Sonographer, Ms B

Radiologist, Dr C

Radiology Clinic

Waitemata District Health Board

A Report by the

Health and Disability Commissioner

(Case 15HDC01258)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In 2015, Ms A presented to her general practitioner (GP) after taking at-home pregnancy tests, the results of which were positive. She reported left-sided abdominal pain and was referred for an urgent ultrasound. Blood samples were sent to the laboratory to check Ms A's β-hCG level,[1] but the result was not available at the time of the ultrasound. The ultrasound was performed by trainee sonographer Ms D on 13 Month1[2] at the radiology clinic. Ms B was the supervising sonographer and Dr C was the reporting radiologist, working from a location remote from where the scan was performed.

2. Ms D performed the scan without Ms B present and then informed Ms B that she thought Ms A had a live ectopic pregnancy.[3] Ms D then rescanned Ms A while Ms B observed. Ms B told HDC that she did not see a fetal heartbeat in the right adnexal[4] mass and the images were not convincing for this diagnosis. However, she accepted Ms D's findings.

3. Ms D telephoned Dr C and told him that she and Ms B both thought that Ms A had a live ectopic pregnancy. The sonographer's worksheet listed the sonographer as "[Ms D/Ms B]" and stated: "Live ectopic pregnancy. … small (empty) [gestational sac] like structure within uterine cavity." Dr C was given the impression that there was consensus between Ms D and Ms B regarding the findings.

4. Dr C telephoned Ms A's GP and advised that an ectopic pregnancy was suspected and that it was recommended that Ms A be referred to a public hospital for urgent specialist assessment. Dr C wrote in the ultrasound report: "… appearances today are consistent with a right sided ectopic pregnancy".

5. Ms A re-presented to her GP and was referred to the public hospital. She underwent surgical removal of her right fallopian tube, but subsequently was found to have a normal intrauterine pregnancy. Prior to surgery, she was provided with a consent form with a tick box relating to return of tissue, but return of tissue was not discussed with her adequately, and this section of the form was not completed. After surgery, Ms A requested the return of her right fallopian tube. Subsequently, it was discovered that all of the tissue had been used during testing, and was placed in paraffin blocks. The paraffin blocks were melted down, and Ms A's tissue was returned to her in Month4.

Findings

6. As Ms B did not agree with Ms D's findings, she should have taken over the care of Ms A and re-assessed her herself, instead of accepting Ms D's findings. Furthermore, she should have conveyed any doubts about the diagnosis to Dr C. By failing to do these things, Ms B failed to provide services to Ms A with reasonable care and skill

[1] β-hCG (beta human chorionic gonadotropin) is a hormone produced during pregnancy. Elevated levels of β-hCG can indicate a viable pregnancy.
[2] Relevant months are referred to as Months 1-4 to protect privacy.
[3] An ectopic pregnancy is any pregnancy that occurs outside the uterus.
[4] The adnexa of the uterus is the surrounding structures, including the fallopian tubes and ovaries.

and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[5]

7. Ms D misinterpreted Ms A's scan and inaccurately documented a live ectopic pregnancy. However, this is mitigated by the fact that she was a trainee sonographer at the time and appropriately extended the examination and consulted her supervising sonographer, Ms B, to establish whether her interpretation was correct.

8. Dr C inaccurately diagnosed a right ectopic pregnancy in his radiology report. Criticism is made that he was aware that the images were not convincing for this diagnosis, but he failed to take further action in this respect.

9. While it is noted that three individual employees each misinterpreted Ms A's images, the respective failings by Ms B, Ms D, and Dr C in this case were matters of individual clinical judgement. Furthermore, the radiology clinic had appropriate policies in place at the time. Therefore, the radiology clinic did not breach the Code.

10. On the basis of the information available to Waitemata DHB staff at the time, it was appropriate to carry out surgery to remove Ms A's right fallopian tube. Nonetheless, criticism is made that the obstetric/gynaecology team did not question the assumption, after Ms A's blood test results were available, that she was nine weeks pregnant. It would have been prudent for the obstetric/gynaecology team to have kept in mind the differential diagnosis of an early intrauterine pregnancy.

11. The process undertaken in regard to returning Ms A's tissue was suboptimal. While Waitemata DHB had detailed policies in place for the return of tissue, these were not followed by numerous staff. In particular, Waitemata DHB did not provide Ms A with information that a reasonable consumer would expect to receive regarding the process for the return of tissue, including information relating to the timeframe, and the consequences of any decision relating to the return of tissue. Accordingly, Waitemata DHB breached Right 6(1) of the Code.[6]

12. Criticism is made that Waitemata DHB did not action Ms A's request for the return of her fallopian tube within a reasonable timeframe.

Recommendations

13. It is recommended that Ms B have an independent sonography peer perform a quality review of a random selection of antenatal ultrasound scans and accompanying sonographer's worksheets that she has completed in the last 12 months, and that she provide a written apology to Ms A. It is also recommended that the Medical Radiation Technologists Board consider whether a review of Ms B's competence is warranted.

14. It is recommended that Ms D have an independent sonography peer perform a quality review of a random selection of antenatal ultrasound scans and accompanying

[5] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[6] Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"

sonographer's worksheets that she has completed in the last 12 months, and that she provide a written apology to Ms A.

15. It is recommended that Dr C have an independent radiology peer perform a quality review of a random selection of antenatal ultrasound reports he has completed in the last 12 months. Dr C has provided a written apology to Ms A.

16. It is recommended that the radiology clinic review its supervision processes for trainee sonographers and consider introducing a requirement that the supervising sonographer must take over the care of the patient if there is disagreement between the trainee sonographer and the supervising sonographer about the interpretation of the scan.

17. It is recommended that Waitemata District Health Board use this case as an anonymised case study for clinical staff, and conduct training for all obstetric/gynaecology staff at the public hospital on the cultural and emotional significance of the return of tissue and body parts, and on Waitemata DHB's policy for the return of tissue and body parts. It is also recommended that Waitemata DHB provide a written apology to Ms A.

Complaint and investigation

18. The Commissioner received a complaint from Ms A about the services provided to her by the radiology clinic and Waitemata District Health Board. The following issues were identified for investigation:

- *Whether sonographer Ms B provided Ms A with an appropriate standard of care in Month1 2015.*
- *Whether radiologist Dr C provided Ms A with an appropriate standard of care in Month1 2015.*
- *Whether the radiology clinic provided Ms A with an appropriate standard of care in Month1 2015.*
- *Whether Waitemata District Health Board provided Ms A with an appropriate standard of care between Month1 and Month4 2015.*

19. An investigation was commenced on 29 March 2016.

20. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Ms B	Sonographer
Dr C	Radiologist
Radiology clinic	Provider
Waitemata District Health Board	Provider

Also mentioned in this report:

Dr E	General practitioner
Dr F	Obstetric/gynaecology registrar
Dr G	Obstetric/gynaecology registrar
RN H	Registered nurse
RN I	Registered nurse
Dr J	Obstetric/gynaecology house officer
Dr K	Obstetric/gynaecology house officer
RN L	Registered Nurse
Ms M	Maternity social worker

21. Information from Ms D, a trainee sonographer, was also reviewed.

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

23. Independent expert advice was obtained from radiologist Dr Mark Leadbitter (**Appendix B)**.

24. Independent expert advice was obtained from obstetrician Dr Michel Sangalli (**Appendix C)**.

Information gathered during investigation

Background

25. On 13 Month1, Ms A, aged 19 years, presented to her general practitioner (GP), Dr E. The previous day, Ms A had taken at-home pregnancy tests, which were positive.

26. Dr E recorded in Ms A's clinical records:

> "[Last menstrual period] was due 11 [the previous month] not always regular. Some pain left side [abdomen] like period pains. No tiredness or nausea. … [On examination] [abdomen] soft. Tender left lower [abdomen]. … Plan [ultrasound] scan today to exclude tubal pregnancy.[7]"

27. Dr E organised an urgent ultrasound for 4pm that day, at the radiology clinic. On the referral form, she typed: "Early pregnancy scan. [Last menstrual period] [around two months ago], dates uncertain." Dr E also handwrote on the form: "?9 weeks. Left sided pain ?site of pregnancy. Please phone result urgently."

[7] A tubal pregnancy is a pregnancy in which the fetus develops in a fallopian tube (see footnote 24), rather than the uterus. The fetus is unable to survive, except in very rare circumstances.

28. Dr E also sent blood samples to the laboratory to check Ms A's β-hCG level,[8] but the result was not available at the time of the ultrasound.

Ultrasound — 13 Month1

29. On the afternoon of 13 Month1, trainee sonographer Ms D performed the ultrasound, under the supervision of sonographer Ms B. Ms B told HDC that, as Ms D was nearly qualified, the radiology clinic protocol was that she scan independently, then discuss her findings with Ms B before calling the radiologist. If the radiologist was not satisfied with the information given, then the supervising sonographer would be involved in further discussions or further scanning as instructed by the radiologist.

30. Initially Ms D assessed Ms A without Ms B in the room. Ms D told HDC that she informed Ms A that she was a trainee sonographer and explained that, with Ms A's permission, she would do the scan and then call in her supervisor to review the images. Ms D stated that she asked Ms A about her last menstrual period, and Ms A responded that she did not know when it had occurred. Ms D told HDC that she scanned trans-abdominally and did not observe any particular abnormality, but visualisation was difficult owing to Ms A's physique, and her bladder not being sufficiently full. Ms D therefore decided to perform a trans-vaginal scan, which she did with Ms A's consent.

31. Ms D stated:

> "On scanning trans-vaginally I observed a very small cystic space[9] within the endometrium.[10] I zoomed up on the space to try to ascertain whether I could see a double decidual reaction.[11] I could not be sure as resolution at this stage was suboptimal. … I then assessed the left adnexa.[12] This was the side where [Ms A] had reported pain. I observed the left ovary, obtained measurements and applied slight pressure asking [Ms A] if she felt any of the pain that she had been experiencing recently. [Ms A] replied that she was not currently experiencing the pain. … I obtained images of the right ovary. Due to the bowel gas overlying this area I asked [Ms A] if I could apply some pressure from above on her abdomen with my left hand. [Ms A] agreed to this. With the pressure applied the bowel cleared away from the right adnexa and a mass came into view, the appearances of which remained consistent during the time I scanned the right adnexa. … The

[8] β-hCG (beta human chorionic gonadotropin) is a hormone produced during pregnancy. In a normal uterine pregnancy, the level of β-hCG increases by at least 53% every two days, peaking at a level greater than 100,000 IU/L. At four to five weeks' gestation, the level of β-hCG in a normal intrauterine pregnancy is between 18–7,340 IU/L. At seven weeks' gestation, the level of β-hCG in a normal intrauterine pregnancy is between 7,650–229,000 IU/L. At nine weeks' gestation, the level of β-hCG in a normal intrauterine pregnancy is between 25,700–288,000 IU/L.

[9] A cystic space (also called a cyst or cystic lesion or mass) is an abnormal sac or closed cavity.

[10] The endometrium is the tissue lining the inner cavity of the uterus. If pregnancy is established, the endometrium becomes the decidua (the modified tissue that lines the wall of the uterus during pregnancy).

[11] A double decidual reaction (also called a double decidual sac sign) is a ring appearing brighter partially surrounded by another such ring. The two rings are separated by a space that appears black. It indicates an intrauterine pregnancy.

[12] The adnexa of the uterus is the surrounding structures, including the fallopian tubes and ovaries.

> mass appeared to be in the shape of a fetal pole[13] and appeared to be pulsating. … I measured the mass and placed an M-mode[14] cursor over the region. I could see pulsations and obtained a reading. … I asked [Ms A] if she was experiencing any pain on this side and she replied that she was not experiencing pain."

