Fertility Associates Holdings Limited

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC00584)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a woman at Fertility Associates when undergoing a cycle of IVF, and highlights the importance of robust test ordering protocols and effective communication between providers to ensure quality of services, as well as the importance of openly and honestly disclosing information about errors that occur during the provision of a healthcare service.

2. On 16 June 2017, a blood test was taken to determine whether or not the woman was in the correct stage of her menstrual cycle in order to begin an IVF cycle. The results of the test showed that her oestrogen, LH, and β-hCG results were normal, but that her progesterone result was higher than expected for the beginning phase of the menstrual cycle, and indicated a possibility that the woman might already have been pregnant.

3. The results of the oestrogen and β-hCG levels were relayed to the on-call doctor to decide whether it was appropriate to begin the IVF cycle, but the progesterone result was not seen by any of the clinical staff at this time.

4. Upon hearing that the β-hCG level indicated that the woman was not pregnant, and that her oestrogen level was consistent with being at the start of a menstrual cycle, the on-call doctor approved the woman starting the medication for her IVF cycle. The woman commenced the treatment and took the prescribed medication from 16 June until 25 June 2017, when it was discovered that she was pregnant.

5. The woman and her husband subsequently contacted Fertility Associates outlining their concerns about the failure to identify that the woman was pregnant before starting the IVF cycle. In Fertility Associates' response to these concerns, it did not mention the woman's high progesterone level, and subsequently failed to provide her husband with the progesterone result from this blood test when he requested a copy of all the woman's blood tests.

Findings

6. The Deputy Commissioner considered that in the IVF clinical setting where cycle management decisions are so precisely linked to the presenting clinical picture and context, Fertility Associates' test ordering protocols must be robust and clear to ensure that the doctor who is to approve the commencement of drugs for an IVF cycle has all the available information prior to authorisation. In this instance, the woman was started on an IVF cycle erroneously and contrary to her progesterone test result, which indicated a possible pregnancy. Accordingly, the Deputy Commissioner found Fertility Associates in breach of Right 4(5) of the Code.

7. The Deputy Commissioner was also critical of Fertility Associates' open disclosure of the error with the family. She noted that a thorough investigation of what had occurred, and full open disclosure of the error, was not undertaken until the woman and her husband

complained to this Office. Accordingly, the Deputy Commissioner found that Fertility Associates breached Right 6(1) of the Code.

Recommendations

8. The Deputy Commissioner recommended that Fertility Associates provide evidence that its new test ordering protocol has been incorporated into its policies and procedures; undertake an audit of staff compliance with its new test ordering protocol; provide evidence of the ongoing education provided to its staff; consider whether any of the learnings and changes made in response to this investigation can be translated into improvements throughout its other Fertility Clinics; review HDC's "Guidance on Open Disclosure Policies" and identify areas for improvement in its practice, and use this to create a policy on open disclosure; consider collaborating with other fertility service providers in New Zealand to ensure that its current test ordering protocols are consistent with sector-wide best practice; and provide the woman and her family with an apology for the breaches of the Code identified in this report.

Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to his wife, Mrs A, by Fertility Associates Holdings Limited (Fertility Associates). The following issue was identified for investigation:

- *Whether Fertility Associates Holdings Limited provided Mrs A with an appropriate standard of care in 2017.*

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

11. The parties directly involved in the investigation were:

Mr A	Complainant
Fertility Associates	Fertility provider

12. Further information was received from:

RN B	Registered nurse/provider
RN C	Registered nurse/provider
Dr D	Obstetrician and gynaecologist

13. Also mentioned in this report:

Dr E	Doctor

14. Independent expert advice was obtained from an obstetrician and gynaecologist, Professor Michael Chapman (Appendix A). Professor Chapman is the Clinical Director of IVF Australia — Southern Sydney.

Information gathered during investigation

Background

15. Mrs A and her husband had been patients of Fertility Associates since late 2012, and had been trying to conceive by undergoing different ovulation induction treatments. Mrs A had been diagnosed with polycystic ovarian disease[1] and had a notably low anti-Müllerian hormone[2] level. In addition, Mrs A did not usually have periods. After successfully becoming pregnant in 2014, Mrs A returned to Fertility Associates in late 2015 to try for another child with the same ovulation induction treatment.

16. At a review consultation in October 2016, after there had been no success with the latest ovulation induction treatments, Mr and Mrs A switched to in-vitro fertilisation[3] (IVF).

17. This report concerns the care provided to Mrs A during her third cycle of IVF — in June 2017 — and the failure of Fertility Associates to identify that Mrs A's progesterone levels were higher than indicated for the start of an IVF cycle, before starting the cycle. The report also concerns the subsequent actions taken by Fertility Associates after the error was discovered.

June 2017 fertility cycle

18. Fertility Associates told HDC that before an IVF treatment is commenced, a meeting is held between the patients and their doctor to discuss the risks and benefits of treatment, and information is given about how the treatment will proceed. After this, it is a case of waiting for appropriate circumstances for the cycle to be started. Fertility Associates stated that usually this is led by the patient reporting that she has had a menstrual period, and is therefore not pregnant.

