Obstetrician & Gynaecologist, Dr B

District Health Board
(now Health New Zealand|Te Whatu Ora)

A Report by the

Deputy Health and Disability Commissioner

(Case 21HDC00031)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. This report concerns the care provided to Ms A in December 2020 at a public hospital, in particular the management of an ectopic pregnancy by an obstetrician & gynaecologist, Dr B, when Ms A presented to the Emergency Department (ED).

Findings

2. The Deputy Commissioner considered that although the decision to manage Ms A's condition conservatively was appropriate, Dr B did not communicate the diagnosis or management of an ectopic pregnancy to a sufficient standard. This meant that Ms A and her lead maternity carer, RM C, did not reach a shared understanding with Dr B regarding Ms A's treatment plan. The Deputy Commissioner found that Ms A did not receive information about other treatment options available and the associated risks and benefits before making an informed choice and giving informed consent. In addition, the Deputy Commissioner considered that Ms A was not given enough information about the best option to preserve her fertility. Accordingly, the Deputy Commissioner found Dr B in breach of Right 6(1) and 7(1) of the Code.

3. The Deputy Commissioner also found that Dr B did not document his verbal consultation with Ms A, as set out by the standards of the Medical Council of New Zealand. The lack of documentation resulted in a lack of clarity about what was said during the consultation, which left Ms A confused. Accordingly, the Deputy Commissioner also found Dr B in breach of Right 4(2) of the Code.

4. The Deputy Commissioner criticised the hospital systems related to its wide practice of clinicians giving verbal advice without completing documentation, clinicians using different guidelines that may be contrary to the guidelines set out by the district, the absence of a discharge summary for Ms A's ED presentation or the lack of a process to register her as a patient attendance on its administration system, and the small assessment spaces in ED, which did not accommodate a patient's privacy and safety.

Recommendations

5. The Deputy Commissioner recommended that Dr B provide a formal written apology to Ms A for his breaches of the Code, reflect on the shortcomings in his care and opportunities for improvement, and complete the RANZCOG communication skills workshop and write a reflection on his learnings from the workshop.

6. The Deputy Commissioner recommended that Health NZ consider establishing space within the ED/assessment unit for review of patients with suspected early pregnancy complications, undertake a review of the deficiencies identified relating to the hospital systems, develop a policy for the management of acute gynaecology patients, undertake an audit to check clinicians' compliance against local policy use, provide staff training on documentation standards, and consider developing information pamphlets about ectopic pregnancy treatment options and safety-netting advice.

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Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her by obstetrician and gynaecologist Dr B at Health New Zealand|Te Whatu Ora (Health NZ).[1] The following issues were identified for investigation:

- *Whether Health NZ provided Ms A with an appropriate standard of care from 18 December 2020 until 31 December 2020.*
- *Whether Dr B provided Ms A with an appropriate standard of care from 18 December 2020 until 31 December 2020.*

8. This report is the opinion of Deputy Commissioner Rose Wall and is made in accordance with the power delegated to her by the Commissioner.

9. The parties directly involved in the investigation were:

Ms A	Consumer
Health NZ	District healthcare provider
Dr B	Obstetrician & gynaecologist

10. Further information was received from:

RM C	Registered midwife (RM)/lead maternity carer (LMC)
Dr D	Independent reviewer/gynaecologist

11. Gynaecologist Dr D is also mentioned in the report.

12. Independent clinical advice was obtained from gynaecologist Dr Jacqueline Smalldridge (Appendix A).

Information gathered during investigation

Background

13. On 28 November 2020, Ms A, aged in her thirties, was confirmed to be pregnant with an estimated due date of 7 August 2021. She had an obstetric history of multiple previous pregnancies, including a molar pregnancy.[2]

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[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Health New Zealand|Te Whatu Ora (previously known as Te Whatu Ora|Health New Zealand).

[2] A molar pregnancy is a rare complication that occurs when the tissue surrounding a fertilised egg develops abnormally.

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14. Ms A's complaint concerns the care and advice she received from consultant obstetrician and gynaecologist Dr B,[3] in particular when she presented with a possible ectopic pregnancy.[4]

15. Ms A told HDC that this was a much-wanted pregnancy, and she suffered two weeks of severe pain, discomfort, bleeding, sleeplessness, and emotional turmoil during this period. She said that this had a life-changing impact on her, and she feels that Dr B's conservative management at the time was inappropriate.

Antenatal care

16. From 1 December 2020, Ms A was under the care of a lead maternity carer, RM C. During December, Ms A and RM C had frequent email and telephone communications about Ms A's pregnancy. Ms A reported that she was experiencing pelvic pain, 'sharp period pain type' cramps, bleeding, and fluid discharge.

17. RM C measured Ms A's serum hCG (human chorionic gonadotropin)[5] to monitor the status of her pregnancy. Serial hCG measurements were taken from 1 December to 17 December 2020.[6] During this period of observation, RM C suggested to Ms A that she might be experiencing a non-viable pregnancy, possibly ectopic (meaning the pregnancy was outside the uterus), as the hCG levels were rising only slowly and were fluctuating, and Ms A was experiencing episodes of severe right-sided pelvic pain with cramping and bleeding.[7]

18. Ms A told HDC that RM C consulted with obstetricians at the public hospital about Ms A's hCG levels and blood results. Although this consultation was not documented in the clinical record, Ms A told HDC that RM C was advised to continue to monitor her hCG levels and to request an obstetric ultrasound scan (USS) when her hCG levels were above 1000mIU/mL.

19. On 14 December 2020, at 6 weeks' gestation, Ms A's hCG level was 695mIU/mL. RM C requested a USS for Ms A at the public hospital to investigate her pain and intermittent bleeding.

20. The USS was completed on the same day (14 December). It found that there was 'no visible intrauterine gestation sac' (ie, there did not appear to be a pregnancy in the uterus). The

[3] Dr B was the senior medical officer with primary responsibility for the services provided and was on call for the Gynaecology Department on 18 December 2020.

[4] An ectopic pregnancy occurs when a fertilised egg implants outside the uterus. The fertilised egg cannot survive outside the uterus and if left to grow may damage nearby organs and cause life-threatening loss of blood. Symptoms include pelvic pain and vaginal bleeding.

[5] Human chorionic gonadotropin (hCG) is a hormone produced by cells formed in the placenta. Levels of hCG can be used to measure the status of a woman's pregnancy.

[6] The relevant levels taken for Ms A at the time were: 1 December 52mIU/mL, 3 December 105mIU/mL, 5 December 149mIU/mL, 7 December 285mIU/mL, 9 December 409mIU/mL, 12 December 615mIU/mL, 14 December 695mIU/mL, and 17 December 850mIU/mL.

[7] Slow rising hCG levels may indicate issues in pregnancy; hCG levels higher than 5mIU/ml typically indicate pregnancy and typically hCG levels will double every two or three days during the first four weeks of a viable pregnancy.

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report noted that an ectopic pregnancy could not be excluded on the USS alone[8] and advised that the scan be interpreted with the hCG results and to seek advice from gynaecology services or information based on gynaecological protocols for pregnancy of an unknown location. Ms A told HDC that she was advised by RM C to continue hCG testing and to repeat the USS scan in seven days.

18 December 2020 — consultation with Dr B

21. Health NZ told HDC that prior to 18 December 2020, Ms A was solely under the care of RM C.

22. Ms A told HDC that following the completion of the first USS, RM C was still worried that her symptoms and pain were persistent,[9] and that her hCG levels were rising only slowly. On 18 December 2020, Ms A and RM C presented to the Emergency Department (ED) following an episode of pain and bleeding on 17 December 2020.