32. Ms D told HDC that she then left the room and explained to Ms B that she was seeing a mass in the right adnexa and fluid in the Pouch of Douglas,[15] and that she had used the M-mode Doppler and observed a fetal heartbeat in the area of the mass. Ms D informed Ms B that she thought Ms A had a live ectopic pregnancy.[16]

33. Ms D re-entered the room with Ms B and rescanned Ms A, while Ms B observed. Ms D told HDC that Ms B asked her to apply the M-mode Doppler over the mass to observe the fetal heartbeat and then to apply the colour Doppler[17] over the mass to confirm that they were seeing a pulsation. Ms D recalled that they observed colour over the mass, following which Ms B said "that was fine" and they could end the scan. There is no record of this conversation.

34. Ms A recalls that, after she was rescanned, Ms B told Ms D that she agreed with her scan findings.

35. Ms B told HDC:

> "[Ms D] informed me of the ectopic pregnancy findings, I looked over her shoulder and saw an empty intrauterine gestational sac,[18] trace of pelvic free fluid, fetal pole like structure in the right ovary[19] (no pain on [trans-vaginal] probe pressure), no fetal heartbeat. The M mode for heartbeat couldn't be demonstrated for me so we took some images of colour Doppler which again wasn't convincing of a fetal heartbeat. We did discuss this at the time of scan … (The trainee was confident of seeing a heartbeat before I came in). Because the trainee was close to qualifying department instructions were that she speak directly to the radiologist … I offered to speak to the radiologist but the trainee insisted on doing so herself."

[13] The fetal pole is a thickening on the margin of the yolk sac (see footnote 30) of a fetus during pregnancy. It is normal for a fetal pole not to be visible until about nine weeks' gestation.
[14] In M-mode (motion-mode) ultrasound, pulses are emitted in quick succession (a high sampling rate) with an image taken each time. The high sampling rate means that even very rapid motions can be recorded.
[15] The Pouch of Douglas (recto-uterine pouch) is the extension of the peritoneal cavity between the rectum and the posterior wall of the uterus. Ectopic pregnancy (see footnote 16) can be a cause of free fluid in the Pouch of Douglas.
[16] An ectopic pregnancy is any pregnancy that occurs outside the uterus.
[17] In colour Doppler, velocity information is presented as a colour-coded overlay on top of a B-mode (2 dimensional) image.
[18] The gestational sac is the large cavity of fluid surrounding the embryo. The first ultrasound evidence of pregnancy is the gestational sac within the thickened decidua (see footnote 29).
[19] The mass was in the right fallopian tube (see footnote 24), not in the right ovary.

36. The reporting radiologist was Dr C. Dr C reported on the ultrasound from a site remote from where the scan was performed, via teleradiology.[20] Dr C explained that supervision of sonographers is shared by all qualified radiologists working in the organisation.

37. Ms D stated that she telephoned Dr C and explained that she and Ms B both thought that they were seeing a live ectopic pregnancy in the right adnexa and some free fluid in the Pouch of Douglas. Ms D stated that she told Dr C that visualisation was limited, owing to Ms A's physique and bowel gas. There is no record of this conversation. According to Ms D, Dr C said that he would call her back once he had reviewed the images. Ms D told HDC that Ms B was sitting next to her while she conversed with Dr C. However, Ms B told HDC that she left Ms D to speak with the radiologist while she scanned the next patient.

38. The sonographer's worksheet lists the sonographer as "[Ms D/Ms B]". The worksheet was completed by Ms B, and states:

> "*Live ectopic pregnancy. Single live seen in [right ovary];[21] [Crown rump length] = 12mm. Free fluid seen. No pain on scan. [Left ovary] normal. 1 x small (empty) [gestational sac] like structure within uterine cavity = 4mm."

39. The crown rump length measurement section of the worksheet was filled in as "12mm = 7 [weeks] 2 days". The last menstrual period, expected due date by dates, and gestational age sections of the worksheet were each filled in with two question marks.

40. Ms B stated that she had to raise a strong suspicion of an ectopic pregnancy on the sonographer's worksheet, especially when Ms D was confident that she had seen a fetal heartbeat outside of the uterus, because missing an ectopic pregnancy can have dire consequences. Nonetheless, Ms B told HDC that she assumed that Dr C's report would request a repeat ultrasound scan with serial β-hCG levels, because the scan findings were an intrauterine gestational sac, a possible fetal pole-like structure in the right adnexa (but pain on the left side) and a fetal heartbeat that was not well demonstrated; there were no β-hCG levels supplied by the referrer; Ms A was unsure of the date of her last menstrual period; and her understanding was that hospital practice was to perform a repeat ultrasound scan with serial β-hCG before surgery.

41. Ms D sent the scan images, along with the sonographer's worksheet, to Dr C electronically while Ms A was still at the clinic. Dr C told HDC:

> "After an initial review of the films I questioned both sonographers (telephonically) at some length. Both the trainee sonographer and the qualified sonographer confirmed that a fetal heart beat had been demonstrated outside the uterus despite the images being less convincing. This was confirmed on the sonographic worksheet. I then rang the referring general practitioner, [Dr E], and

[20] Teleradiology is a system where radiology images are sent from the site of acquisition to the reporting location, to be reported on remotely. In this case, Dr C (as the radiology clinic employee) was located in another clinic in Auckland and was available at the time of the scan.
[21] The mass was in the right fallopian tube, not in the right ovary.

advised that we suspected an ectopic pregnancy and recommended that the patient be referred to [the public hospital] for urgent specialist assessment."

42. Ms D told HDC that, approximately five minutes after her call to him, Dr C called her back and asked her to tell Ms A that it was "imperative" that she go straight back to her GP, who would explain the result of the ultrasound to her. Ms D stated that only she spoke to Dr C about the findings.

43. Ms B told HDC that Dr C did not speak to her, so she assumed that he was satisfied with the information he received from Ms D.

44. After the telephone calls, Dr C completed his ultrasound report. The ultrasound report stated:

> "There is no evidence of an intrauterine gestational sac. A pseudosac[22] is noted. In the right adnexal region there is a cystic lesion with a 12mm fetal pole and fetal heart activity was observed within this.
>
> Free fluid is seen about the right ovary. Patient did not appear particularly tender at the time of examination.
>
> Left ovary and left adnexal region normal.
>
> **Comment: As discussed by phone appearances today are consistent with a right sided ectopic pregnancy.**"[23]

45. An electronic copy of the report was sent to Dr E and to the public hospital. The images were not sent with the report. Waitemata DHB told HDC that the images of the ultrasound were not available to Waitemata DHB staff on the evening of 13 Month1, as they can be provided by the radiology clinic only during working hours. However, the radiology clinic told HDC that images can be made available after 5pm on request.

Admission to the public hospital — 13–15 Month1

13 Month1

46. Ms A re-presented to Dr E after the ultrasound, on the evening of 13 Month1. Dr E discussed the ultrasound report findings with her and referred her to the public hospital. The referral stated: "Thank you for seeing [Ms A] with right ectopic pregnancy on scan." A copy of the consultation notes from the initial appointment earlier in the day was also reproduced on the referral, including the statement: "[Last menstrual period] was due 11 [the previous month] not always regular."

47. Ms A attended the Emergency Department (ED) at the public hospital at 5.57pm. At 6pm, nursing staff triaged her as a category two (to be seen within 10 minutes by a doctor), with "? ectopic" recorded on the triage assessment. At 6.03pm, Ms A's β-

[22] A pseudosac is a small amount of intrauterine fluid without a proper wall or lining, as opposed to a gestational sac.
[23] Emphasis as per original.

hCG level, from the blood test taken at the medical centre that morning, was reported as 1,450 IU/L. At 6.20pm, it was documented by nursing staff that Ms A was nine weeks pregnant and that a scan that day had confirmed an ectopic pregnancy.

48. Further blood tests were taken in the ED, and Ms A's β-hCG level was reported as 1,211 IU/L at 7.26pm.

49. Obstetric/gynaecology house officer Dr K reviewed Ms A at 7.40pm. Waitemata DHB told HDC that Ms A was not seen by a doctor within 10 minutes, as appropriate for her triage category, because the obstetric/gynaecology team was involved in a medical emergency.

50. Dr K recorded: "[Left lower quadrant] pain during pregnancy. 9/40 [weeks' gestation]. [Right] ectopic on scan at GP. … Patient informed of the scan results [and] falling β-hCG … [Last menstrual period] [11th of the previous month]." His impression was recorded as "[Right] ectopic. Fetal heart activity. [Decreasing] β-hCG." Dr K's plan included admitting Ms A to the ward, and keeping her nil by mouth, for possible surgery that night to remove her right fallopian tube.[24]

51. Waitemata DHB stated that the appropriate management of a live tubal ectopic pregnancy is surgical removal of the fallopian tube, especially in the presence of a normal tube on the other side. It told HDC that there was no clinical indication to repeat the ultrasound prior to surgery.

52. Dr K went through the informed consent procedure for surgery with Ms A, including completing the Surgical Consent form. The section of the form asking whether the patient wishes to have any body part/tissue removed during this procedure that is not required for diagnosis returned to them had a box for "yes" and a box for "no". Neither of the boxes were ticked. Similarly, neither of the boxes were ticked for the section where staff indicate whether the release of tissue/body part request has been documented. Ms A and Dr K signed their names at the bottom of the form.

53. Dr K's usual practice was to discuss with patients whether they wanted their tissue returned. He told HDC that he has a vague recollection of a conversation with Ms A about tissue return, but no specific recall, and cannot explain why the relevant section of the Surgical Consent form was incomplete.

54. Ms A told HDC that she was not told about return of tissue at this time, and did not read the relevant section of the Surgical Consent form. There is no record of a conversation between Dr K and Ms A regarding return of tissue.

55. While waiting in the ED, Ms A ate food, having been told that she could do so. Waitemata DHB told HDC that usual practice is for the primary nurse to be consulted prior to food being given to patients in the ED, and that it was unable to identify who told Ms A that she could eat. However, Waitemata DHB stated that, while this

[24] Fallopian tubes are a pair of long narrow ducts, located in the female abdominal cavity, that lead from the ovaries to the uterus.

contributed to Ms A being unable to have surgery that night, the main reason her surgery was delayed until the next day was the overall clinical priorities of the obstetric/gynaecology team at the time.[25] Waitemata DHB said that, although live ectopic pregnancies are usually operated on as soon as possible, Ms A was stable, her intermittent pain was managed with analgesia, and there was a plan in place for review if her condition changed.

56. Obstetric/gynaecology registrar Dr F reviewed Ms A at 8.45pm. Dr F recorded:

> "[Complaining of] left-sided pain currently … Live [right] ectopic pregnancy. Has just eaten. … [On examination] … left lower quadrant tenderness, [abdomen] soft. [Impression] 1) [Right] ectopic pregnancy — live. [Plan] 1) [nil by mouth] 2) ? [operating theatre] [morning] …"

57. Dr F did not note that the return of tissue section of the Surgical Consent form had not been completed.

58. Ms A was transferred to the obstetric/gynaecology ward at 10pm.

14 Month1

59. At 9.15am on 14 Month1, Ms A was reviewed in the preoperative area of the operating theatre by obstetric/gynaecology registrar Dr G. Dr G discussed the operation with Ms A and was satisfied that there was a valid surgical consent. Dr G did not notice that the return of tissue section of the Surgical Consent form had not been completed. She recorded that Ms A had been seen preoperatively, and documented the word "consent" with a tick next to it.

60. A registered nurse (RN) from the operating theatre, RN H, and an obstetric/gynaecology ward nurse, RN I, completed Ms A's preoperative assessment checklist at 9.20am. Both ticked the boxes next to the section stating "Surgical Consent Form dated and signed". However, neither noted that the return of tissue section of the Surgical Consent form had not been completed.

