Canterbury District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC00487)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. Ms A had a history of an ectopic pregnancy[1] resulting in the removal of her right fallopian tube.[2] Ms A became pregnant again and, on 30 April 2012, she had an ultrasound, which showed a 15mm by 13mm left adnexal mass[3] and no intrauterine gestation sac.[4]

2. Ms A was referred to hospital with a suspected ectopic pregnancy. Her β-hCG level was 334 IU/L.[5] Ms A consented to the removal of her fallopian tube but told HDC that this was on the understanding that the tube was abnormal.

3. Ms A repeatedly advised staff that she wanted the fetal tissue returned to her following surgery.

4. On 2 May 2012 Ms A's left fallopian tube was removed, and Ms A underwent a LLETZ procedure[6] at the same time. On 9 May 2012 the histology showed no pregnancy tissue in the tube. Ms A's β-hCG was rising and was now at 10,064 IU/L. A further ultrasound confirmed a live singleton intrauterine pregnancy at eight weeks' gestation.

5. Ms A was uncertain whether she should continue the pregnancy. Obstetrician/gynaecologist Dr C advised Ms A that while he would not expect any pregnancy complications from her recent surgery, he would offer her a surgical termination of pregnancy within the following four weeks.

6. Ms A decided to terminate the pregnancy because of her concerns that the surgery may have harmed the fetus. She again requested that the fetal tissue be returned to her.

7. The termination of pregnancy was performed on 8 June 2012. Subsequently, the procedure for the return of the fetal tissue to Ms A was not followed and the tissue was destroyed.

[1] An ectopic pregnancy is any pregnancy that occurs outside the uterine cavity.
[2] Fallopian tubes are a pair of long narrow ducts, located in the human female abdominal cavity, that transport the male sperm cells to the egg.
[3] An adnexal mass is a lump in the tissue of the adnexa of the uterus, usually in the ovary or fallopian tube.
[4] The gestational sac (or gestation sac) is the only available intrauterine structure that can be used to determine if an intrauterine pregnancy exists, until the embryo is identified.
[5] β-hCG (beta human chorionic gonadotropin) is a hormone produced during pregnancy. In a normal intrauterine pregnancy the level of β-hCG increases by at least 53% every two days, peaking at a level greater than 100,000 IU/L.
[6] The large loop excision of the transformation zone (LLETZ) is one of the most commonly used approaches to treat high-grade cervical dysplasia discovered on colposcopic examination. The physician uses a wire loop through which an electric current is passed at variable power settings. The cervical transformation zone and lesion are excised to an adequate depth, which in most cases is at least 8mm, and extending 4 to 5mm beyond the lesion.

Findings

8. Canterbury District Health Board (DHB) clinicians diagnosed Ms A with a likely ectopic pregnancy without taking all reasonable steps required to allow them to conclude this definitively. They were uncertain about the pregnancy gestation, and did not check Ms A's β-hCG level prior to surgery. They arranged for Ms A to undergo a LLETZ procedure, which is not normal practice if a pregnancy is viable. As a result, they unnecessarily removed Ms A's left fallopian tube when the fallopian tube was not unequivocally abnormal. They did not communicate sufficiently to Ms A that there was a possibility that she might not have an ectopic pregnancy and instead might have a uterine pregnancy, or that her fallopian tube might be normal. The cumulative effect of a number of individual errors resulted in Ms A receiving suboptimal care. Accordingly, Canterbury DHB failed to provide services to Ms A with reasonable care and skill and breached Right 4(1)[7] of the Code of Health and Disability Services Consumers' Rights (the Code).

9. Canterbury DHB breached Ms A's right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a healthcare procedure and, accordingly, breached Right 7(9)[8] of the Code.

10. Adverse comment was made about the care provided to Ms A by obstetrician/gynaecologist Dr C and obstetrician/gynaecologist Dr B. In addition, the Commissioner commented on the care provided by obstetric/gynaecological registrar Dr F.

Complaint and investigation

11. The Commissioner received a complaint from Ms A about the services provided by Canterbury District Health Board. The following issue was identified for investigation:

- *The appropriateness of the care provided to Ms A by Canterbury District Health Board in 2012.*

12. An investigation was commenced on 31 May 2013.

13. The parties directly involved in the investigation were:

Ms A	Consumer
Mr A	Consumer's partner
Canterbury District Health Board	Provider

[7] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[8] Right 7(9) states: "Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure."

14. Information was reviewed from:

ACC	
Dr B	Obstetrician/gynaecologist
Dr C	Obstetrician/gynaecologist
Dr D	Radiologist

Also mentioned in this report:	
Dr E	Registrar
Dr F	Obstetric/gynaecological registrar
Dr G	Gynaecological registrar

15. Independent expert advice was obtained from gynaecologist Associate Professor Neil Johnson, and is attached as **Appendix A**.

Information gathered during investigation

Ectopic pregnancy

16. An ectopic pregnancy is any pregnancy that occurs outside the uterine cavity. Pregnancies in the fallopian tube account for 97% of ectopic pregnancies. Risk factors most strongly associated with ectopic pregnancy include having had a previous ectopic pregnancy and/or tubal surgery.

17. The treatment of ectopic pregnancy is either by expectant management, which is between 47% and 82% effective; medical treatment by use of methotrexate, a folic acid antagonist, which takes three to seven weeks to resolve the ectopic pregnancy; or by surgical treatment. Laparoscopy with salpingostomy (removal of the ectopic tissue through an abdominal incision) has become the preferred method of surgical treatment.

Ms A

18. In May 2011 Ms A, then aged 40 years, had an ectopic pregnancy, which resulted in the removal of her right fallopian tube.

19. In April 2012 Ms A was again pregnant. On 30 April 2012 a radiology service referred Ms A to hospital because the result of an ultrasound performed that day showed a left adnexal mass, 15mm by 13mm, and no intrauterine gestation sac.

Radiologist comment

20. ACC obtained advice from radiologist Dr D regarding the ultrasound performed on 30 April 2012. Dr D advised that the appearance of the left adnexal mass on the scan is consistent with several diagnoses, including ovarian ectopic pregnancy. He stated that, in general terms, an ectopic pregnancy cannot be conclusively diagnosed on an ultrasound scan unless a beating fetal heart is seen within the adnexal mass. This was not seen in Ms A's case.

