Sonographer, Mr C

Radiologist, Dr B

District Health Board

A Report by the

Health and Disability Commissioner

(Case 15HDC00881)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Ms A, aged 32 years at the time, was referred to the Early Pregnancy Clinic at a public hospital, owing to concerns that her β-hCG levels[1] were rising at a slower than expected rate. When Ms A underwent a transvaginal scan on 26 Month1[2] 2015, the consultant obstetrician was unable to confirm a viable pregnancy, as no fetal heartbeat was seen on ultrasound.

2. Ms A attended the Radiology Department on 5 Month2 for a further viability scan. The sonographer, Mr C, accessed Ms A's β-hCG results from 20, 23 and 25 Month1, which were 1,068, 2,679 and 4,268 IU/L respectively. Mr C then performed a transabdominal scan. From this, he measured a mean sac diameter of 12mm, and found no observable yolk sac, and no fetal pole or heartbeat. Mr C recorded on the sonographer worksheet that the pregnancy had not developed, and was non-viable. He did not offer Ms A a transvaginal scan, or document that he had not done so. Obstetrician and gynaecologist Dr D accepted Mr C's report as accurate, and made arrangements for Ms A to return to the Early Pregnancy Clinic in five days' time to schedule a dilation and curettage, in the event that she did not miscarry naturally.

3. On 7 Month2, Ms A was seen in the ED for constipation and vaginal discharge. Whilst managing Ms A, Dr E signed off on Ms A's β-hCG test result from 5 Month2 (39,667 IU/L) but did not inform Ms A of the result.

4. The ultrasound images from Mr C's scan were reviewed by a radiologist, Dr B, on 8 Month2. Dr B said he saw that there were no transvaginal images; however, he omitted to document this in his report.

5. Ms A requested a further ultrasound during her appointment at the Early Pregnancy Clinic on 10 Month2. As the transvaginal ultrasound showed a viable embryo, Ms A did not undergo a dilation and curettage, and her pregnancy was able to continue.

Findings

6. Mr C should not have reported that the pregnancy was non-viable based on his findings from the transabdominal examination, and ought to have offered Ms A a transvaginal scan. He also omitted to document that no transvaginal scan had been performed. For these reasons, Mr C breached Right 4(1) of the Code.[3]

7. By failing to report the absence of a transvaginal scan and that further investigation was needed to determine the viability of Ms A's pregnancy, Dr B breached Right 4(1) of the Code.

8. Criticism is made that Dr E signed off on Ms A's β-hCG result but did not inform her of the significant increase in β-hCG.

[1] β-hCG (beta human chorionic gonadotropin) is a hormone produced during pregnancy. In a normal intrauterine pregnancy the level of β-hCG increases by at least 53% every two days, peaking at a level greater than 100,000 IU/L.
[2] Relevant months are referred to as Months 1-5 to protect privacy.
[3] Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states: "Every consumer has the right to have services provided with reasonable care and skill."

9. The DHB did not directly or vicariously breach the Code. Criticism is made about its outdated policies and procedures; however, Mr C and Dr B should have been aware of, and complied with, the professional guidelines in place.

Recommendations

10. It is recommended that Mr C arrange an audit of his first trimester viability scans and accompanying worksheets in the last three months, report back to HDC on his learnings from the Australasian Society for Ultrasound Medicine's (ASUM) professional development programme, and apologise to Ms A, and for the Medical Radiation Technologists Board to consider whether a review of Mr C's competence is warranted.

11. It is recommended that Dr B arrange an audit of his reporting of first trimester viability scans in the last three months, and apologise to Ms A.

12. It is recommended that the DHB:

a) Use this case as an anonymised case study for clinical staff, to highlight, amongst other things, the importance of clear communication between sonographers and radiologists.

b) Update the sonographer worksheet to identify that it is a provisional report, pending review and issuing of a final report by a radiologist.

c) Broaden the scope of the "Clinical images and photography" project regarding the storage of information, to include consideration of transmitting ultrasound images to Picture Archiving and Communication Systems (PACS) or the Clinical Portal, with specific reference to this case.

d) Develop a specific guideline to clarify whether first trimester viability scans should be reported on urgently.

Complaint and investigation

13. The Commissioner received a complaint from Ms A about the services provided by the DHB. An investigation was commenced and the following issues were identified for investigation:

- *The appropriateness of the care provided to Ms A by the DHB in 2015.*
- *The appropriateness of the care provided to Ms A by Mr C in 2015.*
- *The appropriateness of the care provided to Ms A by Dr B in 2015.*

14. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Provider/radiologist

Mr C	Provider/sonographer
The DHB	Provider

15. Information was also reviewed from:

Dr D	Provider/obstetrician and gynaecologist
Dr E	Provider/emergency medicine specialist
Ms F	Friend of consumer

16. Independent expert advice was obtained from sonographer Jillian Muirhead **(Appendix A)**.

17. Independent expert advice was obtained from radiologist Dr Robert Sim **(Appendix B)**.

18. Independent expert advice was obtained from obstetrician Dr David Bailey **(Appendix C)**.

Information gathered during investigation

Timeline of events

Early Pregnancy Clinic consultation — 26 Month1

19. Ms A, aged 32 years at the time and pregnant with her second baby, was referred to the public hospital's Early Pregnancy Clinic by her GP, owing to concerns that her β-hCG levels[4] were rising at a slower than expected rate.

20. A transvaginal scan was completed by a consultant obstetrician on 26 Month1. The findings were reported on a standard DHB form by a resident medical officer. The resident medical officer noted the presence of a gestational sac,[5] yolk sac,[6] and embryo/fetus, but noted that the fetal heartbeat was "[not] clearly visible". The diagnosis "[i]ntrauterine pregnancy of uncertain viability" is circled.

21. The resident medical officer scheduled Ms A for a further ultrasound 10 days later, immediately followed by an appointment at the Early Pregnancy Clinic and a repeat β-hCG.

22. The ultrasound request form states:

> "5+5/40; HCG > 4000; Intrauterine; yolk sac [tick]; No heart beat seen[7]; For Fri 5th [Month2] am please … viability scan."

[4]

[5] The gestational sac is the large cavity of fluid surrounding the embryo.

[6] The yolk sac is a membranous sac attached to an embryo.

[7] With a high resolution vaginal transducer, fetal heart movements are often visible from five to six weeks but may not be seen until the crown rump length is 3–4mm.

Ultrasound appointment with Mr C — 5 Month2

23. At 10am on 5 Month2, Ms A saw sonographer Mr C for the repeat ultrasound scan. Mr C has been practising as a sonographer for over 30 years. He has been employed previously as the DHB's Ultrasound Unit Charge Sonographer. At the time of these events, Mr C was employed part time at the DHB.

24. Ms A attended the appointment accompanied by her husband, her daughter, and her friend, Ms F. Based on her earlier dating scan, Ms A was 7+1 weeks pregnant.

25. A transabdominal ultrasound was performed by Mr C. Mr C told HDC that he accessed Ms A's laboratory results on the computer, as there was insufficient information on the request form. There were three β-hCG levels on file, the most recent of which was from 10 days earlier (25 Month1). Mr C said that usually referrers are asked to provide a β-hCG result within one day of the ultrasound scan being carried out.

26. Mr C did not have access to the images from 26 Month1, which confirmed intrauterine pregnancy and recorded a mean sac diameter of 9mm, a yolk sac, and a fetal pole crown rump length (CRL)[8] of 2.7mm.[9] He told HDC that almost all early pregnancy scans at the DHB are performed by the Early Pregnancy Clinic; they are seldom done by the Radiology Department.

27. Mr C's report states:

> "Scan Quality: fair
> Clinical indication
> Viability scan
> bHCG 20 [Month1] [20]15 = 1068
> 23 [Month1] = 2679
> 25 [Month1] = 4268
> 26 [Month1] [2015]: 'no heartbeat seen'
> …
> Mean Sac [Diameter] = 12mm
> …
> Comment: It is 10 days since the previous scan (Early Pregnancy Clinic). The pregnancy has not developed — non-viable."

28. According to Mr C, there was no observable yolk sac, and no fetal pole[10] or heartbeat.

29. Mr C did not offer Ms A a transvaginal scan. The DHB protocol's "First Trimester Obstetric Ultrasound" in place at the time of Ms A's scan states:

[8] Crown rump length is the measurement of the length of an embryo or fetus from the top of the head to the bottom of the buttocks.
[9] This information was not included with the referral form or worksheet from the scan.
[10] The fetal pole is a thickening on the margin of the yolk sac (see footnote 4) of a fetus during pregnancy.

"Transabdominal scan is routinely done first, a transvaginal transducer would always be offered to the patient if it will yield further information, verbal consent must be obtained, after an explanation, the patient may decline to have the transvaginal scan. (see transvaginal scanning)"

30. The DHB's protocol "Transvaginal Ultrasound" in place at the time states:

"Often performed post transabdominal ultrasound to offer additional information. Whether to proceed is at the discretion of the examining Sonographer.

…

Before proceeding to a [transvaginal] scan the Sonographer should explain the procedure involved. Verbal consent should be given by the patient.

If the patient declines to proceed to the transvaginal scan this should be recorded on the worksheet."

31. The DHB's "Foetal Demise" protocol in place at the time states:

"**First trimester**

Early pregnancy failure can be considered when

- No live foetus is visible in a gestation sac (mean sac diameter of 2cms or greater)
- There is a visible foetus (CRL greater than 6mm) but no foetal heart movements can be demonstrated. Foetal heart should be observed for at least 30sec.

…

The Sonographer may inform the patient at the time of the scan."

32. Mr C said that he considered the pregnancy was non-viable given his findings from the transabdominal scan, Ms A's "declining" β-hCG levels,[11] and the lack of heartbeat noted in the previous radiology report. Mr C observed that the DHB's policy required sonographers to offer a transvaginal scan only if the images would yield further information. He told HDC that he did not believe at the time that additional information would be obtained through a transvaginal scan.

33. There is nothing on Mr C's worksheet to indicate that a transvaginal scan had not been performed. He stated that sonographers were not required to document this information.

34. Mr C did not consult with a radiologist about his findings. According to Mr C, there is often no radiologist on site, as the DHB employs only one radiologist, who reports on half of the ultrasound cases. The other half is reported on remotely by a private radiology service. Mr C told HDC that a radiologist from the radiology service visits the DHB every fortnight for 1.5 days.

[11] Ms A's levels did not decline, but they did not rise as quickly as expected.

35. Mr C said:

> "To manage the lack of access to radiologists, sonographer's worksheets are sent directly to the wards and specialists as an 'unofficial report'. The clinicians receive two reports, a hand written tick sheet style report from the Sonographer immediately following the appointment with the patient and an official verified report from the Radiologist after a variable period of time. It is tacitly understood that clinicians are not meant to act upon the Sonographer's worksheet but wait for the Radiologist's report or they can contact a Radiologist directly for a verbal report."

36. The DHB told HDC that its expectation is for radiologists to "'instruct, monitor and advise' sonographers as required to ensure clinical standards are maintained … This includes advising sonographers on the images, protocols, positions and procedures necessary for reporting investigations."

37. The DHB said that, while there are times when there is no radiologist on site during normal hours, there is always a radiologist available to review any images and to provide advice for the sonographers.