61. At 9.21am, Ms A's β-hCG level was reported as 1,329 IU/L, from blood tests taken earlier that morning.

62. Waitemata DHB told HDC that when a consultant obstetrician/gynaecologist (consultant O&G) entered the theatre, Ms A had already been anaesthetised. The consultant O&G confirmed with Dr G that she (Dr G) had met with Ms A prior to surgery and discussed the consent process. Waitemata DHB told HDC that Dr G and the consultant O&G had no clinical suspicion that the pregnancy was intrauterine, and that falling β-hCG levels confirmed the diagnosis of ectopic pregnancy.[26]

[25] Three emergency Caesarean sections were carried out that night.
[26] Ms A's β-hCG level from blood tests taken on the morning of 13 Month1 was 1,450 and her β-hCG level from blood tests taken that evening was 1,211.

63. A laparoscopic right salpingectomy[27] was commenced at 9.23am. The surgery was performed by Dr G and the consultant O&G. The operation note stated:

> "[Left] tube/ovary [normal]. [Right] tube swollen/long. … ectopic pregnancy. [Uterus] normal."

64. Ms A's right fallopian tube was sent to the pathology unit for testing.

65. After she had returned to the ward, Ms A told RN I that she wanted her removed fallopian tube returned to her. RN I asked the on-call obstetric/gynaecology house officer, Dr J, to complete the consent process for the return of tissue.

66. Ms A told HDC:

> "[After surgery] I asked for my fallopian tube back because I thought there was a baby in the tube, I was devastated and all I wanted to do was take it home but because I did not tick/sign/left that part of the form empty I got attitude from the nurses and was spoken to rudely. I feel like because I was young (19 years old) that they cared less about my situation and how I was feeling. They kept saying that they most likely would not be able to get it back for me because I did not complete that part of the form and that it was already with the Lab. The thing is I was never told or read that part of the form and I was trying to explain this to them but all I was getting back was an I do not care attitude."

67. Waitemata DHB told HDC that it has been unable to clarify with RN I if she told Ms A about the process for return of tissue at this time.

68. Dr J ticked the "yes" boxes in the relevant sections of the original Surgical Consent form and faxed it to the pathology unit. Dr J reviewed Ms A at 8pm and recorded that Ms A was aware that return of her tissue had been addressed.

15 Month1

69. Ms A was discharged at 2.30pm on 15 Month1. Her discharge summary stated: "Tissue returned as per patient request"; however, Ms A's fallopian tube was not returned to her on discharge.

Clinical care post-discharge — 19 Month1–9 Month2

70. The pathologist'shistology report, dated 19 Month1, stated:

> "The entire specimen was submitted for histology and multiple levels were examined. … There [is] no evidence of pregnancy related changes. … No fetal tissue is noted. … Recent [β-hCG] levels are higher than those done at the time of surgery.[28] This suggests that the pregnancy may be located intra-uterine or intrapelvic. Further investigations are advised."

[27] A salpingectomy is the surgical removal of one or both fallopian tubes.
[28] Ms A's β-hCG levels had gone from 1,211 IU/L at the time of admission to 1,329 IU/L the next morning.

71. The pathologist contacted the obstetric/gynaecology team to inform them of the histology report.

72. Dr G telephoned Ms A the next day to explain the histology findings and ask that she attend the outpatient pregnancy clinic. Ms A attended and had blood tests taken. Her β-hCG level was reported as 13,616 IU/L at 4.09pm, an increase from the blood tests taken prior to her salpingectomy.

73. Subsequently, Ms A was reviewed by Dr G, who undertook a portable ultrasound, which showed a cyst in the uterine cavity with decidual reaction[29] and a possible yolk sac.[30] A formal ultrasound carried out later confirmed an intrauterine gestation sac, but could not confirm viability in the absence of a fetal pole. A follow-up scan in 10–14 days was recommended.

74. The further ultrasound was carried out on 27 Month1 at the public hospital and confirmed a live intrauterine pregnancy, with a visible yolk sac and a fetal pole. No free fluid was identified. A gestational age of six weeks and three days was given.

75. On 3 Month2, a Waitemata DHB consultant obstetrician/gynaecologist wrote to Dr C about Ms A's ultrasound of 13 Month1. The letter states:

> "On reviewing your images there are several misinterpreted features of described 'cystic lesion with 12mm fetal pole and observed fetal heart activity'
>
> — There is no defined gestational sac with trophoblastic reaction present.
> — There is no surrounding increased vascularity.
> — 'Fetal pole' appears morphologically different on subsequent images and does not have proportions of 7 weeks size embryo.
> — M-mode vibrations are registered within the hypoechoic cystic area underneath the presumed sac and not from the presumed fetal pole.
> — Small cystic lesion within the uterine cavity is described as 'pseudosac' without consideration of alternative differential diagnosis."

Return of tissue post-discharge — 16 Month1–Month4

76. Waitemata DHB told HDC that, on 16 Month1 (the day following Ms A's discharge), Dr K was made aware that the return of tissue section on Ms A's Surgical Consent form had not been completed, and that she had asked for the return of her fallopian tube. He discussed this with Dr G, who suggested that there might still be time to have some of the tissue set aside for return to Ms A. Dr K then discovered that Dr J had already completed the relevant sections of the Surgical Consent form after Ms A's surgery, and sent it to the pathology unit.

[29] The decidual reaction is the set of changes in the endometrium of the uterus to prepare it for implantation of an embryo.
[30] The yolk sac is a membranous sac attached to an embryo.

77. However, all of Ms A's right fallopian tube was needed for testing. After testing, the tissue was stored in paraffin blocks.[31]

78. On 19 Month1, Registered Nurse (RN) L followed up on the return of tissue with the pathology unit, and was told that there was no available tissue to return. Waitemata DHB told HDC that RN L then needed to confirm with Ms A, via the obstetric/gynaecology team, whether she wanted to have the paraffin blocks melted and the processed tissue returned. Waitemata DHB told HDC that RN L vaguely recalled informing an obstetric/gynaecology consultant or registrar (but could not recall whom) that the tissue was not available for return, with the expectation that the person she informed would follow this up with Ms A at her pregnancy clinic appointment the next day. However, this is not documented, and a letter setting out the process for having paraffin blocks melted and processed tissue returned was not sent to Ms A, as was required by Waitemata DHB's policy (outlined below).

79. Waitemata DHB told HDC that, on 20 Month1, an offer was made to melt the paraffin blocks for Ms A, so that the tested tissue could be returned, but she declined this offer. Waitemata DHB was not able to identify who made this offer, and there is no documentation regarding such an offer.

80. Ms A told HDC that no offer was made to melt the paraffin blocks and return her tissue at this time. She stated that, while she particularly wanted her fallopian tube returned when she thought it contained fetal tissue, she would still never have declined an offer to return it, as it was a part of her body and she wanted it returned.

81. Waitemata DHB told HDC that, in clinic on 9 Month2, Ms A indicated that she had reconsidered her decision not to have the tissue returned and now wanted it returned.

82. Waitemata DHB stated that a maternity social worker, Ms M, contacted the Surgical Pathology Unit on 13 Month2 to request the return of the tissue. Waitemata DHB told HDC that Ms M arranged to meet with Ms A to return her tissue to her on 2 Month4; however, Ms A did not attend that meeting. Ms A's tissue was returned to her the following day.

83. Waitemata DHB told HDC that Ms M was unable to recall what occurred between requesting the tissue on 13 Month2 and providing the tissue to Ms A in Month4. It stated that the pathology unit was unable to determine the cause of the delay, but it is possible that a pathologist was waiting for a clinician to confirm with Ms A that she understood that melting the paraffin blocks would mean that there would be no tissue available for any further testing.

Further information

Ms A

84. Ms A gave birth to a healthy baby, who is developing well.

[31] Paraffin blocks are used in preparing a selected portion of tissue for pathological examination. The tissue is fixed so that it will not change, and then the water is removed and replaced with paraffin, forming a block that is cut into 8mm slices for examination.

85. Ms A stated that the surgery to remove her fallopian tube was physically and emotionally hard on her. She told HDC:

> "Even though I did not lose my baby in the end, I lost a piece of [my] body and my spirit. I could not talk to my family or friends about it for weeks, especially in that week in between the surgery and the blood tests because I would break down."

Ms D

86. Ms D told HDC: "I am sorry about the outcome [Ms A] experienced in this case."

Ms B

87. Ms B told HDC that, in her view, communication breakdown was the major contributing factor in this case. She stated that, if she was in a similar situation in the future, she would ensure that the lines of communication were clearly defined by herself, the trainee sonographer, and the radiologist.

Dr C

88. Dr C told HDC:

> "I would like to outline regret and offer apologies for the outcome [Ms A] has experienced. I have met personally with [Ms A] and her mother to offer my apologies directly and have followed this up in writing to them."

The radiology clinic

89. The radiology clinic stated:

> "We would again like to outline our regret and offer apologies for the outcome [Ms A] has experienced. We have met with [Ms A] and her mother and offered these apologies directly."

90. The radiology clinic acknowledged that the diagnosis of ectopic pregnancy was incorrect. However, it noted that the referral form asked a specific question about the site of the pregnancy, indicated that there was pain in the abdomen, and suggested that Ms A was possibly nine weeks pregnant. There was no β-hCG result available. The radiology clinic stated that it was reasonable that there was a high index of suspicion for an ectopic pregnancy with the information on the referral and the clinical presentation.

91. The radiology clinic told HDC:

> "[The radiology clinic] has robust supervision processes and practices in place for trainee sonographers. All trainee sonographers are on-site with a fully trained and experienced sonographer. All trainee sonographers' scans and work must be signed off by the supervising sonographer. Discussions with supervising radiologists are also facilitated either in person or on the telephone (tele-radiology model). … Ultimately our radiologists and trained sonographers take responsibility for the work of our trainee sonographers."

92. The radiology clinic told HDC:

> "The facts in the present case lead clearly to the conclusion that the adverse outcome here was as a result of individual error not systemic error. Further, [the radiology clinic] had done everything that a radiology provider organisation could be expected to have done to prevent an error of this kind occurring. … [the radiology clinic] has robust policies and procedures in place to manage obstetric ultrasound scans. We are audited on an annual basis and our quality systems are reviewed regularly by our own staff. … There is no suggestion that [the radiology clinic] had inadequate systems or processes that have led to this error occurring."

93. Nonetheless, the radiology clinic told HDC that it has continued with its education programme in terms of clinical interpretation skills for sonographers. It also stated that it has now implemented the use of new technology for better documentation of fetal heart activity in obstetric ultrasound scanning.

Ultrasound Manual — the radiology clinic[32]

94. The radiology clinic's ultrasound manual (reviewed on an as-required basis or annually at a minimum) provides policy and procedural information for all ultrasound scans, including details on patient preparation, equipment, image sequence, structures/organs and normal vs abnormal progression. The Ultrasound Manual contains prompts and reminders about appearances and red flags in relation to ectopic pregnancies.

95. The Ultrasound Manual also contains policies and procedures outlining communication and escalation paths between supervising radiologists and sonographers. The radiology clinic stated that the standard process is that, if there is any doubt in relation to a scan, there is a conversation and review between a radiologist and the sonographer/s conducting the scan.

Adverse event investigation report — the radiology clinic

96. The radiology clinic carried out an adverse event investigation into these events. The investigation found that it was appropriate to refer for urgent specialist review based on the ultrasound findings, as ectopic pregnancy could not be excluded. However, it also found that clinical and technical interpretation by sonographers were key areas for improvement, and that the language used in reports was also a potential area for improvement.

97. The investigation report recommended: ongoing education on ectopic pregnancy as part of professional development plans; including the name of the sonographer who carried out the scan on reports; and ensuring that the language used in reports is tailored to the clinical context.

[32] The Manual was issued before the events in this opinion.