21. Dr D noted that the ultrasound was not able to be confidently interpreted without knowledge of the β-hCG levels on the day of the scan. He stated: "I would not be prepared to give a confident diagnosis or to suggest further management without knowledge of the BHCG result."

22. Dr D's conclusions were that the scan did not support the diagnosis of intrauterine pregnancy, although that possibility still existed as the gestation sac cannot be detected by ultrasound in very early normal pregnancy. However, he concluded that the scan did not support a diagnosis of ectopic pregnancy either, as the complex adnexal mass was more likely to be a corpus luteum,[9] which may be present irrespective of whether the woman is pregnant.

Record of last menstrual period

23. On 30 April 2012, registrar Dr E recorded on Ms A's admission sheet that the date of Ms A's last menstrual period (LMP) was 31 March 2012 and that her LMP had been one week later than usual. On 1 May 2012, obstetrician/gynaecologist Dr C recorded the LMP as 30 March 2012, which indicated that the gestation by date at that time was four weeks and four days. However, although Dr E recorded on the admission sheet that the LMP was 31 March 2012, she also recorded that Ms A was five to six weeks pregnant instead of around four weeks and three days.

24. On 24 May 2012 and 1 June 2012 Dr C wrote to Ms A's general practitioner (GP), stating that Ms A had been at six weeks' gestation at the time of the surgery on 1 May 2012.

β-hCG

25. β-hCG levels assist in interpreting ultrasound findings. In a normal intrauterine pregnancy, these levels increase by at least 53% every two days, peaking at a level greater than 100,000 IU/L.

26. β-hCG levels alone cannot differentiate between ectopic and intrauterine pregnancy. Serum β-hCG levels that do not increase appropriately in a woman with a suspected ectopic pregnancy are only 36% sensitive and approximately 65% specific for detection of ectopic pregnancy.

Admission to ward

27. On 30 April 2012 at 8.45pm, the clinical notes record: "Pt [patient] has requested if for OT [operating theatre] POC [products of conception] to be returned after histology." Ms A was admitted to the ward at 10.40pm, and the records note that her β-hCG level was 334 IU/L.

28. The records note that the possibility of methotrexate treatment was to be discussed the following day, and "if goes to OT pt would like POC returned".

[9] The corpus luteum is what is left of the follicle after a woman ovulates.

29. Ms A had been diagnosed with CIN3[10] and required a LLETZ procedure to her cervix. The LLETZ procedure had been scheduled previously, but Ms A had cancelled it once she was aware she was pregnant.

30. At around 9.55am on 1 May 2012, Ms A was seen by Dr C. The clinical note, which appears to be written and signed by obstetric/gynaecological registrar Dr F, records:

> "CWR [consultant ward round] [Dr C]
> …
> Impression: ectopic pregnancy
>
> Plan: 1. Does not want Methotrexate
> 2. Laparoscopic salpingectomy [removal of fallopian tube] or salpingostomy.
> ? LLETZ at the same time.
> Discuss w/ [with] colposcopist[11] re doing LLETZ at same time."

31. At 11am on 1 May 2012, a registered nurse commenced the preoperative checklist and noted: "[P]atient would like her POC returned." Ms A was reviewed again by Dr C at 12.45pm.

Consent

32. Sometime on 1 May 2012, surgical consent was obtained from Ms A by gynaecological registrar Dr G. The form states that the procedure was "laparoscopy plus salpingectomy — does NOT want tube left in situ. LLETZ biopsy/treatment."

33. Ms A stated to HDC that the doctors told her they thought her tube was abnormal, and she replied that if it was abnormal she wanted it removed, so that she would have no further problems with it. However, she told HDC that she did not want it removed if there were no problems with it.

34. The form does not record any discussion of differential diagnoses. The risks were stated to be "bleeding — treat, transfuse if needed. Infection. Damage to bowel/bladder/other tissues. Failure or incomplete procedure and conversion to laparotomy." A sticker was attached stating: "[S]pecimen to be returned to patient."

35. On 1 May 2012, a form titled "Return of Tissue/Body Parts" was completed and signed by Ms A and the registered nurse. The form noted that Ms A would collect the tissue/body parts after the surgery.

Surgery

36. The surgery took place in the afternoon on 2 May 2012, performed by Dr F and assisted by obstetrician/gynaecologist Dr B. Ms A's left fallopian tube was removed. The operation report prepared by Dr F stated that the findings were a small left tubal

[10] Grade three cervical intra-epithelial neoplasia (CIN). CIN is the potentially premalignant transformation and abnormal growth (dysplasia) of squamous cells on the surface of the cervix.
[11] A medical practitioner who performs a colposcopy, a diagnostic procedure to examine the cervix and vagina.

pregnancy. The uterus and ovaries were found to be normal and the right tube was missing.

37. Canterbury DHB told HDC that "at the time of surgery the left tube was noted to be abnormal looking with ectopic considered [the] most likely diagnosis". In contrast, on 12 December 2012, Dr B advised ACC that there was no clear evidence of a left tubal pregnancy, "but the tube did not look entirely normal". Dr B further stated to ACC:

> "The registrar [Dr F] and myself discussed the findings and we agreed that an early tubal pregnancy could not be excluded by what we could observe. I felt at the time it was consistent with the pre operative discussions to remove the tube."

38. On 2 May 2012 at 10.10pm, the RN again recorded: "POC to be returned to pt post histology."

39. Ms A recovered well and, on 3 May 2012, was discharged home. The discharge summary prepared by the Registered Medical Officer stated that the ultrasound scan was consistent with a five- to six-week pregnancy and that "a small left tubal pregnancy was seen".

Histology result

40. On 9 May 2012 it was noted that the histology showed no pregnancy tissue in the tube, and that Ms A's β-hCG was rising and was now at 10,064 IU/L. Dr B telephoned Ms A and informed her that she had not had an ectopic pregnancy. Dr F then telephoned Ms A to advise that, in light of the β-hCG result, it was likely that she had an ongoing pregnancy.

Subsequent ability to have children

41. Ms A was distressed by having had her remaining fallopian tube removed unnecessarily. She told HDC that her partner, Mr A, had previously undergone a radical programme of radiation and chemotherapy, resulting in only a slight chance of a viable sperm count.