23. A second obstetric USS was undertaken and Ms A was seen by Dr B at the ED. Health NZ said that at this time the formal USS report was not available to Dr B, but he reviewed the images and interpreted the scan. Health NZ explained that Dr B interpreted the scan as showing 'no evidence of significant free fluid in the peritoneal cavity and the presence of a small cystic space in the uterine cavity'. Health NZ said that Dr B believed that Ms A was experiencing a 'failing pregnancy with [an] unknown location'.

24. Ms A told HDC that immediately after her scan in ED:

> '[Dr B] disputed the scan findings, he talked about there being a sac in the uterus visible on scan. He said there maybe is something in the tube but it might be a clot. He talked about monitoring the hCG [level] and repeating the scan the following week.'

25. Health NZ told HDC that Dr B received the formal report for the second USS around 30 minutes after his initial consultation with Ms A. He then approached Ms A and RM C to discuss the findings of the USS report. Health NZ said that Dr B told both Ms A and RM C that the 'outcome of the pregnancy was not looking good … and the ultrasound had not shown an intrauterine pregnancy'.

26. The second USS report noted that a mass had been identified near to the right ovary, with a small cyst in the endometrium.[10] The radiologist who reported on the scan concluded: '[T]he ultrasound appearance in conjunction with previous imaging and the rising beta hCG is highly suspicious for a right-sided ectopic pregnancy.'

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[8] The USS also reported cysts (abnormal pockets of fluid) in the left ovary, myometrium, and cervix. Haemorrhage/fluid was also visible.

[9] Ms A said that she had breathing problems and pain in her shoulder, and her mental and emotional wellbeing was also suffering.

[10] The scan found a 20 x 14 x 22mm echogenic mass with some vascularity medial and inferior to the right ovary, and a small cyst (3 x 3 x 4mm) in the endometrium (the layer of tissue that lines the uterus).

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27. Ms A's recollection is that following the second USS report, Dr B considered that a uterine pregnancy was still possible. Ms A told HDC:

> '[Later in the maternity ward, Dr B] stated he had read the report, that there might be something in the tube maybe something in the uterus. He talked about me having "proven fertility with no issues before" and he spoke of my saline infusion scan that showed clear tubes so my risk of ectopic being low. I said that during the scan the right tube had been difficult and they had some difficulty getting the saline through it initially. That it was painful during the scan. [Dr B] also stated that if it was an ectopic it was unlikely to rupture as my hCG was less than 1,000. He told me I was low risk for an ectopic. I left the hospital feeling upset and confused and still in considerable pain.'

28. Ms A stated: 'I was sent home with a diagnosed ectopic pregnancy in significant pain and bleeding at high risk of suffering further injury or death to wait to have surgery 5 days later.'

29. Dr B told HDC that following the formal reporting of the USS scan, he diagnosed Ms A with an ectopic pregnancy. However, this was not documented in the electronic patient management system and was conveyed to Ms A and RM C only verbally.

30. RM C documented the interaction with Dr B in her clinical notes as follows:

> '18/12/21: Met with [Dr B] in room [at] ED. Conversation as recollected by [Ms A]. He said he could see a sac in the uterus — maybe corpus luteum?[11] Disputing ectopic though briefly mentioned Methotrexate as we stood to leave as another drug could use. Bloods Mon[day], USS Tues[day], Theatre list Wed[nesday]. I said [Ms A] has had pain, bleeding, non-rising hCG, nothing in uterus on scan, he still said thought he could see something in uterus. [Ms A] felt bamboozled by the conversation.'

31. Dr B told HDC that he did not say that a uterine pregnancy was still possible. He stated that RM C's notes were an 'inaccurate recollection of the conversation [they] had'.

Conservative management plan

32. In response to Ms A's recollection of events, Dr B told HDC:

> 'After seeing the formal [u]ltrasound report, I mentioned to [Ms A] and [RM C] that there was a cystic space in the uterus and the scan was suspicious of ectopic pregnancy. I told them that while the scan was suspicious for an ectopic pregnancy, as she was stable with a low beta hCG level it was still a reasonable option to consider conservative management.'

33. Dr B said he considered that conservative management of Ms A's findings was appropriate for the following reasons:

[11] A corpus luteum is a small cyst-like structure that forms in the ovary during ovulation and produces the hormone progesterone.

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- Conservative management is one of the options for women with ectopic pregnancies when beta hCG levels are low (<1000 IU), if the mass identified is small,[12] and the free fluid is minimal or absent.[13] Dr B considered that Ms A's clinical findings met this criterion, which came from a policy from another district health board (DHB1) but was used by clinicians at the public hospital (see Appendix C).
- Conservative management is an option for women who are not keen on methotrexate[14] and want to avoid the removal of their fallopian tube(s).
- The risk of rupture of Ms A's ectopic pregnancy was low because her recent saline infusion scan[15] had indicated 'normal endometrial cavity', the rise of her beta hCG levels was 'very slow',[16] and the ectopic mass was not located clearly.
- He gave safety-netting advice to Ms A that he was on call over the weekend, and she could return to the hospital at any time if she felt unwell or if there was any increase in her bleeding or pain.

34. Ms A told HDC that she was concerned that her fallopian tube could rupture at any point, and she would have difficulty reaching the hospital.

35. A plan was made for Ms A to undertake further hCG testing and ultrasound after the weekend (both were completed on Tuesday 22 December 2020), and for Dr B to review the results of the tests before deciding whether surgery was required. Accordingly, the operating theatre was pre-booked for 23 December 2020. This conservative plan was documented in RM C's maternity notes as 'bloods [Monday]', 'USS [Tuesday]' and 'Theatre on [Wednesday]'.

36. Dr B told HDC that he 'mentioned other options of medical management (i.e. methotrexate) or surgical intervention as alternatives'.

Communication and discussion about methotrexate

37. Ms A told HDC that as she was preparing to leave the hospital, Dr B briefly mentioned to her 'in passing' the use of methotrexate as a treatment option. Ms A said that she was aware of methotrexate at the time but was concerned about the use of it. She told HDC:

> 'I expressed that I wasn't keen on methotrexate but I wanted to save that tube because surgery was massive, losing my tube was huge and my fertility was very important to myself and my partner.'

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[12] An adnexal mass is a growth that develops around or outside the uterus and can be fluid-filled or solid. Dr B identified the size of the mass as less than 3cm.

[13] A moderate to large amount of complex fluid/haemoperitoneum (intra-abdominal bleeding) is suggestive of a ruptured ectopic pregnancy.

[14] Methotrexate is a drug that can be used to treat an ectopic pregnancy. It stops certain cells from dividing, and the pregnancy is then absorbed by the body over four to six weeks.

[15] A saline infusion scan (sonohysterography) uses a small amount of salt solution inserted into the uterus to allow the lining of the uterus (endometrium) to be seen more clearly.

[16] Ms A's hCG levels rose from 850mIU/mL to 882mIU/mL between 17 December and 18 December. Both levels remained less than 1000mIU/mL.

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38. Dr B told HDC that at the time, Ms A advised him that she was not keen on methotrexate, and hence the method was not discussed further. He said that Ms A elected 'to wait until the result of her repeat beta hCG and ultrasound scan were available before having further discussion'.

39. Health NZ told HDC that usually the discussion of management options would be contained in the documentation of a patient consultation. Similarly, normally a discussion and decision not to choose a particular treatment or clinical management approach that was offered (in this case the use of methotrexate) would not be written on a consent form but rather be documented in the clinical notes or electronic record. Unfortunately, for Ms A, this did not occur, as discussed below.

Documentation

40. Dr B did not document his consultation with Ms A contemporaneously on 18 December 2020.

41. Health NZ told HDC that Ms A was not registered formally on the patient management system as an outpatient or as an emergency attendance, so there was no discharge summary for Ms A's presentation on 18 December 2020. Health NZ explained that acute gynaecological presentations to ED were common, but there was no specific process for these, and often physical clinical notes were not present, and some consultants relied on LMC midwives to document their verbal advice.