38. Dr B is the head of the Radiology Department, and has been practising as a radiologist for nearly 30 years. Dr B told HDC that he was on site that day, located physically very close to the ultrasound suite. Dr B said that between 8.30am and 10.30am he was in a multidisciplinary meeting, but the sonographers knew where he was and were able to speak with him if needed. According to Dr B, sonographers regularly step into his office to seek assistance from him. Dr B left the hospital close to 1pm as he works only a half-day on Fridays.

Early Pregnancy Clinic consultation — 5 Month2

39. Ms A, together with her family and a friend, met with obstetrician and gynaecologist Dr D[12] and a midwife following the ultrasound appointment.

40. Dr D had a copy of Mr C's sonographer worksheet at the consultation. Dr D told HDC that ultrasound images are available if requested, but it is not his routine practice to do so, and he did not request them on this occasion.

41. Dr D said that he accepted Mr C's report as accurate, being aware that the study had been performed by an experienced sonographer. The DHB does not have a formal policy around clinicians' reliance on a sonographer's worksheet, but said that it expects all results to be considered within the clinical context, including other results and assessment of the patient, and it would expect the clinician to discuss the case with the radiologist and/or sonographer if he or she had any questions.

42. Dr D provided Ms A with three options: medical evacuation of the uterus using misoprostol, dilation and curettage (D&C), or to wait and see if the early pregnancy tissue would be expelled without intervention. Ms A elected to return to the Early Pregnancy Clinic in five days' time to arrange a D&C if she had not miscarried

[12] Dr D has 20 years' experience in obstetrics and gynaecology.

naturally. Dr D told HDC that it is his usual practice to recommend conservative management in the first instance, with the option to review the decision at any time.

43. Dr D also ordered a β-hCG test for Ms A.

Emergency Department presentation — 7 Month2

44. On 7 Month2, Ms A presented to the Emergency Department with constipation and vaginal discharge. She was seen by Dr E, a consultant in emergency medicine.[13]

45. During his evaluation, Dr E reviewed Ms A's medical records, and noted that Ms A had been diagnosed with a missed miscarriage when she had attended a gynaecology review two days prior. He also noted that Ms A had a further review at the Early Pregnancy Clinic on 10 Month2.

46. Dr E recorded that Ms A had had decreased bowel movements over the preceding three to five days. On examination, he found that Ms A had a soft, non-distended abdomen with bowel sounds present and without rebound tenderness, guarding or rigidity. Based on his examination, he also considered that Ms A was experiencing physiological vaginal discharge.

47. Dr E said that, in light of these findings, he "opted to treat [Ms A] with increased dietary fibre & fluids, increased light aerobic activities, and prescriptions for bulk-forming laxatives,[14] faecal softeners,[15] osmotic agents,[16] & stimulant laxatives[17] to be taken one at a time in a stepwise fashion — not all at once — until effect". Dr E said that he prescribed medications found to be safe in pregnancy.

48. Dr E signed off Ms A's β-hCG test result from 5 Month2. Dr E told HDC that it was Emergency Department policy to sign off outstanding laboratory results, particularly for patients being managed by Emergency Department doctors, but they were also urged by administration to sign off other results during down time, and to action follow-up for those that were abnormal. Ms A's β-hCG was 39,667 IU/L. Dr E noted that Ms A's β-hCG on 25 Month1 was 4,268 IU/L.

49. Dr E said that he neither confirmed nor denied the viability of Ms A's pregnancy in discussions with her, and that he considered that a repeat β-hCG and outpatient review within three days by an obstetrician was safe and appropriate action. Dr E said that, as an additional precaution, he also gave Ms A verbal and printed instructions to ensure that she would attend her upcoming appointment.

50. Dr E discharged Ms A home. The discharge summary includes the following advice:

> "**Advice To Patient**
> 1 Take medications one at a time until effect (resolution of constipation), not all at once; in other words, if one does not work after a day or two, try the next medication

[13] Dr E has been practising emergency medicine for nearly 10 years.
[14] Psyllium powder Metamucil.
[15] Docusate.
[16] Magnesium citrate and Golytely.
[17] Bisacodyl.

2 Return to the EPC this Wednesday at your scheduled appointment
3 Increased oral fluids and light aerobic activity (i.e., walking, swimming, etc.)

Recommendations To Primary Care Provider
1 Ensure outpatient dietary, medication, & activity compliance
2 Ensure outpatient EPC review this Wednesday
3 Monitor for improvement"

Radiology review by Dr B — 8–9 Month2

51. On Monday 8 Month2, Dr B reviewed Mr C's scan from the previous Friday (5 Month2). The scan had not been marked as requiring urgent radiology reporting.

52. Mr C said that a matter is considered urgent if there is an immediate or potential risk to the patient or the baby. He told HDC that urgent matters with regard to pregnancies at the DHB are directed to the obstetrician rather than the radiologist.

53. Dr B's response to HDC indicated that he would have expected the scan to be marked as urgent. He wrote:

> "Unfortunately the exam performed by [Mr C] was not marked as STAT (red) on our [radiology information system] and the Sonographer did not contact me or another Radiologist to make us aware that the case needed urgently reporting."

54. The DHB stated that it does not have a specific guideline around reporting expectations for first trimester viability scans. However, the "First Trimester Obstetric Ultrasound" protocol states: "If abnormal tick the 'Process Urgently[']' box on the patient details page on Comrad, so the Radiologist knows to report ASAP."

55. The DHB told HDC that it considered the reporting of Ms A's examination on the next working day acceptable, given that the sonographer's worksheet had been provided to the obstetrician.

56. Dr B said he saw that there were no transvaginal images, but assumed that it was because Ms A had declined the procedure, which he said was not uncommon. Dr B told HDC that outpatient scans are not stored in the hospital computer system, so he was unaware of the fact that Ms A had undergone a transvaginal scan earlier in the pregnancy. As Mr C was not at work, Dr B was unable to discuss the examination with him.

57. Dr B dictated his report on 8 Month2 and verified the typed report the following day. The report states:

> "Findings:
> There is an intrauterine gestational sac with a mean sac diameter measuring 12mm. No yolk sac. No foetal pole. No heart rate.
>
> Conclusion:
> 10 days since the previous scan and the pregnancy has not developed, so it is most likely consistent with non-viability."

58. Dr B did not record that a transvaginal scan had not been performed. He said that, while his ultrasound report did not document that the study was incomplete or recommend recall, he was conscious of these matters, and that his "plan was to speak with the sonographer as soon as possible and then, taking into account any new information from [Mr C], speak with [Dr D] in person".

59. The DHB's "Foetal Demise" protocol at the time states: "The referrer should be phoned by reporting Radiologist immediately and the follow up care should be established."

9 Month2

60. On 9 Month2, Ms A had a further β-hCG result of 51,479 IU/L. The laboratory faxed a copy of the result to the Early Pregnancy Clinic and sent the results to the electronic information system used at the DHB.[18]

10 Month2

61. On 10 Month2, Ms A attended the Early Pregnancy Clinic. Ms A said that, after agreeing to a D&C, she requested a final ultrasound for her peace of mind. The transvaginal ultrasound showed a viable embryo of 17.6mm (equivalent to a gestation of 8+2 weeks). On the basis of this scan, a D&C was not performed, and Ms A's pregnancy was able to continue.

62. Dr D said that, with his finding that Ms A's β-hCG levels had risen appropriately for an ongoing pregnancy, and Ms A's report that she still felt pregnant, he considered that the repeat scan was appropriate.

63. Ms A said that she was very distressed when she thought that she had lost her pregnancy, and that during the period of 5–10 Month2 she drank alcohol, ate unsafe foods, and took prescribed medications that were potentially harmful to the baby.

64. Dr B said that he spoke to Mr C on the morning of 10 Month2, as this was the first day on which they were both at work following the scan. Dr B said that he reminded Mr C of the DHB's protocols and the need to recommend a transvaginal scan in such circumstances. Dr B said he also told Mr C that he should document the reasons for not proceeding with a transvaginal scan.

65. Dr B told HDC that he then telephoned the Early Pregnancy Clinic and spoke with Dr D directly to discuss the case and his findings. Dr B stated:

> "The reason I called was because no [transvaginal] scan had been performed. [Dr D] told me that he knew that a [transvaginal] scan had not been performed as he had read the Sonographer's worksheet on the Friday and subsequently was planning on repeating the beta HCG and doing a [transvaginal] scan himself."

66. There is no reference to this telephone conversation in Dr B's radiology report or anywhere else in Ms A's clinical records.

[18] The Critical Systems Analysis conducted by the DHB later found that, although the laboratory had sent this information, it was not received by the system.

67. Dr D told HDC that, while he recalls talking to Dr B about the scan in question and early pregnancy scans more generally, he does not recall any discussion occurring prior to Ms A's presentation on 10 Month2. Dr D said that he was of the belief that a miscarriage had been confirmed when he saw Ms A on that date. Dr B acknowledged that the telephone conversation must have occurred after Ms A's consultation with Dr D. Dr B submitted that there was no longer any need to recommend Ms A's recall at that point.

Subsequent events

3 Month5 — Critical Systems Analysis

68. On 3 Month5 the DHB completed a Critical Systems Analysis (CSA), which found that Ms A's care was suboptimal. The review identified the following factors as main issues/concerns:

"
- The sonographer did not perform a [transvaginal] scan
- The sonographer did not follow [Australasian Society for Ultrasound Medicine (ASUM)] or [DHB] guidelines[19]
- The ultrasound worksheet does not provide a prompt to complete a [transvaginal] scan or if not, explain why not
- The radiologist made an assumption that a [transvaginal] scan was not done because the patient had declined
- The obstetrician did not pick up that a [transvaginal] scan had not been done and therefore, the examination was not complete
- A diagnosis was made based on information gained from an incomplete scan
- Peer review is not routinely conducted in the radiology ultrasound department
- Ultrasound images from the early pregnancy clinics and radiology are stored in different places

Incidental findings:

- The β-hCG on 9 [Month2] did not transfer to the [electronic information system] — it appears that systems checks are not in place to identify results that have not been transferred. This has been referred to the information, communication and technology (ICT) department for follow up.

- The ED doctor should either not have signed off the beta-hCG or should have taken action based on the result."

[19] The report refers to "the Australasian Society for Ultrasound Medicine (ASUM) guideline D11 which states that a transvaginal scan should be offered to the patient where 'it is anticipated that this would result in a more diagnostic study' … [and that] 'an experienced operator using high quality transvaginal equipment may diagnose pregnancy failure' where 'no live foetus with a CRL cut off 7mm but no foetal heart movements can be demonstrated'. If there is any doubt, a second opinion or a review scan in one week should be recommended in the report."