42. Ms A said that she and Mr A have no other children together, and they were surprised but pleased to conceive on the occasion that led to this complaint. Ms A told HDC that, given her age and Mr A's sperm quality, their chances of future conception, even with the assistance of in vitro fertilisation (IVF), were very low.

Termination of pregnancy

43. On 24 May 2012, a further ultrasound confirmed a live singleton intrauterine pregnancy at eight weeks' gestation. Ms A and Mr A met with Dr C. Ms A was well and her pregnancy was continuing without further complication.

44. Dr C reported to Ms A's GP:

> "I discussed with [Ms A] today that I would not expect any pregnancy complications from the laparoscopy and salpingectomy at six weeks. Should she decide to carry on I think this pregnancy carries the same risk as any pregnancy in

> a 41 year old woman. If a first trimester screening is low risk then given her previous obstetric history I think it is most likely her pregnancy would be uncomplicated."

45. Dr C noted that Ms A was uncertain whether she should continue the pregnancy, and that he had offered her surgical termination of pregnancy within the following four weeks. Dr C recorded that he had asked Ms A to consider matters further, and that he would review her in a week.

46. On 31 May 2012, Dr C saw Ms A again and noted that she had decided to terminate the pregnancy. Ms A advised HDC: "I elected to terminate this pregnancy due to my concerns that the salpingectomy may have harmed the fetus."

47. Ms A completed a form titled "Women undergoing suction termination of pregnancy", and on that form noted that she wished to take the pregnancy tissue home. The "Request for treatment of operation/procedure" form completed on 31 May 2012 by Dr C and signed by Ms A has a section asking, "Do you have any specific requirements for the return or disposal of body tissue, body parts or prothesis?" That section of the form was not completed.

48. Dr C performed the termination of pregnancy on 8 June 2012.

Disposal of fetus

49. Following the termination of pregnancy procedure, the procedure for the return of the tissue to Ms A was not followed, and Canterbury DHB did not return the tissue to Ms A.

50. Ms A advised that when she became pregnant in May 2011, and the pregnancy tissue was removed along with her right fallopian tube, the fetus was returned at her request and was buried during a small ceremony carried out by her and her partner.

51. Ms A stated that when she became pregnant again in 2012 and was admitted to hospital, she wanted the tissue returned to her because she intended to bury it with the previous fetus and have a similar ceremony. Ms A was of the view that Canterbury DHB could not have doubted her intentions in this regard, and was very distressed by the failure to return the fetus to her.

Canterbury District Health Board review

52. Canterbury DHB completed a review of the care it provided to Ms A in relation to the diagnosis and management of her suspected ectopic pregnancy. The review included the laparoscopy and salpingectomy performed on 2 May 2012, and the termination of pregnancy procedure performed on 8 June 2012.

53. In relation to the removal of Ms A's left fallopian tube, the review concluded that "the surgical consent form indicated consent for Salpingectomy regardless of surgical findings and this is signed by [Ms A]. … There is no documentation of the discussion that took place to establish informed consent …"

54. In regard to the termination of pregnancy procedure, the review found that the relevant documentation had not been appropriately completed to ensure that Canterbury DHB's "Return of Tissue/Body Parts to Patients" policy was followed. It identified the following problems:

- On 8 June 2012 the pre-admission nursing assessment and pre-procedure checklist in the Day Surgery Unit document pathway were completed in the Assessment Unit (the Unit).
- "Yes" was written next to the section relating to "Tissue/parts returned".
- The supporting paperwork was not completed and the appropriate "orange stickers" had not been applied to the notes.

55. The DHB found that, as a result of these errors, when Ms A was transferred to the operating theatre from the Unit, the operating theatre staff did not identify the need for tissue to be returned following the procedure. Accordingly, the theatre staff commenced the operation as planned and disposed of the tissue.

Action taken

56. Canterbury DHB advised that it has taken the following steps as a consequence of its review:

- The nurse involved in the incorrect completion of the relevant documentation was required to attend a Canterbury DHB Documentation Study Day in August 2012.

- All nursing staff, including day surgery staff, "will receive an update to ensure they are familiar with" Canterbury DHB policies titled "Return of Tissue/Body Parts to Patients" and "Women's and Children's Health Policy — Return of Products of Conception/Pregnancy Tissue".

- The references to documentation in the "Return of Tissue/Body Parts to Patients" policy have been updated to accurately reflect current documentation numbers.

Response to provisional opinion

57. In response to my provisional opinion, Dr C stated that the fact that Ms A's LMP was one week late "rais[ed] the possibility that this period was not reliable for dating purposes". Dr C expressed the view that:

> "it was reasonable for [Dr E] to consider the possibility that the pregnancy was more advanced, though there was not enough evidence to state the gestation for certain …"

58. Dr C stated that he does not recall whether he was aware of Dr E's calculation of the gestation when he examined Ms A on 1 May 2012. He stated:

> "[Ms A's] last period was recorded as 30 March. On the other hand the history of pain including shoulder tip pain for 10 days and the ultrasound findings raised the possibility that the pregnancy was ectopic at a more advanced gestation […] We

> now know that her period date was accurate and she was just under 5 weeks pregnant, but on 1 May I could not have been certain of that. […] In discussion with her I counselled her against [Methotrexate] because I did not consider there was enough evidence to exclude an early intrauterine pregnancy. I was entirely aware that there was a chance of an intrauterine pregnancy.
>
> I considered the dates to be uncertain."

59. Dr C further stated that the subsequent error in his letter to Ms A's GP on 24 May 2012, stating that Ms A had been at six weeks' gestation at the time of surgery on 1 May 2012, was "not contiguous" with the gestation estimate prior to surgery.

60. In relation to the diagnosis of a likely ectopic pregnancy, Dr C stated:

> "My opinion was that for the patient in front of me the likelihood of ectopic pregnancy was high, the risk of conservative management carried risks I perceived to be unacceptable, so I advised in favour of laparoscopy … Taking everything into account I was confident that laparoscopy would allow us to make the diagnosis one way or the other.
>
> I discussed all this with [Ms A]. … I was satisfied that she understood the principle that the procedure was to confirm the diagnosis and treat as necessary. …
>
> Considering the complex circumstances of the case … documentation of the differential diagnosis and the discussion with [Ms A] was inadequate … This should not be taken as evidence that our [clinicians'] own understanding of the differential diagnosis and the plan for surgery was inadequate."