42. Dr B told HDC that he did not have access to Ms A's clinical file to document the consultation. He gave her verbal advice and devised a management plan based on the information available on the electronic system.

43. Dr B said that the management plan was not recorded, as verbal advice was given to Ms A and RM C. Dr B stated:

> 'The advice consisted of repeating the blood tests and then deciding whether a follow-up scan was required once the blood tests were available. I also advised that [Ms A] should come to the hospital if there [was] any increase in bleeding or pain, or if she was feeling unwell.'

44. Health NZ told HDC that it is normal and accepted practice to document all clinical consultations and assessments in the electronic patient management system by adding a document and creating a contact note. However, Health NZ acknowledged that Dr B was not aware of this process at the time. Health NZ said that following the review of Ms A's complaint, Dr B received education on how to do this.

45. Dr B had no further comments on Health NZ's above response.

Events following consultation with Dr B on 18 December 2020

Informal consultation sought from another obstetrician and gynaecologist

46. Following her consultation with Dr B in the maternity ward, Ms A rang RM C with concerns that there was a '2cm pregnancy growing in [her] fallopian tube' and asked for a second

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opinion. RM C then informally approached another consultant obstetrician and gynaecologist, Dr D, on the same day (18 December), at the same maternity ward, and requested a second opinion on Ms A's management plan.

47. Health NZ told HDC that Dr D explained to RM C that she did not have sufficient information to offer a clinical opinion and that she respected Dr B's clinical judgement. RM C was advised to go back to Dr B if she had any further questions about his management plans. RM C documented that she informed Ms A about the response from Dr D. Ms A did not go back to Dr B as she considered that 'he did not believe the ultrasound report'.

48. Health NZ told HDC that no notes were taken of this brief conversation between RM C and Dr D.

49. RM C retrospectively documented in her incident review report on 24 December 2020 (after Ms A was discharged back home) that she advised Ms A to contact her immediately for transfer to the ED if she had further bleeding or pain.

50. Ms A told HDC that during the weekend of 19 and 20 December 2020, she felt further pain, which included 'acute bouts of pain up to [her] ribs, the pain in [her] shoulder and [she] passed some large blood clots'.

22 December 2020

Repeat test and scan

51. On Tuesday 22 December 2020, four days following Ms A's consultation with Dr B, she presented to hospital for the planned repeat beta hCG test and obstetric USS.

52. The beta hCG test showed an increase in hCG levels.[17] The USS reported a persistent mass separate to the right ovary and consistent with an ectopic pregnancy.

53. The ED record documents that following the USS report Dr B reviewed Ms A in the ED and confirmed that the scan indicated a 'right ectopic [pregnancy] with empty uterus'. Health NZ told HDC that Dr B explained that the appropriate treatment was surgical management, which included the removal of the right fallopian tube if an ectopic mass was found.

54. Ms A told HDC that she was not surprised by the results of the third USS but was devastated. She stated that she also felt that Dr B was talking to her 'as if he didn't believe there was a pregnancy in the tube'.

Surgery

55. Ms A consented to a laparoscopy and right salpingectomy,[18] +/- ERPC[19] surgery. Her care was handed over to the doctor on call for acute gynaecology, as Dr B was rostered to the outpatient clinic that afternoon.

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[17] 1099mIU/mL.

[18] Salpingectomy is the surgical removal of a fallopian (uterine) tube.

[19] ERPC is an evacuation of retained products of conception.

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56. Laparoscopic surgery was performed that day and confirmed that Ms A had a right tubal ectopic pregnancy with an empty uterus and small amounts of blood in the peritoneal space. Ms A's right fallopian tube was removed.

57. Ms A was transferred to the general ward for further observation before being discharged home on 23 December 2020 with planned follow-up at the gynaecology outpatient clinic in six weeks' time.

Further information

Ms A

58. Ms A told HDC that she feels that Dr B did not provide timely treatment for her ectopic pregnancy. She considers that it was clear that her pregnancy was non-viable and she could not see the benefits of Dr B delaying treatment after he reviewed her initially on 18 December 2020. She said that when Dr B sent her home, she had felt upset and confused and was still in considerable pain. Her impression is that she might not have lost her right fallopian tube if Dr B had offered her 'appropriate treatment' during the 18 December 2020 consultation.

59. Ms A told HDC:

> 'This had a life changing impact on me, my partner and my family. For almost a year my partner and I had been trying for a baby, our chances of conceiving that baby are now reduced as I have one fallopian tube.'

Health NZ and Dr D's internal report

60. Health NZ told HDC that Ms A's concern was lodged in its incident management safety system by RM C and was raised as an SAC 2 event (a major incident).[20] Under Health NZ's normal process, Ms A's complaint was discussed by the Serious Incident Review Committee before it was reviewed independently by obstetrics and gynaecology consultant Dr D (see Appendix B).

61. Dr D's report noted that the diagnosis of ectopic pregnancy was clear on 18 December 2020 and ideally treatment would have been started at this point. Health NZ acknowledged that in hindsight, the delay in management led to significant stress for Ms A and 'the diagnosis of an ectopic could have been made on 18 December and could have given [Ms A] the option of earlier surgical management at that time', which would have reduced the 'risk of a serious clinical deterioration' and lessened Ms A's distress.

62. Dr D's report concluded:

> 'There was a delay in diagnosis and treatment of an ectopic pregnancy by at least 4 days. This delay does not appear to have led to any additional physical harm to the

[20] A Severity Assessment Code (SAC) 2 event is a clinical incident that has, or could have, caused moderate harm to the patient and is attributed to the healthcare provision (or lack thereof) rather than the patient's underlying condition or illness.

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patient and the outcome of salpingectomy is unlikely to have been altered by earlier intervention.'

63. Health NZ expressed condolences to Ms A for the loss of her pregnancy and fallopian tube.

64. Health NZ told HDC that the hospital has a senior medical person on call at all times. The senior medical person may be a specialist obstetrician gynaecologist. Health NZ acknowledged that there is limited ability for patients to see a second clinician in an acute setting over the weekends.

Dr B

65. Regarding Dr D's report, Dr B told HDC that he does 'not agree that there was a delay in diagnosis or treatment'. He said that the ectopic pregnancy was diagnosed on 18 December (following the USS report) and he believes that conservative management was appropriate in the first instance.

Pathway for early pregnancy advice

66. Health NZ told HDC that at the time Ms A presented to the hospital, most patients with suspected ectopic pregnancy or early pregnancy complications were seen in the ED in small assessment spaces, as there was 'no ideal place to review patients with such complications in a safe and private way'.[21]

67. Health NZ told HDC:

> 'Depending on the finding and degree of clinical concern, some women will be discharged home without a formal admission to the wards, whilst others may be admitted to the hospital ward or short stay area whilst awaiting further investigations.'[22]

Ectopic pregnancy management guidelines

68. Health NZ told HDC that the protocol for ectopic pregnancy was the one used by another DHB (DHB2) (see Appendix D). Health NZ said that 'no further protocol is needed but staff are reminded on where to find this guideline'. However, Dr B indicated to HDC that at the time of events he had followed the DHB1 guideline (see Appendix C) for the conservative management of ectopic pregnancy. Neither Dr B nor Health NZ commented on which guideline was the appropriate one to have used.

ACC

69. On 2 March 2021 ACC accepted Ms A's treatment injury claim for the removal of her right fallopian tube. The ACC report stated that the surgery was covered on the basis that the treatment injury was caused by a failure (delay) in treatment. This caused 'the necessity [o]f the right fallopian tube removal, and is not a necessary part or ordinary consequence of treatment'.

[21] Health NZ said that the ideal place for review of patients with pregnancy complications is the short-stay rooms close to the ED, but these rooms were inaccessible because the hospital was unable to staff them.

[22] Further investigations included repeat blood tests or ultrasound.

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70. ACC did not seek internal or external clinical advice for Ms A's complaint.