69. Following completion of the CSA, the DHB made the following changes:

a) The ultrasound protocols for first trimester pregnancy and intrauterine fetal demise have been updated to include clearer wording that reflects the ASUM D11 guideline. Of note, the "First Trimester Ultrasound" protocol now states: "Transvaginal should be offered to the patient if the Transabdominal is non diagnostic (all images/views below are not demonstrated) — see Transvaginal scan protocol." Under the "yolk sac" category, it states: "Normally seen before a foetal pole is identifiable. Yolk sac should be seen if gestation sac >8mm (<25mm gestational sac — recall in one week with HCG)."

b) The ultrasound worksheet for first trimester ultrasound has been updated to prompt the sonographer to circle whether or not a transvaginal scan has been completed and, if not, to record the reason why not.

c) A reminder was sent to all sonographers and radiologists that radiologists reporting ultrasound scans are responsible for ensuring "that the images obtained are sufficient in quantity and quality to allow for accurate interpretation and reporting of the scan". The reminder also stated that, if the images are insufficient, the radiologist should speak with the sonographer and request a repeat scan.

d) A reminder was sent to all obstetricians that they "should ensure that all obstetric ultrasound scans have been completed according to *ASUM Guideline D11* before acting on the findings, and should request a repeat scan if there is uncertainty about the completeness of the scan".

e) In April 2016, the DHB introduced key performance indicators that include general expectations for reporting. These state:

"Reporting
- All acute exams should be marked as STAT by the [medical radiation technologists] and not assigned to any particular radiologist
- STAT cases will be given priority by reporting radiologists and reported immediately. Where clinically required, the referring clinician will be contacted directly. Also see Critical Results Policy
- Urgent cases should be reported within two hours
- All other cases within 24 hours."

70. Shortly after the incident, Dr B audited 24 cases, which included ascertaining whether transvaginal scans had been completed by Mr C when indicated and whether images had been sent to the radiologist according to the respective protocol. Three cases were first trimester scans, and in all of these a transvaginal technique was used. The DHB told HDC that it intends to arrange a follow-up audit, targeted to the issues raised in Ms A's case.

71. The CSA recommended that the DHB consider the storage of images for point-of-care ultrasound in the Early Pregnancy Clinic. Currently, images are printed and stored in hard copy but an electronic image is not retained. The DHB told HDC that this has been considered at both local and regional levels. It said that there are differences of

opinion as to how/if images should be stored, but it has been agreed that any new equipment purchased must be able to transmit the information electronically into either its PACS or Clinical Portal. The DHB has created terms of reference for a local group to look at the storage of images.

Dr B

72. In his response to HDC, Dr B stated:

> "I would like to apologise to [Ms A] for what happened. It must have been very distressing to be told that her pregnancy was not viable, only to find out a few days later that she was still pregnant."

73. Dr B accepts that it would have been better for him to have documented in his report that a transvaginal scan had not been performed. He said that he has reflected on the need for fuller documentation in future.

74. Dr B does not consider that his supervision of Mr C was inadequate, as he was on site and available when Mr C carried out the ultrasound. Dr B said that the Radiology Department at the DHB is small, and he is the supervising radiologist for all modalities. He therefore relies on medical radiation technologists and sonographers to follow protocols and to discuss with him or a radiology service radiologist any matters that fall outside of the protocol, or any matters they are uncertain about. Dr B said that, at numerous meetings, he has reiterated that "anything significantly abnormal or unusual needs to be discussed immediately with the Radiologist, preferably while the patient is still in the Department".

Mr C

75. In his response to HDC, Mr C apologised to Ms A for the distress she had experienced.

76. Mr C said that when a transabdominal ultrasound is inadequate in demonstrating a viable pregnancy, there are four options available:

1. Additional β-hCG tests over an adequate period of time;
2. A repeat scan in one week or longer;
3. A transvaginal scan; or
4. A referral to a specialist who is able to do a repeat scan (either transabdominal or transvaginal) and determine what further treatment is required.

77. Mr C said that at the time he carried out the transabdominal scan on Ms A, he had limited information and was without access to the images or reports from her previous scan. On reflection, Mr C said that if he had had a copy of the images and earlier ultrasound report, he would have suggested a transvaginal scan or the option of waiting to see the obstetrician, whichever was preferred by Ms A.

78. Mr C stated that not being able to observe a heartbeat is always inconclusive, regardless of how unlikely viability may seem, and it was not his intention to make a definitive diagnosis. He acknowledged that he should have made it clearer in his

report that he was questioning the viability of the pregnancy rather than making a confirmed diagnosis.

79. Mr C told HDC that he has reviewed the ASUM Protocol D11 Guidelines for the performance of first trimester ultrasound, and accepts that he should have offered Ms A the option of a transvaginal scan. Mr C said that, in hindsight, he placed too much emphasis on the three β-hCG results he had accessed on the computer.

80. Mr C said that he has taken the concerns raised very seriously and will adhere strictly to the ASUM D11 protocol going forward. Further, he stated that, if he does not have adequate information at his disposal, he will contact the obstetrician to ensure that additional investigations are carried out, and he will also endeavour to record clearer notes regarding ultrasounds.

81. Mr C said that he has enrolled in ASUM's continuing professional development programme.

Responses to first provisional opinion

82. Mr C, Dr B, Dr D, Dr E, and the DHB were provided with an opportunity to respond to the first provisional opinion.

83. Dr E acknowledged the distress Ms A experienced, and apologised for what happened. Dr E stated that it is his usual practice to discuss abnormal or significant laboratory results with his patients. He told HDC:

> "I regret not discussing the significant increase in [Ms A's] β-hCG with her. Informing [Ms A] of this rising β-hCG would have constituted the ideal management and most appropriate action. I regret that this omission was made in her management and, again, I apologise to her."

84. Mr C acknowledged his contribution to these events, and said that he was "very saddened by the profound distress that these events have caused [Ms A], her husband and family". He accepted the recommendations as set out below.

85. Dr B said that it was reasonable to speak with Mr C before speaking with Dr D. He also submitted a report from a radiologist as part of his response. Relevant aspects of the report are as follows:

> "With respect to the 5 [Month2] scan and the reporting thereof, [Dr B] states that he was aware that no transvaginal scan had been performed and that a further scan was required before a definitive diagnosis could be made. [Dr B] states that he communicated his concerns to the referring clinician ([Dr D]) via a phone call. Assuming this phone call took place then I believe [Dr B] met the required standard of care.
>
> …
>
> [Dr B's] concerns regarding the incomplete nature of the scan was appropriate and he phoned the [referring] obstetrician. It is unfortunate this phone call was not

documented somewhere. This documentation could have been either in the formal report or by documentation of the phone call to [Dr D]."

86. Dr B's response to my provisional decision and the radiologist's report were submitted to Dr Sim for his comments. His further advice is set out in Appendix B.

87. Other comments from Dr B, the DHB, and Dr E have been incorporated into this report, where appropriate. Dr D had no further information to add.

88. Ms A provided a response to the "information gathered" section of the first provisional opinion.

Responses to second provisional opinion

89. Dr B and the DHB were provided with the opportunity to respond to the second provisional opinion and the further advice from Dr Sim.

90. The DHB had no further comments to make.

91. Dr B submitted that Dr D had identified at the Early Pregnancy Clinic that Ms A might still be pregnant, and that no clinical reliance had been placed on his report. He also maintained that it was important to speak with Mr C to ascertain the reason for the lack of transvaginal imaging before contacting Dr D because "there would be little point in further recommending a transvaginal scan where this had already been refused by the patient".

Opinion: Mr C — breach

Assessment

92. Ms A presented to Mr C for a viability scan on 5 Month2. Mr C did not have access to the images from the previous scan, but was aware from the referral that, on 26 Month1, Ms A was approximately 5 + 5 weeks pregnant, had β-hCG levels greater than 4,000 IU/L, and that the ultrasound taken on that date showed a yolk sac but no fetal heartbeat.

93. Mr C accessed further β-hCG results from 20, 23 and 25 Month1, which were 1,068, 2,679 and 4,268 IU/L respectively. He interpreted them as declining.

94. Mr C performed a transabdominal scan on Ms A. From this, he measured a mean sac diameter of 12mm, and found no observable yolk sac, and no fetal pole or heartbeat. He wrote on the sonographer worksheet: "The pregnancy has not developed — non-viable."

95. The ASUM D11 protocol "Guidelines for the Performance of First Trimester Ultrasound"[20] 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 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."

96. The DHB's "Foetal Demise" protocol at the time of events did not mirror the ASUM guidelines. It provides that early pregnancy failure can be considered in the following circumstances:

> "• No live foetus is visible in a gestation sac (mean sac diameter of 2cms or greater)
>
> • There is a visible foetus (CRL greater than 6mm) but no foetal heart movements can be demonstrated. Foetal heart should be observed for at least 30sec."

97. The DHB's protocol "First Trimester Obstetric Ultrasound" at the time states that a transabdominal scan is routinely done first, but a transvaginal scan would always be offered "if it will yield further information".

98. Mr C did not believe that a transvaginal scan would yield further information. He said he considered that the pregnancy was not viable based on the findings from the transabdominal scan he performed, the β-hCG levels, and because the previous radiology report had also stated that no heartbeat was seen. The failure to offer a transvaginal scan was inconsistent with the DHB's "First Trimester Obstetric Ultrasound" protocol, and the finding of non-viability did not match the criteria set out in the DHB's "Foetal Demise" protocol or the ASUM guidelines.

99. My expert advisor, sonographer Jillian Muirhead, advised that Mr C should have performed a transvaginal scan, in accordance with ASUM protocol, when no content in the gestation sac could be identified from the transabdominal scan. Ms Muirhead advised:

[20] The ASUM D11 protocol was updated in May 2015. However, the quoted section on pregnancy failure has not changed from the August 2014 version.

> "[P]regnancy failure can only be confirmed with a transvaginal scan if the gestation sac is greater than 25mm (MSD) and contains no embryo. As this sac was estimated to be only measuring 12mm, it would be necessary to use the [transvaginal] technique to try and identify gestation sac content, eg yolk sac and/or embryo. If no content could be identified then the patient would be scheduled for follow-up scan. This is the protocol that my peers would have followed and is based on the ASUM D11 protocol."

100. Ms Muirhead advised that it was a moderate departure from expected standards not to perform a transvaginal scan in these circumstances.

101. I accept Ms Muirhead's advice. Mr C should have been familiar with the ASUM and DHB protocols and acted in accordance with them. I am critical that Mr C omitted to offer a transvaginal scan to Ms A, which stemmed from the failure to appreciate that the procedure was indicated. In addition, Mr C did not make it clear on his sonographer worksheet that he had performed only a transabdominal scan. Although it was not a requirement under DHB policy to record the lack of a transvaginal scan when it had not been offered, it was clinically significant information and ought to have been documented by Mr C in accordance with his own professional responsibilities. Further, while Mr C stated that he did not intend to definitively diagnose a non-viable pregnancy, his worksheet did not convey any ambiguity, thereby impacting on the care provided by those who used it.

102. For these reasons, I find that Mr C failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Opinion: Dr B — breach

Reporting of ultrasound

103. On 8 Month2, Dr B reviewed the images and corresponding worksheet from the transabdominal scan performed by Mr C on 5 Month2. He dictated his report, and verified it the following day.

104. Dr B's typed report concludes that the findings are most likely consistent with non-viability. It does not state that a transvaginal scan had not been completed, nor does it make any recommendations for further investigation.

