 10 [Month1].

[Dr B] was a foreign medical graduate, with [an overseas] specialist radiology qualification, working under MCNZ required supervision, with provisional vocational registration for a period of six months [in] 2015.

A supervision plan for [Dr B], approved by the MCNZ, has been provided.

The MCNZ approved radiology supervisor was [Dr C], with [the clinical director] covering in her absence.

The event relating to this complaint occurred on 10 [Month1], the first day that [Dr B] worked at FRSL, and this was stated to be his first working day in New Zealand.

[Dr C] records that: *[Dr B] had a period of observation* (duration not specified) *with Fulford Radiology Services prior to his first clinical day of work.* On 9 [Month1] he was an observer attached to [Dr C].

[Dr C] also records that on: *10 [Month1] [Dr B] was responsible for the supervision and reporting of an ultrasound list. As outlined in the supervision plan, several radiologists were immediately available to him for advice, second opinion and guidance as he required.*

[Dr B] states: *my experience of obstetric scanning was limited mainly to first trimester obstetric emergencies such as ectopic pregnancy detection because the practice [overseas] is such that other obstetric scanning is done in obstetric departments rather than in radiology.*

He also states: *... as the consultant radiologist [overseas] I performed ultrasound examinations and did not supervise Sonographers. Sonographers were able to issue their own reports. Whereas in New Zealand a consultant radiologist supervises and reports a sonographer's ultrasound lists.*

[Dr B] further indicates he was not present during the scan for [Ms A], and reported it after she left the department.

He also describes his view that: *our indirect supervision of sonographers scanning requires us to have a certain level of trust. ...* He then goes on to indicate he was not asked to review images and assistance was not sought by the sonographer.

[Dr B] also records that the sonographer was an experienced locum sonographer.

[Dr B] also states: *supervision of sonographers is indirect and there is very little conferring with the sonographers unless they feel they have a query in certain appearances or want clarification on a scan, and this is rare.*

[Dr B] also records: *I had no reason to doubt the sonographer's experience, nor did I have any concerns about the equipment being used.*

A state of flux has existed with regard to ownership of FRSL, which is now 100% owned by [the DHB] from [2016].

Protocols and US worksheets of FRSL in existence at the time of scan have been provided. The protocol for First Trimester Obstetric Ultrasound (written 1/12/1999 and reviewed 20/3/2007) references the use of transvaginal US (TVUS) in the event of any difficulty in delineating any organ or fetus. The worksheet (authorised 6/11/2013) provided no formalised requirement to record that TVUS has been performed, agreed to or declined by the woman.

An updated FRSL current protocol for First Trimester Obstetric US (reviewed 9/3/2016) and worksheet (reviewed 1/8/2016) reference the use of TVUS for determination of fetal cardiac activity in the event of difficulty, and the worksheet has checkboxes for recording the use of TVUS. An expanded FRSL draft protocol (July 2016) expands further on the requirement to perform TVUS and the role of repeat scan in suspected fetal/embryonic demise.

Three further appropriate FRSL protocols are provided: Transvaginal US Scanning (updated 28/5/2010 and reviewed 1/8/2916), US Fetal Death (introduced 28/3/2007 and not reviewed), and Interpretation of Ultrasound Examinations (introduced 25/6/2007 reviewed 1/8/ 2016).

A draft new protocol for US Diagnosis of Failed First Trimester Pregnancy (authorised 22/7/2016) with references to ASUM and NICE guidelines and journal references is commended.

The FRSL Staff Induction and Orientation plans issued [2012 and 2015] are provided, but both are largely generic and applicable to all staff and students. The documents are not targeted for radiologists.

Issues:

1. Whether the additional information received from [the DHB] (on behalf of FRSL) and radiologist [Dr B] alters my expert advice previously provided in any way, or raises new issues?

What I categorised in my opinion of 14 March 2016 as an inexplicable miss is now more readily understood.

The combination of a foreign medical graduate radiologist, on his first day in a new job, in a new country with limited obstetric US experience, and misplaced trust in a locum sonographer who did not perform a transvaginal ultrasound, and with whom he held no dialogue all contributed to the outcome.

It is of serious concern that FRSL and [the DHB] did not previously provide information that this event occurred on [Dr B's] first day of work in a new job, when he was working under MCNZ supervision with provisional vocational registration.

It is also of concern that advice was not provided that the sonographer was working in a locum capacity for [the DHB].

It is reasonable to assume that on his first working day [Dr B] could not have established any level of trust or confidence in the work of the locum sonographer despite his statement that: *our indirect supervision of sonographers scanning requires us to have a certain level of trust.*

Radiologist inexperience in obstetric ultrasound is the major contributor to the outcome. Failure to perform or recommend TVUS may not have been influenced by protocols in place. Indeed it is not known if [Dr B] had read any protocols as part of his induction process.

It is encouraging that [Dr B] attended further CPD in obstetric ultrasound at the Australasian Sonographers Association's Special Interest Group Meeting [in 2016].