19. In Mrs A's case, the IVF medication was to start on the second day after her period commenced. Mr A told HDC that Mrs A rarely had periods, and they understood that the plan was first to undertake blood tests to determine whether Mrs A was in the correct part of her menstrual cycle prior to beginning IVF.

20. Fertility Associates told HDC that for the protocol in place for Mrs A, the clinical indicator for commencing treatment is the patient's reported commencement of a period (the

[1] A hormonal disorder that causes enlarged ovaries with small cysts on the outer edges.
[2] A hormone secreted by cells in developing egg follicles. A low anti-Müllerian hormone level indicates that the egg reserve in a woman is low.
[3] A process of fertilisation where an egg is combined with sperm outside the body.

beginning of the menstrual cycle), and that blood tests are not required at this time. Fertility Associates noted that additional blood tests can be undertaken to check hormone levels before commencing treatment if there is an indication that this is required. An example of this would be when there has been no period, in which case usually oestrogen[4] would be measured.

21. Fertility Associates stated that in New Zealand, there are four providers of fertility services (including Fertility Associates), and noted that on surveying their practices, no clinics in New Zealand have a standard practice of testing for progesterone and oestrogen before starting an IVF cycle where a patient presents with a period.

22. On 15 June 2017, Mr A emailed Dr E, their doctor at Fertility Associates, as he believed that Mrs A had begun her period. The email stated:

> "Hi [Dr E], [Mrs A is] just having her day 1 today. She doesn't normally have them so we want to take advantage of this and start a new IVF cycle on this day 1."

23. At this time, Dr E was on leave, and so she communicated this information to a nurse at Fertility Associates to action the IVF cycle.

16 June 2017

24. Commencement of the IVF treatment started the following day, on 16 June 2017. Mr A told HDC that on this day, Mrs A asked Fertility Associates whether the bleeding could be implantation bleeding, as it was different from any of her previous menstrual cycles.

25. Registered Nurse (RN) C was responsible for ordering tests on 16 June. She told HDC that she remembered Mrs A from her previous treatments, and that usually she did not get periods. RN C stated that for this reason, she wanted to check Mrs A's oestrogen level to ensure that her ovaries were "quiet[5]" enough to begin treatment and, accordingly, she issued a blood test order for "Fertility Hormones". RN C selected the pre-set test order group of "Hormones Only" in Fertility Associates' system, which includes β-hCG,[6] luteinizing hormone[7] (LH), progesterone,[8] and oestrogen.

26. Fertility Associates told HDC that the treatment protocols determine which blood tests are wanted at each stage for each type of treatment cycle (including before a cycle starts). The usual process for ordering and reporting tests at Fertility Associates was as follows: The nurses order the tests specified in the patient's treatment protocol at the time (eg, before

[4] The primary female sex hormone that helps the development of a baby's organs and the correct function of the placenta in the womb.
[5] "Quiet" ovaries refer to ovaries that are not producing an egg.
[6] Beta human chorionic gonadotropin (β-hCG) — a hormone produced by cells that surround a growing embryo. The presence of β-hCG is detected in some pregnancy tests.
[7] A hormone that helps to control the menstrual cycle and triggers the release of an egg from the ovary (ovulation). Luteinizing hormone levels rise quickly just before ovulation.
[8] A hormone that helps to prepare the body for conception and pregnancy and regulates the monthly menstrual cycle.

starting a certain drug, after seven days of the drug, etc), as well as any extra tests requested by the patient's doctor.

27. Tests that are to be considered on the same day on which they are ordered are placed on the "daily cycle list", and will then be discussed at the lunch-time decision meeting with the registered nurses and embryologists. All other tests that do not require same-day assessment are sent directly to the patient's doctor, and are not included on the daily cycle list. Fertility Associates told HDC that doctors typically review new results in their inbox several times a week.

28. RN C did not enter Mrs A's test order into the daily cycle list, and accordingly the clinical team reviewing all daily blood tests were not expecting any test results for Mrs A. RN C told HDC that she believes she told the nurse who was assigned to review the test results (RN B) that she had ordered additional blood tests. However, it is not clear whether RN C advised RN B that she had ordered a test for progesterone. RN C stated: "I was not assigned to review test results that day and was not aware of [Mrs A's] test result."

29. The tests were reported in Mrs A's electronic medical record at 3.37pm, and showed the following: Oestradiol — 273 picomoles per litre, β-hCG — less than 1 unit per litre,[9] LH — 1.1 units per litre, and progesterone — 39.6 nanomoles per litre (nmol/L).

30. The progesterone result was higher than expected for the beginning phase of the menstrual cycle. A progesterone result between 8–90nmol/L indicates that a woman is in the "luteal" phase of the menstrual cycle, which is the latter phase. A progesterone result of more than 25nmol/L indicates that ovulation is likely to have occurred already, and that the corpus luteum[10] is producing sufficient progesterone to assist in the implantation of an embryo.[11] Accordingly, the high progesterone result meant that Mrs A might already have been pregnant.