105. Dr B said he was aware that Mr C had not performed a transvaginal scan and assumed that it was because Ms A had declined the procedure. Dr B subsequently told HDC that his plan was to obtain further information from Mr C before speaking with Dr D; however, because Mr C did not work on Mondays or Tuesdays, Dr B was not able to hold this conversation any earlier than the morning of 10 Month2. In both Dr B's and Dr D's accounts of events, Ms A had already attended her appointment by the time Dr B called Dr D about the scan.

106. My expert advisor, radiologist Dr Robert Sim, is critical that Dr B omitted to document that the study was incomplete and inconclusive without a transvaginal scan,

or recommend that Ms A be recalled for a transvaginal scan in one week's time. Dr Sim noted that the reason for Mr C's failure to perform a transvaginal scan was not critical to the content of the report, and that there was no need to delay calling Dr D until he had spoken with Mr C.

107. Dr B said that, at the time of the telephone conversation with Dr D, there was no longer any need to recommend Ms A's recall. Dr B also provided a report from a radiologist, who considered that Dr B met the required standard of care by communicating his concerns to Dr D via telephone. The radiologist was, however, critical of the fact that there was no documentation of the telephone call.

108. Dr Sim accepts that a telephone call to Dr D "to record concern is commended as good practice". However, Dr Sim stated:

> "Reliance on a phone call to [Dr D] to convey uncertainty, whilst providing a written report, and no subsequent addendum, which did not record uncertainty, express the limitation of the study or recommend recall is not good practice or reasonable."

109. Dr Sim emphasised the importance of providing an accurate written report in the environment of a DHB hospital, given the potential that someone other than Dr D would be involved in clinical review and intervention.

110. Having considered all of the available information, including the radiologist's report, I accept Dr Sim's advice. As the reporting radiologist, Dr B was responsible for interpreting the images and providing a clear and comprehensive report. While I note that Dr B said he wished first to discuss the scan with Mr C, this should not have prevented him from including in the report the fact that no transvaginal scan had been done, and that further investigation was needed to determine the viability of the pregnancy. The fact that Dr B later spoke with Dr D via telephone did not absolve Dr B of the need to document this information, especially given the delay between his observation and the conversation with Dr D. In relation to Dr B's submission that there had been no clinical reliance on his report, I note Dr D's statement that he was of the belief that a miscarriage had been confirmed when he saw Ms A at the Early Pregnancy Clinic on 10 Month2.

111. In my view, Dr B's reporting fell short of reasonable care and skill, and I therefore find that he breached Right 4(1) of the Code.

Supervision

112. The DHB expects its radiologists to instruct, monitor, and advise sonographers as required to ensure that clinical standards are maintained. Dr B is an experienced radiologist and the head of the DHB's Radiology Department. Dr B said that he relies on medical radiation technologists and sonographers to follow protocols, and that he has instructed sonographers to speak to him or a radiology service radiologist about issues that fall outside protocol, or if there are any other uncertainties.

113. Dr B was on site, located close by, when Mr C performed the ultrasound on Ms A. I consider it reasonable that Dr B would rely on Mr C to contact him if he wanted advice.

114. Dr B stated that he met with Mr C on 10 Month2, as soon as Mr C had returned to work, and they discussed the examination. Dr B said that, in this meeting, he reminded Mr C of the DHB's protocols and that Mr C must recommend a transvaginal scan and document the reasons when the procedure is not carried out. Subsequently, the DHB initiated a CSA review of Ms A's care and reviewed Mr C's performance in relation to its Code of Conduct. In my view, the actions taken were an appropriate response to the incident.

Opinion: Dr D — other comment

Provision of information and clinical decision-making on 5 Month2

115. Dr D accepted Mr C's worksheet as accurate, and acted on the findings on that worksheet prior to receiving the radiologist's report. Dr D said that his decisions were influenced by his knowledge of Mr C's level of experience.

116. My expert advisor, obstetrician Dr David Bailey, advised that he considered it was reasonable for Dr D to have based his recommendations and management on Mr C's ultrasound report. Dr Bailey advised that, as the scan showed little change in size of the gestational sac and none of the other features associated with normal embryonic development, the appropriate conclusion would be early fetal demise and a non-viable pregnancy.

117. I agree that it was reasonable that Dr D, being aware that Mr C had over 30 years' experience, had confidence in the accuracy of Mr C's findings. However, given the consequences that can stem from an incorrect result, I consider that it would be prudent practice, in future, for obstetricians to either wait for verification of the sonographer's findings by the radiologist or to review the images before offering immediate medical intervention.

Opinion: Dr E — adverse comment

Information provided to Ms A

118. Dr E signed off on Ms A's β-hCG results when she attended the Emergency Department on 7 Month2, but did not advise her of the significant increase in her β-hCG level.

119. Dr E told HDC that he signed off the result because it was Emergency Department policy to sign off outstanding laboratory results, particularly for patients being managed by Emergency Department doctors, and he considered that a repeat β-hCG and outpatient review within three days by an obstetrician and gynaecologist was safe and appropriate action. Dr E said that he gave Ms A verbal and printed instructions to ensure that she would attend her upcoming appointment. However, Dr E acknowledged that he ought to have informed Ms A of the significant increase in β-hCG after signing off on the result, and I agree that this would have been appropriate.

Opinion: DHB — adverse comment

Services provided to Ms A

120. The mistakes of clinical staff at the DHB led Ms A to believe that her pregnancy was not viable. As stated above, Mr C erred in his conclusion that Ms A's pregnancy had failed. He ought to have known that a transvaginal scan was indicated, and offered this procedure to Ms A. Dr B subsequently failed to report that the study was incomplete and inconclusive, and did not make a recommendation for a transvaginal scan to be performed.

Policies and procedures

121. The DHB policies and procedures relevant to Ms A's care were authorised in October 2012 and were due to be reviewed in October 2013. However, in 2015, at the time of these events, this had not occurred.

122. Dr Sim considered that the protocols/procedures were deficient in many areas. Most notably, they required the incorporation of the ASUM D11 guideline. However, Ms Muirhead advised that, in her view, the policies for first trimester obstetric ultrasound and fetal demise covered all the areas contained in the ASUM D11 guideline, but measurements were not taken from the most current version.

123. The DHB's protocols/procedures lacked clarity in that the transvaginal ultrasound protocol required sonographers to document on their worksheet if a patient declined to proceed with a transvaginal scan, but there was no requirement to record when a transvaginal scan was not completed for any other reason. In addition, there was no dedicated space on the worksheet to record this information.

124. Dr Sim also advised that "[t]he provision of any report on an [ultrasound] examination by a sonographer to clinicians must be very clearly identified as a provisional report, pending review and issuing of a final report by a radiologist". The DHB worksheet does not contain a similar message.

125. Since these events, the DHB has updated its "First Trimester Obstetric Ultrasound" protocol to include stronger wording, and has amended its sonographer worksheet for first trimester ultrasounds to include a requirement to indicate whether a transvaginal scan has been completed and, if not, the reason why not. The current protocol states: "Transvaginal should be offered to the patient if the Transabdominal is non diagnostic (all images/views below are not demonstrated) — see Transvaginal scan protocol." It also provides that the woman should be recalled in one week's time with a repeat β-hCG if the yolk sac is not visualised in a gestational sac with a mean sac diameter smaller than 25mm. The "Foetal Demise" protocol now mirrors the criteria used in the updated ASUM guidelines for diagnosing early pregnancy failure.

126. I am critical of the DHB for having outdated policies and procedures. Nevertheless, both Dr Sim and Ms Muirhead agree that the sonographers and radiologists should be aware of the ASUM guidelines and not reliant on the DHB's protocols/procedures in this regard, and I endorse this advice.

Grading for radiology reporting

127. Mr C's findings of Friday 5 Month2 were reported by Dr B on the next working day (Monday 8 Month2) and verified by Dr B on 9 Month2.

128. The examination performed by Mr C was not marked urgent on the radiology information system. He said that he did not consider the matter urgent, as there was no immediate or potential risk to the patient or the baby. However, Dr B's response to HDC indicated that he would have expected the scan to have been marked as requiring urgent reporting.

129. The DHB told HDC that it does not have a specific guideline around reporting expectations for first trimester viability scans, and it considers it appropriate that Ms A's scan was reviewed by Dr B on the first working day after it was taken. Notwithstanding this, I note that the DHB's "First Trimester Obstetric Ultrasound" protocol states: "[I]f abnormal, tick the 'process urgently['] box … so the Radiologist knows to report ASAP." Given Mr C's and Dr B's differing views on this matter, I consider it would be desirable for the DHB to provide its staff with some clarification on whether viability scans require urgent reporting.

Communication between sonographer and radiologist

130. Although the transabdominal scan was performed on 5 Month2, there was no direct communication between Mr C and Dr B until 10 Month2, other than through the sonographer worksheet. In light of the questions that arose from the scan, this is a concerning delay.

131. Safe and seamless ultrasound service requires effective communication between sonographers and radiologists. Dr Sim stated:

> "Dialogue between radiologist and sonographer needs to be straightforward. Regular conversation and phone calls should be usual to alert one another of significant findings. Unsupervised sonographers place patients at risk. The use of appropriate worksheets is good practice. Ultrasound scans are most commonly reported on the basis of the radiologist reviewing the images from the study, the referral form and associated data from the clinician and the sonographer worksheet. Uncertainty and ambiguity requires clarification and dialogue."

132. Had Mr C consulted with Dr B on 5 Month2, he might have been alerted to the non-diagnostic nature of the scan and the appropriateness of offering Ms A a transvaginal examination. This level of communication is particularly important where formal reporting is unable to occur prior to the patient's appointment with the Early Pregnancy Clinic.

133. Mr C told HDC that he would have contacted the obstetrician immediately if an urgent matter had arisen from Ms A's scan. It is of concern that there does not appear to be a practice of speaking with the radiologist regarding significant findings.

Point-of-care images

134. Point-of-care images at the DHB are currently printed and stored in hard copy, but an electronic image is not retained. Both Dr Sim and Ms Muirhead advised that this is

common throughout New Zealand. Dr Sim said: "It is rare for point of care images to be archived to hospital PACS networks, and rare for image correlation and multidisciplinary review to occur."

135. Ms Muirhead advised:

> "One of [the] recommendations I make to doctors completing the Post Graduate Certificate in Clinician Performed Ultrasound is that all ultrasound imaging performed, where clinical decisions are being made from that imaging, should be stored on a PACS system accessible by all staff members involved in the care of that patient. With the growing use of ultrasound imaging outside of Radiology Departments this has become an issue and should be recommended to all hospitals."

136. The documents provided show that the DHB is considering this, and also show that Radiology Department protocols for ultrasound of early pregnancy are being addressed and updated.

137. I support the steps that the DHB is taking towards the development of systems to implement electronic storage and transmission of point-of-care images.

Recommendations

138. I recommend that Mr C:

a) Arrange an audit of his first trimester viability scans and accompanying worksheets in the last three months, to be conducted by an independent sonographer. The results of this review should be sent to HDC within three months of the date of this report.

b) Report back to HDC on his learnings from ASUM's continuing professional development programme.

c) Provide a formal written apology to Ms A. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

139. I recommend that the Medical Radiation Technologists Board consider whether a review of Mr C's competence is warranted.