71. ACC's treatment injury report made no reference to Ms A's intraoperative blood loss.

Responses to provisional opinion

Dr B

72. Dr B was provided with a copy of the provisional report and given an opportunity to comment. Dr B confirmed to HDC that he did not wish to make any comments.

Health NZ

73. Health NZ was provided with a copy of the provisional report and given an opportunity to comment. Health NZ's comments related to a proposed recommendation, and this was considered when developing the final recommendations.

Ms A

74. Ms A was provided with a copy of the 'information gathered' section of the provisional report and given an opportunity to comment. Many attempts were made to follow up with Ms A, but this Office did not receive a response.

Opinion: Dr B — breach

75. This opinion concerns the care Dr B provided to Ms A from 18 December to 31 December 2020 when she presented to hospital for a second obstetric USS after experiencing an episode of pain and bleeding. I consider that there are three main issues with Dr B's care, as discussed below.

Communication of ectopic pregnancy and informed consent — breach

76. On 18 December 2020, Ms A presented to hospital for her second USS after she had experienced an episode of pain and bleeding. Dr B was the senior obstetrician and gynaecologist on call at the time and reviewed Ms A's USS images and test results. Health NZ told HDC that before the formal USS report was available, Dr B reviewed Ms A's hCG level taken the previous day (17 December) and discussed with both Ms A and her LMC that the outcome of Ms A's pregnancy was 'not looking good'.

77. The USS report of 18 December concluded that the 'ultrasound appearance in conjunction with previous imaging and the rising beta hCG [was] highly suspicious of right-sided ectopic pregnancy'. My clinical advisor, Dr Smalldridge, the serious incident reviewer, Dr D, and Dr B, all considered that the diagnosis of an ectopic pregnancy was clear on 18 December 2020.

78. However, Ms A and her LMC have provided a different account as to their discussion with Dr B about the USS results.

79. Both Ms A and RM C told HDC that when Dr B spoke to them on the maternity ward after he had reviewed the scan report, he was still suggesting that it could be a uterine pregnancy.

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This was recorded in RM C's incident review, which noted that Dr B had disputed the USS findings for ectopic pregnancy as he could see on the scan a visible sac within the uterus.

80. On the other hand, Dr B told HDC that he did not say that a uterine pregnancy was still possible, and he considers that RM C's notes are an 'inaccurate recollection of the conversation [they] had'. Dr B told HDC that he does not agree that there was a delay in diagnosis of Ms A's ectopic pregnancy, and he 'made the diagnosis of ectopic pregnancy on 18 December following the ultrasound report'. However, Dr B did not document in the electronic patient management system his findings and clinical impressions, along with his discussions with Ms A and RM C on 18 December 2020 (as discussed below).

81. Dr D's report written for the Serious Incident Review Committee (see Appendix B) was 'based primarily on information held on [the electronic patient management system]'. Dr D concluded that there was a 'delay in diagnosis and treatment' for Ms A's ectopic pregnancy by at least four days, and 'the diagnosis of ectopic pregnancy was clear on 18 December' following the second USS.

82. Dr Smalldridge reviewed the information contained in the clinical records, as well as the accounts of Ms A, RM C, Health NZ, and Dr B. Dr Smalldridge advised HDC that Ms A's ectopic pregnancy was diagnosed by Dr B on 18 December 2020 in a timely manner.

83. Dr D and Dr Smalldridge have come to different conclusions about the timeliness of Ms A's diagnosis. However, as primarily this is a question of fact, it is one for me to determine. I have reviewed all the available evidence gathered during this investigation. Due to the different accounts of what was discussed, and Dr B's lack of contemporaneous documentation, I am unable to determine conclusively whether Dr B formally diagnosed Ms A's ectopic pregnancy on 18 December 2020 or four days later.

84. However, regardless of whether Dr B made the diagnosis of ectopic pregnancy on 18 December 2020, it is apparent from the statements of Ms A and RM C that Dr B did not communicate the diagnosis or management of an ectopic pregnancy to a sufficient standard. As such, Ms A and RM C did not reach a shared understanding with Dr B regarding Ms A's treatment plan after the second USS.

85. Ms A told HDC that she could not see the benefits of Dr B delaying treatment, and her impression is that if appropriate treatment had been offered and had taken place on 18 December, she may not have lost her fallopian tube.

86. Dr Smalldridge advised that there was a misunderstanding by Ms A that 'earlier surgical intervention would have saved her fallopian tube'. Dr Smalldridge considers that inadequate discussions occurred between Dr B and Ms A at the time (given that there was no clinical documentation) and that Ms A did not 'really understand the options clearly'.

87. Dr Smalldridge said that there are three options for the management of an ectopic pregnancy (conservative, medical, and surgical), which should have been discussed with Ms A. Dr Smalldridge advised:

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> 'The pros and cons of each approach and the patient and the doctor need to come to a decision together based on many factors that are at play. These may include the best approach with regard to future fertility, anxiety around access to hospital if there are worsening symptoms, ability to be followed up with blood tests, sometimes for many weeks.'

88. It is not disputed that Dr B mentioned the use of methotrexate (medical management) to Ms A and that Ms A was 'not keen', so he did not discuss it with her further. Ms A told HDC that she was aware of methotrexate at the time but was concerned about the use of it. Dr Smalldridge confirmed that methotrexate was an option available to Ms A at the time.[23] Dr Smalldridge told HDC:

> 'In this case, we have the recollections of the patient and the later documentation after the fact of [Dr B]. This makes it very difficult to know exactly what was explained to the patient at the time. However, the fact that the midwife then tried to canvas an opinion from a different senior medical officer, [Dr D] in the corridor, may mean that there was inadequate discussion or that the decisions being made were not mutually agreed between the patient and doctor (and the midwife).'

89. As a result, Dr Smalldridge was critical of the communication by Dr B and the shared decision-making in determining whether Ms A understood and agreed with the plan he had devised (for conservative management).

90. I share my advisor's concerns and find that the communication between Dr B and Ms A was inadequate at the time.

91. I acknowledge that Ms A had expressed that she did not want to use methotrexate. However, I consider that insufficient information was provided to allow her to understand all the treatment options available to her at the time and, importantly, the associated benefits and risks of these options. This is supported by my clinical advisor's observation that RM C had to 'canvas an opinion from a different senior medical officer', and by Ms A's statement to HDC that she felt confused, upset, and in considerable pain after she was sent home by Dr B. It appears that Dr B also gave no further consideration to managing Ms A's pain.

92. From the evidence available to me, I agree with my clinical advisor that each option (conservative, medical (with the use of methotrexate) or surgical), together with the associated risks and benefits, needed to be explained fully to Ms A by Dr B during the consultation. I do not accept that there was a fulsome discussion with Ms A, and this is reflected by Ms A's complaint to HDC in which she indicated that she expressly wanted to 'save [the fallopian] tube because surgery was massive'.

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[23] Dr Smalldridge based her findings on the DHB1 Guidelines for ectopic pregnancy. Ms A was observed to be clinically stable, had no significant free fluid, there was a less than 5cm sac, and her hCG level was less than 5000mIU/mL.

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93. In addition, it appears that no consideration was given in the discussion with Ms A on whether conservative management would be the most appropriate option in the context of future fertility to allow her to keep her fallopian tube. As indicated by my clinical advisor, there was no shared agreement between Dr B and Ms A regarding the conservative management approach, which is indicative of inadequate communication. Accordingly, I consider that Dr B failed to communicate effectively to enable Ms A to understand the information so that she was fully informed of the choices available to her.