31. RN B was assigned to review blood test results on 16 June 2017, and told HDC that she cannot be sure, but believes that RN C told her that she had ordered bloods for Mrs A that needed to be checked. RN B stated that she recalls receiving the β-hCG and oestrogen results, and in Dr E's absence she called the on-call doctor, Dr D, to enquire about Mrs A's oestrogen level, as it was slightly elevated.

32. Upon hearing that the β-hCG level indicated that Mrs A was not pregnant, and that Mrs A's oestrogen level was consistent with being at the start of a menstrual cycle, Dr D approved Mrs A starting the medication for her IVF cycle.

[9] A value less than 5 indicates a non-pregnant result.
[10] A mass of cells that form in an ovary and produce progesterone.
[11] https://www.fertilityassociates.co.nz/info-for-gps/hormones-explained-fsh-progesterone/

33. RN B documented the call in Mrs A's clinical records as:

> "D/W [Discussed with] [Dr D]
> E2 [oestrogen] 275. Fine to take today as day 2 and commence cycle. [RM B]."

34. Fertility Associates told HDC that it appears likely that RN B called the laboratory and asked for the β-hCG and oestrogen results, unaware that other tests had been ordered, and then passed on these results to Dr D. Fertility Associates noted that the audit trail shows that the discussion with Dr D took place at 3.08pm, while the full results of the blood test arrived in Mrs A's electronic medical record at 3.37pm. RN B advised HDC that she cannot remember much of what occurred, but stated that she did not discuss the progesterone result with Dr D, as she "probably had not seen it".

35. Dr D told HDC that he was not aware that Mrs A's progesterone levels had also been tested, and did not have any reason to ask whether they had been, as it is not a standard practice to measure progesterone levels for this protocol. He stated:

> "Therefore, there was no reason for me to suspect there were further results available. If I had been advised that progesterone levels were tested and the results of the test, I would not have started the cycle."

36. Fertility Associates told HDC:

> "We agree that it was not the most appropriate clinical decision to commence treatment when [Mrs A's] [progesterone] level was as high as it was. As noted above, this occurred because [Dr D] did not have all the clinical information, namely the missing [progesterone] result. Regrettably, this was due to a communication error in conveying those results. Since [Mrs A] presented with a period there was no indication for [Dr D] to order or expect a [progesterone] result at this stage."

37. Once Dr D had approved Mrs A starting the medication for her IVF cycle, Mrs A commenced the treatment and took the prescribed medication from 16 June to 25 June 2017.

25 June 2017

38. Mrs A presented to Fertility Associates to undergo a scan and further blood tests on 25 June 2017.

39. At this appointment it was noted that Mrs A had been experiencing continued spotting, and the scan identified that Mrs A's endometrium[12] was too thick to continue with the IVF cycle. Mrs A was informed that the transfer of a fresh embryo[13] was not able to occur, and that the best course of action would be to continue with the egg collection, and then to have the embryos frozen for implantation at a more appropriate time.

[12] The innermost lining layer of the uterus.
[13] An early stage of development of a multicellular organism.

40. Later that day, Dr E contacted Mrs A and explained that she was unsure about the reason for her thickened endometrium. Dr E advised that she had requested a pregnancy test using the bloods that had been taken that day, to investigate further.

41. Dr E told Mrs A that the results of the test would be available the following day, and to continue taking the fertility medication that evening as usual.

42. That night, Mrs A took a home pregnancy test and discovered that she was pregnant. The IVF medication was stopped immediately, and after a normal pregnancy scan at seven weeks, Mrs A was discharged to her usual general practitioner for further care of her pregnancy.

Subsequent events

Response to complaint

43. On 11 August 2017, Mr and Mrs A sent a letter to Fertility Associates outlining their concerns about the failure to identify that Mrs A was pregnant before starting the IVF cycle, and expressing apprehension that the IVF medication may have caused harm to their unborn baby.

44. Fertility Associates responded to Mr and Mrs A's concerns in a letter dated 21 August 2017. The letter stated:

> "On 16 June 2017, 'day 2' after [Mrs A's] bleeding, we tested the BHCG levels. The results came back negative. The Oestrogen level was low as well, as is seen at the beginning of a menstrual cycle. With the reported bleeding and these test results, there was no other indication to suggest early stages of pregnancy. The earliest sign to suspected pregnancy was [Mrs A's] abnormally thick uterine lining seen during her second scan on 25 June, in conjunction with a high [progesterone] blood test on the same day."

45. Fertility Associates also reassured Mr and Mrs A that the medication taken during the IVF cycle would not have had an adverse effect on the pregnancy or embryo, because of the very early stage of the pregnancy cycle at which the medication was taken.

46. While Fertility Associates acknowledged the high progesterone levels from the 25 June blood test, there was no mention in the letter of Mrs A's high progesterone results from her earlier blood test on 16 June.