Waitemata District Health Board

98. Waitemata DHB stated it: "…would … like to extend…sincere apologies to [Ms A] for the distress this event has caused. Her distress as a result is acknowledged and deeply regretted."

99. Waitemata DHB acknowledged that aspects of its policy and process for the return of tissue were not followed, that the process for return of tissue was not communicated to Ms A adequately, and that its communication with Ms A in relation to arranging for the return of her tissue did not meet accepted standards and was unacceptable. It stated that it has followed up with the relevant teams regarding the appropriate management and communication of information in relation to return of tissue.

100. Waitemata DHB told HDC that Dr K sincerely apologised for not completing the relevant section of the Surgical Consent form and regrets that this contributed to Ms A's distress. Dr G also apologised for her oversight in not noticing that the return of tissue section had not been completed and the distress this caused Ms A. Dr G's usual practice does not include discussing return of tissue, and she does not alter the Surgical Consent form unless the procedure described differs from the one the surgeons intend to undertake.

101. Waitemata DHB explained that tissue is unlikely to be ready for collection at the time of discharge, so the process for its return (a letter to be sent to the patient from the Director of Nursing and Midwifery when the tissue is released and ready to pick up, and then a time and place arranged for return of the tissue) is part of the information that the patient must receive at the time of consent for removal of the tissue. Waitemata DHB stated that an information sheet titled "Clinical Tissue Return of Patient Tissue" can be given by staff to patients at the time of consent for removal.

102. Waitemata DHB told HDC that it is standard protocol for the pathology unit to return only any extra tissue that has not been used. It explained that the pathology unit adheres to the National Pathology Accreditation Advisory Council (NPAAC) standards as part of its International Accreditation New Zealand accreditation, which it needs in order to operate. Waitemata DHB stated that NPAAC requires retention of tested specimens for one month; however, the DHB retains specimens for eight weeks.

103. Waitemata DHB stated that Ms M acknowledged that she should have documented her interactions with Ms A in more detail. Social work management staff are working with their social work team and other relevant services in Women's Health to ensure that staff are meeting expected standards in relation to their responsibilities and documenting interactions and planned follow-up. This will help to ensure that there is a clear understanding of Waitemata DHB's policy and procedures for returning tissue.

104. Waitemata DHB told HDC that it now has a single contact person for the return of all tissue — the Director of Nursing and Midwifery. It stated that this change has been working effectively since implementation. Waitemata DHB has also put in place a fixed day and time for collection of tissue from the pathology unit. Where there are

difficulties with transport, the Director of Nursing and Midwifery arranges to have the tissue delivered to the patient.

105. Waitemata DHB has updated its Release of Tissue form to require the date on which the specimen was packed, and to add the word "requested" to the "date received" section. It told HDC that this will assist in tracking the progress of the return of tissue and clarify whether a verbal or written request has been made.

Body Parts, Tissue Storage, Cremation and Return Policy — Waitemata DHB

106. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy — 2. Policy Statements"[33] states:

> "2.2 Tissue not held in Tissue Libraries …
>
> Tissue is retained by Surgical Pathology for 8 weeks to ensure availability for diagnostic testing and where a patient has not indicated return of the body part/tissue. After which time the body part/tissue will be disposed of using appropriate processes or returned to the patient if requested.
>
> Paraffin blocks which contain a very small quantity of tissue are required by the Royal College of Pathologists of Australasia to be retained for 20 years from the date of surgery. On request these can be returned to a patient. …
>
> 2.5 Consent
>
> Patients … must receive sufficient information regarding body parts/tissue management to give informed consent.
>
> Patients … are to receive the appropriate information leaflet prior to giving informed consent and this is to be documented in the clinical record.
>
> The information to the patient … regarding management of body parts/tissues will include an explanation on testing, storage, return or disposal and will be relevant to the patient's clinical management. It is the responsibility of the team carrying out the procedure to gain this consent and to ensure that the patient … understand[s] the information regarding the management of body parts/tissue. …
>
> 2.7 Collection
>
> Tissue that the patient wishes for return is
>
> — either returned to the patient at the time. …
>
> — or held by Surgical Pathology and returned to the [patient] after diagnostic testing."

107. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy — 3. Storage of Tissue for Pick Up" states:

[33] Issued December 2012.

"3.2 Notification of Readiness for Return

Patients are formally advised of the process for retrieval of tissue

- verbally at the time they sign the consent form in a copy of an approved pamphlet explaining the procedure and contact process …
- If [the] diagnostic process [is] not complete [on discharge] then [the nurse/midwife/maternity social worker discharging the patient] should discuss the process with the charge nurse/midwife/maternity social worker or Duty Nurse Manager, who will assist in retrieving the tissue and prepare the specimen for handover from the Surgical Pathology

The patient is sent a letter from the Director of Nursing & Midwifery advising them that the tissue is released for pick up."

108. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy — 4. Body Parts/Tissue for Return" states:

"4.2 Body Parts/Tissue for Laboratory Testing & later return to patient

Follow the steps below to ensure the management of body parts/tissue for laboratory testing is followed

Steps	Action
1	Before any procedure there is discussion with the patient/ family/whanau regarding the testing and return/disposal of body parts/tissue. Information leaflets are given and discussed.
2	Patient/family/whanau indicates on 'Agreement to Treatment' form that the tissue to be returned after Laboratory testing. Consenting doctor completes the 'Body Parts/Tissue Release' form (tba) according to information on 'Agreement to Treatment' form.
…	…
9	After testing Surgical Pathology Tissue Management oversee return."

109. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy — 7. General" states:

"7.1 No Tissue to Retrieve

Where Surgical Pathology has received little tissue to test and therefore has little to return to the patient, the patient is advised that the tissue cannot be returned.

A letter is written as follows

> 'The tests undertaken on your tissue have been placed in paraffin blocks as required by the diagnostic test. This has only left a small amount that can easily be returned. The majority of the tissue is in the paraffin blocks. We're happy to show you the paraffin blocks so you can see what they look like and to explain 'face to face' why it is recommended by the Royal College of Pathologists of Australasia that we retain all tissue blocks and slides for 20 years from the time of surgery. By keeping the paraffin blocks, we could do further tests for you or your family in the future should this be needed for diagnostic and prognostic reasons. If the tissue is returned we may not have the blocks available to do the molecular studies if needed'.
>
> If the patient insists on receiving the tissue after an explanation, this is released after the person has signed appropriate release documents."

110. Waitemata DHB also has a policy titled "Specimen Management Policy".[34] Part 14 of this policy, "Return of Clinical Tissue to Patients", refers to the "Body Parts, Tissue Storage, Cremation and Return Policy".

Responses to provisional opinion

111. Responses to the provisional opinion were received from Ms A, Ms D, Ms B, Dr C, the radiology clinic, and Waitemata DHB. Waitemata DHB had no further comments. The radiology clinic's feedback has been incorporated into the "information gathered" section of the report where appropriate.

112. Ms A stated:

> "I am Māori with strong connections to my tikanga. In addition to this, I was a 19 year old stressed and sickened with what was happening to me, frightened … no one asked me if I wanted my tissue returned. … The bottom line is, that for a week after the Surgery I believed that my removed fallopian tube contained a baby and I wanted to have it returned to me so that I could dispose of it in line with tikanga."

113. Ms D stated that she has learned from these events and has since undertaken significant training and professional development. She acknowledged that she misinterpreted the scan images and stated that she is sincerely sorry for her actions and the implications of them for Ms A. Ms D also stated that, while she does not wish to minimise her actions or deflect responsibility, as a trainee sonographer, she was under the supervision of Ms B, who had the final say and overall responsibility.

114. Ms B stated that she is extremely sorry for the bad experience Ms A had. Ms B said that she has learned from this experience and will make sure that her doubts and disagreements are documented and communicated in future. Nonetheless, Ms B stated that the radiology clinic's processes did not require her to take over the care of Ms A and reassess her, when she disagreed with Ms D's diagnosis of a live ectopic

[34] Issued February 2015.

pregnancy. Ms B stated that her role in the scan was simply to provide Ms D with her opinion on it. Ms B said that she understood that the process in place at the radiology clinic allowed a trainee sonographer to work independently and seek advice, which Ms D did.

115. Ms B also stated that the radiology clinic's processes did not require her to speak to Dr C or to convey her doubts about the diagnosis of ectopic pregnancy to him. She told HDC that she believed Ms D would convey to Dr C that she (Ms D) had seen a heartbeat, but Ms B had not. Ms B also stated that the process was that the radiologist would call her if he was dissatisfied with the findings, which Dr C did not do.

116. Ms B acknowledged that she made a mistake in not personally ensuring that Dr C was aware of her interpretation. However, she stated that she does not believe she was provided with the radiology clinic's ultrasound manuals, but believes that her actions were in accordance with the processes put in place by the radiology clinic.

117. Dr C conveyed his sincere regret and apologies for the outcome experienced by Ms A. In response to the provisional opinion, the radiology clinic stated that it is the role of the sonographer, not the radiologist, to identify ectopic pregnancies sonographically. The radiology clinic said that radiologists are bound to accept the direct observations of sonographers and are not personally responsible for ensuring that their observations are correct. The radiology clinic stated that the senior sonographer is responsible for ensuring that the worksheet provided to the radiologist is an accurate reflection of the findings. The radiology clinic said that Dr C's recommendation for onward referral for Ms A was appropriate, given the sonographers' findings and Ms A's clinical presentation.

Opinion: Introduction

Factual findings

118. Ms A presented to her GP, Dr E, after taking at-home pregnancy tests, the results of which were positive. She reported left-sided abdominal pain and Dr E referred her for an urgent ultrasound, noting on the referral: "?9 weeks. Left sided pain ?site of pregnancy." Dr E also sent blood samples to the laboratory to check Ms A's β-hCG level, but the result was not available at the time of the ultrasound.

119. Ms A's ultrasound was performed by trainee sonographer Ms D on 13 Month1 at the radiology clinic. Ms B was the supervising sonographer and Dr C was the reporting radiologist, working from a location remote from where the scan was performed. Ms D performed the scan without Ms B present, and then informed Ms B that she thought Ms A had a live ectopic pregnancy.

120. Ms D then rescanned Ms A while Ms B observed. Ms B stated that she saw an empty intrauterine gestation sac, a trace of free fluid, a fetal pole-like structure in the right adnexa and no fetal heartbeat. Ms B asked Ms D to apply the M-mode Doppler and

then the Colour Doppler over the right adnexa, to observe and then confirm the fetal heartbeat. Ms D stated that they "observed colour over the mass", following which Ms B said "that was fine" and that they could end the scan. Ms A recalls that Ms B told Ms D that she agreed with her findings. However, Ms B told HDC that she did not see the fetal heartbeat on M-mode and the Colour Doppler images were not convincing of a fetal heartbeat. She stated that she discussed this with Ms D at the time, and Ms D was confident that she had seen a fetal heartbeat earlier.

121. I accept Ms B's statement that she did not see the fetal heartbeat and that she discussed this with Ms D at the time. However, having considered the different accounts of events, and given that Ms A recalls Ms B agreeing with Ms D's findings, I consider it more likely than not that, at the time, Ms B accepted Ms D's finding that a fetal heartbeat could be seen in the right adnexal mass.

122. Ms D telephoned Dr C and told him that she and Ms B both thought that Ms A had a live ectopic pregnancy. Ms D noted that visualisation was limited. Ms D and Ms B told HDC that only Ms D spoke to Dr C. After reviewing the images, Dr C called back Ms D and asked her to tell Ms A to go straight back to her GP. Again, Ms D and Ms B told HDC that Dr C spoke with only Ms D.

123. In contrast, Dr C told HDC that he questioned both sonographers on the phone at some length and they both confirmed that a fetal heartbeat had been demonstrated outside the uterus.