61. Dr C also considered that the documentation of the consent procedure was inadequate and that, as a result, the consent form was potentially misleading to the theatre team.

62. Dr C further stated that he had a conversation with Dr B about the case and his willingness and availability to perform a LLETZ if appropriate. In Dr C's view, the decision to do a LLETZ procedure "should not be taken as evidence that we did not consider the possibility of a viable pregnancy". Dr B told HDC: "It seemed at the time appropriate to do the [LLETZ procedure] with the same general anaesthetic rather than have to repeat a general anaesthetic within a short space of time."

63. In contrast, Ms A stated in response to my provisional opinion that no other possible diagnosis (other than a likely ectopic pregnancy) was discussed with her. She stated that her understanding was that the pregnancy was ectopic, which is why a LLETZ would be performed at the same time.

64. In response to my provisional opinion, Dr B also stated that, during Ms A's surgery, he was the senior surgeon present and "it was [his] final decision, and not that of [Dr F], to remove the [fallopian] tube". Dr B told HDC: "In retrospect this was clearly not the correct diagnosis and decision and I have to acknowledge my part in this unfortunate outcome."

65. Dr B also noted that subsequent to the removal of Ms A's fallopian tube and two other cases concerning the diagnosis of ectopic pregnancy, senior and junior medical staff and radiology staff at the hospital have met, and discussed and reviewed their management of ectopic guidelines with a view to minimising further potential for incorrect diagnosis and management.

Opinion: Breach — Canterbury District Health Board

Removal of fallopian tube

66. Ms A had previously had her right fallopian tube removed as a consequence of an ectopic pregnancy. The removal of her left fallopian tube has now rendered it impossible for Ms A to have children without the use of IVF.

67. After several surgical procedures, including the removal of Ms A's left fallopian tube, that tube was subsequently found to have been normal, and Ms A was found to be experiencing an intrauterine pregnancy, rather than an ectopic pregnancy. My expert adviser, gynaecologist Associate Professor Neil Johnson, advised me that it was reasonable for clinicians to undertake a laparoscopy to confirm or exclude an ectopic pregnancy. However, Professor Johnson concluded that there were several factors that led to Ms A's fallopian tube being removed unnecessarily.

68. The date of Ms A's LMP was initially recorded in the notes as 31 March 2012, which indicated that the gestation by date was four weeks and three days at the time of admission. However, the LMP was also recorded as having been one week late. The gestation documented by Dr E on the admission sheet on 30 April 2012 was five to six weeks. Dr C said he considered the dates to be uncertain. Professor Johnson advised that a serum β-hCG level of 334 IU/L is normal for a viable pregnancy of four to five weeks' gestation, but is lower than expected in a viable pregnancy of five to six weeks' gestation.

69. Professor Johnson was of the view that one of the reasonable steps that should have been taken to avoid the removal of Ms A's fallopian tube was "[m]aintenance of the possibility" that the pregnancy might be intrauterine and potentially viable, in light of the fact that there had been no vaginal bleeding and the serum β-hCG level was only 334 IU/L. He advised that it is normally considered that if the β-hCG level is greater than 1,500 IU/L, a transvaginal ultrasound offers a reasonably accurate diagnosis of intrauterine pregnancy. He stated that many gynaecologists are careful not to exclude an intrauterine pregnancy on the basis of a transvaginal ultrasound unless the β-hCG level is greater than 2,500–5000 IU/L.

70. Professor Johnson advised that viable pregnancies are usually associated with an approximate doubling of the β-hCG level every 48 hours. Professor Johnson considered that, if Ms A's β-hCG level had been checked immediately prior to

surgery (which took place two days after the initial measurement), it would have increased the suspicion that the pregnancy was viable, and not ectopic.

71. Professor Johnson considered that there were reasonable steps that should have been taken preoperatively to assess whether the pregnancy was ectopic, and any diagnosis of ectopic pregnancy should have been confirmed by laparoscopic visualisation of the fallopian tube. He stated that it is not normal practice or appropriate to undertake a LLETZ procedure at the time of a viable pregnancy. In Ms A's case, it was planned in advance that the LLETZ procedure would be carried out following the laparoscopy and salpingectomy, which he considers indicates that a preoperative assumption was made that the pregnancy was indeed ectopic. Dr C submitted in response to my provisional opinion that the decision to do a LLETZ procedure should not be taken as evidence that the clinicians did not consider the possibility of a viable pregnancy.

72. I accept Professor Johnson's advice as follows:

> "Those responsible for removing the fallopian tube must be certain that they are doing so for an ectopic pregnancy and that they are not removing a healthy fallopian tube in the context of uterine pregnancy … given that Ms A had only one fallopian tube remaining, the duty of care for clinicians in this case was arguably even more exacting."

73. The consent form completed by Dr G notes that Ms A did "NOT want [her] left fallopian tube left in situ". In response to my provisional opinion, Dr C stated that he discussed differential diagnoses with Ms A and was satisfied that she understood "the principle that the procedure was to confirm the diagnosis and treat as necessary". However, Ms A told HDC that no possible diagnoses other than a likely ectopic pregnancy were discussed with her. Ms A said that the doctors told her they thought her tube was abnormal, and she replied that if it was abnormal she wanted it removed, so that she would have no further problems with it. She stated to HDC that she did not want it removed if there were no problems with it.

74. There is no documentation of the discussion that took place to establish Ms A's consent, or of any discussion of the possibilities that her fallopian tube might be normal and/or that she might have a viable pregnancy. Based on the evidence as outlined above, I remain of the view that the possibility that Ms A might not have an ectopic pregnancy and instead could have a uterine pregnancy, was not sufficiently communicated to her, and this had unfortunate consequences in terms of her consent to the removal of her fallopian tube. I accept that Ms A consented to her fallopian tube being removed in the context where she had been told that there was an ectopic pregnancy resulting in an abnormal fallopian tube. However, as acknowledged by Dr C in response to my provisional decision, the documentation of the consent procedure was inadequate and, as a result, the consent form was potentially misleading to the theatre team.