47. Fertility Associates told HDC that it believes that at this time, staff were not aware of Mrs A's high progesterone result from her 16 June blood test, and became aware of the result only when it was raised by HDC in response to Mr and Mrs A's complaint. The records were reviewed following receipt of the complaint, and the progesterone level would have been seen at this time.

Sharing of blood test results

First request

48. After receiving Fertility Associates' letter on 21 August 2017, Mr A responded (on behalf of Mrs A) requesting Mrs A's blood test results. He stated:

> "Just one extra request, could we please be emailed all of [Mrs A's] day 1/2 and day 8 blood tests from all of the fertility cycles that she has undertaken since the birth of [our first child]? Thanks."

49. Fertility Associates attached the information requested by Mr A, and responded: "This contains all the hormone levels during these cycles to give you a full picture."

50. In the email to Mr A, Fertility Associates attached all of the blood test results from November 2015 to March 2017, but did not include the blood test results for the latest cycle undertaken in June 2017.

51. Fertility Associates told HDC that the information from the final, incomplete cycle (June 2017) was not provided to Mr A at this time, as it had understood Mr A's request to be for information from completed cycles only.

Second request

52. Mr A responded to Fertility Associates' email again requesting all of the results of the Day 1 or 2 and Day 8 blood tests. Fertility Associates asked for clarification and responded: "All cycle tests are on the graphs [emailed previously]." Mr A noted that the information sent did not include the results from the June 2017 IVF cycle, and again requested "[t]he blood results as sent to [Fertility Associates] from the local medical laboratory for day 1 (or 2) and day 8 for the [ovulation induction] and IVF cycles".

53. Fertility Associates told Mr A that it had printed all of the blood results from the laboratory and posted them to Mr and Mrs A.

54. Mr A provided HDC with the results that were sent to them in the post. The β-hCG result from the 16 June 2017 blood test was included this time, but the other results from the test (progesterone, oestradiol, and LH) were not included.

55. Fertility Associates told HDC that it posted all the blood test results at this time, including all the results from 16 June 2017.

Third request

56. Mr A emailed Fertility Associates again, noting that the results from the last cycle were missing. He requested that these be emailed to him as soon as possible.

57. Fertility Associates responded attaching a table that included the progesterone, oestradiol, β-hCG, and LH results from the blood test taken on 16 June 2017. The table was in a different format from the results sent to Mr and Mrs A previously, and was not in the original medical laboratory format. Accordingly, these results did not include the level

indicators for each hormone to show the stage of the menstrual cycle represented by each hormone value range.

58. Mr A told HDC that on receipt of these results, they "saw immediately the reason for [Fertility Associates] not giving [them] the results straight away. The **progesterone level on the day 2 (16 June 2017) blood test was 39.6**",[14] which indicated that Mrs A had already ovulated and therefore could have been pregnant.

Fourth request

59. Mr A emailed Fertility Associates again, stating:

> "We have now asked four times to have the last cycle blood results, and it looks like you have finally provided them but in your own spreadsheet as opposed to the [medical laboratory's] format of the other cycles. It seems that you have been withholding these results from us. Please send through the last fertility cycle blood test results in the format as sent from [the medical laboratory]."

60. Fertility Associates told HDC that the reason for the different table formats was that in 2017 the company transitioned its patient management software to a fertility dedicated programme — Meditex. This meant that from April 2017, all laboratory results were imported electronically to Meditex, and hence had a different format to results that were displayed using the previous software.

61. Fertility Associates responded to Mr A explaining the reason for the difference in format of the results, and advised that it had asked the laboratory to send the original results in the old format directly to Mr and Mrs A.

62. All of the results from the blood test of 16 June 2017, including the level indicators, were sent to Mr A on 11 September 2017. The results showed that Mrs A's progesterone result on 16 June 2017 indicated that she was in the luteal phase of her menstrual cycle, and that ovulation was likely to have occurred already.

63. Mr A told HDC that the medical laboratory ranges confirmed what he and Mrs A already knew by this stage — that Mrs A had been in the wrong stage of her cycle, and that the high progesterone was a result of ovulation having occurred already, which meant that there was a chance that Mrs A could have been pregnant already.

64. Mr A told HDC that he and Mrs A are "confident" that there has been a deliberate cover-up of the mistake made by Fertility Associates. He stated:

> "This is indicated by their failure to discuss progesterone levels of the 16/6/17 blood test in their initial investigation report to [Mrs A] and I. The indication of a cover-up is further strengthened by their continued failure to provide the results we requested … The final indicator of the cover-up is that when the progesterone results were finally

[14] Emphasis in original.

> provided to us, Fertility Associates placed them in a different format so we could not see the [medical laboratory] level indicators."

65. In response to these concerns, Fertility Associates told HDC that all requested results were contained in the results provided to Mr A at every stage. Fertility Associates stated: "We reject the accusation that we were somehow covering up providing the results to [Mr and Mrs A]."