94. In my view, a reasonable consumer in Ms A's circumstances would expect to receive information about all the treatment options available and the associated risks and benefits of each option before making an informed choice and giving informed consent. I also consider that insufficient information was conveyed to Ms A about the best option to preserve her fertility. Accordingly, I find Dr B in breach of Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[24]

95. It follows that Ms A was not able to give informed consent to the conservative management plan and, accordingly, I find Dr B in breach of Right 7(1) of the Code.[25]

96. I now consider whether Dr B's management of Ms A was reasonable and appropriate.

Appropriateness of conservative management as an option — no breach

97. Ms A complained that she did not receive timely treatment from Dr B following the USS report, and that the conservative management option was not appropriate at the time given her symptoms and the likelihood of an ectopic pregnancy.

98. Dr B told HDC that after he had reviewed Ms A's USS report, he recommended that conservative management of her pregnancy was still possible. This meant that no action was to be taken for Ms A on 18 December, but she was told by Dr B to undertake further hCG testing and an ultrasound after the weekend (both were completed on Tuesday 22 December 2020) before further review would be undertaken. An operating theatre was pre-booked for the following week in case Ms A required surgery after further testing.

99. Dr B told HDC that his reasons for considering that conservative management of Ms A's condition was appropriate included the fact that Ms A's beta hCG level was low at the time, which met the criteria for conservative management, the risk of rupture was 'low' because the rise of Ms A's beta hCG levels was 'very slow', the ectopic mass was small, and there was no evidence of significant free fluid in the peritoneal cavity.

100. Dr B also gave safety-netting advice by informing Ms A that she could return to the hospital if she felt unwell or if there was increased bleeding or pain.

[24] 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 …'

[25] Right 7(1) of the Code states: 'Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.'

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101. Dr Smalldridge advised that the three ways to manage an ectopic pregnancy are conservative (expectant) management, medical management (methotrexate), and surgical management.[26] The approach taken depends on the clinical signs and status of the patient at the time.[27] Dr Smalldridge said that based on the conservative management criteria used by Dr B (the DHB1 guidelines), Ms A's condition at the time fitted the criteria for all three types of management.

102. Accordingly, Dr Smalldridge considered that it was reasonable for Dr B to proceed with the conservative approach. Dr Smalldridge stated:

> '[Ms A] fitted the criteria for [conservative management]. She had minimal symptoms, no significant free fluid in the pelvis, hCG less than 1500 IU, less than 3cm on ultrasound. With this approach, the majority of pregnancies of unknown location resolve (66% if less than 1500 IU and 90% if hCG less than 1000 IU). This is the approach that has the least intervention and complications but does involve follow up and careful monitoring.'

103. Notwithstanding my earlier criticisms about Dr B's communication and the information he provided to Ms A about her options and management plan, I accept Dr Smalldridge's advice that the conservative management plan itself was a clinically appropriate option for Ms A's presentation. I now consider the adequacy of Dr B's documentation.

Documentation — breach

104. The consultation between Dr B, Ms A, and RM C was not documented at the time of events. Dr B told HDC that he did not have access to Ms A's clinical file to document the consultation, but he did have access to the electronic patient management system and he used this to view her records.

105. Health NZ told HDC that it is normal and accepted practice for clinicians to document all clinical assessment in the clinical notes via the electronic patient management system. However, Health NZ acknowledged that Dr B was not aware of this at the time and said that after the review of Ms A's complaint he received education on how to do this.

106. Dr Smalldridge advised that it is very important that any clinical interaction with a patient is well documented so that the exact details of the history, clinical findings, and discussion are recorded. She stated that from a medico-legal perspective it was 'professionally unwise' for Dr B not to document the information above, citing the prevailing opinion that 'unless it is documented then it didn't happen'.

107. Dr Smalldridge concluded that the lack of documentation was a severe departure from accepted practice and stated:

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[26] Dr Smalldridge advised that surgical management involves a general anaesthetic, a laparoscopy, and generally a salpingectomy if the other fallopian tube looks normal.

[27] Dr Smalldridge advised that if the patient is clinically unstable, with a suspicion of large blood loss, then the surgical option is taken. If the patient is stable, then usually a shared decision-making approach is taken to determine which option would be best.

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> 'Non documentation of clinical findings and management plans is never a good idea. It makes it difficult if the patient re-presents [to] the hospital and there is no prior documentation of the interaction which can mean that errors can occur. Discussions that the doctor has had with the patient need to be documented so that there is a record that they have taken place and the patient understands and agrees with the plan.'

108. I accept this advice. As a clinician, Dr B has a responsibility to 'maintain clear and accurate patient records' and provide services that are consistent with the relevant Medical Council of New Zealand (MCNZ) standards. This specifically includes documenting information and options discussed with the patient, concerns discussed during the consultation, and the proposed management plan, including any follow-up (see Appendix E).

109. In my view, given the clear standards set out by the MCNZ, Dr B's omission to document fell well short of the expectations of a reasonable doctor. The lack of documentation also resulted in a lack of clarity about what was said during the consultation, which left Ms A confused.

110. Accordingly, I find Dr B in breach of Right 4(2) of the Code.[28]

Opinion: Health NZ — adverse comment

111. On 18 December 2020, Ms A and RM C presented to the ED following an episode of pain and bleeding. A USS was performed but the report was not available to Dr B during the consultation. However, Dr B reviewed the USS images during the consultation with Ms A and RM C.

112. Although Ms A did not raise a direct complaint against Health NZ, as the group provider, Health NZ was responsible for the systems in place for supporting the care provided by Dr B. I am critical of several issues.

Assessment pathway

113. Health NZ told HDC that at the time Ms A presented to the hospital, most patients with a suspected ectopic pregnancy or early pregnancy complications were seen in the ED or in small assessment spaces, as there was 'no ideal place to review patients with such complications in a safe and private way'. Health NZ said that depending on the degree of clinical concern, some obstetrics/gynaecology patients 'will be discharged home without a formal admission to the wards'.

114. I am concerned that Health NZ assesses patients with early pregnancy complications in the ED in small assessment spaces, which may affect a patient's privacy and safety. Whilst I acknowledge that this process may be due to resource constraints, I am concerned that it places consumers in a vulnerable position. This was evident from Ms A's experience at the

[28] Right 4(2) states: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

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hospital on 18 December 2020. She told HDC that following her clinical review she was sent home feeling confused, upset, and in pain.

115. I will make recommendations for review and consideration of how the assessment pathway can be improved.

Inconsistent use of external guidelines for management of ectopic pregnancy

116. When Ms A was reviewed on 18 December 2020, Dr B considered that Ms A's ectopic pregnancy could be managed conservatively. Dr B told HDC that he used the DHB1 guideline to assess the conservative management plan (see Appendix C). However, Health NZ provided HDC with a copy of its guideline for managing ectopic pregnancy that was in place at the time of events (see Appendix D). The guideline provided was from DHB2.

117. Health NZ told HDC that 'no further protocol is needed' but staff are reminded on where to find the guideline. Neither Dr B nor Health NZ commented on why clinical staff were referring to two different guidelines for the management of ectopic pregnancies.

118. My clinical advisor, Dr Smalldridge, did not comment on the inconsistency of the guidelines used at the time of events but advised HDC that the 'two guidelines[29] that [Health NZ] will be using are consistent with best practice nationally'.

119. Whilst there has been no comment on the inconsistent use of the guidelines, I accept that both guidelines were detailed and consistent regarding the appropriate management of ectopic pregnancies. I have reviewed the conservative (expectant) management criteria found within both guidelines and accept Dr Smalldridge's assessment that Ms A's condition fitted these criteria.

120. However, I am concerned about the wider practice of clinicians at Health NZ using different guidelines that may be contrary to the guidelines set out by Health NZ. The fact that Health NZ was unaware that Dr B was using the DHB1 guidelines indicates issues with the knowledge and training of staff about these guidelines. Whilst this issue may not have affected Ms A's care directly, I am critical that there was no system in place at Health NZ to identify and rectify this discrepancy. Accordingly, I will make further recommendations and seek clarification from Health NZ on this issue.