75. I also accept that, at the time of the operation, Dr F believed she was removing an abnormal fallopian tube. Dr F was assisted by Dr B. However, both failed to recognise that the tube was not abnormal. I am advised by Professor Johnson that the

photographs he has viewed suggest that the fallopian tube does not appear to be unequivocally abnormal, and there was no free blood apparent in the pelvic cavity, which would normally be expected in the context of shoulder tip pain in association with ectopic pregnancy. He noted that the histology report of a microscopically normal fallopian tube "lends weight to the argument that, in defining appearance of the fallopian tube as abnormal, a misjudgement occurred on the part of the surgeon". Although wrong, Dr F and Dr B believed, at the time of removal, that the fallopian tube was abnormal, and consent had been obtained for the removal of an abnormal fallopian tube.

76. Given the serious consequences for Ms A resulting from the removal of her remaining fallopian tube, I consider that the clinicians should have acted more cautiously.

77. A number of factors contributed to Ms A's remaining fallopian tube being removed unnecessarily. The gestation was considered uncertain, and clinicians did not conduct a further serum β-hCG test and a vaginal ultrasound prior to surgery, both of which may have assisted the diagnosis. In addition, during the surgery, neither Dr F nor Dr B recognised that Ms A's fallopian tube was not abnormal before removing it.

78. Several clinicians provided Ms A with information about the diagnosis and surgery; however, as stated above, based on the evidence, I am of the view that the possibilities that Ms A might not have had an ectopic pregnancy, and instead could have had a uterine pregnancy and a normal fallopian tube, or a uterine pregnancy and an abnormal fallopian tube, were not communicated to her sufficiently.

79. In my view, none of the above errors can be viewed in isolation from one another. I consider that, in this case, the cumulative effect of a number of individual errors resulted in Ms A receiving suboptimal care. I note my expert advisor's view:

> "[T]he outcome, resulting from a sequence of incorrect assumptions and misjudgments, for which numerous clinicians were responsible was a substantially adverse one …"

80. I have stated previously that providers have a responsibility to operate their facilities in a manner that provides patients with services of an appropriate standard. As I have commented:

> "This organisational duty of care includes providing a safe healthcare environment for its consumers and ensuring that staff comply with policies and procedures … it also includes responsibility for the actions and omissions of its staff."[12]

81. In my view, Canterbury DHB failed to ensure that services were provided to Ms A with reasonable care and skill in respect of the clinical care she received and, accordingly, Canterbury DHB breached Right 4(1) of the Code.

[12]Opinion 11HDC00712, available at www.hdc.org.nz.

Return of tissue

82. Under Right 7(9) of the Code, Ms A had the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a healthcare procedure.

83. As stated, there are records of numerous instances of Ms A specifying that she wished to have the fetal tissue returned to her. These were prior to the operation on her fallopian tube, and again before the termination of pregnancy.

84. Prior to the termination of pregnancy, Dr C completed a "Request for treatment by operation/procedure" form, which is signed by Dr C and Ms A. On that form, the section relating to the return of body tissue has not been completed. Professor Johnson commented:

> "[S]crutiny of this form suggests to me that the respective tick boxes are insufficiently closely related to the questions about blood testing in relation to exposure to body fluids and tissue return, probably increasing the chance of ambiguity (the surgeon may have believed that the 'yes' answer related to the return of tissue, rather than the agreement to have blood testing in relation to exposure to body fluids)."

85. It is clear that the return of the fetal tissue was a matter of considerable emotional significance to Ms A. In my view, it was Dr C's responsibility to ensure that the forms were completed correctly. I consider that the preoperative checking procedures should have identified and remedied the fact that the relevant form was incomplete. I note that Canterbury DHB has accepted that its processes failed in this case. I find that Canterbury DHB breached Ms A's right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a healthcare procedure and, accordingly, I find that Canterbury DHB breached Right 7(9) of the Code.

Other comment

86. It is notable that in this case a number of clinicians at Canterbury DHB showed a regrettable laxness in the completion of necessary documentation. There is no documentation of what, if any, discussion took place to establish informed consent for the salpingectomy regardless of the surgical findings.

87. On 8 June 2012, the pre-admission nursing assessment and pre-procedure checklist in the Day Surgery Unit document pathway were completed in the Unit, and "yes" was written next to the section relating to "Tissue/parts returned"; however, the supporting paperwork was not completed, and the appropriate "orange stickers" were not applied to the notes.

88. As stated above, the "Request for treatment by operation/procedure" form completed by Dr C prior to the termination of pregnancy included a section relating to the return of body tissues, which was not completed. Professor Johnson has advised me that the layout of the form may have been a causal feature of this omission. However, I

consider it concerning that on at least three occasions standard forms were not completed adequately to ensure that Ms A's wishes were respected.

Opinion: Adverse comment — Dr C

89. Dr C stated in response to my provisional opinion that he considered the gestation of Ms A's pregnancy to be uncertain. Professor Johnson advised that a serum β-hCG level of 334 IU/L is normal for a viable pregnancy of four to five weeks' gestation, but is lower than expected in a viable pregnancy of five to six weeks' gestation. Professor Johnson was of the view that the possibility that the pregnancy might be intrauterine and potentially viable should have been maintained, in light of the fact that there had been no vaginal bleeding and the serum β-hCG level was 334 IU/L.

90. Dr C was the clinician responsible for concluding that Ms A's pregnancy was likely ectopic on the day before surgery (1 May 2012) and discussing that diagnosis with Ms A. Dr C needed to be sure his diagnosis was based on relevant and correct information, which included Ms A's β-hCG levels at that time. He interpreted the β-hCG level of 334 IU/L as being low, based on a gestation that he considered uncertain. Dr C stated in response to my provisional opinion that he considered that the likelihood of ectopic pregnancy was high, and the risk of conservative management carried risks he perceived to be "unacceptable", so he advised in favour of laparoscopy.

91. At the time he diagnosed a likely ectopic pregnancy, Dr C had a responsibility to discuss with Ms A the following differential diagnoses: an ectopic pregnancy, an intrauterine pregnancy with a normal fallopian tube, or an intrauterine pregnancy with an abnormal fallopian tube. According to Ms A, no possible diagnosis other than a likely ectopic pregnancy was discussed with her. There is no documentation regarding the discussion of differential diagnoses with Ms A. On the basis of the evidence, I am not satisfied that Dr C discussed the second or third possibilities with Ms A, or ensured that Dr G did so. This was information that Ms A needed to give informed consent to the LLETZ procedure and removal of her fallopian tube.