66. All of Mr A's requests and Fertility Associates' responses occurred over a period of eight working days.

Further information

Mr and Mrs A

67. Mr and Mrs A told HDC:

> "We were saddened that what should have been an exciting and joyous moment in our life, the occurrence of a spontaneous pregnancy, turned into a very stressful and concerning time for us."

68. Mr A told HDC that as Mrs A did not have regular periods, it was their expectation that Fertility Associates would check her hormone levels with a blood test to ensure that she was at the correct stage of her cycle prior to starting any fertility treatment. He stated:

> "We do not feel that starting a cycle without undertaking prior fertility hormone blood test would be appropriate for [Mrs A's] case. Furthermore, if at the time it was suggested to us to start fertility drugs without undertaking a hormone blood test first, we would have expressed our concerns."

Fertility Associates

69. Fertility Associates told HDC that it wishes to apologise to Mr and Mrs A, and that it was not its intent to provide treatment that did not meet its expectations, or to provide any additional stress during subsequent communications.

70. Fertility Associates stated that, on review, it thinks that the source of this matter was an unfortunate miscommunication regarding blood work. It told HDC that it has considered the situation at length, including changes to protocols that may prevent any similar miscommunications in the future. As a result, it has made changes to its test ordering protocol. Now, if a woman with irregular periods has a period when one is not expected, the doctor will decide what additional tests and investigations are required (in addition to β-hCG) and will record in the medical record whether the patient is ready to start ovarian stimulation after reviewing the results.

71. Fertility Associates' review of these events has also resulted in the ongoing education of its staff, including presentations on the following:

a) Interpreting various combinations of hormone levels for doctors, nurses, and embryologists.

b) The existing protocols for ordering and interpreting blood tests, emphasising that blood tests that contribute to decisions on the management of current treatment cycles must be added to the daily cycle list for review.

c) The SBAR (Situation, Background, Assessment, and Recommendation) communication technique and how to present these elements accurately in a clinical setting. This is to ensure that doctors are given the full clinical picture and context when nurses ask doctors to make cycle management decisions arising from the daily blood test results.

Responses to provisional opinion

72. Mr and Mrs A were provided with an opportunity to comment on the "information gathered" section of the provisional opinion, and stated that they stand by their previous responses and comments to HDC on the matter. Fertility Associates was provided with an opportunity to comment on the provisional opinion. It stated that it accepts that staff ordered the progesterone test and that the result was not reviewed by the doctor when making the decision about whether to start drugs for an IVF cycle.

73. Fertility Associates also accepted that its communication with Mr and Mrs A was flawed, but stated that it "strongly refute[s] the comment that [Fertility Associates] deliberately did not disclose the progesterone results to [Mr and Mrs A]". It said that the provision of results multiple times and Mr A's need to make multiple requests to obtain the information wanted was not caused by a deliberate withholding of information, but to the following two key factors:

1. The initial responses were all processed quickly without stopping to understand properly what Mr and Mrs A wanted; and
2. All initial responses were handled by an administrative staff member, without involving a clinical staff member.

74. Fertility Associates stated that it has reviewed the recommendations and accepts all steps as useful to minimise anything similar happening again.

Opinion: Fertility Associates Holdings Limited

Introduction

75. As a healthcare provider, Fertility Associates is responsible for providing services in accordance with the Code of Health and Disability Services Consumers' Rights (the Code). Mrs A had been a patient of Fertility Associates since late 2012, and had been trying to conceive by undergoing different ovulation induction treatments and ultimately IVF at the clinic.

76. Fertility Associates told HDC that for the protocol being used for Mrs A, the clinical indicator for starting treatment is the patient's reported commencement of a period, and blood tests are not required at this time.

77. Expert advice was sought from an Australian obstetrician and gynaecologist, Professor Michael Chapman, who stated that "the protocol of measuring progesterone and oestrogen on the first day of menstruation is standard practice before starting medication". He said that this is the case in his own practice, and it has been IVF policy in Australia for the last 20 years.

78. In response to this advice, Fertility Associates noted that on surveying the three other fertility services in New Zealand, no clinics have a standard practice of testing for progesterone and oestrogen before starting an IVF cycle where a patient presents with a period. Fertility Associates also noted that it enquired about practices in Australia, and two of the three IVF clinics in Australia responded that measuring progesterone and oestrogen prior to starting an IVF cycle was not standard practice.

79. I acknowledge that IVF practices in Australia and New Zealand may differ, and therefore cannot be compared directly. However, regardless of whether it was standard practice in New Zealand at this time to test a patient's progesterone and oestrogen levels before starting an IVF cycle, in this case those tests were undertaken by Fertility Associates. The results of the tests indicated that Mrs A was not at the beginning of her menstrual cycle, and therefore that it was not appropriate for her to commence IVF treatment at that time.

80. This case highlights the importance of robust test ordering protocols and effective communication between providers to ensure quality of services, as well as the importance of openly and honestly disclosing information about errors that occur during the provision of a healthcare service.