140. I recommend that Dr B:

a) Arrange an audit of his reporting of first trimester viability scans in the last three months, to be conducted by an independent radiologist. The results of this review should be sent to HDC within three months of the date of this report.

b) Provide a formal written apology to Ms A. The apology should be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

141. I recommend that the DHB:

a) Use this case as an anonymised case study for clinical staff, to highlight, amongst other things, the importance of clear communication between sonographers and radiologists, and report back to HDC on this within three months of the date of this report.

b) Update the sonographer worksheet to identify that it is a provisional report, pending review and issuing of a final report by a radiologist. The updated worksheet should be provided to HDC within three months of the date of this report.

c) Broaden the scope of the "Clinical images and photography" project regarding the storage of information to include consideration of transmitting ultrasound images to PACS or the Clinical Portal, with specific reference to this case.

d) Develop a specific guideline to clarify whether first trimester viability scans should be reported on urgently.

142. I recommend that the Health Quality & Safety Commission consider the issues raised in this report.

Follow-up actions

143. 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 Radiation Technologists Board, and it will be advised of Mr C's name.

144. 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, and it will be advised of Dr B's name.

145. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal Australian and New Zealand College of Radiologists, the Australasian Society for Ultrasound in Medicine, and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent sonography advice to the Commissioner

The following expert advice was obtained from sonographer Jillian Muirhead on 16 February 2016:

"My name is Jill Muirhead (Jillian Claire Muirhead). My qualifications are Diploma of Medical Ultrasound, Australasian Society of Ultrasound in Medicine (ASUM) 1982, American Registry of Diagnostic Medical Sonographers 1981. As well as being a clinical sonographer, I also teach for the University of Otago as a clinical lecturer in Clinician Performed Ultrasound.

I have read and agree to follow the guidelines for the Independent Advisors. Issues requiring review and opinion:

1. [Mr C's] failure to complete a transvaginal scan, following a transabdominal ultrasound, which showed a 12 mm sac and no heartbeat.

2. Do you consider that a transvaginal scan should have been completed in these circumstances?

3. Any further comments.

Report:

The standard of care and accepted practice is based on the clinical protocols from the Australasian Society of Ultrasound in Medicine. The Protocol D11, Guidelines for the Performance of First Trimester Ultrasound (latest revision [Month1]), provides criteria for the diagnosis of pregnancy failure and states:

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

When the mean sac diameter (MSD) is >25mm with no visible fetal pole.

When there is a visible 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 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.' www.asum.com.au Clinical Protocols D11.

With review of the timeline and the diagnosis of an intrauterine gestation sac, with an embryo measuring appropriate for 5 weeks and 5 days ([Ms A] was 5 weeks and 4 days from her LMP) on 26 [Month1], then at the time of the scan by [Mr C] in the Radiology Department, on 5 [Month2], [Ms A] would have been 7 weeks 1 day (from the measurement dates on 26 [Month1]). By the third scan by [Dr D],

performed on 10 [Month2], [Ms A] was 7 weeks and 6 days going by the first scan estimate of dates and there was a viable embryo of 17.6mm present, equivalent to 8 weeks and 2 days.

With hindsight, clearly there has been a mistake made during the scan by [Mr C], as he did not identify a 7 week embryo within the gestation sac, and the criteria set out by ASUM have not been adhered to. This may reflect the ultrasound protocols set down in the Radiology Department at that time.

It is not always necessary to perform a transvaginal (TV) scan in the first trimester, if viability is shown with the transabdominal scan. Depending on the position of the uterus, sometimes the transabdominal scan will display the uterus and uterine contents better than the transvaginal approach, particularly if the uterus is in an axial position, so each patient must be assessed independently, and decisions made on the most appropriate technique.

However, a patient who has previously been assessed with the transvaginal technique should be assessed with the transvaginal technique again, when trying to assess viability, if the pregnancy cannot be adequately seen showing viability using the transabdominal technique.

If [Mr C] was relying just on Radiology department scans, it is likely he would have had the patient return to assess growth of the gestation sac at a later date, as with a gestation sac measurement of 12mm, viability assessment cannot be made. However he was relying on information from a scan performed in another department, of which he had no access to the images.

My thoughts on this incident are that a transvaginal scan should have been performed after the transabdominal scan, in accordance with ASUM protocol, when no content in the gestation sac could be identified. The reason here is that pregnancy failure can only be confirmed with a transvaginal scan if the gestation sac is greater than 25mm (MSD) and contains no embryo. As this sac was estimated to be only measuring 12mm, it would be necessary to use the TV technique to try and identify gestation sac content, eg yolk sac and/or embryo. If no content could be identified, then the patient would be scheduled for follow-up scan. This is the protocol that my peers would have followed and is based on the ASUM D11 protocol.

Often BHCG results are not available to sonographers and so decisions are made independent of these.

Further Comments:

It appears that [Mr C] was basing his assessment on data from a previous scan of which he had no access to the images.

There are always difficulties when a patient is being scanned in more than one facility and the images are not available to the person performing the follow-up scan. One of the recommendations I make to doctors completing the Post Graduate Certificate in Clinician Performed Ultrasound is that all ultrasound imaging performed, where clinical decisions are being made from that imaging, should be

stored on a PACS system accessible by all staff members involved in the care of that patient. With the growing use of ultrasound imaging outside of Radiology Departments this has become an issue and should be recommended to all hospitals. The documents provided show that [the DHB] is considering this and also show that Radiology Department protocols for ultrasound of early pregnancy are being addressed and updated.

Additional comments:

I think that it was a moderate departure from expected practice to not perform a transvaginal scan, after the sonographer could not identify a viable 7 week pregnancy with the transabdominal scan. At the least he should have had the patient return for a follow-up scan a week later to identify growth or failure of growth of the gestation sac. The sonographer could not have diagnosed a non viable pregnancy in this case, going by the size of the gestation sac, as it was under the threshold of size to call non viable, when relying purely on this scan. I am sure his practice was modified from his normal because he was relying on a report of a scan to which he had no access to the images, and from clinical information that the Beta HCG was rising slower than expected. However that is something that happens frequently now, with more ultrasound being performed by clinicians and so the sonographer needs to adapt to that. I'm sure the sonographer realises he made a mistake, however he didn't acknowledge that in his letter.

And we all do make mistakes, and learn from them. Hopefully this is the case."

The following additional advice was provided by Ms Muirhead on 3 October 2016:

"As previously stated, I have no personal or professional conflict in this case.

I have reviewed the information received since my earlier report and would like to add some further comments.

1. The adequacy of the relevant policies in place at [the DHB] at the time of the events complained of.

The policies for 1st trimester ultrasound and fetal demise, in place at the time of the complaint appear to contain all the areas covered in the current Australasian Society of Ultrasound in Medicine (ASUM) policy for first trimester ultrasound and fetal demise, although it was not the most current version, with CRL length quoted as 6mm and the latest version quotes 2mm. This latest version is dated May 2015 on the MUM Website. The policy did include the statement that 'a transvaginal transducer would always be offered to the patient if it will yield further information'.

2. The adequacy of the relevant policies and procedures currently in place at [the DHB], including any further changes that you consider may be appropriate.

Policies in place at [the DHB] are totally adequate. The policy for early pregnancy demise is that of ASUM 2015 and so is the relevant policy.

… Any matters in this case that you consider warrant comment.

It is still my very strong opinion that CPU images have to be made available to the sonographer/radiologist, if follow-up scanning is being performed in the Radiology department.

Being a sonographer who works without a radiologist on site, I am very used to this situation where you are making a decision without direct contact with the radiologist and I feel that all sonographers should treat every case in this way, being sure they have not left any doubt or questions unanswered before letting the patient go. The sonographer is not just the image taker, but is the diagnostician in these cases, and so I would disagree with leaving any decision on the patient care to the radiologist, unless they have been in contact with the patient at the time of the scan. My colleagues are also of this view.

4. Any further recommendations for improvement that may help prevent a similar occurrence in the future.

The occurrence of this case itself and the subsequent investigation are guarantees that this will not happen again with this sonographer, as the learning from a mistake is always the most complete learning. Not one of us ever wants to make mistakes and I am certain this is the case with someone of the experience of [Mr C]. Also department practices have been reviewed and improved to insure support for the sonographers.

In response to my previous report, [Mr C] has agreed that he made a mistake and did not follow the ASUM protocol and the [DHB's] protocol for the establishment of early pregnancy viability and pregnancy failure. This was a moderate departure from expected practice, but I do think it was influenced by the fact the patient had had a CPU scan, but there was unavailability of images and report from that scan. [Mr C] didn't feel there was a need to proceed to a TV scan, because he felt he was getting adequate visualization, however with a subsequent scan showing a viable 9 week embryo, there must have been a viable 7 week embryo present at the time of the scan per by [Mr C], which had not been identified. This will change [Mr C's] practice and going forward he is committed to ensuring that he meets the expected standards of practice in the future.

As the [DHB's] policy for [first trimester obstetric ultrasound] stated that the case should be marked as urgent [if abnormal], then probably one of the biggest mistakes made was to not mark the study as urgent. This resulted in delayed reporting and all the pressure going on [Mr C], as the decisions were made from his worksheet reporting. This is not the standard of practice expected in [the DHB]. Had this study been dealt with as an urgent case, the recommendation may have been made to investigate further with TV scan and BHCG evaluation.

…"

Appendix B: Independent radiology advice to the Commissioner

The following expert advice was obtained from radiologist Dr Robert Sim on 7 February 2016:

"I have received your letter of 8 January 2016 seeking my opinion on the care provided to [Ms A] by [Dr B] (Radiologist) and [Mr C] (Sonographer).

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).

You have asked that I review the documents and provide an opinion on the following issues:

1. Was [Dr B's] assumption that [Ms A] did not want a transvaginal scan reasonable?
2. Please comment on the action taken by [Dr B] when he noticed a transvaginal scan had not been performed. What steps do you believe should have been taken when he realised this?
3. Any comment you may have on the referral systems between the 'medical imagist' and the radiologist.
4. Any further comments you wish to make.

For each question you have asked that I 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 I consider it is?

c) How would it be viewed by my peers?

In your letter you have summarised the background to the complaint and outlined [Ms A's] ultrasound scan and associated early obstetric care on 26 [Month1], 5 [Month2] and 10 [Month2] at the public hospital.

Documentation provided:

1. Letter of Complaint from [Ms A].
2. Response and clinical notes from [the DHB].
3. Critical Systems Analysis from [the DHB].
4. Response from [Dr B] dated 9 [Month5].

5. Paper hard copy images from Early Pregnancy Clinic ultrasound scans performed by [the consultant obstetrician] using transvaginal technique on 25 [Month1] and by [Dr D] using transvaginal technique on 10 [Month2].

6. Images from [the DHB] PACS for ultrasound scan 5 [Month2] performed by [Mr C] using transabdominal technique.

Review of clinical notes from the public hospital:

Point of care ultrasound (US) provided by [the consultant obstetrician] using transvaginal ultrasound (TVUS) on the second Early Pregnancy Clinic visit 26 [Month1] was appropriate and correlated with her serum beta HCG results. The four TVUS images archived confirm an intrauterine pregnancy; with mean sac diameter 9mm, with a yolk sac and fetal pole crown rump length (CRL) recorded as 2.7mm. These findings are appropriate for gestational age of 5 weeks 6 days (plus or minus 5 days). A work sheet records this as a '*mobile scanner*' examination, in which a fetal heart beat was '*no(t) clearly visible*' and with a circled diagnosis of '*Intrauterine pregnancy of uncertain viability*'.