System in place for documentation

121. Health NZ told HDC that at the time of events, Dr B was aware that he should have documented his consultations with Ms A, and his failure to do so was not best practice. However, Health NZ said that Dr B was not aware of the processes relating to documenting consultation notes on the electronic patient management system. He has since received education on how to add his consultation information note on the system.

[29] The other guideline provided to HDC concerned miscarriages, which was also from DHB2.

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122. Health NZ told HDC that Ms A was not formally registered on the patient management system as an outpatient or as an emergency attendance, and no discharge summary was recorded for her presentation with Dr B.

123. Health NZ said that at the time of events, it was more frequent for discussions about patient management to be made in a more 'ad-hoc' way rather than in a formal setting. This was because the hospital had no specific facility or process in place for managing these acute reviews, and there was no ready access to the hard copy clinical notes. As a result, clinicians had to rely on the LMC midwives following up and documenting the advice given verbally.

124. Dr Smalldridge told HDC that it was 'unacceptable that the hospital did not have an appropriate system in place for [clinical documentation] to occur', which put patients and doctors in a difficult situation and was 'unsafe'. Dr Smalldridge acknowledged that medical notes were available electronically and that a system was in place to discuss complex patients, but she remained concerned about the working conditions.

125. Dr Smalldridge told HDC:

> 'The hospital needs to have a [foolproof] system in place so that no clinical interactions can be held without documentation. Steps are being taken to resolve this by the hospital. The Obstetrics and Gynaecology Department need to have patient handouts to discuss the three options for management of ectopic pregnancy.'

126. I accept this advice. I am critical that at the time of events there was a wider practice, as Health NZ has acknowledged, of discussions about patient management being conducted in an ad hoc way and verbal advice given without physical documentation. This is evidenced by Dr B's record-keeping of Ms A's care on 18 December 2020, when he provided verbal advice but did not document his discussion or management plan.

127. I am also critical that no discharge summary was recorded for Ms A's presentation with Dr B on 18 December 2020. Although I have criticised Dr B's record-keeping, I am concerned that no formal system was in place at Health NZ for acute gynaecology reviews to be undertaken or managed. This system failure affected patient registration processes, physical clinical note availability, and documentation requirements. On 18 December 2020 it was unclear whether Ms A should have been registered in the patient management system as an ED presentation or as an outpatient. Accordingly, I have made a further recommendation for Health NZ to clarify its patient registration process and documentation requirements.

128. I note that in Dr Smalldridge's subsequent review of Health NZ's statements, she advised HDC that Health NZ has 'taken steps to put a more robust system in place for documentation' so that this scenario is unlikely to happen again. Accordingly, I will seek clarification from Health NZ on this issue.

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Changes made since events

129. Dr B told HDC that since Ms A's complaint he has made the following changes:

- He ensures that all patients are registered in the Emergency Department or the Maternity Unit on presentation.
- He ensures that medical notes will be available for documentation of discussions and management plans. If the notes are not available immediately, Dr B writes on paper and transfers the information to the medical notes when they become available.
- He uses the electronic patient management system to record consultations with his patients.
- He discusses complex cases with his peers to make a consensus management plan.

130. Health NZ told HDC that it is in the process of making the following changes (HDC will seek confirmation of the changes):

- Review of the pathway for early pregnancy advice and consultation between health professionals when a review of care is required.
- Planned upgrade to the primary care electronic medical records to assist with documentation. This includes a more robust system for physical clinical documentation of notes for acute reviews by clinicians.
- 'Utilisation of the present hospital based [electronic patient management] system' to be adapted to capture short-notice consultation.
- Health NZ's obstetrics and gynaecology team has become more stable as part of the rural generalist model of care. This has allowed collegial support within the obstetrics and gynaecology team. Health NZ also told HDC that several suspected ectopic pregnancy cases have been discussed between colleagues to decide on the 'best and safest' plan, especially in the context of limited scanning and no scanning after hours. Dr B has been active in this change.
- Provision of education to Dr B on how to document consultations in the electronic patient management system and for verbal, telephone, and email contact to be included.

Recommendations

131. In light of the changes implemented by Dr B, I recommend that Dr B:

a) Provide a written apology to Ms A for his breaches of the Code as outlined in this report. The apology should include the changes made by Dr B since the complaint. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

b) Reflect on his failings and opportunities for improvement in this case and provide HDC with a summary of the changes implemented to his practice to ensure that the documentation of his consultation and management plans are recorded in the electronic

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systems appropriately. Dr B is to provide a copy of this summary to this Office within three months of the date of this report.

c) Undertake further training from the 'Communication Skills Workshop' provided by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Evidence of attendance and a written reflection on the learnings and how these will be applied in practice are to be provided to this Office within three months of the date of this report.

132. In light of the response and changes made by Health NZ, I recommend that Health NZ:

a) Consider the feasibility and value of establishing space within the ED/assessment unit for the safe and private review of patients with suspected early pregnancy complications such as a suspected ectopic pregnancy. An update on this consideration is to be provided to this Office within six months of the date of this report.

b) Undertake a review of the deficiencies identified by my independent advisor relating to the hospital systems, including, but not limited to, the pathway for patients with pregnancy complications, the inconsistent use of external guidelines, and the implementation of a system to ensure that all clinical interactions are documented. A summary of the review is to be provided to this Office within six months of the date of this report.

c) Develop a policy for the management and registration of acute gynaecology patients within the patient management system, and outline documentation requirements whenever advice is given, including the requirement for a discharge summary to be recorded in the system. A copy of this policy is to be sent to this Office within six months of the date of this report.

d) Once a formal system has been introduced for registration of acute gynaecology patients within the patient management system, complete an audit of all acute gynaecology patients registered on the system over the last three months, to determine the number of occurrences where a medical consultation note has not been completed. A summary of the audit findings with actions for improvement is to be provided to this Office within nine months of the date of this report.

e) Undertake an audit of compliance to determine whether clinicians within the Obstetrics and Gynaecology Department are using the guidelines and protocols that are endorsed by Health NZ. A summary of the audit findings with actions for improvement is to be provided to this Office within six months of the date of this report.

f) Provide staff training on documentation standards and the process for documenting within the electronic patient management system. Evidence of the training is to be provided to this Office within six months of the date of this report.

g) Consider developing information pamphlets about ectopic pregnancy treatment options and safety-netting advice on when consumers should return to hospital for a further review. An update on this consideration is to be provided to HDC within six months of the date of this report.

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Follow-up actions

133. A copy of this report with details identifying the parties removed, except the clinical advisor on this case, will be sent to the Medical Council of New Zealand, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and Te Tāhū Hauora|Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes. The Medical Council of New Zealand will be advised of Dr B's name.

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Appendix A: Independent clinical advice to Commissioner

The following independent clinical advice was obtained from gynaecologist Dr Jacqueline (Jackie) Smalldridge:

‘**HDC Complaint 21HDC00031**

My name is Dr Jacqueline Smalldridge, MB BS, FRCOG, FRANZCOG. I am a practising Gynaecologist. I am familiar with the condition that I have been asked to comment on, and last managed an ectopic pregnancy in 2015 acutely. I have read the documents that were sent to me and have no conflict of interest.

I have been asked to comment on the following:

The timeliness in diagnosis and treatment of an ectopic pregnancy

[Ms A] presented with the clinical signs and symptoms of an ectopic pregnancy on 18/12/20. The slow rising HCG levels and the findings on the ultrasound were consistent with this. A diagnosis was made.

There are three ways to manage an ectopic pregnancy — conservative management (expectant), medical management, or surgical management. The approach taken depends on the clinical status of the patient in the first instance. If she is clinically unstable, with suspicion of a large blood loss, then the surgical option is taken. If she is stable, then a shared decision-making approach is usually taken to determine which option would be best.