16 June 2017 IVF cycle — breach

81. On 15 June 2017, Mrs A experienced what she and Mr A thought was her period, indicating "Day 1" of the IVF cycle. A blood test taken on 16 June showed that Mrs A's progesterone levels were higher than expected for the beginning phase of the menstrual cycle. This indicated that ovulation was likely to have occurred already and that the corpus luteum was producing sufficient progesterone to assist in the implantation of an embryo. However, the result was not acted on, and Mrs A was started on IVF medication, which she took until 25 June, when she discovered that she was pregnant.

82. Professor Chapman advised that it was not appropriate to commence the IVF cycle in the presence of elevated progesterone levels. He stated that elevated levels may indicate an early pregnancy causing persistence of the corpus luteum, and advised:

> "The bottom line should be that [IVF] treatment should not have been started if staff were aware of the elevated progesterone levels. Two possibilities exist to explain the error:

a. the level was seen but ignored on the basis that the patient had had menstrual type bleeding and it was assumed hormone levels were baseline

b. the level was missed and the cycle was advised to begin on the basis that she had had menstrual type bleeding and it was assumed hormone levels were baseline.

Either option suggests lack of rigour in clinical practice by those making the decision to treat. The only excuse is that pregnancy in a couple with repeated fertility treatments is a rare event."

83. I accept Professor Chapman's advice, and note that Fertility Associates acknowledged that it was not the most appropriate clinical decision to commence treatment when Mrs A's progesterone level was as high as was shown by the result.

84. Professor Chapman's views were put to Fertility Associates. On review, Fertility Associates believes that the source of the matter was an unfortunate miscommunication regarding blood work (Professor Chapman's possibility "b."). Fertility Associates stated that RN C was responsible for ordering the tests on 16 June, in order to check Mrs A's oestrogen level to ensure that her ovaries were "quiet" enough to begin treatment. Accordingly, RN C selected the pre-set group of "Hormones Only" in Fertility Associates' system, which includes β-hCG, LH, progesterone, and oestrogen, but failed to add these to the daily cycle list.

85. Fertility Associates told HDC that it appears likely that RN B, who was assigned to review the test results on this day, called the laboratory and asked for the β-hCG and oestrogen results, unaware that other tests had been ordered, and then passed these results on to Dr D. Dr D stated that as it is not standard practice to measure progesterone levels for the protocol being used for Mrs A, there was no reason for him to suspect that further results were available.

86. RN C told HDC that she believes she advised RN B that she had ordered additional blood tests. However, I am critical that these tests were not entered into the daily cycle list to ensure that they were communicated adequately, especially when RN C was not assigned to review the results. RN B was assigned to review the blood tests on this day, but did not do so adequately. Had RN B reviewed the test results once they had been received in Mrs A's medical record, instead of telephoning the laboratory for the β-hCG and oestrogen results, she would have seen Mrs A's high progesterone level. Furthermore, Dr D was then allowed to approve Mrs A's IVF cycle without physically reviewing her test results.

87. I am pleased to see that Fertility Associates has made changes to its test ordering protocol, namely that if a woman with irregular periods has a period when one is not expected, the doctor will decide what additional tests and investigations are required and will note in the medical record whether the patient is ready to start ovarian stimulation after having reviewed the results. However, I consider that this should have been standard practice at the time of these events. The system of a nurse ordering tests and then communicating the results to the doctor in charge of approving the IVF cycle was ambiguous and led to a

situation where not all test results were being reviewed and communicated to the doctor. When communication systems are not sufficiently robust, there is an increased risk of important information being missed.

88. The failure of Fertility Associates' staff to communicate with each other effectively and coordinate Mrs A's care meant that Mrs A was started on an IVF cycle erroneously and contrary to her progesterone test result, which indicated a possible pregnancy. Accordingly, I find Fertility Associates in breach of Right 4(5)[15] of the Code.

Open disclosure — breach

89. When the provision of a health service is not as expected, it is only natural for a consumer to have questions and to seek a clear explanation of what went wrong. As per Right 6(1) of the Code, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. This includes a clear explanation of the services that were provided, as well as the results of all tests undertaken.

90. When it was discovered that Mrs A was actually pregnant at the time of starting the June 2017 IVF cycle, Mr A sent a letter to Fertility Associates outlining concerns that this had not been picked up beforehand.

91. Fertility Associates responded to Mr and Mrs A's concerns, stating that as the β-hCG level was negative and Mrs A's oestrogen level was low, there was no indication that Mrs A was in the early stages of pregnancy before beginning the IVF cycle. The response contained no mention of Mrs A's high progesterone results from her 16 June blood test.

92. After receiving Fertility Associates' response, Mr A requested all the Day 1 and 2 and Day 8 blood tests from all of the fertility cycles undertaken since the birth of their first child. Fertility Associates responded and attached all of the blood test results from November 2015 to March 2017, but did not include the blood test results for the latest cycle undertaken in June 2017. Fertility Associates stated that it had understood Mr A's request to be for information from completed cycles only. On receipt of these results, Mr A again requested all Day 1 and 2 and Day 8 blood test results.