92. Dr C also failed to complete the section pertaining to the return of body tissues in the "Request for treatment by operation/procedure" form prior to the termination of pregnancy. I acknowledge that the layout of the form may have contributed to that omission.

93. Dr C was just one of multiple clinicians who provided Ms A with care that led to the unnecessary removal of her last remaining fallopian tube. I do not find that Dr C's actions and omissions amount to a breach of the Code. However, Dr C's actions and omissions contributed to the overall unsatisfactory care provided to Ms A in this case.

Opinion: Other comment — Dr F

94. Obstetric/gynaecological registrar Dr F, assisted by obstetrician/ gynaecologist Dr B, performed the surgery on Ms A to remove her fallopian tube.

95. As stated, I accept that, at the time of the operation, Dr F believed she was removing an ectopic pregnancy within an abnormal fallopian tube.

96. I am advised by Professor Johnson that the photographs he has viewed suggest that the fallopian tube does not appear to be unequivocally abnormal and there was no free blood apparent in the pelvic cavity, which would normally be expected in the context of shoulder tip pain in association with ectopic pregnancy. He noted that the histology report of a microscopically normal fallopian tube "lends weight to the argument that, in defining appearance of the fallopian tube as abnormal, a misjudgement occurred on the part of the surgeon".

97. However, Professor Johnson advised that there is a wide range of normal appearances of a fallopian tube. He stated:

> "[B]ased on the black and white copies of the laparoscopic images that are available to [him], and bearing in mind that those best placed to make a judgment about the appearance of the fallopian tube would be the surgeons, it is difficult to comment authoritatively on this interpretation of the laparoscopic appearances."

98. In my view, Dr F should have critically considered whether or not Ms A had an ectopic pregnancy. As a result of not doing so, she undertook procedures that were not appropriate in the context of a uterine pregnancy. However, I note that Dr F was one of several clinicians who provided Ms A with care that led to the unnecessary removal of her fallopian tube. Dr F was also influenced by the conclusions and decisions of those other clinicians.

99. I accept Professor Johnson's comments that it is difficult to conclusively criticise Dr F's and Dr B's failures to recognise that the tube was not abnormal. I note that Dr F was an obstetric/gynaecological registrar and was assisted by obstetrician/gynaecologist Dr B, who stated that he was the senior surgeon present and the one responsible for deciding to remove the fallopian tube. In addition, the clinical error was influenced by the diagnosis made before surgery by various clinicians.

100. For these reasons I do not find that Dr F's actions and omissions amount to a breach of the Code.

Opinion: Adverse comment — Dr B

101. Dr B was the senior obstetrician/gynaecologist assisting obstetric/gynaecological registrar Dr F with surgery when Ms A's fallopian tube was removed. He told HDC that the final decision to remove Ms A's fallopian tube was his. He stated to ACC that, at the time of surgery, he and Dr F discussed the appearance of the fallopian tube and decided that a tubal (ie, ectopic) pregnancy could not be excluded. He said that they considered that removing the tube was consistent with preoperative discussions.

102. As above, I accept Professor Johnson's comments that it is difficult to conclusively criticise Dr F's and Dr B's failures to recognise that the tube was not abnormal. As stated, the preoperative information given to Ms A was inadequate; however, I also accept that, in light of the record of the preoperative discussions that "[Ms A] did 'NOT want [her] left fallopian tube left in situ'", plus the diagnosis of a likely ectopic pregnancy, both Dr B and Dr F judged that the tube should be removed.

103. Nonetheless, I consider that, as the more senior clinician in the operating theatre, Dr B should have more critically considered the assumption that Ms A had an ectopic pregnancy and that her left fallopian tube was abnormal. While I do not find that Dr B's actions and omissions amount to a breach of the Code, they contributed to the overall unsatisfactory care provided to Ms A in this case.

Recommendations

104. I recommend that Canterbury District Health Board:

- Apologise to Ms A for its breaches of the Code. The apology is to be sent to HDC within **three weeks** of the date of issue of this report, for forwarding to Ms A.
- Conduct a review of its consent documentation to ensure that all sections are unambiguous and clear.
- Conduct training for all staff on the cultural and emotional significance of tissue and body parts and Canterbury DHB's policy on the return of tissue and body parts.

Canterbury DHB is to report to HDC on compliance with these recommendations, within **three months** of the date of issue of this report.

105. I recommend that Dr C:

- Apologise to Ms A for his failings in this case. The apology is to be sent to HDC within **three weeks** of the date of issue of this report, for forwarding to Ms A.

Follow-up actions

106.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case and Canterbury DHB, will be sent to the New Zealand Committee of the Royal Australasian College of Obstetricians and Gynaecologists, the Royal Australasian College of Surgeons, Women's Health Action, and the Medical Council of New Zealand, for educational purposes.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case and Canterbury DHB, will be placed on the HDC website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from Associate Professor Neil Johnson CREI, Gynaecologist:

"Thank you for the invitation to provide expert advice regarding the care provided to [Ms A] by the Canterbury District Health Board.

The 'Background' section of your letter to me dated 8 July 2013 provides a good summary of the facts of the case. This report is based upon the relevant documents provided to me.

Whether overall care provided to [Ms A] by CDHB was reasonable in the circumstances and why

The overall care provided to [Ms A] was not reasonable in the circumstances in relation to two issues.

1) In the removal of a fallopian tube for a suspected ectopic pregnancy on 2 May 2012 in light of the pregnancy subsequently turning out to be a viable intrauterine pregnancy.

2) In the failure to return the fetal tissue to [Ms A] following the termination of pregnancy on 8 June 2012.

1) *Removal of a fallopian tube for a suspected ectopic pregnancy in light of the pregnancy subsequently turning out to be a viable intrauterine pregnancy*

This should never happen, but occasionally it does. There are occasions in which a 'negative laparoscopy' is undertaken for a suspected ectopic pregnancy, but only very rarely is a 'negative salpingectomy' undertaken, in which a fallopian tube is removed for a presumed ectopic pregnancy and the fallopian tube does not have any histologic evidence of ectopic pregnancy, then the pregnancy is subsequently confirmed as intrauterine. Clinicians undertaking gynaecological surgery should be well aware of this potential adverse outcome and should take all steps possible to avoid this outcome. There was a particular need to avoid this outcome in the case of [Ms A] as she only had one remaining fallopian tube, the other having been removed when she had a previous ectopic pregnancy.