124. The sonographer's worksheet, provided to Dr C, listed the sonographer as "[Ms D/Ms B]". The worksheet states:

> "*Live ectopic pregnancy. Single live seen in [right ovary]; [Crown rump length] = 12mm. Free fluid seen. No pain on scan. [Left ovary] normal. 1 x small (empty) [gestational sac] like structure within uterine cavity = 4mm."

125. The crown rump length measurement section of the worksheet was filled in as "12mm = 7 [weeks] 2 days".

126. Having considered the different accounts of events, I accept Ms B and Ms D's recollection that only Ms D spoke with Dr C. However, I also note Ms D's statement that she told Dr C that she and Ms B both thought that Ms A had a live ectopic pregnancy, and that the worksheet listed the sonographer as "[Ms D/Ms B]". Accordingly, I consider it more likely than not that Dr C gained the impression, either expressly or impliedly, that there was consensus between Ms D and Ms B regarding the findings.

Opinion: Ms B — Breach

127. My expert advisor, sonographer Jillian Muirhead, advised that a thorough scan was performed, but the scan images were misinterpreted. She stated:

> "[T]he area in the right adnexa, measured as an embryo, does not display the usual morphological appearance of an embryo, in these still images. There is also no defined gestation sac and yolk sac seen, which would be expected with a live ectopic. The 'pseudosac' within the uterus, does in fact display the double decidual sign, which would make it more likely to be a gestation sac than a pseudosac, although cannot be proved until a follow up after a period of time, shows the development of the yolk sac and embryo. … Correlation with β-hCG would have indicated that the levels were too low to be consistent with a 'live' 7-week pregnancy … The m-mode does not show fetal heart activity (which would be seen just at the depth of the supposed embryo (2cm)), but shows some [pulsations] coming from the level of about 1.3cm and extending through the image, so coming from maternal vessels. So this has definitely been misinterpreted …"

128. Ms B told HDC that she assumed that Dr C's report would request a repeat ultrasound scan with serial β-hCG levels, given the presence of an intrauterine gestation sac and as the fetal heartbeat was not well demonstrated, but did not discuss this with him. Regarding this point, Ms Muirhead advised:

> "[If] [Ms B] was unable to support the interpretations that [Ms D] made, she should have taken over the patient, as the supervising sonographer and fully assessed the patient herself, then discussed the case with the reporting radiologist."

129. In response to the provisional opinion, Ms B stated that the radiology clinic's processes did not require her to take over the care of Ms A and reassess her, or to speak to Dr C or convey her doubts about the diagnosis of ectopic pregnancy to Dr C. However, Ms Muirhead stated that ultimately Ms B was responsible for the information going out, and I agree.

Conclusion

130. As the supervising sonographer, it was Ms B's responsibility to ensure that Ms D's interpretation of the scan was correct. I acknowledge that Ms B has stated that she did not agree with Ms D's findings, as she did not see a fetal heartbeat in the right adnexal mass. In my view, in that case, Ms B should have taken over the care of Ms A and re-assessed her herself, instead of accepting Ms D's findings. Furthermore, Ms B should have conveyed any doubts about the diagnosis to Dr C, including her assumption that his report would request a repeat ultrasound scan with serial β-hCG levels, given the scan findings. I acknowledge Ms B's statement that these actions were not required by the radiology clinic's policies. However, I remain of the view that, by failing to take these actions, Ms B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Opinion: Ms D — Other comment

131. Ms D performed a trans-abdominal and trans-vaginal scan for Ms A. Ms D saw a cystic space in the uterine cavity, but was unsure whether a double decidual reaction was present. She also saw free fluid in the Pouch of Douglas and a mass in Ms A's right adnexa, which she thought was in the shape of a fetal pole. Ms D placed an M-mode cursor over the region and thought she could see pulsations representing the fetal heartbeat. She left the room and told her supervising sonographer, Ms B, that she thought Ms A had a live ectopic pregnancy. Ms B then re-scanned Ms A while Ms B observed.

132. My expert advisor, sonographer Jillian Muirhead, stated:

> "A thorough scan was performed, including both transabdominal and transvaginal imaging. Imaging covered the necessary areas within the pelvis and an abnormality in the right adnexal region was identified."

133. However, Ms Muirhead advised that the images were misinterpreted. She stated:

> "[T]he area in the right adnexa, measured as an embryo, does not display the usual morphological appearance of an embryo, in these still images. There is also no defined gestation sac and yolk sac seen, which would be expected with a live ectopic. The 'pseudosac' within the uterus, does in fact display the double decidual sign, which would make it more likely to be a gestation sac than a pseudosac, although cannot be proved until a follow up after a period of time, shows the development of the yolk sac and embryo …
>
> There has been a mistake made in the interpretation of the abnormality in the right adnexa, however this did look extremely abnormal and warranted referral for immediate assessment with an O&G specialist …
>
> Correlation with β-hCG would have indicated that the levels were too low to be consistent with a 'live' 7-week pregnancy … The m-mode does not show fetal heart activity (which would be seen just at the depth of the supposed embryo (2cm)), but shows some [pulsations] coming from the level of about 1.3cm and extending through the image, so coming from maternal vessels. So this has definitely been misinterpreted …"

134. Ms Muirhead concluded:

> "The care offered to [Ms A] [by Ms D] was of adequate standard. There was obvious difficulty with interpreting the scan … but that is acceptable for a trainee. And she did bring the supervising sonographer in to check appearances."

Conclusion

135. Ms D misinterpreted the images and inaccurately documented a live ectopic pregnancy. While there was an abnormal mass in Ms A's right adnexa, the appearance of this was not consistent with an ectopic pregnancy. Further, the M-mode did not

demonstrate a fetal heartbeat in this area, and the intrauterine sac displayed the double decidual sign, making it likely to be a gestational sac. Ms D misinterpreted the scan; however, this is mitigated by the fact that she was a trainee sonographer at the time, she appropriately extended the examination, and she consulted her supervising sonographer, Ms B, to establish whether her interpretation was correct.

Opinion: Dr C — Adverse comment

136. Dr C discussed the ultrasound images with Ms D, and gained the impression that both of the sonographers agreed that a fetal heartbeat had been demonstrated outside the uterus. This was supported by the sonographer's worksheet. Dr C stated that this was "despite the images being less convincing".

137. Dr C telephoned Dr E and advised that an ectopic pregnancy was suspected and that it was recommended that Ms A be referred to the public hospital for urgent specialist assessment. Dr C wrote in the ultrasound report:

> "There is no evidence of an intrauterine gestational sac. A pseudosac is noted. In the right adnexal region there is a cystic lesion with a 12mm fetal pole and fetal heart activity was observed within this.
>
> Free fluid is seen about the right ovary. Patient did not appear particularly tender at the time of examination.
>
> Left ovary and left adnexal region normal.
>
> **Comment: As discussed by phone appearances today are consistent with a right sided ectopic pregnancy.**"[35]

138. My expert advisor, radiologist Dr Mark Leadbitter, advised:

> "There are 5 images of the right adnexa which demonstrate a solid looking complex area with increased echogenicity centrally. The central area has been measured as a 1[2]mm crown rump length, but does not look like a foetal pole. There are no images of a definite gestational sac. A foetal heartbeat was said to be present, but this has not been demonstrated on the pulsed Doppler trace. There is no increased vascularity in the right adnexa. These are not convincing sonographic appearances for a live ectopic pregnancy."

139. While Dr Leadbitter advised me that Dr C should have recognised that the appearances were not those of a live ectopic pregnancy and questioned the sonographers about this, he also stated:

[35] Emphasis as per original.

> "There would be nothing unusual about the Radiologist only speaking to the trainee Sonographer about the case … as he could reasonably expect to be given the consensus view of the 2 sonographers. … the bottom line of the written worksheet was 'Live Ectopic Pregnancy' and any reporting Radiologist is bound to proceed on that basis and expedite admission to hospital through the referring clinician."

140. Dr Leadbitter concluded:

> "Overall, I have concluded that the departure from the expected standard of care was moderate. But I think the majority of this departure derives from the 2 Sonographers agreeing that there was a foetal heartbeat seen outside of the uterus. Even though the documented appearances of the 'ectopic pregnancy' that the Radiologist had to review were not convincing for this diagnosis, the diagnosis of ectopic pregnancy is inescapable if a heartbeat is said to be seen outside of the uterus."

141. In response to the provisional opinion, the radiology clinic stated that it is the role of the sonographer, not the radiologist, to identify ectopic pregnancies sonographically. The radiology clinic said that radiologists are bound to accept the direct observations of sonographers and are not personally responsible for ensuring that their observations are correct.

Conclusion

142. In his radiology report of 13 Month1, Dr C inaccurately diagnosed a right ectopic pregnancy. I acknowledge that Dr C did not see the ultrasound in real time and was under the impression that Ms D and Ms B agreed that there was a live ectopic pregnancy, and, in this respect, I acknowledge Dr Leadbitter's advice that the diagnosis of ectopic pregnancy was inescapable, given a fetal heartbeat was said to have been seen outside of the uterus. However, I also note Dr Leadbitter's advice that the captured images were not convincing for a live ectopic pregnancy. Dr C also stated that, in his view, the images were "less convincing" for a fetal heartbeat outside of the uterus.

143. As the reporting radiologist, Dr C was responsible for ensuring that his interpretation of the ultrasound images was correct. I am critical that Dr C held the view that the images were "less convincing" for a fetal heartbeat outside of the uterus, but failed to take any further action in that respect. It was open to him, for example, to request that the examination of Ms A be extended (request further images be taken), or to have conveyed in his report and to Dr E his view that the images were not convincing for ectopic pregnancy.

Opinion: Radiology clinic — No breach

144. Radiology clinics have a responsibility to ensure that they have adequate systems and procedures in place to support staff, in order to facilitate consumers receiving an appropriate standard of care.

145. At the time of these events, Ms D, Ms B, and Dr C were employees of the radiology clinic. The radiology clinic is a healthcare provider and an employing authority for the purposes of the Health and Disability Commissioner Act 1994. As such, the radiology clinic may be held directly liable for the care provided to Ms A, and it may be held vicariously liable for any actions or omissions of its employees and/or agents.

146. It is noted that three individual employees each misinterpreted Ms A's images. However, at the time of these events, the radiology clinic had relevant policies and procedures in place relating to antenatal ultrasound, including in regard to ectopic pregnancy. It also had processes in place for trainee sonographers to be supervised by qualified sonographers.

147. My expert advisor, sonographer Jillian Muirhead, advised me that the radiology clinic's policies relating to sonography were adequate.

148. My expert advisor, radiologist Dr Mark Leadbitter, also advised that "[the radiology clinic's] policies and procedures … seem consistent with accepted best practice standards for Radiology Clinics and departments in New Zealand".

149. I am satisfied that the respective failings by Ms B, Ms D, and Dr C in this case were matters of individual clinical judgement. Furthermore, there were appropriate policies and processes in place at the radiology clinic at the time. Therefore, I do not consider that the radiology clinic breached the Code.

Opinion: Waitemata District Health Board — Breach

150. Ms A presented to the public hospital on 13 Month1 after an antenatal ultrasound scan earlier that day diagnosed a live ectopic pregnancy. She underwent surgical removal of her right fallopian tube, but subsequently was found to have a normal intrauterine pregnancy. Prior to surgery, she was provided with a Surgical Consent form with a tick box relating to return of tissue, but this section of the form was not completed. After surgery, Ms A requested the return of her right fallopian tube, but this was not returned until Month4.

Clinical care

151. Ms A was referred to the public hospital by her GP, Dr E, on 13 Month1. The referral stated: "Thank you for seeing [Ms A] with right ectopic pregnancy on scan." It noted that her last menstrual period had been due on the 11th day of the previous month, but was not always regular, and that she had left-sided abdominal pain. The ultrasound

report diagnosed a right-sided ectopic pregnancy and stated that there was a pseudosac, with no evidence of an intrauterine gestational sac. A cystic lesion was noted in the right adnexal region with a 12mm fetal pole within which fetal heart activity was observed.