93. This time, the results were sent via post. Mr A provided HDC with these results. The β-hCG result from the 16 June 2017 blood test was included, but the other results from this test, including the progesterone level, were not included. Fertility Associates stated that at this time it posted all the blood results. However, no evidence was provided to HDC to confirm this.

94. On Mr A's third request, Fertility Associates emailed the 16 June 2017 blood tests to him, but these were in a different format to all other results and did not include the level indicators for each hormone. Fertility Associates told HDC that the reason for the different table formats was that it had changed its management software.

[15] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

95. Mr and Mrs A received all the blood test results in the original medical laboratory format after their fourth request for the information.

96. Mr A told HDC that he and Mrs A are confident that there has been a deliberate cover-up of the mistake made by Fertility Associates. In contrast, Fertility Associates told HDC that all requested results were contained in the results provided to Mr A at every stage, and it rejects the accusation that it was covering up by not providing the results to Mr and Mrs A.

97. Based on the evidence provided to HDC, it is apparent that all the results were not sent to Mr and Mrs A as requested. It took three requests for all of Mrs A's Day 1 and 2 and Day 8 blood tests to be provided, which, in addition to the failure to inform Mr and Mrs A of the high progesterone level from the June cycle, is significantly concerning. It then took a further request to have the information sent to Mr and Mrs A in the original medical laboratory format, to assist them to understand the results.

98. Professor Chapman advised:

> "The evidence of [Mr and Mrs A] in relation to the disclosure of the pathology results provide concerns which I share with them. Whether by intent or oversight, I would be critical that important information when requested by the couple was not provided."

99. I concur. Fertility Associates told HDC that it did not inform Mr and Mrs A of the progesterone level from the 16 June test because it was not aware of the result until Mr and Mrs A complained to HDC. Fertility Associates had multiple chances to fully investigate the care provided to Mrs A, the earliest being upon discovering that Mrs A was in fact pregnant; however, this did not occur. A thorough investigation of what had occurred, and full open disclosure of the error was not undertaken until Mr and Mrs A complained to this Office.

100. Furthermore, when Fertility Associates finally sent Mr and Mrs A the full blood test results on 11 September 2017, Mrs A's high progesterone level from 16 June 2017 would have been seen, but this was not highlighted to Mr and Mrs A at this time either. The multiple requests should have prompted Fertility Associates to engage with the couple sooner to clarify exactly what information they were seeking.

101. Taking the above evidence into consideration, I believe it likely that Mrs A's high progesterone level was intentionally not disclosed to Mr and Mrs A at this time. In my view, this is unacceptable. Mr and Mrs A had a right to know about the high progesterone level and the error that had occurred, and instead — in response to their initial enquiry — they were told that "there was no other indication to suggest early stages of pregnancy" at the time of starting the July IVF cycle, when this was not the case.

102. In addition to the right to know what has happened, consumers have a right to know the circumstances of how an error occurred. Furthermore, Mrs A had the right to receive the results of all her tests when she requested them, and Fertility Associates failed to provide

these promptly. I am highly critical of these failures and, accordingly, find that Fertility Associates breached Right 6(1)[16] of the Code.

Recommendations

103. I recommend that Fertility Associates Holdings Limited:

a) Provide evidence that its new test ordering protocol (as outlined in paragraph 70) has been incorporated into its policies and procedures. This information is to be sent to HDC within one month of the date of this report.

b) Undertake an audit of staff compliance with its new test ordering protocol. Where the results do not show 100% compliance, Fertility Associates Holdings Limited should consider what further improvements could be made to its system. The results of the audit are to be sent to this Office within six months of the date of this report.

c) Provide evidence of the ongoing education provided to its staff, as outlined in paragraph 71. This information is to be sent to HDC within six months of the date of this report.

d) Consider whether any of the learnings and changes made in response to this investigation can be translated into improvements throughout its other fertility clinics, and report back to HDC on its consideration within one month of the date of this report.

e) Review HDC's "Guidance on Open Disclosure Policies" and identify areas for improvement in its practice, and use this to create a policy on open disclosure. This policy is to be sent to HDC within three months of the date of this report.

f) Consider collaborating with other fertility service providers in New Zealand to ensure that its current test ordering protocols are consistent with sector-wide best practice, and report back to HDC on its consideration within one month of the date of this report.

g) Provide Mrs A and her family with an apology for the breaches of the Code identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

[16] 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."

Follow-up actions

104. A copy of this report with details identifying the parties removed, except the name of Fertility Associates Holdings Limited and the expert who advised on this case, will be sent to the Ministry of Health and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Professor Michael Chapman:

"**Complaint: [Fertility Associates] Our ref: 19HDC00584**

I provide … expert advice to the Health and Disability Commissioner (the Commissioner) related to this case.