The reasonable steps that should have been taken that might have led to the fallopian tube not being removed were:

— Greater diligence over calculation of the gestation at presentation on 30 April 2012. The date of the last menstrual period was recorded initially as 31 March 2012 in the gynaecology clinical notes. This should have led to a conclusion that the best estimate of the gestation by dates was 4 weeks and 3 days (even allowing for [Ms A's] documented short regular cycle, this estimate would have been less than 5 weeks), however the gestation was

documented on the admission sheet as 5–6 weeks and this seems to have been perpetuated thereafter, with no recognition that this estimate of the gestation was incorrect. A serum β-hCG level of 334 IU/L is normal for a viable pregnancy of gestation 4–5 weeks, but it is lower than expected in a viable pregnancy of gestation 5–6 weeks.

— Maintenance of the possibility that the pregnancy might be intrauterine and potentially viable in light of the fact that there had been no vaginal bleeding and the serum β-hCG level was only 334 IU/L. It is normally considered that, if the β-hCG level is greater than 1,500 IU/L, transvaginal ultrasound offers a reasonably accurate diagnosis of intrauterine pregnancy, although many gynaecologists are careful not to assume that an intrauterine pregnancy has been excluded unless the β-hCG level is greater than 2,500 to 5,000 IU/L, depending on the level of confidence regarding the accuracy of ultrasound diagnosis.
— A recheck of the serum β-hCG level prior to surgery, as the surgery took place two days after this level had been initially measured. Viable pregnancies are usually associated with an approximate doubling of β-hCG level every 48 hours and this finding would have increased the suspicion that the pregnancy was viable and not ectopic.
— Not assuming that the pregnancy was ectopic prior to laparoscopic visualisation of the fallopian tube. It is not normal practice to undertake a large loop excision of the transformation zone (LLETZ) procedure at the time of a viable pregnancy, so, given that it appears from the operation note dated 2 May 2012 that the LLETZ procedure was undertaken prior to laparoscopy, it appears that a preoperative assumption that the pregnancy was ectopic had been made — in cases where there has been pain but no vaginal bleeding and where the preoperative β-hCG level is only 334 IU/L, this will be an incorrect assumption in a reasonable proportion of cases.

2) *Failure to return the fetal tissue to [Ms A] following the termination of pregnancy*

There are numerous instances of [Ms A] clarifying that she wished to have the pregnancy tissue returned to her following termination of pregnancy, as she has correctly highlighted in her letter to the Health and Disability Commissioner dated [date]. This did not occur.

In the final consent taken by the surgeon prior to surgery, signed by both patient and surgeon, the part of the consent form relating to return of body tissues was incomplete. Scrutiny of this form suggests to me that the respective tick boxes are insufficiently closely related to the questions about blood testing in relation to exposure to body fluids and to tissue return, probably increasing the chance of ambiguity (the surgeon may have believed that the 'yes' answer related to the return of tissue, rather than the agreement to have blood testing in relation to exposure to body fluids). Nonetheless it is the responsibility of the surgeon to ensure that these forms are completed correctly. The option of return of pregnancy tissue has rightly been long considered to be an important issue in New Zealand

and all gynaecologists should be aware of this. If this part of the consent form is incomplete, there are usually preoperative checking procedures in the operating theatre to identify and remedy this.

Should [Ms A's] left fallopian tube have been removed? Reasons for this view

[Ms A's] left fallopian tube should not have been removed.

The left fallopian tube was removed at 4–5 weeks gestation (but documented as 5–6 weeks gestation) based on the following.

a) A suspicion of ectopic pregnancy from symptoms of cramping and lower abdominal pain for 10 days followed by the occurrence of left shoulder tip pain, in association with abdominal tenderness, on the day of the patient's admission to hospital at gestation 4 weeks and 3 days.
b) A serum β-hCG level of 334 IU/L on the day of hospital admission.
c) A pelvic ultrasound scan that identified an adnexal mass and no intrauterine pregnancy.
d) the finding at laparoscopy of appearances consistent with 'a small left tubal pregnancy'.

The fact that [Ms A] was ultimately found to have a viable intrauterine pregnancy of itself is sufficient to reach a conclusion that [Ms A's] fallopian tube should not have been removed, as the management of this type of case in early pregnancy should be designed to prevent this ever happening. Those responsible for removing the fallopian tube must be certain that they are doing so for an ectopic pregnancy and that they are not removing a healthy fallopian tube in the context of uterine pregnancy, viable or otherwise.

When this error does occur there are sometimes mitigating circumstances and, whilst some of these may have been present in this case, given that [Ms A] had only one fallopian tube remaining, the duty of care for the clinicians in this case was arguably even more exacting.

The symptoms of cramping, lower abdominal pain, with recent occurrence of shoulder tip pain, do raise the suspicion of ectopic pregnancy, particularly in a women over 40 years old with a history of salpingectomy for a previous ectopic pregnancy and multiple previous laparoscopic procedures for endometriosis. However most women with ectopic pregnancy have vaginal bleeding or brown-coloured vaginal discharge and the absence of this symptom should have led to a suspicion that the pregnancy might not be ectopic.

A serum β-hCG level of 334 IU/L is normal for gestation 4–5 weeks (but lower than that expected for gestation 5–6 weeks). Even if the serum β-hCG is lower than expected, there can be two reasons for this, either an insufficient rise of serum β-hCG as can occur with ectopic pregnancy, or an incorrect assumption about the maturity of the pregnancy when based on the date of the last menstrual period in the context of an early viable pregnancy and this is a common scenario.

Whilst the best estimate of the gestational age might help in improving the accuracy of the diagnosis, it appears that the miscalculation of the gestational age in this case has led to incorrect assumptions.

The ultrasound identification of an adnexal mass (measuring 15x 13mm) and no intrauterine pregnancy, with serum β-hCG level 334 IU/L, should lead to a suspicion that the pregnancy might be ectopic. However a small percentage of these cases will have a corpus luteum cyst of the ovary in association with an early but potentially viable intrauterine pregnancy, as has probably occurred in this case.