152. Ms A was triaged by ED nursing staff as a category two (to be seen within 10 minutes by a doctor), but was not seen by a doctor for over one hour and 40 minutes. Waitemata DHB told HDC that the delay was due to the obstetric/gynaecology team being involved in a medical emergency at that time.

153. At 7.40pm, Ms A was reviewed by obstetric/gynaecology house officer Dr K, who recorded that Ms A was nine weeks pregnant, the due date of her last menstrual period, and that her β-hCG levels were falling. Her β-hCG level from a blood test taken that morning was 1,450 IU/L and her β-hCG level from a blood test taken in the ED that evening was 1,211 IU/L. Dr K's plan was for Ms A to remain nil by mouth, for possible surgery that night to remove her right fallopian tube.

154. While waiting in the ED, Ms A ate food, having been told that she could do so. Waitemata DHB told HDC that usual practice is for the primary nurse to be consulted prior to food being given to patients in the ED. However, this does not appear to have occurred, and the DHB was unable to identify who told Ms A that she could eat. The DHB stated that, while this contributed to Ms A being unable to have surgery that night, the main reason her surgery was delayed until the next day was the overall clinical priorities of the obstetric/gynaecology team at the time. Waitemata DHB noted that Ms A was stable, her intermittent pain was managed with analgesia, and there was a plan in place for review if her condition changed.

155. Waitemata DHB told HDC that there was no clinical indication to repeat the ultrasound prior to surgery. It stated that there was no clinical suspicion that the pregnancy was intrauterine, and falling β-hCG levels confirmed the diagnosis of ectopic pregnancy. Ms A's β-hCG level was reported as 1,329 IU/L at 9.21am on 14 Month1, from blood tests taken earlier that morning. Surgery was commenced at 9.23am and her right fallopian tube was removed. The operation note recorded that the right fallopian tube was swollen.

156. My expert advisor, obstetrician Dr Michel Sangalli, stated: "When there is a live ectopic pregnancy, the diagnosis is clear cut and so is the treatment. A laparoscopy with a salpingectomy is the treatment of choice." He advised:

> "[W]hen there is a clear report/diagnosis of ectopic pregnancy, particularly live, there [is] a strong chance that the diagnosis would not be doubted as the scan findings are straight forward and that the scan would not be repeated in the department. … The majority of consultants would not scan or ask for a scan under such circumstances. Some registrars would review the films from the scan, if available or review them with a sonographer."

157. While Dr Sangalli advised that, when there is a clear diagnosis of a live ectopic pregnancy, the diagnosis is not usually re-checked by correlation with β-hCG levels,

he also advised that the β-hCG levels falling from 1,450 in the morning to 1,211 in the evening was not diagnostic of a failed or ectopic pregnancy, as the tests were taken too close together in time. He stated that there is a margin of error for each β-hCG measurement, and the level had not fallen significantly enough.

158. Dr Sangalli advised that the β-hCG levels were too low to be consistent with an ectopic pregnancy with a 12mm live embryo, and were more consistent with Ms A's real pregnancy (four to five weeks' gestation). He stated that Waitemata DHB staff could have been more suspicious, given how low the β-hCG levels were.

159. Dr Sangalli also advised that perhaps Waitemata DHB staff could have been suspicious of an erroneous diagnosis at the time of the surgery, as the fallopian tube was probably not as swollen as it would have been with a tubal ectopic pregnancy with a 12mm live embryo. However, he acknowledged that the right tube does appear swollen from the images taken during the surgery.

160. Dr Sangalli concluded: "[Ms A] was unfortunately firmly misdiagnosed with a right live ectopic pregnancy and she received standard and appropriate care, in a timely manner, from the team at [Waitemata DHB]." He also stated: "In my opinion, overall, there was no departure from the standard of care, but the care could have been better. There was a missed opportunity to pick up the misdiagnosis of ectopic pregnancy."

161. I accept Dr Sangalli's advice regarding the clinical care provided to Ms A.

Conclusion

162. I consider that, on the basis of the information available to Waitemata DHB staff at the time, it was reasonable to carry out surgery to remove Ms A's right fallopian tube. While, in hindsight, it would have been beneficial if an additional ultrasound had been carried out at the public hospital prior to surgery, or the images of the community ultrasound reviewed, I consider that it was reasonable in the circumstances for the obstetric/gynaecology team not to have done so. I note that the ultrasound report did not convey any doubt about the diagnosis of live ectopic pregnancy.

163. Nonetheless, I am concerned that Waitemata DHB stated that Ms A's falling β-hCG levels confirmed the diagnosis of ectopic pregnancy, given Dr Sangalli's advice that the β-hCG levels falling from 1,450 in the morning to 1,211 in the evening was not diagnostic of a failed or ectopic pregnancy, as the tests were taken too close together in time. I also note that, while Ms A's right fallopian tube was swollen, Dr Sangalli advised that it was probably not as swollen as it would have been with a tubal ectopic pregnancy with a 12mm live embryo.

164. I am also concerned that, after Ms A's β-hCG results were available and showed low β-hCG levels, the obstetric/gynaecology team did not question the estimated gestation of nine weeks and, therefore, consideration was not given to the possibility that Ms A could be four to five weeks pregnant, which would be more consistent with her β-hCG levels. I consider that it would have been prudent for the obstetric/gynaecology team to have kept in mind the possibility of an early intrauterine pregnancy.

165. I am also mildly critical that there was considerable delay before Ms A was seen by a doctor after being triaged in the ED, and that she was told that she could eat when she was supposed to be nil by mouth. However, I accept that Ms A was managed in accordance with overall clinical priorities at the time, and that there was a plan in place to review Ms A if her condition changed.

Return of tissue

166. Under Right 6(1) of the Code, Ms A had the right to the information that a reasonable consumer, in her circumstances, would expect to receive. In my view, a reasonable consumer undergoing removal of her fallopian tube would expect to receive information about the return of tissue process, including expected timeframes for the return of tissue and the consequences of any decision regarding the return of tissue.

167. On the evening of 13 Month1, Dr K went through the informed consent procedure with Ms A for surgery to remove her right fallopian tube, including completing the Surgical Consent form. The section relating to the return of body part/tissue was not completed. Waitemata DHB told HDC that Dr K's usual practice was to discuss with patients whether they wanted their tissue returned, and he had a vague recollection of a conversation with Ms A about tissue return, but no specific recall. Ms A told HDC that she was never told about return of tissue at that time, and never read that part of the Surgical Consent form. Having considered the different versions of events (including that the relevant sections of the consent form were not completed), I consider it more likely than not that Dr K did not have an adequate discussion regarding return of tissue with Ms A prior to surgery.

168. Ms A was reviewed later that night by Dr F, who did not note that the return of tissue section of the Surgical Consent form had not been completed by Dr K.

169. The next morning, Dr G reviewed Ms A preoperatively. Waitemata DHB told HDC that Dr G discussed the operation with Ms A and was satisfied that there was a valid surgical consent. Dr G did not notice that the return of tissue section of the Surgical Consent form had not been completed. Ms A's preoperative assessment checklist was completed by RN I and RN H. Both ticked the boxes next to the section stating "Surgical Consent Form dated and signed". Neither noted that the return of tissue section of the Surgical Consent form had not been completed.

170. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy" set out that patients must receive sufficient information regarding body parts/tissue management to give informed consent (including an explanation on testing, storage, return or disposal), and that they are to receive the appropriate information leaflet prior to giving informed consent, which is then documented in the clinical record.

171. After surgery, Ms A told RN I that she wanted her removed fallopian tube returned to her. RN I asked Dr J to complete the consent process for the return of tissue. Ms A told HDC that nursing staff were rude to her when she asked for the return of her fallopian tube, and that she was told that she would most likely not be able to get it back, because she did not complete the relevant section of the Surgical Consent form. Waitemata DHB has been unable to clarify with RN I whether she told Ms A about

the process for return of tissue, and there is no record of this conversation. Accordingly, I am unable to make a finding as to what was discussed with Ms A regarding return of her tissue at this time.

172. Dr J completed the relevant section of the Surgical Consent form on 14 Month1 and faxed it to the pathology unit. Dr J recorded in Ms A's clinical records that Ms A was aware that return of her tissue had been addressed.

173. All of Ms A's right fallopian tube was used during testing, so none was set aside for return to her. After testing, the tissue remained in paraffin blocks. On 19 Month1, RN L followed up on the return of tissue with the pathology unit and was told that there was no available tissue to return. Waitemata DHB told HDC that RN L then needed to confirm with Ms A, via the obstetric/gynaecology team, whether she wanted to have the paraffin blocks melted and the processed tissue returned. RN L vaguely recalls informing an obstetric/gynaecology consultant or registrar (but could not recall whom) that the tissue was not available for return, with the expectation that the person she told would follow this up with Ms A at her pregnancy clinic appointment the next day.

174. Waitemata DHB told HDC that, on 20 Month1, an offer was made to melt the paraffin blocks for Ms A, so that the tested tissue could be returned, but she declined this offer. However, Waitemata DHB was not able to identify who made this offer, and there is no documentation of such an offer. Ms A told HDC that no offer was made to melt the paraffin blocks and return her tissue at this time. She stated that, while she particularly wanted her fallopian tube returned when she thought it contained fetal tissue, she would still never have declined an offer to return it, as it was a part of her body and she wanted it returned. Having considered the different accounts of events, I find it more likely than not that on 20 Month1 no offer was made to melt the paraffin blocks for Ms A and return her tissue.

175. On 9 Month2, Ms A had an appointment with Ms M, during which she asked for her tissue to be returned. Waitemata DHB stated that Ms M contacted the pathology unit on 13 Month2 to request the return of the tissue. The tissue was not returned until Month4. Waitemata DHB told HDC that neither Ms M nor the pathology unit were able to determine the cause of the delay, but it is possible that a pathologist was waiting for a clinician to confirm with Ms A that she understood that melting the paraffin blocks would mean that there would be no tissue available for any further testing.

176. Waitemata DHB's policy "Body Parts, Tissue Storage, Cremation and Return Policy" stated that, when there is little tissue left to return to a patient, a letter is to be sent explaining the process and the consequences of returning tissue after it had been placed in paraffin blocks (that there would be no tissue left for any further testing).

177. If the patient insists on receiving the tissue after an explanation, the tissue is released when the person has signed appropriate release documents.

178. Ms A was not sent a letter regarding the return of her tissue. Waitemata DHB acknowledged that aspects of its policy and process for the return of tissue were not followed, that the process for return of tissue was not communicated to Ms A adequately, and that its communication with Ms A in relation to arranging for the return of her tissue did not meet accepted standards and was unacceptable.

Conclusion

179. I am concerned that, prior to surgery, there were a number of missed opportunities by numerous staff members to ensure that return of tissue was discussed with Ms A adequately, and that the relevant section of the Surgical Consent form was completed. I am further concerned about the lack of information provided to Ms A after testing on her fallopian tube, including the length of time it would take to return her tissue, and the consequences of returning her tissue after it had been stored in paraffin blocks.

180. Overall, I consider that the process undertaken in regard to returning Ms A's tissue was suboptimal. While Waitemata DHB had detailed policies in place for the return of tissue, these were not followed by numerous staff. This is concerning and, in my view, the DHB has a responsibility to ensure that its staff follow its policies. In particular, Waitemata DHB did not provide Ms A with information that a reasonable consumer would expect to receive regarding the return of tissue process, including information relating to the timeframe for her tissue to be returned, and the consequences of any decision relating to the return of tissue. Accordingly, Waitemata DHB breached Right 6(1) of the Code.