Obstetric management was described as 'conservative' with further US scan requested on a Radiology Department referral form with all appropriate clinical details provided. Appointment was scheduled for 1030 on 5 [Month2].

Radiology Department US scan was conducted by [Mr C] on Friday 5 [Month2]. Based on the previous scan gestational age would be calculated as 7 weeks 2 days.

Images acquired over about 6 minutes confirm transabdominal images were obtained using a 5MHz transducer. The use of both zoom function and focusing were not optimal. No transvaginal images were archived.

A first trimester US worksheet has been completed and initialed MR.

Appropriately rising serum beta HCG levels were transcribed from 20 [Month1] (1068 IU/L), 23 [Month1] (2679 IU/L) and 25 [Month1] (4268 IU/L), but none are available from the interval between the first and second scan. Further serum HCG results of 5 [Month2] of 39667 IU/L (reported on 5 [Month2] at 13; 16 after the US scan, but before radiologist reporting), and 9 [Month2] of 51479 IU/L.

The worksheet does not state whether this US was performed transabdominally or transvaginally. It records the mean sac diameter as 12mm. No measurement of a fetal CRL is recorded. Two oblique pen strokes adjacent tick boxes for yolk sac and fetal pole are open to equivocal interpretation. One oblique stroke in the tick box for an intrauterine gestational sac is unequivocal. The comment states: '*It is 10 days since the previous scan (early pregnancy clinic). The pregnancy has not developed — non viable.*' [Mr C] records scan quality as '*fair*'.

The Critical Systems Analysis of [the DHB] states that a transvaginal scan was not offered, and also records that the sonographer stated that he told the patient that he could not see a heartbeat and that he could not prove that the pregnancy was viable.

[Mr C's] worksheet was provided as the only report available to [Dr D] at the Early Pregnancy Clinic on 5 [Month2]. [Dr D] concluded [Ms A] had an anembryonic pregnancy or missed miscarriage as recorded in his dictated letter.

A report was dictated by [Dr B] on Monday 8 [Month2] (three days following the examination) and verified on 9 [Month2]. This report, in common with the US worksheet from [Mr C], does not record whether transabdominal or transvaginal scan was performed. It records a mean gestational sac diameter of 12mm with no yolk sac or fetal pole and '*no heart rate*'. The conclusion states, '*10 days since the previous scan and the pregnancy has not developed, so it is most likely consistent with non-viability.*'

Point of care US provided by [Dr D] using TVUS in the Early Pregnancy Clinic visit of 10 [Month2] confirmed a live intrauterine pregnancy. The single archived image and worksheet record a fetal CRL of 17.6mm with cardiac activity present and with a diagnosis of '*viable intrauterine pregnancy*'. Gestational age based on fetal CRL is 8 weeks 2 days (plus or minus 5 days) which correlates with the initial scan of 26 [Month1].

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[21] 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:*

When the mean sac diameter (MSD) is >25mm with no visible fetal pole.

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.'

[21] The ASUM D11 guideline was also updated in May 2015. However, the quoted the quoted section has the same wording as that of August 2014.

… Diagnosis of missed miscarriage is based on no fetus being visible in a gestational sac of mean diameter 25mm or greater ([Mr C] measured a mean sac diameter of 12mm by transabdominal technique). Similarly it requires a fetal pole to have CRL of 7mm with no visible heartbeat to confirm failure. It is also noted that sac growth is 1mm/day from 5.5 weeks to 8 weeks. (It is noted that based on the earlier scan of 26 [Month1] the sac diameter might be expected to be 19–25mm and CRL 11mm at the date of [Mr C's] scan).

The protocol 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.'

Issues:

1. Was [Dr B's] assumption that [Ms A] did not want a transvaginal scan reasonable?

There is no written record of what [Dr B], the reporting radiologist thought in the report, and indeed he failed to document in the report whether a transvaginal scan was performed. The reporting radiologist was clearly unaware or ignored the guidelines provided by ASUM D11. It is not known what [the DHB's] protocol for first trimester recommended, but it does seem to breach Radiology Department policy based on subsequent letter.

The written response from [Dr B] is dated 9 [Month5]. In this he notes that he observed a TVUS had not been performed when he reviewed the images from [Mr C's] examination. He observes that there is no reason recorded on [Mr C's] worksheet for this omission, and '*made an assumption that a transvaginal scan was not performed because the patient declined it.*' Based on [Ms A's] prior experience with transvaginal scan at her Early Pregnancy Clinic this assumption is clearly not reasonable. She had not declined TVUS at the prior visit.

[Dr B] also notes it was departmental policy '*that a transvaginal scan be routinely performed in every first trimester pregnancy if the transabdominal scan does not give enough information*'.

2. Please comment on the action taken by [Dr B] when he noticed a transvaginal scan had not been performed. What steps do you believe should have been taken when he realised this?

Supervision of Sonographers and other Medical Radiation Technologists in the conduct and performance of examinations is a basic and required role of the radiologist. It is not known if [Dr B] was the supervising radiologist on 5 [Month2] for [Mr C]. If so, he has failed to supervise appropriately. Certainly as

the subsequent reporting radiologist he omitted to document that the study was incomplete and inconclusive without TVUS. His written conclusion was wrong.

A reasonable and best course of action should have been to phone the obstetrician and/or Early Pregnancy Clinic to voice his concern regarding the inadequate and incomplete scan from [Mr C] and most importantly insist that [Ms A] be recalled for TVUS. This should have been documented in the report he wrote. He did not recommend a review scan in one week.

[Dr B] should also have talked with [Mr C], and discussed the inexplicable omission of TVUS in [Mr C's] scan with him.

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

[Dr B's] departure from the standard of care expected is significant on both these points, 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.

3. Any comment you may have on the referral systems between the 'medical imagist' and the radiologist.

The 'medical imagist' is assumed to be the Radiology Department sonographer. Dialogue between radiologist and sonographer needs to be straightforward. Regular conversation and phone calls should be usual to alert one another of significant findings. Unsupervised sonographers place patients at risk. The use of appropriate worksheets is good practice. Ultrasound scans are most commonly reported on the basis of the radiologist reviewing the images from the study, the referral form and associated data from the clinician and the sonographer worksheet. Uncertainty and ambiguity requires clarification and dialogue.

Issuing of timely reports is referenced in the Section 88 notice for obstetric ultrasound. Urgent written reports (which can be phoned) should be generated by the supervising radiologist where appropriate, and in response to a sonographer expressed concern. This can include scans recording pregnancy failure, particularly when unexpected.

In this instance the worksheet from [Mr C] is deficient in not recording that TVUS was not performed.

There is no record that [Mr C] indicated in any way to a supervising radiologist that an urgent report be provided for pregnancy failure. There was a four day delay in issuing a verified formal written report.

There is clearly failure of adequate and sufficient communication between [Mr C] and [Dr B], which again constitutes a significant departure from expected standards of practice and in this context would be viewed as a moderate to severe departure.

4. Any further comments you wish to make.

…

The evolution of point of care ultrasound poses an increasing dilemma for radiologists. Clinicians, usually less experienced than radiologists, perform point of care studies. It is rare for point of care images to be archived to hospital PACS networks, and rare for image correlation and multidisciplinary review to occur.

It is more usual for error to occur in examinations conducted by point of care US practitioners than by more fully trained sonographers working with radiologist supervision. Indeed point of care clinicians frequently seek formal verification of their findings from more experienced sonographers and radiologists.

As noted in the Critical Systems Analysis Report:

First trimester ultrasound protocols should be reviewed.

Point of care ultrasound image archiving should be considered.

Radiology peer review and audit meetings are required.

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

In addition:

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

Both radiologist and sonographer education updates may be required.

Review of radiologist and sonographer CPD applicable to obstetric ultrasound is suggested.

Increasing subspecialisation may require consideration and review of individual scopes of both radiologist and sonographer practice.

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 by [Mr C] and studies have been reported by [Dr B]. This may require a formal retrospective audit.

Summary

There has been a very significant moderate to severe departure from standards of accepted practice by [Dr B] … in the conduct and reporting of early pregnancy ultrasound.

The issues are fundamental and critical to the safety of the fetus in early pregnancy. This case is a prime example of the reason for the ASUM Dll pregnancy failure guideline being incorporated in radiological protocols and guidelines in New Zealand.

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, with potential

interruption of a wanted pregnancy as a consequence of the omission of TVUS was a severe departure from expected standards of practice.

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 [Month4]"

Dr Sim provided the following additional advice on 14 October 2016:

"Thank you for your letter of 23 September 2016 seeking further advice.

You have provided further documents and asked whether review of these causes me to add to or amend my previous advice provided 7 February 2016.

You have asked that I limit my advice to the care provided by [Dr B].

Documents provided:

1. [The DHB's] response dated 1 April 2016 with attachments.

2. [Dr B's] response dated 23 March 2016 with attachments.

3. [Mr C's] response dated 22 March 2016.

4. [The DHB's] response dated 31 [Month4] including statement from [Dr D], index and extracts from Radiology Department Specific Procedure document and information about the shift rosters of [Dr B] and [Mr C].

5. Statement from [Ms F], friend of [Ms A].

You have also noted that [Dr B] and [Dr D] have provided differing accounts about whether or not they discussed [Ms A's] case prior to [Dr D's] review on 10 [Month2].

You have asked that I comment on:

1. The reasonableness of the care provided by [Dr B] if:

a. [Dr B] discussed [Ms A's] case and the absence of a transvaginal scan with [Dr D] prior to [Dr D's] consultation with [Ms A] on 10 [Month2] (as described by [Dr B]); or

b. [Dr B] did not discuss [Ms A's] scan prior to [Dr D's] consultation with [Ms A] on 10 [Month2] (as discussed by [Dr D]).

2. The adequacy of the relevant policies and procedures in place at [the DHB] at the time of the events complained of, including but not limited to, whether they adequately incorporated the relevant clinical protocols from the Australasian Society of Ultrasound in Medicine.

3. The adequacy of the relevant policies and procedures currently in place at [the DHB], including any further changes that you consider may be appropriate.

4. Any other matters in this case that you consider warrant comment.

New information:

[The DHB] has provided and commented on the First Trimester Obstetric Ultrasound protocol, indicating it has been updated to include stronger wording.

[The DHB] has confirmed [Dr B] was the supervising radiologist on 5 [Month2].

[The DHB] [has] confirmed that [Dr B], as supervisor (and subsequent reporting radiologist) and [Mr C], as sonographer, were both in the hospital at the time the US scan was conducted.

[The DHB] agree[s] that [Mr C's] worksheet caused the obstetrician to be misled.

[The DHB] agree[s] that VB should have been offered a transvaginal ultrasound by [Mr C].

[The DHB] [does] not agree that subspecialisation is appropriate for a DHB [of this size] stating: '*we require generalist skills with access to specialist advice when required. We currently have this via our contractor service with [the radiology service]*.'

[The DHB] has provided an undated statement: [the DHB's] expectation — supervision of Sonographers by radiologists.