At the time of surgery, it appears that the surgeons have assumed that the patient definitely had an ectopic pregnancy by apparently first proceeding with a LLETZ. However it is doubtful whether proceeding first with the laparoscopic component of the surgery, as the laparoscopic finding documented in the operation note was a 'small left tubal pregnancy', would have changed what was undertaken surgically. Based on the black and white copies of the laparoscopic images that are available to me, and bearing in mind that those best placed to make a judgment about the appearance of the fallopian tube would be the surgeons, it is difficult to comment authoritatively on this interpretation of the laparoscopic appearances. However the fallopian tube does not appear to be unequivocally abnormal and there was no free blood apparent in the pelvic cavity, which would normally be expected in the context of shoulder tip pain in association with ectopic pregnancy. There is a wide range of normal appearances of a fallopian tube; some abnormal appearances (such as a hydrosalpinx) could increase the chance of misdiagnosis of a tube as containing an ectopic pregnancy. However the histology report of a microscopically normal fallopian tube lends weight to the argument that, in defining the appearance of the fallopian tube as abnormal, a misjudgment occurred on the part of the surgeons. Although it had been written on the consent form that [Ms A] 'does not want [her left fallopian] tube left in situ', this would normally be the case only with the finding of a definite ectopic pregnancy at laparoscopy. Commonly, in the consent process for surgery for unruptured tubal ectopic pregnancy, patients are given the choice as to whether they prefer to have the fallopian tube removed or to retain the fallopian tube. If the tube is removed, this substantially lowers the chance of a future ectopic pregnancy (but for [Ms A] this meant that IVF treatment would be required to offer any chance of a future pregnancy). If the tube is conserved, although the chance of a future ectopic pregnancy is increased, the chance of conceiving naturally is retained and this is often considered important in cases where only one fallopian tube remains.

The absence of pregnancy tissue on histological evaluation of the left fallopian tube excluded the possibility that the pregnancy was heterotopic (a twin pregnancy in which one embryo implants in the uterus and the other in the fallopian tube).

Severity of departure from appropriate standard of care

In relation to the removal of a fallopian tube for a suspected ectopic pregnancy in light of the pregnancy subsequently turning out to be a viable intrauterine

pregnancy, I judge the departure from appropriate standard of care to be moderate, as it appears that the clinicians always acted in what they believed was the patient's best interests, but the outcome, resulting from a sequence of incorrect assumptions and misjudgments, for which numerous clinicians were responsible was a substantially adverse one that left the patient with a considerable burden.

In relation to the failure to return the fetal tissue to [Ms A] following the termination of pregnancy, I judge the departure from appropriate standard of care to be moderate, as there is no evidence that staff did not act in the patient's best interests, but the adverse outcome resulted from insufficient attention to important details in relation to consent for surgery and checking procedures.

Comment on other aspects of care provided by CDHB

It is not appropriate to undertake a LLETZ procedure during a viable pregnancy and the fact that this occurred was another negative aspect of care. However the discussion that took place with the colposcopy team reflects attempts to individualise care for [Ms A] (and thus avoid an additional procedure for which she was already scheduled), which is a positive aspect.

A further positive aspect of care provided by CDHB was the advice given by gynaecologist, [Dr C], after the confirmation of a viable ongoing pregnancy, who stated: 'I would not expect any pregnancy complications from the laparoscopy and salpingectomy at 6 weeks. Should she decide to carry on I think this pregnancy carries the same risk as any pregnancy in a 41 year old woman.' This advice, along with the additional time afforded to [Ms A] for consideration of the decision whether to proceed with the pregnancy, appeared to recognise that the ongoing intrauterine pregnancy presented the only opportunity for [Ms A] to have a child with her partner without the need for medically assisted reproduction and the best opportunity for them to have a child together at all.

Associate Professor Neil Johnson MD FRANZCOG FRCOG CREI
Independent Advisor for Health and Disability Commissioner"

Further advice

The following additional advice was provided by Professor Johnson:

"Thank you for the invitation to provide further comment on the letter from [Dr C], dated 10 February 2014. The documents available to me to provide further comment are my report dated 29 July 2013 and [Dr C's] letter dated 10 February 2014.

I have been invited in particular to comment on:

The letter itself
The evidence provided by [Dr C] in the letter dated 10 February 2014 is all completely reasonable. In my opinion, it reflects a thoughtful clinician providing a

thoughtful response to the provisional decision of the Health and Disability Commissioner.

I am of the view that there is no aspect of this response that cannot be accepted. [Dr C's] acknowledgement, in summary, of the inadequacies of his own clinical care is both acceptable and meritworthy.

Some of the positive aspects of care to which I alluded in my report have been reiterated.

I fully support [Dr C's] assertion that it was reasonable to undertake a laparoscopy to confirm or exclude an ectopic pregnancy for the reasons highlighted by [Dr C].

Whether acceptance of [Dr C's] letter would change my initial advice
I do not consider that acceptance of the evidence about clinical reasoning in [Dr C's] letter would change my initial advice.

If not, why not?
I do not consider that the evidence in [Dr C's] letter challenges any of the evidence in my report, although it does provide clear reasoning behind the clinical decision making.

I am of the view that my advice remains sound regarding the removal of a fallopian tube for a suspected ectopic pregnancy in light of the pregnancy subsequently turning out to be a viable intrauterine pregnancy being a moderate departure from appropriate standard of care. I have acknowledged in my report that some mitigating circumstances were present in the case of [Ms A] and that the clinicians always acted in what they believed was the patient's best interests. To a large extent, the adverse outcome could be considered highly unfortunate for the patient and the clinicians, an outcome far greater in severity than the deficiencies in clinical care. It could be reasonably argued that the adverse outcome was a consequence of a combination of minor clinical management deficiencies and deficiencies at an institutional systems level (and to some extent misfortune that these deficiencies combined) rather than suboptimal care by any individual clinician.

I am also of the view that my advice remains sound regarding the failure to return the fetal tissue to [Ms A] following the termination of pregnancy as being a moderate departure from appropriate standard of care.

Disclosure
I disclose no personal or professional conflict of interest in this case. I will be happy to answer further specific questions if required."