Conservative (expectant) management is as described in the ADHB Guideline included in the documents for review. [Ms A] fitted the criteria for this. She had minimal symptoms, no significant free fluid in the pelvis, HCG less than 1500 IU, less than 3cm on ultrasound. With this approach, the majority of pregnancies of unknown location resolve (66% if less than 1500 IU and 90% if HCG less than 1000 IU). This is the approach that has the least intervention and complications but does involve follow up and careful monitoring.

Medical management is done using Methotrexate. I do not have a copy of the guidelines for this from [the hospital], but I have referred to the ADHB Guidelines for ectopic pregnancy (1). She would also meet the criteria for medical management. She was clinically stable, had no significant free fluid, there was a less than 5 cm sac and her HCG level was less than 5000 IU. She had no previous history of ectopic pregnancy (as far as I know — I do not have all of her obstetric and gynaecological history) and she desired future fertility.

Surgical management involves a general anaesthetic, a laparoscopy, and generally a salpingectomy if the other Fallopian tube looks normal. Sometimes a salpingostomy (opening the tube and removing the ectopic pregnancy) is undertaken. This occurs if the other Fallopian tube is damaged. It is associated with a higher risk of a further ectopic pregnancy and requires follow up with HCG levels. A laparoscopy procedure has

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associated risks including the risks of a general anaesthetic and viscus injury. The decision to remove the Fallopian tube was the correct one given that her other Fallopian tube was normal. She still may be able to conceive normally.

The reasonableness of [Dr B's] conservative management plan

[Ms A] did fit the criteria for all three types of management. It was reasonable to proceed with this conservative approach.

However, there are issues around communication and documentation. The three options needed to be discussed with [Ms A] and documented. There are pros and cons of each approach and the patient and the doctor need to come to a decision together based on many factors that are at play. These may include the best approach with regard to future fertility, anxiety around access to a hospital if there are worsening symptoms, ability to be followed up with blood tests, sometimes for many weeks.

[Ms A] was very anxious and upset about the uncertainty around a much-wanted pregnancy. Quoting from the complainant's letter "I expressed that I was not keen on Methotrexate but I wanted to save that tube because surgery was massive, losing my tube was huge and my fertility was very important to myself and my partner". This shows that she did not really understand the options clearly. There was also considerable input from the midwife whose opinion was also being sought by the patient.

What information would you expect to have been provided to [Ms A] regarding the risks and benefits of methotrexate and other treatment options

She should have had all three options explained. In [Dr B's] response, he said that he did mention Methotrexate as an option but the patient was "not keen" so he did not discuss it further. Most hospitals have a patient handout detailing the options. The best options for conserving her Fallopian tube were conservative or medical management. There seems to be a misunderstanding on the patient's behalf that earlier surgical intervention would have saved her Fallopian tube.

Quoting from the complainant's letter "While I don't know the outcome would have been different, I am devastated that I did not receive timely treatment for a serious medical event. It was clear much earlier in the timeline that it was not a viable pregnancy. I don't know what the benefits were of delaying treatment. Had the appropriate treatment been offered and taken place on Friday, 19th December 2020, I may not have lost my Fallopian tube. We will never know whether the damage was already done because I was instead given the 'wait and see' treatment option".

I do not know if this was discussed with [Ms A]. As I have described above, this is not likely to be the case. If she had a laparoscopy sooner, the salpingectomy would still have been performed at the time since her other Fallopian tube was normal.

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The contemporaneous documentation of the consultation on 18th December 2020

It is very important that any clinical interaction with a patient is well documented so that exact details of the history, clinical findings, and discussion can be recorded. It was unacceptable that the hospital did not have an appropriate system in place for this to occur. This puts patients and doctors in a very difficult situation and is unsafe.

In this case, we have the recollections of the patient and the later documentation after the fact of [Dr B]. This makes it very difficult to know exactly what was explained to the patient at the time. However, the fact that her midwife then tried to canvas an opinion from a different senior medical officer, [Dr D], in the corridor, may mean that there was inadequate discussion or that the decisions being made were not mutually agreed between the patient and the doctor (and the midwife).

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

The ectopic pregnancy was diagnosed in a timely manner on 18/12/20.

b. If there has been a departure from the standard of care/accepted practice and how significant?

The conservative management initiated was appropriate clinically, but the issue is around documentation and shared decision making. There has been a severe departure from accepted practice that there were no clinical notes made at the time.

This is the responsibility of the hospital to provide facilities for their staff to practise safely. From the response from the hospital, it seems that there are some changes to practice. All patients are to be admitted and the medical notes available electronically. There is a system to discuss complex patients.

However, it is professionally unwise, as a clinician, not to document details of clinical findings, discussions, and management plans from a medico legal perspective. “Unless it is documented then it didn’t happen” is the prevailing opinion.

c. How would this be viewed by your peers?

Non documentation of clinical findings and management plans is never a good idea. It makes it difficult if the patient re-presents to the hospital and there is no prior documentation of the interaction which can mean that errors can occur.

Discussions that the doctor has had with the patient need to be documented so that there is a record that they have taken place and the patient understands and agrees with the plan. This would be viewed as a severe departure from accepted practice.

The hospital is responsible for providing appropriate working conditions for their staff to practise safely so that patients can be managed safely.

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

The hospital needs to have a [foolproof] system in place so that no clinical interactions can be held without documentation. Steps are being taken to resolve this by the hospital. The Obstetrics and Gynaecology Department need to have patient handouts to discuss the three options for management of ectopic pregnancy.

The importance of documentation and shared decision making needs to be reinforced. Each clinician needs to document that they have discussed all options with the patient as appropriate and have agreed on a management plan and that the patient understands and agrees with that plan.

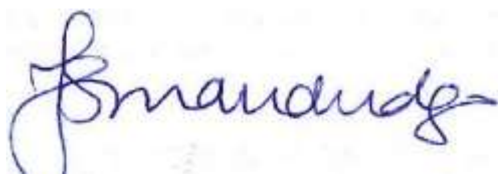
Any other matters in this case that you consider warrant comment

The conduct of the midwife canvassing for other opinions in the corridor is unsafe. It is unfair to ask another doctor to comment on a case on which she does not have all the information. It is undermining the clinician who is looking after the patient. It would have been more professional for the midwife to re-engage with [Dr B] in the presence of the patient, if she felt there were outstanding issues that needed to be resolved.

I am surprised that the ACC treatment injury claim was successful. The so-called delay in diagnosis did not lead to the Fallopian tube being removed. As I have stated previously, if surgery had been performed earlier, the outcome would have been the same. If there is an ectopic pregnancy that needs surgical intervention, then the salpingectomy is the treatment not a treatment injury. She signed the consent form knowing she would have a salpingectomy.

Kind regards

Yours sincerely



Dr Jackie Smalldridge
Consultant

References

(1) …

The following further advice was obtained from Dr Smalldridge on 24 February 2023:

'I have reviewed the records sent on 18 January 2023 including:

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- Comment from [Dr B] dated 7/12/2022;
- Comment from [Health NZ] dated 19/12/2022;
- Guidelines from [DHB2] miscarriage and an ectopic pregnancy
- Copy of the consent form.

I note that [Dr B] had no comments to add to my report.

I note that the comments from [Health NZ] concerning the missing information confirm that [Mrs A] was not at increased risk of an ectopic pregnancy. It confirmed that [Dr B] was the responsible clinician and that the "corridor consultation" was not recorded. It seems that [Health NZ] have taken steps to put a more robust system in place for documentation and informed consent so that this scenario is unlikely to happen again. Collegial support … has been strengthened. It mentions that [Dr B] has been an active participant in this process. I also note the comment that it is not usual to complete a consent form unless surgical intervention is planned but meticulous documentation in the clinical records must be recorded.

The two guidelines that [Health NZ] will be using are consistent with best practice nationally.

I have no further comments to make.