Statement from [Dr D] dated 2 March 2016 describes working in the Early Pregnancy Assessment Unit on 5 [Month2] and his receipt of '*a scan report describing a failed pregnancy, this report was accepted as accurate, having been performed by an experienced sonographer*'.

[Dr D] relates [Ms A's] return to the clinic, '*when no spontaneous miscarriage had ensued, requesting surgical intervention. VB did however report still feeling pregnant and her Beta-HCG was noted to have risen appropriately for an ongoing pregnancy. She did ask that the scan be repeated and this was done with the finding of an ongoing pregnancy. The immediate impetus for the scan was VB's request, but with her report of ongoing symptoms and a rising Beta-HCG a repeat scan was the appropriate action at that time. I like to think a scan would have been offered without her request.*'

[Dr B] has written with further explanation on 23 March 2016, and partly in response to my previous opinion made available through the HDC process:

He confirms he was on site and '*available to supervise the sonographers*' on the morning of 5 [Month2]. He is commonly the only radiologist on site.

He states that: '*Unfortunately the examination performed by [Mr C] was not marked as STAT (red) on our RIS, and the sonographer did not contact me or another radiologist to make us aware that the case needed urgent reporting.*'

The scan was reportedly not brought to his attention until Monday, 8 [Month2].

[Dr B] also confirms [Mr C] was not available to speak with until Wednesday, 10 [Month2].

[Dr B] also states:

'*On Monday and Tuesday my assumption was that [Ms A] had declined a TV scan, which is not at all uncommon. [Mr C] was not available for me to check this.*

I was however conscious of the diagnostic limitations of a TV scan not having been performed and so, upon verifying my report, I called the Early Pregnancy Clinic and spoke with [Dr D] directly to discuss the case and findings. The reason I called was because no TV scan had been performed. [Dr D] told me he knew a TV scan had not been performed as he had read the sonographer's worksheet on the Friday and subsequently was planning on repeating the beta HCG and doing a TV scan himself.

Whilst I recognised the importance of the fact that [Ms A] had not had a TV scan and I communicated this to the O&G consultant caring for her, I accept that, with hindsight, I could also have documented as part of my reporting that no TV scan had been undertaken and that I had assumed that this was due to a lack of consent. However, I do not believe that my report exacerbated any confusion as I spoke with [Dr D] directly on the day my report was verified.'

He also states: '*Had I reported this scan at a time when [Mr C] was at the hospital, I would have asked him about the lack of a TV scan before finalising my report. Unfortunately he was not available and so I made the assumption (that [Ms A] did not want a TV scan) coupled with the precaution of telephoning [Dr D].*'

He also writes: '*I did speak with [Mr C] as soon as he returned to work. I met with [Mr C] on Wednesday 10 [Month2] regarding this matter, and we discussed for over 30 minutes the examination. [Mr C] stated that he did not feel a TV scan needed to be performed. I reminded him of our protocols and made it clear that in such circumstance he must offer and recommend a TV scan, and if one is not performed, document the reasons why.*'

[Dr B] reiterates a number of times that he was the supervising radiologist. His stated view was that the sonographer, '*[Mr C] chose not to discuss with me his decision, contrary to protocols chose not to offer and recommend a TV scan, and chose not to discuss the case with me. At a systems level, it was also unfortunate that [Mr C] did not request urgent reporting …*'

[Dr B] also states: '*I do not think Dr Sim's conclusion that the O&G team were "mislead by the formal incorrect radiology report" verified by me is justifiable.*' He acknowledges it was incomplete by not referencing a TV scan.

In correspondence from [Mr C] to the HDC reference is made to work related exigencies at [the DHB]. He states 'There is only one radiologist employed by [the DHB].' [Mr C] describes sonographers' worksheets being sent to wards and specialists as '*unofficial reports*' due to a reported '*lack of access to radiologists*'. The final verified report from the radiologist arrives after a variable length of time.

[Mr C] also states that at [the DHB] any urgent matters with regard to pregnancies are directed to the obstetrician not a radiologist. He did not consider [Ms A's] case in regard to the viability of her pregnancy as urgent.

Opinion:

Does review of these cause me to add to or amend my previous advice provided 7 February 2016?

The advice I have provided previously remains unchanged.

1. The reasonableness of the care provided by [Dr B] if:

a. [Dr B] discussed [Ms A's] case and the absence of a transvaginal scan with [Dr D] prior to [Dr D's] consultation with [Ms A] on 10 [Month2] (as described by [Dr B]);

[Dr D] had already based his clinical decision on the interim/provisional report provided by [Mr C], sonographer on 5 [Month2], five days previously.

If [Dr B] had communicated with [Dr D] his concern regarding an absent TVUS at the time of dictating his report on 8 [Month2] this would be plausible, it is less plausible that he didn't recognise this until he verified the report on 10 [Month2].

It is also of concern that, despite a phone call, he did not record in an amended report that TVUS was required, and that he was not confident of his original statement in the report regarding pregnancy failure.

The importance of the availability of the amended written report for the consultation on 10 [Month2] is critical. If an obstetrician or medical officer, other than [Dr D], had seen the patient there is no certainty that they would be aware of the content of the conversation between [Dr D] and [Dr B].

Five days delay in issuing a report for what was considered early pregnancy failure, the absence of TVUS, failure to acknowledge the shortfall and uncertainty in a written amended report despite a phone call five days after the examination do not seem like reasonable care. This does not constitute timely reporting as required by Section 88.

This would constitute a moderate departure from expected level of care.

b. [Dr B] did not discuss [Ms A's] scan prior to [Dr D's] consultation with [Ms A] on 10 [Month2] (as discussed by [Dr D]).

[Dr D] had already based his clinical management on his acknowledged acceptance of the interim/provisional report provided by [Mr C], who he describes as an experienced sonographer on 5 [Month2].

Neither in the sonographer's report or the final radiology report from [Dr B] is there any reference to TVUS.

Understaffing of radiology services, particularly in smaller and provincial DHBs, has resulted in an evolving, increasingly widespread and unsafe practice with clinical acceptance and reliance being placed on reports provided by sonographers. Radiologist observation, interpretation and reporting is required in all instances. This is an example of a clinician accepting and being misled by the sonographer's report.

This is not reasonable radiology care, and was clearly wrong and unsafe from the perspective of [Ms A]. This constitutes a moderate departure from expected level of care.

In both scenarios it seems the delay in reporting could potentially have been circumvented by the contractual arrangement held by [the DHB] with [the radiology service]. Likewise the potential for radiology reporting, supervision and review of the adequacy of the US study and images via PACS (picture archiving and communication system) by [the radiology service] has not been alluded to by [Dr B] or [the DHB]. [The DHB has] confirmed their ability to access specialist radiology advice via the contract.

2. The adequacy of the relevant policies and procedures in place at [the DHB] at the time of the events complained of, including but not limited to, whether they adequately incorporated the relevant clinical protocols from the Australasian Society of Ultrasound in Medicine.

[Dr B] stated in his letter to HDC of 9 [Month5] that: '*As it is departmental policy that a transvaginal scan be routinely performed in every first trimester pregnancy if the transabdominal scan does not give enough information, I made an assumption that a transvaginal scan was not performed because the patient declined it.*'

Review of the First Trimester Obstetric Ultrasound protocol [The DHB]- (states '*a transvaginal transducer would always be offered the patient if it will yield further information, verbal consent must be obtained, after an explanation, the patient may decline to have the transvaginal scan*'. Subsequent statement refers to use of TVUS for evaluation of ectopic pregnancy.

The First Trimester Ultrasound sonographer worksheet [The DHB]- does not provide for formalised recording of whether TVUS was conducted.

Review of the Foetal Demise protocol [The DHB]- references early pregnancy failure should be considered when: '*No live fetus is visible in a gestation sac (mean sac diameter of 2cm or greater)*' and references absent fetal movement in a fetus of CRL greater than 6mm. It also states: '*Second scan performed in 7 days if embryo measures <6mm or apparently empty sac <20mm.*

Second opinion should be sought if any doubt in the diagnosis.

It should not be necessary for a second sonographer to confirm demise as long as the primary sonographer is confident of the diagnosis.'

No reference to TVUS is provided in this protocol.

The Transvaginal Ultrasound protocol [The DHB]- is not helpful in regard to first trimester ultrasound and states:

'*Often performed post transabdominal ultrasound to offer additional information. Whether to proceed is at the discretion of the examining sonographer.*'

The ASUM guideline D11 (2014) previously referenced requires incorporation.

TVUS is a well established ultrasound technique that is commonly used in obstetrics particularly in the first trimester. TVUS requires patient consent, and the use of a chaperone.

The protocols in place at the time of the complaint are outdated, deficient in many areas, and require updating to an evidence and consensus based and best practice guideline level.

Methods of determination of fetal life using ultrasound are considered to be basic sonographer and general radiologist knowledge. These are addressed in radiology registrar and trainee sonographer training programmes and subject to professional examinations to confirm competence. Sonographers and radiologists should not be reliant on reference to locally derived protocols for this.

3. The adequacy of the relevant policies and procedures currently in place at [the DHB], including any further changes that you consider may be appropriate.

The updated Radiology Department Specific Procedure [number] (version 5) for Fetal demise (referencing ASUM D11 revised [Month1]), First Trimester Ultrasound and the First Trimester Ultrasound worksheet have been provided. These represent a significant improvement and incorporate the suggestions, particularly ASUM D11, made previously.

4. Any other matters in this case that you consider warrant comment.

The provision of any report on an US examination by a sonographer to clinicians must be very clearly identified as a 'provisional report, pending review and issuing of a final report by a radiologist'.

[Mr C's] statement that, at [the DHB] any urgent matters with regard to pregnancies are directed to the obstetrician not a radiologist, requires comment. All obstetric ultrasound, other than point of care examination, requires formal reporting.

Section 88 requires obstetric US examinations to be supervised and reported by a radiologist or specialist obstetrician with Diploma of Diagnostic Ultrasound. The notice requires reports to be provided in a timely manner.

It is critical that rules for remote radiologist supervision are in place and that ultrasound worksheets are unambiguous, particularly as based on [Mr C's] statement half the ultrasound workload from [the DHB] is reported remotely by [the radiology service].

Reduced radiologist manpower, particularly witnessed in smaller and provincial DHBs, has resulted in an evolving, increasingly widespread and unsafe practice with clinical acceptance and reliance being placed on reports provided by sonographers. Radiologist observation, interpretation and reporting is mandatory in all instances.

The difficult role of working as a sole generalist radiologist in a DHB hospital is recognised. The availability of teleradiology and PACS access permits the advantage of remote supervision and reporting by radiologists with appropriate specialist skills. It is unclear why this contracted service was not used.

[The DHB] record an audit was completed by [Dr B]. Only three of 24 cases were first trimester US scans. [The DHB] agree a more targeted audit would be appropriate. A strong recommendation is made that an audit should be conducted by an independent radiology peer, not by [Dr B] himself."

Dr Sim provided the following additional advice on 13 July 2017:

"You have provided [Dr B's] response dated 5 July 2017 (which includes [peer review] dated 30 June 2017) via his legal counsel.