181. I am also critical that Waitemata DHB did not action Ms A's request for return of her fallopian tube within a reasonable timeframe.

Recommendations

182. I recommend that Ms B:

a) Have an independent sonography peer perform a quality review of a random selection of antenatal ultrasound scans and accompanying sonographer's worksheets that she has completed in the last 12 months, and provide the results of the review to HDC within three months of the date of this report.

b) Provide a 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.

183. I recommend that the Medical Radiation Technologists Board consider whether a review of Ms B's competence is warranted.

184. I recommend that Ms D:

a) Have an independent sonography peer perform a quality review of a random selection of antenatal ultrasound scans and accompanying sonographer's worksheets that she has completed in the last 12 months, and provide the results of the review to HDC within three months of the date of this report.

b) Provide a 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.

185. I note that Dr C has already provided a written apology to Ms A. I recommend that he have an independent radiology peer perform a quality review of a random selection of antenatal ultrasound reports he has completed in the last 12 months, and provide the results to HDC within three months of the date of this report.

186. I recommend that the radiology clinic review its supervision processes for trainee sonographers and consider introducing a requirement that the supervising sonographer must take over the care of the patient if there is disagreement between the trainee sonographer and the supervising sonographer about the interpretation of the scan, and report back to HDC on the outcome of the review within three months of the date of this report.

187. I recommend that Waitemata District Health Board:

a) Use this case as an anonymised case study for clinical staff, and report back to HDC on this within three months of the date of this report.

b) Conduct training for all obstetric/gynaecology staff at the public hospital on the cultural and emotional significance of the return of tissue and body parts, and on Waitemata DHB's policy for the return of tissue and body parts, and report back to HDC on this within three months of the date of this report.

c) Provide a 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.

Follow-up actions

188. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waitemata District Health Board, will be sent to the Medical Council of New Zealand, and it will be advised of Dr C's name.

189. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waitemata District Health Board, will be sent to the Medical Radiation Technologists Board, and it will be advised of Ms B's name.

190. A copy of this report with details identifying the parties removed, except the experts who advised on this case and Waitemata District Heath Board, will be sent to the Royal Australian and New Zealand College of Radiologists, the Australasian Sonographers Association, HealthCERT (Ministry of Health), 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:

"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. What is the standard of care/accepted practice?
2. If there has been a departure from the standard of care or accepted practices, how significant a departure do you consider it is?
3. How would it be viewed by your peers?

Timeline of Case:

13 [Month1]
GP visit, pain LIF with pregnancy
LMP believed to be [approximately one month ago] (9 weeks gestation)

Sent for US on 13 [Month1] at [the radiology clinic].
Report: right adnexal mass with embryo and believed to be FH activity.

Images:
Complete study, transabdominal and transvaginal scan.
Found abnormality in the right adnexal. Showed free fluid and what was thought to be embryo. Thought fetal heart could be identified and what was thought to be CRL indicated a 7-week pregnancy, live ectopic.

Small hypoechoic sac in the endometrial cavity, interpreted as a pseudosac.
In hindsight, does look like a double decidual ring, indicating a possible gestation sac.

? Beta HCG result was not available at time of scan.
BHCG was 1450 IU/L — Low — indicated early pregnancy (would have been 4w 4d at this scan going by subsequent findings)

17 [Month1]
Surgery for ectopic pregnancy. Enlarged fallopian tube consistent with ectopic — removed → histology

19 [Month1]
Histology report — no fetal material

20 [Month1] Beta HCG 13,616
Rescanned — I/U GS 5w4d size — Embryo not yet identified

27 [Month1]
Embryo 7mm 6 weeks 3 days [EDD] fetal cardiac activity seen.

Report:

Evaluation of [radiology clinic's] Ultrasound Scan:
A thorough scan was performed, including both transabdominal and transvaginal imaging. Imaging covered the necessary areas within the pelvis and an abnormality in the right adnexal region was identified.

This, however, was misinterpreted by the sonographer (and a second sonographer) as a live embryo, showing cardiac activity. It is difficult to evaluate a scan from still images only, as they are just snap shots of the live imaging. The sonographer has recorded an m-mode trace, which she believed displayed a recording of a fetal heartbeat. On reviewing this, it is difficult to identify an area, which would represent a fetal heartbeat. There is a pattern of movement thoughout the whole of the image, which probably represents the maternal heart rate picked up from the pelvic vessels.

Also the area in the right adnexa, measured as an embryo, does not display the usual morphological appearance of an embryo, in these still images. There is also no defined gestation sac and yolk sac seen, which would be expected with a live ectopic.

The 'pseudosac' within the uterus, does in fact display the double decidual sign, which would make it more likely to be a gestation sac than a pseudosac, although cannot be proved until a follow up after a period of time, shows the development of the yolk sac and embryo. Note is made that this was initially measured as a gestation sac and came out at the size of a 4 week 6 day gestation sac.

My view is that the sonographer has probably had in her mind that this patient was about 9 weeks pregnant, and so overlooked the fact that she could be just 4 to 5 weeks pregnant and the intrauterine sac could be an early gestation sac, which it proved to be. Knowledge of the BHCG would have been useful here.

The patient did have an abnormality in the right fallopian tube region, which was interpreted incorrectly. Having two sonographers identifying this as fetal cardiac activity is difficult to understand, but it is what the sonographers believed at the time.

With review of the timeline, the pregnancy would have been only 4 weeks and 4 days at the time of the scan at [the radiology clinic]. At this stage a gestation sac cannot reliably be seen, although with hindsight, an area suggestive of a gestation sac can be identified in the uterus, and this would have needed further follow-up scans to prove this was a gestation sac. The abnormality in the right

adnexa/fallopian tube, has distracted from the interpretation of this intra-uterine region.

There has been a mistake made in the interpretation of the abnormality in the right adnexa, however this did look extremely abnormal and warranted referral for immediate assessment with an O&G specialist.

Ultrasound scan result was correct in diagnosing an abnormality in the right adnexa, but incorrect in diagnosing it as a 'live' ectopic. Correlation with BHCG would have indicated that the levels were too low to be consistent with a 'live' 7-week pregnancy.

The standard of care was accepted practice, with a complete ultrasound evaluation being performed, and the introduction of a second sonographer to check appearances is commendable. Unfortunately, interpretation has been incorrect for both sonographers, and the radiologist hasn't questioned appearances.

This is a difficult case and only with hindsight, can the misinterpretations be appreciated.

The comments from [Ms A] about the sonographer's behavior/lack of communication are generally a result of the emotion at the time. It is very difficult to deal with the questions from the patient during a difficult scan and with a negative outcome, experience tells us there will often be bad feelings towards the sonographer. There is no indication as to the experience of this sonographer, but she would have been in a difficult position and needed time to concentrate before telling the patient anything. I have had many personal experiences of this and I freely communicate with the patient whenever possible."

The following further expert advice was obtained from Ms Muirhead:

"This is a really difficult thing to assess, but I guess since the interpretation was incorrect, then this is a moderate departure from the standard of care that is accepted practice.

The study showed an abnormality in the right fallopian tube, but the interpretation of this was incorrect. Certainly the quality of the scan was accepted practice, but it fell short in interpretation.

This is something the sonographer will learn an enormous amount from and will never make the same mistake again.

I do believe the sonographers should be reporting these and not the radiologist, who doesn't see the patient. They rely totally on the [s]onographer's interpretation. However the radiologist hasn't interpreted the images correctly either."

The following further expert advice was obtained from Ms Muirhead:

"Addendum:

On reading the additional information which I have been provided with, I make the following comments:

1. The reasonableness of the care provided by [Ms D]:

The care offered to [Ms A] was of adequate standard. There was obvious difficulty with interpreting the scan, which led to the trainee sonographer not passing on a great deal of information to the patient, but that is acceptable for a trainee. And she did bring the supervising sonographer in to check appearances. It did obviously cause some stress for the patient and [Ms A] wasn't happy to remain in the room while her case was being urgently dealt with. It is always a difficult and emotive situation to deal with.

2. The reasonableness of the care provided by [Ms B], including in relation to her supervision of [Ms D] and consultation with [Dr C]:

There is some variation of the facts between [Ms B], [Ms D] and [Dr C], with [Ms B] stating she didn't discuss the case with [Dr C] and also saying she did not identify fetal cardiac activity. [Ms B] states she assumed the report would request a repeat ultrasound, but hadn't discussed this with the radiologist.

[Ms B] states that 'an intrauterine gestation sac was seen' but again didn't discuss this with the radiologist. 'The radiologist did not speak to me and I assumed he was satisfied with the information he got from the trainee'.

When [Ms B] was unable to support the interpretations that [Ms D] made, she should have taken over the patient, as the supervising sonographer and fully assessed the patient herself, then discussed the case with the reporting radiologist.

3. Whether any of the additional information causes you to amend your original advice or make further comments:

On reading the reply from [Dr C], it appears the radiologist did question appearances, but it was insisted by the trainee sonographer that fetal cardiac activity had been seen in the mass in the right adnexa.

The m-mode does not show fetal heart activity (which would be seen just at the depth of the supposed embryo (2cm)), but shows some pulsatility coming from the level of about 1.3cm and extending through the image, so coming from maternal vessels. So this has definitely been misinterpreted and this has influenced the previous interpretation of the intrauterine gestation sac, showing with the double decidual ring.

The supervising sonographer has accepted the decision of the trainee sonographer, that there was a fetal heart activity, despite not observing it herself. I feel she has let herself down by not following through with her interpretation. However, this is

a difficult situation to be put in with a senior trainee who was convinced of her findings.

4. The adequacy of the relevant policies and procedures in place at the [radiology clinic] at the time of the events complained of, including any further changes that you consider may be appropriate

The policies are adequate when adhered to. The change of including video clips to record findings such as fetal cardiac activity will help avoid this situation. Another useful change would be a directive that the supervising sonographer must take over the case if there is disagreement about the interpretation, when working with a trainee."

The following further expert advice was obtained from Ms Muirhead:

"Yes I agree that [Ms D] made a misinterpretation of the scan and although [Ms B] did not agree with [Ms D's] diagnosis, she was happy to let the worksheet be written up with [Ms D's] diagnosis and so made a moderate departure from standard practice. She was in a difficult situation, obviously busy with another patient and dealing with a senior trainee, but allowed information to go out, with which she did not agree. She was ultimately responsible for the information going out. Until I received the copy of the letter [Ms B] wrote, I assumed she had agreed with [Ms D], but that was not the case. She stated she did not agree with the diagnosis."

Appendix B: Independent radiology advice to the Commissioner

The following expert advice was obtained from radiologist Dr Mark Leadbitter:

"**1. Materials Reviewed**

- Clinical notes from Waitemata DHB
- Ultrasound scan report from [the radiology clinic] dated 13 [Month1] from [Dr C] (Radiologist).
- 31 images from [the radiology clinic] ultrasound examination on [Ms A] from 13 [Month1]
- Ultrasound reports from examinations performed on 20 [Month1] and 27 [Month1] at [the public hospital].

2. My Assessment of the Imaging Findings

[Ms A] had an ultrasound examination performed at [the radiology clinic] in the afternoon of 13 [Month1]. The equipment used, number of images documented and presentation of the images are all consistent with usual clinical practice.

Both transabdominal and transvaginal scanning of the pelvis have been performed. The bladder was only partly full for the transabdominal examination.

There is a tiny rounded fluid collection in the endometrial cavity, and there is possibly a 'double sac sign', but no yolk sac or foetal pole. Average internal diameter of the sac is 4mm. Both ovaries are seen, and appear normal. No fluid collection in the pelvis. There are 5 images of the right adnexa which demonstrate a solid looking complex area with increased echogenicity centrally. The central area has been measured as a 13mm crown rump length, but does not look like a foetal pole. There are no images of a definite gestational sac. A foetal heartbeat was said to be present, but this has not been demonstrated on the pulsed Doppler trace. There is no increased vascularity in the right adnexa.