2. The adequacy of the system in place at FRSL for training new employees on 10 [Month1], including the induction policy and the supervision plan for [Dr B] which was in place at the time.

The protocol for training new employees is a generic document, and does not really assist in the induction of a new radiologist to the coal face.

The supervision plan, approved by MCNZ, for [Dr B] is appropriate and typical of those used for overseas trained Radiologists subject to the period of supervision and provisional vocational registration.

3. The adequacy of the protocols in place at FRSL on 10 [Month1].

Radiology protocols are living documents, should be subject to frequent change and thus reflect new evidence and consensus and the culture of a service, and may be subject to audit for purposes of accreditation. The FRSL protocols which were in place in [Month1] are cursory and outdated. The lack of evidence and consensus based reference in the old protocols in place at FRSL is of concern.

The protocol for First Trimester Obstetric Ultrasound (written 1/12/1999 and reviewed 20/3/2007) references the use of transvaginal ultrasound (TVUS) in the event of any difficulty in delineating any organ or fetus and ectopic pregnancy. The First Trimester Ultrasound worksheet (authorised 6/11/2013) provided no formalised requirement to record that TVUS has been performed, agreed to or declined by the woman.

A radiologist or sonographer approaching this protocol for guidance with regard to assessment of failed pregnancy and the use of transvaginal ultrasound would have been disappointed.

4. The adequacy of the protocols in place at FRSL currently and those that are in draft form.

These are typical of those seen in other radiology services in New Zealand.

5. The adequacy of the diagnosis of first trimester failed pregnancy protocol which FRSL has informed HDC is currently in draft form.

The draft new protocol for US Diagnosis of Failed First Trimester Pregnancy (authorised 22/7/2016) with references to ASUM and NICE guidelines and journal references is commended. This is contemporary and well referenced. As other protocols are updated this could be considered a model of what new protocols could be.

6. Please also comment on any other aspects of the care provided to [Ms A] that I consider warrant such comment.

My reading of the documents provided for review previously and in the more recent bundle affords me considerable disquiet.

In correspondence from [the DHB] and FRSL to [Ms A] there are no references to the ultrasound scan being interpreted and reported by a provisionally registered vocationally trained radiologist, working under supervision on his first day in a new job, in a new country. I do not know whether this was discussed in face to face meetings.

The new evidence of a provisionally registered vocationally trained radiologist, on his first day of work in a new country, with limited obstetric ultrasound experience by his own admission, providing supervision for a locum sonographer performing obstetric ultrasound examinations was a recipe for potential disaster.

His level of trust in the sonographer could not have been established and was misplaced. He did not talk with the sonographer about the examination.

It is unclear whether [Dr B] had previously advised his MCNZ supervisors of his limited obstetric ultrasound experience.

The principal radiologist supervisor for [Dr B], according to MCNZ requirements, has indicated in her letter that *several radiologists were immediately available to him for advice, second opinion and guidance as required.* There is no reference to whether he availed himself during his supervision and reporting of the US list.

Summary

My opinion previously expressed 14 March 2016, is unchanged.

Again you have requested I not provide advice about sonographer care provided to [Ms A].

Review and revision of protocols and worksheets is commended.

The reasons for radiologist failure to supervise, observe, recommend transvaginal ultrasound and report appropriately are now clearly identified as radiologist inexperience in obstetric US, coupled with performance issues on the first day in a new job in a new country.

This case provides a good example of the reasoning for supervision imposed by the MCNZ on non Australian and New Zealand vocationally trained radiologists, and the issuing of provisional vocational registration only. Identification of areas of deficiency relating to their scope of practice can then be addressed and if required subjected to a vocational practice assessment by the MCNZ.

It is not known whether the MCNZ was acquainted with the shortfall in [Dr B's] obstetric ultrasound expertise, and this was taken into account before granting full registration in [2015]. This particularly as the first record of formally addressing this at an educational level is not until September 2016.

It is of concern that in none of the previously available correspondence or documentation provided to [Ms A] and the HDC from Fulford Radiology or [the DHB] is there any record or previous acknowledgement that [Dr B] held provisional vocational registration and was new in the job in [the region], with limited obstetric ultrasound experience. There is no record that this information was conveyed to [Ms A].

Robert Sim"

Appendix B: Independent sonographer advice to the Commissioner

The following expert advice was obtained from a sonographer, Ms Naomi Rasmussen:

> "As a Sonographer I will comment on the ultrasound scan preformed on the 10 [Month1].
>
> There has been an appropriate length of time spent performing the transabdominal scan (13 minutes). And both the uterus and adnexa have been examined.
>
> The machine settings are correct. A higher frequency probe may have given better resolution, but this may not have been available to the sonographer.
>
> It is difficult to comment from still images why fetal cardiac activity was not detected as this can only be seen in real-time or in a video clip.
>
> An m-mode trace is able to document cardiac activity but in this case it is difficult to know if the region of the early fetal heart has been assessed, so it does not exclude cardiac activity.
>
> In the sonographers comments there is a '? CRL', and mention of 'colour/power Doppler flow seen adjacent to the YS' These comments suggest there was some uncertainty regarding the CRL and the significance of the colour Doppler.
>
> There are 3 images taken that demonstrate colour adjacent to the yolk sac making this unlikely to be artifact. Therefore my assumption would be that this was real finding, not artifact and caused by movement. It is difficult to say from the image where the movement was, but it could represent the umbilical cord or fetal heart.
>
> The sonographer in the check sheet **has not said it is a non viable pregnancy**. It says:
> — FHR not seen
> — ? CRL seen
> — Colour / Power Doppler flow seen adjacent to the yolk sac
> — Comment is made of 15mins allocated scan time
> — If TV scan needed suggest follow up
>
> I agree that it is rare to not be able to assess cardiac activity in an 8 week fetus by trans abdominal scan but if there is any doubt a trans vaginal scan should be offered at the time of the scan.
>
> The ill defined borders of the measured ?CRL and the Colour Doppler shown would suggest to me there was some doubt regarding the findings and therefore a Transvaginal scan should have been offered to the patient.

Current ASUM (Australasian Society of Ultrasound in Medicine) guidelines for Pregnancy Failure are:

'*An experienced operator using **high quality transvaginal equipment** may diagnose pregnancy failure under either or both of the following circumstances.*

1. *When the means sac diameter (MSD) is >25mm with no visible fetal pole.*
2. *When there is a viable fetus with a CRL cut off >7mm but no fetal heart movements can be demonstrated. The area of the fetal heart should be observed for a prolonged period of at least thirty (30) seconds to ensure that there is no cardiac activity.*

In situations where pregnancy failure is suspected by an operator who either does not have extensive experience in making the diagnosis or does not have access to high quality equipment or if there is any doubt about the viability of the fetus, a second opinion or a review scan in one week should be recommended in the report.'

These guidelines were revised [later in] 2015 so I cannot be sure of the exact wording on 10 [Month1] when this scan in question was performed.

In this case both the size of the MSD and the CRL were above the size where pregnancy failure can be diagnosed but it was not a **transvaginal scan**.

Issues

1. *Should the sonographer have performed a transvaginal scan?*

   Yes. My opinion is that a transvaginal scan should have been performed.

   Best practice would have been to do a transvaginal scan at the time of the initial scan.

   But the information written on the work sheet is correct and the sonographer has not said it is a non viable pregnancy. They have mentioned they had limited time and put the responsibility on the Radiologist to recommend a further scan if they thought it required.

   Generally the decision to do a transvaginal scan should be made at the time of the scan even if there is time pressure.

   I work in Private Practice and in a Public Hospital and in both places I think the majority of people would have performed a transvaginal scan at the time of the initial scan.

   This would be regarded as a mild departure from accepted practice.

2. *The appropriateness of the techniques and tools used in the circumstances*.

   The transabdominal scan has been adequately preformed and not rushed (13min scan time).

   Machine settings were appropriate.

3. *In light of the flash of colour observed outside the embryo from the colour Doppler (as stated in [the DHB's] response of 13 November 2015), was it appropriate to conclude there was no fetal heart beat?*
   The Sonographer's work sheet and the report dated 10 [Month1] say 'colour/Power Doppler flow adjacent to the yolk sac', **not outside the embryo.** My opinion is that this should have created doubt, raising the possibility that this was a viable pregnancy, prompting a TV scan or recommendation for a further scan.

4. *Please comment on the clinical soundness of [the DHB's] responses from a sonography perspective.*
   It is beyond my expertise to comment on [the DHB's] responses.

   I am pleased that all pregnancy scans under 10 weeks, where no cardiac activity is seen, are now offered a transvaginal scan.

Conclusion

My opinion is that the Sonographer did not follow best practice by not offering a transvaginal scan at the time of the initial scan, but it is not a significant departure from accepted standards.

Yours Sincerely

Naomi Rasmussen"

The following further expert advice was obtained from Ms Rasmussen:

"***Whether the degree of training provided by Fulford Radiology Services Limited to Locum Sonographer [Ms D] would be viewed as consistent with accepted practice in relation to the training of locum sonographers.***

I would not expect Fulford Radiology to have provided any training for [Ms D] in regard to her scanning technique, but she would have required time to familiarize herself with the department. Her competencies skill list […] say that she is competent in scanning Obstetric 0–10 weeks and pelvis ultrasound including transvaginal scans.

All departments are different. Their computer systems, booking systems, and means of reporting all require time to adjust to and absorb their details of operation.

[Ms D] started work on the 9th of [Month1] and the scan in question was performed on the 10th [Month1], which would have been her second day.

To perform a full list of scans on her first couple of days would have been difficult. I have not worked as a locum sonographer or where locums have been employed. Qualified staff joining the private practice I work in are usually given a

week to become familiar with the department before they are given a full list of patients.

Scanning 15 patients over a day is busy, but reasonable, once you are familiar with the systems of the department, as this allows approximately 30 mins per scan.

Regards

Naomi Rasmussen"