You have asked that I review this information and advise on the following:

Was it reasonable for [Dr B] to rely on calling [Dr D] as opposed to including his concerns as part of the report he dictated on 8 [Month2]?

Was it reasonable for [Dr B] to wait until he had been able to speak with the sonographer before calling [Dr D]?

Do you have any further comments in light of this additional information?

1. Was it reasonable for [Dr B] to rely on calling [Dr D] as opposed to including his concerns as part of the report he dictated on 8 [Month2]?

Patient safety is paramount. It is appropriate to record factors which might reduce diagnostic accuracy in the formal radiology report. This is a common occurrence in ultrasound practice. In the report issued on 9 [Month2] it is not recorded that TVUS was not performed. The criteria for recognition of early pregnancy failure referenced previously as ASUM guideline D11 require TVUS.

There can not be certainty that any clinical review or intervention, particularly which could have included potential interruption of what proved to be a viable pregnancy, would be performed solely by [Dr D] in the environment of a DHB hospital.

There can be no certainty that any other obstetrician or medical officer would be aware of the content of the telephone conversation between [Dr B] and [Dr D], as noted in my letter to the HDC of 14 October 2016. Therefore an accurate written radiology record is a requirement to guide clinical management.

A phone call to [Dr D] to record concern is commended as good practice.

Reliance on a phone call to [Dr D] to convey uncertainty, whilst providing a written report, and no subsequent addendum, which did not record uncertainty, express the limitation of the study or recommended recall is not good practice or reasonable.

Was it reasonable for [Dr B] to wait until he had been able to speak with the sonographer before calling [Dr D]?

Review of the US images by [Dr B] was the simplest way to confirm TVUS was not performed. The nature of the images and probe identification on these enables recognition by a radiologist. Indeed [Dr B] records in his letter of 9 [Month5] that he noticed there were no TVUS images available.

This did not require a conversation with the sonographer for confirmation.

The reason for failure to perform TVUS, which might be ascertained in subsequent conversation with the sonographer was subject to delay, but is not critical to the report content.

The radiologist should have clearly identified the failure to perform TVUS, in the report and documented the uncertainty regarding fetal viability in the report.

This did not require [Dr B] delaying calling [Dr D] until he had spoken with the sonographer, who was unavailable until 5 days following the scan.

2. Do you have any further comments in light of this additional information?

The only new or changed information in the response is in para 11, 12, 13 from Counsel relating to [Dr B] telephoning [Dr D] on Wednesday 10 [Month2] after conversing with the sonographer.

I have no additional comment."

Appendix C: Independent obstetric advice to the Commissioner

The following expert advice was obtained from obstetrician Dr David Bailey on 27 January 2017:

> "I have been asked to provide expert advice to the Health and Disability Commissioner regarding the care provided by [Dr D] to [Ms A] in early pregnancy on 5 [Month2]. I have read the Guidelines for Independent Advisors provided by your office and agree to follow these guidelines.
>
> I am a Consultant in Obstetrics & Gynaecology at Northland District Health Board. I graduated in Medicine from London University in 1985 and trained in Obstetrics & Gynaecology in New Zealand and the United Kingdom, with advanced training in Maternal Medicine and Fetal Medicine. I became a Member of the Royal College of Obstetricians and Gynaecologists in 1999 and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in 2005. I also have a Diploma in Advanced Obstetric Ultrasound from the Royal College of Obstetricians and Gynaecologists. My main interest is in quality improvement in maternity care.
>
> I have been asked to comment on the following:
>
> The reasonableness of [Dr D's] decision to accept [Mr C's] report as accurate and to recommend management on the basis of that report.
>
> The appropriateness of [Dr D's] management plan on 5 [Month2] — to have a repeat β-hCG done and review in 5 days.
>
> Whether it is reasonable that [Dr D] did not review the β-hCG results of 5 [Month2] and contact [Ms A] prior to her planned appointment of 10 [Month2].
>
> Any other matters in this case that I consider warrant comment.
>
> In providing this advice I have relied on the following documents and resources:
>
> The letter of complaint from [Ms A] and subsequent correspondence between the Office of the Health and Disability Commissioner and the Chief Executive of [the DHB].
>
> The responses from [Dr D].
>
> The clinical notes from [the DHB] provided by the commission.
>
> References as listed at the end of this report.
>
> **Background**
>
> [Ms A] was referred to the Early Pregnancy Clinic at [the public hospital] in [Month1] by her General Practitioner. The indication appears to have been that the rate of increase of serial serum β-hCG measurements, requested by the General

Practitioner, was less than expected. An initial trans-vaginal scan was performed on 26 [Month1] by [the consultant obstetrician] in the clinic using a mobile ultrasound device and this showed an intrauterine gestational sac containing a small yolk sac and fetal pole. Fetal heart activity was not detected. These findings are normal for a gestation of 5 weeks 5 days, as suggested by [Ms A's] last period date. As viability had not yet been confirmed, a follow-up scan was arranged, to be done in the Radiology Department on 5 [Month2], with follow-up in the Early Pregnancy Clinic. Another β-hCG measurement was also requested.

When [Ms A] attended the Radiology Department on 5 [Month2] a trans-abdominal scan was performed, which was reported to show a 12 mm gestational sac in the uterus; no fetal pole, yolk sac or fetal heart activity were seen. At this gestation (7 weeks 1 day based on last period date), a fetal pole and fetal heart activity should be detected, so it was reported that the pregnancy was not viable. This report was conveyed to [Dr D], who saw [Ms A] in the Early Pregnancy Clinic the same day. He agreed that the scan result indicated the pregnancy would miscarry and on that basis advised [Ms A] that the management options were to await spontaneous miscarriage, or to end the pregnancy with either medical management or surgical evacuation. It was agreed that she would await events for a few days, but would be reviewed in the Early Pregnancy Clinic on 10 [Month2] and that another serum β-hCG measurement would be done.

[Dr D] saw [Ms A] again in the Early Pregnancy Clinic on 10 [Month2]. She continued to experience symptoms of pregnancy and it was noted that β-hCG assays on 5 [Month2] and 9 [Month2] were reported at 39667 IU/L and 51479 IU/L respectively. These findings were suggestive of a viable pregnancy and [Dr D] performed a trans-vaginal scan on the mobile scanner in the clinic. Based on [Ms A's] last period date, the expected gestation was 7 weeks 6 days and the scan demonstrated a live intrauterine scan with measurements and appearances consistent with this gestation.

Advice

This advice is given with reference to the Australasian Society for Ultrasound in Medicine Guidelines for the Performance of First Trimester Ultrasound, which is the standard for early pregnancy ultrasound practice in New Zealand. Reference is also made to the NICE Guideline for Ectopic Pregnancy and Miscarriage, which is widely viewed as an international standard. At the time of preparing this report the Royal Australian and New Zealand College of Obstetricians and Gynaecologists did not have any guidance or position statement on the diagnosis of early pregnancy loss.

Was it reasonable for [Dr D] to accept [Mr C's] report as accurate and to recommend management on the basis of that report?

I believe it was reasonable that [Dr D] accepted [Mr C's] ultrasound report on 5 [Month2] and based his recommendations and management on this report. When a scan was performed on 26 [Month1] this showed a gestational sac containing a yolk sac and fetal pole. Reviewing the images from that scan the mean sac diameter was 9.5 mm. A scan performed 10 days later would be expected to show

a much larger gestational sac with an obvious fetal pole and yolk sac and fetal heart activity. When this scan reported little change in the size of the gestational sac and none of the other features associated with normal embryonic development, the appropriate conclusion would be early fetal demise and a non-viable pregnancy. The preliminary scan report and subsequent formal report did not state whether or not a trans-vaginal scan was performed.

In general clinicians expect that scans performed in the Radiology Department are of superior quality to those performed on mobile scanners in clinics. The expertise of the sonographer and the quality of the equipment in the Radiology Department are assumed to be superior. There was no reason for [Dr D] to assume the scan on 5 [Month2] had not been performed competently. As a general principle, when clinicians organise investigations they assume the findings are correctly reported and act accordingly.

Was [Dr D's] management plan on 5 [Month2] appropriate — to have a repeat β-hCG done and review in 5 days?

It is not clear from the records why [Dr D] arranged a further appointment and β-hCG measurement on 10 [Month2]. It appeared that a confident management plan was made on 5 [Month2] and it was unlikely further investigations would change this plan. It is not unreasonable to arrange a review appointment when women are undecided about management and need some time to consider options. It would also be appropriate to arrange follow-up and further investigation if there was doubt about the diagnosis; however, on 5 [Month2] this did not appear to be the case. There may have been reasons for arranging another appointment which were not documented in the written records.

Was it reasonable that [Dr D] did not review the β-hCG results of 5 [Month2] and contact [Ms A] prior to her planned appointment of 10 [Month2]?

The question of using serial β-hCG measurements in this context is contentious. The main role for β-hCG measurement is in the investigation of early pregnancy bleeding, to distinguish intrauterine from ectopic pregnancies. Once an intrauterine pregnancy is diagnosed the follow-up should be with further scans and at this stage further β-hCG measurements are unhelpful and may be misleading. β-hCG is produced by the trophoblast and placenta, not by the fetus, and although high levels may be assumed to indicate a continuing pregnancy, it is not unusual to see very high β-hCG levels in a non-viable pregnancy, as the trophoblast may continue to produce β-hCG for several weeks after fetal demise. When [Dr D] saw [Ms A] on 5 [Month2] he had a scan report which indicated a non-viable pregnancy, so the β-hCG level at that time was not relevant.

Other matters in this case that I consider warrant comment.

I am aware that since the events in this case took place there has been a review of practice at [the DHB] and more robust processes are in place.

Although the practice of scanning on portable machines in clinics is widespread, it can create problems. When all scanning is performed on high quality equipment

by credentialed practitioners and images are stored digitally, this facilitates the comparison of images over successive examinations and should lead to better overall standards. Having said this, the quality of scanning by the clinicians in the clinic on this occasion appeared to have been of a higher standard than that provided by the Radiology Department.

[…]

References

Australasian Society for Ultrasound in Medicine. Guidelines policies and statements D11. Guidelines for the performance of first trimester ultrasound (latest revision [Month1]).

National Collaborating Centre for Women's and Children's Health. Ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage. Commissioned by the National Institute for Health and Clinical Excellence (NICE) 2012."

Dr Bailey provided the following additional advice on 9 April 2017:

"The ASUM guidelines refer to the features necessary for the confident diagnosis of early fetal demise on a single scan. In summary, if a scan shows a gestational sac >25mm with no fetal pole, or a fetal pole >7mm with no fetal heart activity, then early fetal demise can be confidently diagnosed without further investigation. The ASUM guideline also indicates that the scan should be trans-vaginal.

However, in many cases a failing pregnancy may never reach a stage of development when the ASUM guideline could be used to confirm early fetal demise. In practice, health care professionals responsible for the management of suspected early pregnancy may use one of two criteria to diagnose early fetal demise:

1. The scan shows the appearances of early fetal demise as per ASUM guidelines.

2. Multiple scans over time which do not show appropriate progression from a pregnancy of indeterminate viability to a pregnancy with scan features confirming viability.

A clinician may make a confident diagnosis of early fetal demise if the conditions above are satisfied. This, of course, assumes that the ultrasound findings are accurate."