These are not convincing sonographic appearances for a live ectopic pregnancy.

3. Interpretation

Subsequent ultrasound scans at [the public hospital] on 20 and 27 [Month1] documented the intrauterine pregnancy. It was proven by Crown–rump length to be 6 +3 weeks gestation on 27 [Month1]. This implies that at the time of the original [radiology clinic] scan 2 weeks earlier, the pregnancy would have been only 4 weeks +3 days. It is not surprising that the gestational sac was wrongly interpreted as a pseudosac.

The sonographer has misinterpreted the findings in the right adnexal region, particularly in regard to saying that there was a foetal heartbeat seen. These findings were apparently corroborated by a second sonographer. This does not look like a live ectopic pregnancy on the static images, and the Radiologist ([Dr C]) should probably have questioned the sonographer on that.

A further confirmatory scan was not performed at [the public hospital] prior to proceeding to laparoscopy, and the right fallopian tube was removed despite its normal macroscopic and histological appearances.

4. Conclusion

It is routine in New Zealand for patients to be scanned by sonographers at Radiology branches where Radiologists are not in attendance on site. Radiologists can review the images and discuss the case with the sonographer, but Radiologists still rely heavily on the sonographer's observations, particularly in relation to the presence or absence of a foetal heartbeat. If 2 sonographers say they have seen a foetal heartbeat outside of the uterus, a Radiologist is forced to conclude that the pregnancy is ectopic. The sonographers have misinterpreted vascular pulsation from maternal pelvic arteries. However, both the sonographers and Radiologist should have recognised that the appearances were not those of a live ectopic pregnancy with an intact gestational sac.

This is a moderate departure from the expected standard of care."

The following further expert advice was obtained from Dr Leadbitter:

"Just to expand a little on the conclusion of my report:

Overall, I have concluded that the departure from the expected standard of care was moderate. But I think the majority of this departure derives from the 2 Sonographers agreeing that there was a foetal heartbeat seen outside of the uterus. Even though the documented appearances of the 'ectopic pregnancy' that the Radiologist had to review were not convincing for this diagnosis, the diagnosis of ectopic pregnancy is inescapable if a heartbeat is said to be seen outside of the uterus."

The following further expert advice was obtained from Dr Leadbitter:

"Documents Reviewed

1. Sonographer's worksheet from the radiology clinic dated 13 [Month1]
2. Copy of the [radiology clinic's] response dated 13/4/16
3. Copy of [Dr C's] response dated 12/4/16
4. Copy of [Ms B's] response dated 10/4/16
5. Copy of [Ms D's] response dated 31/5/16

Standard of Care

1. The sonographer's worksheet has the combined names of '[Ms D/Ms B]' at the top. The finding of 'Live ectopic pregnancy' is the bottom line of the report. This is the written basis on which the Radiologist would frame his report.

   [Ms D] (student sonographer) says 'the mass appeared to be in the shape of a foetal pole and appeared to be pulsating'.

However in [Ms B's] response she says she wasn't convinced about the foetal heartbeat (she was present in the room and saw the scan in real-time).

Clearly there is equivocation here, but the senior supervising sonographer must take responsibility, and she apparently filled out the final worksheet (according to [Ms D] the student). The worksheet is unsigned.

[Dr C] apparently discussed the case with both of the sonographers by phone, and 'both the trainee sonographer and the qualified sonographer confirmed that a foetal heartbeat had been demonstrated outside the uterus despite the images being less than convincing'.

However [Ms B] in her response says 'the Radiologist did not speak to me'. She also says that 'Jill Muirhead and Dr M Leadbitter have been misinformed that 2 sonographers had agreed on the ultrasound findings'.

2. The degree of sonographer supervision in this case seems reasonable in terms of standard practice in New Zealand Radiology. Having a senior sonographer available on-site to confirm findings and assist in hands on scanning demonstrates good patient care. It is very common for the reporting Radiologist to be at another site, as was the case here.

   There would be nothing unusual about the Radiologist only speaking to the trainee Sonographer about the case (if this indeed happened), as he could reasonably expect to be given the consensus view of the 2 sonographers.

   The final written worksheet is unequivocal in its diagnosis of Ectopic Pregnancy, and the senior sonographer is responsible for ensuring that the worksheet is an accurate reflection of the findings (whether she actually wrote the document or not).

3. I do not wish to amend my original report of 17/12/15.

4. [The radiology clinic's] policies and procedures as described by [the radiology clinic] seem consistent with accepted best practice standards for Radiology Clinics and departments in New Zealand. There does not appear to have been any major departure from these policies and procedures in this case.

Conclusion:

There is inconsistency between the reports of the Supervising Sonographer ([Ms B]) and the Trainee Sonographer ([Ms D]) in this case. If there truly was substantial doubt about the presence or absence of a foetal heartbeat outside of the uterus at the time, then perhaps the patient should have been re-scanned. However the bottom line of the written worksheet was 'Live Ectopic Pregnancy' and any reporting Radiologist is bound to proceed on that basis and expedite admission to hospital through the referring clinician."

Appendix C: Independent obstetric advice to the Commissioner

The following expert advice was obtained from obstetrician Dr Michel Sangalli:

"Thank you for your letter, dated 4 December 2015, regarding the above mentioned complaint.

I have reviewed the following documents.

1. [Ms A's] complaint.
2. [Ms A's] relevant clinical notes.
3. WDHB's response

Summary of clinical events

[On 13 Month1], [Ms A] ([Ms A]) presented to her GP with a history of left sided pelvic pain. Her pregnancy test was found to be positive and she was sent to have an urgent ultrasound scan at [the radiology clinic]. [The radiology clinic] performed an abdominal and a transvaginal scan which involved two sonographers and the report was emitted by a radiologist. The radiologist informed the GP that [Ms A] had a live right sided ectopic pregnancy. The GP then referred [Ms A] to WDHB where she was assessed.

At WDHB, a decision was made to perform a laparoscopic salpingectomy based on the report of the radiologist who clearly mentioned that in the right adnexal region there was a cystic lesion with a 12mm fetal pole and fetal heart activity was observed within this. There was no evidence of an intrauterine sac, but a pseudo sac was noted. The images were not reviewed and the WDHB response letter states that the images were not available after-hours.

On the next day, [14 Month1], [Ms A] had an uncomplicated right salpingectomy. The tube was sent to histology and on 20 [Month1] the clinicians informed [Ms A] that the tube removed at the time of surgery did not contain an ectopic pregnancy. [Ms A] was seen for further investigations, which showed that she had a live intrauterine pregnancy.

Advice

Diagnosis of a live extra-uterine pregnancy is relatively straight forward. The uterus is empty and the gestational sac with an embryo with a heartbeat is seen in the adnexal region. The radiology report clearly stated these findings and a firm diagnosis of a right sided ectopic pregnancy with a live embryo was made by the radiologist.

Most ectopic pregnancies are located in the fallopian tube. There are a number of therapeutic options for ectopic pregnancies but in the case of a live tubal ectopic, the treatment is surgical. In the absence of an abnormal tube on the unaffected side, the best treatment is usually a salpingectomy (removal of the tube) rather

than a salpingostomy (incision of the tube and removal of the ectopic pregnancy) because of the reduced rate of surgical complications (persistent pregnancy tissue in the tube, need for post-operative monitoring and sometimes treatment with methotrexate or removal of the tube), and an identical rate of successful future pregnancies. The removal of a tube, in the absence of pathology in the other tube, does not reduce the chance of future successful pregnancies.

I interviewed a number of Obstetrics & Gynaecology SHOs, registrars and consultants at [another public hospital] as well as two midwives working at our Acute Assessment unit for years. I asked them whether the images of scans performed in the community were routinely reviewed and whether women were routinely rescanned within the department when a community scan report firmly states that a live ectopic pregnancy is present in the adnexa. The consensus was that when there is a clear report/diagnosis of ectopic pregnancy, particularly live, there was a strong chance that the diagnosis would not be doubted as the scan findings are straight forward and that the scan would not be repeated in the department. Some registrars with an interest in ultrasound, could decide to do a scan themselves to check the findings but also for personal interest/training purposes. The majority of consultants would not scan or ask for a scan under such circumstances. Some registrars would review the films from the scan, if available or review them with a sonographer.

If the diagnosis was uncertain (e.g. the uterus is empty and no (or a possible) mass was diagnosed in the adnexa) the scan findings would be correlated with the level of pregnancy hormone (hCG) and in the absence of severe symptoms the patient could be treated surgically, medically with methotrexate or carefully monitored with hCG levels and pelvic scans. Under such circumstances, a scan is often repeated either at the first or second appointment to clarify the diagnosis and to decide on the best treatment.

When there is a live ectopic pregnancy, the diagnosis is clear cut and so is the treatment. A laparoscopy with a salpingectomy is the treatment of choice.

At the time of the surgery, the tube with the ectopic pregnancy is usually swollen and blood is often protruding through the end of the tube although this is not always the case. If the ectopic is small, the tube may only be mildly enlarged. The images taken during the surgery show a normal left tube and a right tube which appears swollen although the black and white copies of the photos are not of optimal quality.

Once the histology revealed the absence of a tubal ectopic, [Ms A] was promptly reviewed and the findings were explained as well as the rationale for the salpingectomy. [Ms A] decided to continue with the pregnancy and the notes do not mention any pregnancy complications.

I note that [Ms A] received paracetamol, ibuprofen, morphine, tramadol, ondansetron, droperidol, cyclizine, dexamethasone, enoxaparine, atracurium, cephazolin, clonidine, fentanyl, metaraminole, midazolam, propofol, codeine,

lactulose, laxsol and parecoxib during and after hospitalisation. None of these drugs are known to be associated with fetal malformations or major complications of pregnancy and all are considered safe if required (which they were) in early pregnancy.

[Ms A] was unfortunately firmly misdiagnosed with a right live ectopic pregnancy and she received standard and appropriate care, in a timely manner, from the team at WDHB. I could not identify any clear deficiencies with the management of [Ms A] at WDHB. This is an unfortunate outcome. Firm misdiagnoses of live ectopic pregnancies are very rare in clinical practice. However, [Ms A] can be reassured that the misdiagnosis and its treatment should not lead to any problems with her baby. Her future fertility is very likely to be unaffected (normal).

References

Ectopic pregnancy: Clinical manifestations and diagnosis. www.uptodate.com ©2016 UpToDate® Updated: Sep 02, 2015.

Ectopic pregnancy: Surgical treatment. www.uptodate.com ©2016 UpToDate® Updated: Sep 30, 2014.

Briggs — Drugs in pregnancy and lactation 9th edition Lippincott Williams and Wilkins (App version 1).”

The following further expert advice was obtained from Dr Sangalli:

“In my opinion, the βHCG levels falling from 1450 in the morning to 1211 in the evening is not diagnostic of a failed or ectopic pregnancy, as the tests were taken too close together in time. There is a margin of error for each hCG measurement and the level had not fallen significantly enough. βHCG level is expected to double every 2–3 days and results should be compared at this interval. However, in this situation, staff would not usually re-check the diagnosis by correlation with βHCG levels.

The βHCG levels were too low to be consistent with an ectopic pregnancy with a 12mm live embryo. They were more consistent with her real pregnancy (4–5 weeks’ gestation). DHB staff could have been more suspicious, given how low the levels were. Perhaps staff could possibly also have been more suspicious of an erroneous diagnosis at the time of surgery as the fallopian tube was probably not as swollen as it would have been with a tubal ectopic pregnancy with a 12mm live embryo (although it was swollen).

In my opinion, overall, there was no departure from the standard of care, but the care could have been better. There was a missed opportunity to pick up the misdiagnosis of ectopic pregnancy.”