Documents provided were:

1. Letter of complaint dated 27 March 2019, including a summary of events timeline.
2. Fertility Associates' response dated 23 May 2019.
3. Clinical records from Fertility Associates covering the period from April 2017 onwards.
4. Fertility Associates' response dated 10 April 2020, and attachments (including policies and procedures).
5. [Dr E]'s response dated 10 April 2020.
6. Further comments from [Mr and Mrs A] dated 24 April 2020.
7. Fertility Associates' response dated 1 May 2020.

Background

[Mrs A] experienced vaginal bleeding on 15 June 2017 and contacted Fertility Associates to start an IVF cycle. A blood test was undertaken on 16 June 2017, prior to the start of the IVF treatment. [Mrs A] was advised by the nurses that it was fine to begin the IVF cycle on the basis of her blood test results. It was subsequently discovered that [Mrs A] had already conceived naturally and was pregnant when she began the treatment on 16 June 2017.

Opinion

I have been instructed, in particular, to comment on:

1. Whether it was appropriate to begin IVF treatment on the basis of [Mrs A]'s blood test results from 16 June 2017.

… I believe it was not appropriate to commence the IVF cycle in the presence of elevated progesterone levels. It is unclear who was responsible for that decision. The treating doctor was on leave. A conversation appears to have occurred with her covering doctor but it does not seem progesterone levels were discussed.

The protocol of measuring progesterone and estrogen on the first day of menstruation is standard practice before starting medication. An elevated progesterone level (>5 nmol/l) usually means the corpus luteum from the previous cycle has not degenerated.

This could be due to delayed resolution of its function. A repeat blood test one or two days later would normally show falling levels and the cycle treatment can start. Alternatively elevated levels may indicate an early pregnancy causing persistence of the corpus luteum. An HCG level should be done to check this before thinking of starting a cycle. The bottom line should be that FSH treatment should not have been started if staff were aware of the elevated progesterone levels.

Two possibilities exist to explain the error:

a. *the level was seen but ignored on the basis that the patient had had menstrual type bleeding and it was assumed hormone levels were baseline*
b. *the level was missed and the cycle was advised to begin on the basis that she had had menstrual type bleeding and it was assumed hormone levels were baseline.*

Either option suggests lack of rigour in clinical practice by those making the decision to treat. The only excuse is that pregnancy in a couple with repeated fertility treatments is a rare event.

2. The adequacy of the systems in place at Fertility Associates.

The protocol to do Day 1 blood tests was appropriate. Their review by nursing staff and discussion with a doctor was also appropriate but the failure to register the significance of elevated progesterone is an issue. I do not believe that it is stated in their protocol that a progesterone level over 5 should be investigated further. When a clinic relies on nursing to coordinate cycles, appropriate education to interpret basic results is vital to allow them to refer on to the doctors. It is not clear how this training has occurred and how experienced these nurses were.

3. The adequacy of the care provided by registered nurse [RN B].

On the assumption that appropriate training in relation to interpretation of blood results had been undertaken, I would be concerned that if she had seen the elevated progesterone level, that she did not seek advice from [Dr D].

4. The adequacy of the care provided by registered nurse [RN C]. On the assumption that appropriate training in relation to interpretation of blood results had been undertaken, I would be concerned that if she had seen the elevated progesterone level, that she did not seek advice from [Dr D].

5. The adequacy of the relevant Fertility Associates policies and procedures.

I believe the detail in the policies and procedures is appropriate. My concern is whether the nursing staff, upon whom they indicate a significant reliance, have been adequately trained to deal with the blood results to pick up that which is out of the ordinary.

6. The adequacy of the open disclosure, communication and follow up actions undertaken by Fertility Associates after the error was identified.

The evidence of [Mr and Mrs A] in relation to the disclosure of the pathology results provide concerns which I share with them. Whether by intent or oversight, I would be critical that important information when requested by the couple was not provided.

7. Any other matters that you consider amount to a departure from accepted standards.

No.

In terms of suggested improvement, ensuring staff are aware that an elevated progesterone level at the time of vaginal bleeding should be escalated for a doctor's opinion should be implemented.

I hope this report is of assistance.

Professor Michael Chapman"

The following further expert advice was received from Professor Chapman:

"Re: [Mrs A] (consumer/complainant) and [Fertility Associates]

I respond to your forwarded documents.

In relation to their response, I am interested in the poll taken of the routine use of screening bloods before starting stimulation in an IVF cycle. It has been a routine in my practice and is IVF Australia policy for the last 20 years. I have personally seen cases of pregnancy despite the presence of vaginal bleeding, discovered by such a routine of baseline bloods. By not undertaking the test it is saving inconvenience to patients but there is a small risk, as occurred in this case.

There is no doubt that an error occurred in not responding to the progesterone result, whatever the circumstances, but I would not believe this is an ongoing major systems issue.

The FA response to the patient in dealing with the issue remains questionable, but their procedures as outlined should cover this in the future.

Professor Chapman"