Kind regards

Yours sincerely

Dr Jackie Smalldridge
Consultant'

The following further advice was obtained from Dr Smalldridge on 30 June 2023:

'Further to my email on 26 June 2023 in answer to your question "Could you please clarify who made the timely diagnosis and your reasoning for this" with respect to my comments "a diagnosis was made in a timely manner on 18/12/20".

The diagnosis was made by [Dr B] on 18/12/20 when he saw the patient in an area of the hospital where he was unable to record his findings in the medical record. He reported this in his statement to HDC.

The diagnosis was made by history, examination and investigation results (ultrasound findings and HCG levels) as is usual practice when assessing a patient.'

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Appendix B: Health NZ's independent review report

The following report from gynaecologist Dr D was obtained after Health NZ requested an independent review into the care provided to Ms A:

'Report re patient [Ms A] (NHI …)
Review requested by [Health NZ] via "safety first", with specific concern being the potentially unnecessary loss of the fallopian tube due to delayed diagnosis/treatment of ectopic pregnancy.

This report is based primarily on information held on [the electronic patient management system] rather than the clinical notes. Those notes that have been scanned only relate to events from 22/12 onwards and have not scanned well, so anything handwritten is not easy to read. In terms of assessing the issues raised the information held on [the electronic patient management system] appears sufficient.

Background
A [woman in her thirties] in early pregnancy under LMC care.

Previous fertility investigations had confirmed patent fallopian tubes.

Several serum quantitative tests done from 1st dec as follows:

01/12 — 52
03/12 — 105
05/12 — 149
07/12 — 285
09/12 — 409
12/12 — 615
14/12 — 695
17/12 — 850
18/12 — 882
22/12 — 1099

From the available documentation it is not clear why HCG monitoring was commenced.

The first pregnancy ultrasound scan was performed on 14th dec. This did not confirm either the location or viability of the pregnancy.

A second USS on 18th December was highly suspicious for an ectopic pregnancy, with a right adnexal mass 20x14x22mm.

It appears that no treatment was initiated at this stage and that further monitoring with HCG and ultrasound was arranged.

A third USS was performed on 22nd December. The report states "Sonographic appearances are consistent with a ruptured RIGHT adnexal ectopic pregnancy". Surgery

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for this was arranged following subsequent medical review. At laparoscopy, an unruptured right tubal pregnancy was diagnosed and treated by salpingectomy.

Comment

The diagnosis of ectopic pregnancy was clear on 18th December, following the second ultrasound scan. This is based primarily on the USS findings of a characteristic adnexal mass and is further supported by the slow rising HCG. Ideally, treatment would have been initiated at this point.

There is evidence to support a diagnosis of ectopic pregnancy from 14th December, with an empty uterus on USS and slow rising HCG for 2 weeks prior. Depending on patient symptoms, treatment may have been justified at this point.

The third ultrasound misdiagnosed rupture of the ectopic pregnancy. This may have led to increased anxiety for the patient and the attendant staff. Management on 22nd December was otherwise appropriate. Removal of the affected fallopian tube (salpingectomy) is the appropriate treatment for ectopic pregnancy. It has no detrimental effect on fertility when compared to tubal sparing surgery but significantly reduces the risk of future ectopic pregnancy.

Summary

There was a delay in diagnosis and treatment of an ectopic pregnancy by at least 4 days. This delay does not appear to have led to any additional physical harm to the patient and the outcome of salpingectomy is unlikely to have been altered by earlier intervention.

The misdiagnosis of rupture may have led to increased anxiety for all involved. The suggestion of blood on USS does not necessarily indicate a rupture has occurred. Ruptured ectopic pregnancy is a clinical and surgical diagnosis, based on a combination of factors, rather than a radiological diagnosis. The term “rupture” is not infrequently used in reports in the presence of pelvic blood. In ectopic pregnancies this blood is most often from the fimbrial end of the fallopian tube during the process of tubal abortion, rather than from an actual rupture of the tube.

In total 10 measurements of serum quantitative HCG were obtained prior to diagnosis. It is not clear why this monitoring was initiated and what interpretations were made. Without ultrasound assessment with which to correlate HCG levels, it is a test of limited value.

Recommendations

Education for staff involved in ectopic pregnancy diagnosis.

Development of protocols at [Health NZ] for monitoring and interpreting HCG.

Communication with radiology re use of alarming language in reports.’

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Appendix C: DHB1's guideline on expectant management of ectopic pregnancy

The following excerpts are the relevant criteria for conservative (expectant) management of ectopic pregnancy used by Dr B in his care of Ms A:

> '7. Expectant management of ectopic pregnancy and trophoblast of unknown site
>
> **7.1 Criteria for expectant management**
>
> - Minimal symptoms
> - No significant free fluid in pouch of Douglas
> - β-hCG < 1500 IU/L
> - Ectopic pregnancy <30 mm on ultrasound without any fetal cardiac activity seen
> - Patient able to consent, understand the need for and be able to attend follow-up.
>
> **7.2 Follow-up**
>
> Patients should have a repeat serum β-hCG measurement and trans-vaginal ultrasound at 48–72 hours. As many as 66% of ectopic pregnancies in women with serum β-hCG concentration less than 1500 IU/L and 90% with β-hCG < 1000 IU/L will resolve spontaneously (Elson et. al., (2016)). However, some women will experience pain associated with tubal abortion and there is a risk of tubal rupture even at low β-hCG levels. If β-hCG levels are rising, then medical or surgical treatment should be considered.'

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Appendix D: DHB2's guideline on expectant management of ectopic pregnancy

The following excerpts are the relevant criteria for conservative (expectant) management of ectopic pregnancy that applied at the time of events at Health NZ:

'**Expectant management**

- In some cases ectopic pregnancy will resolve spontaneously without any treatment.
- Expectant management is suitable for women who fulfil the following criteria:[1]
    - Clinically stable with normal haemoglobin
    - Falling βhCG — If patient has been admitted, the βhCG level can be repeated at 24–48 hours this is to confirm a fall from previous levels; the 48hr timing is only relevant when interpreting rises in βhCG, in terms of an unexpected fall the timing is not critical; any fall below previous level is relevant so 24–48 hrs can be reasonable.
    - Absence of fetal heart on scan
    - No significant free fluid (with SMO discretion and interpretation of the whole picture)
- Monitor weekly until βhCG <5 mlU/ml. Any clinical concerns prior to this should prompt review.'

[1] Royal College of Obstetricians and Gynaecologists, green top guideline no 21, the management of tubal pregnancy London. RCOG Press. Reviewed 2010

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Appendix E: Relevant standards

The Medical Council of New Zealand | Te Kaunihera Rata o Aotearoa statement on 'Managing patient records' notes:[1]

> '**Introduction**
>
> Patient records reflect a doctor's reasoning and are an important source of information about a patient's care.
>
> Patient records are a crucial part of medical practice. They help ensure good care of patients and clear communication between doctors and other health practitioners.
>
> …
>
> **Maintaining clear and accurate patient records**
>
> 1. You must maintain clear and accurate patient records that note:
>   a. Clinical history including allergies
>   b. Relevant clinical findings
>   c. Results of tests and investigations ordered
>   d. Information given to, and options discussed with, patients (and their family or whānau where appropriate)
>   e. Decisions made and the reasons for them
>   f. Consent given
>   g. Requests or concerns discussed during the consultation
>   h. The proposed management plan including any follow-up
>   i. Medication or treatment prescribed including adverse reactions.
> 2. It is good practice to record information that may be relevant during the patient's health-care journey.
> 3. Records must be completed at the time of the events you are recording, or as soon as possible afterwards.'

[1] The Medical Council of New Zealand | Te Kaunihera Rata o Aotearoa statement on 'Managing patient records' was published in October 2019. The statement guides doctors on the information they should record, and for how long they should retain patients' records. The current version was published in December 2020.

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