

Fertility Associates Holdings Limited

**A Report by the
Deputy Health and Disability Commissioner**

(Case 19HDC02186)

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Executive summary

1. This report concerns the care provided to a woman by a fertility clinic, and the failure of the clinic to return the embryos.
2. In October 2017, the woman and her husband were informed that the storage of their embryos was due to expire. They were given three options — to discard the frozen material immediately and stop paying storage fees; to continue to store the embryos and not apply for an extension of storage; or to apply for an extension to continue to store the embryos.
3. The woman chose to have the embryos discarded from storage, and completed the “Consent to Discard Frozen Embryos” form. She selected the option to collect the embryos from the clinic within 14 days of notification, and told HDC that she and her husband planned to take the embryos to her mother’s grave.
4. The embryos were removed from storage on 16 July 2018, after the 10-year expiry date, and there is no evidence that the woman was contacted to collect them. The embryos were disposed of by the fertility clinic.

Findings

5. The Deputy Commissioner was satisfied that the woman’s rights under Right 7(9)¹ were upheld, in that Fertility Associates Holdings Limited (Fertility Associates) gave the woman the right to make a decision about the return or disposal of the embryos, and she decided to have the embryos returned to her. However, the lack of an effective system at the fertility clinic resulted in the failure to return the embryos as requested.
6. The Deputy Commissioner considered that the fertility clinic needed to have in place a more effective system to ensure that the important step of contacting patients once their reproductive material was ready for collection was not missed. Accordingly, she found that Fertility Associates failed to provide services with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

7. The Deputy Commissioner recommended that Fertility Associates undertake an audit of a total of 30 “Consent to discard” forms to confirm that the consumer’s request was acted upon on each occasion; further update its laboratory procedure for “Discarding Frozen Gametes, Embryos & Ovarian Tissue” to include the requirement to document the call, email, or letter sent to the patient advising that reproductive material was ready for collection or couriering; provide its staff with training on the updated laboratory procedure for “Discarding Frozen Gametes, Embryos & Ovarian Tissue”; and provide the woman and her husband with a written apology for the breach of the Code identified in this report.

¹ Right 7(9) states that every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a healthcare procedure.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by the fertility clinic. The following issue was identified for investigation:
- *Whether Fertility Associates Holdings Limited provided Mrs A with an appropriate standard of care in 2018.*
9. This report is the opinion of Deputy Commissioner Rose Wall, and is made in accordance with the power delegated to her by the Commissioner.
10. The parties directly involved in the investigation were:
- | | |
|----------------------|----------|
| Mrs A | Consumer |
| Fertility Associates | Provider |
11. Also mentioned in this report:
- | | |
|------|--------------|
| Mr B | Embryologist |
|------|--------------|
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Information gathered during investigation

Background

12. In 2008, Mrs A and her husband, Mr A, underwent in vitro fertilisation (IVF).² Mrs A gave birth to her first child in 2009. As a result of the 2008 IVF cycle, Mrs A had three remaining embryos, which were frozen in storage at the public hospital.
13. In 2015, the public hospital outsourced all fertility services — including embryo storage — to the fertility clinic. Mrs A was informed that the fertility clinic would be taking over the care and storage of her three remaining embryos.
14. This report concerns the care provided to Mrs A by the fertility clinic in 2018.

Consent to discard³

15. On 10 October 2017, the Fertility Associates Extended Storage Coordinator wrote to Mrs A and her husband to advise them of the Human Assisted Reproductive Technology Act's 10-year limit on the storage of reproductive material such as embryos. The letter noted that Mrs A's embryos were due to reach their legal expiry date on 15 July 2018.

² A process of fertilisation where an egg is combined with sperm outside the body.

³ "Discarding" in this case refers to the removal of the frozen embryos from storage. Fertility Associates advised HDC that the words "discard" and "dispose" were used interchangeably in consent forms and procedures.

16. The letter enclosed information on the options available, as well as a return slip and “Consent to Discard Frozen Embryos” form for Mrs A and her husband to complete. The return slip stipulated the following three options:
- “1. **Request [the fertility clinic] to discard the frozen material and stop paying storage fees.**⁴ I/We have enclosed the completed discard form.
2. **Continue to store and not apply for extension to storage ...**
3. **I/We plan to apply to ECART [Ethics Committee on Assisted Reproductive Technology]⁵ for extended storage on Date: ...”**
17. Mrs A told HDC:
- “After very careful consideration of the options, including investigating embryo donation, we decided that we would discard our embryos at the 10 year mark, July 2018. We completed the appropriate document in October 2017. The document gave consent for the embryos to be discarded, and we ticked the box saying we would like to collect the embryos, rather than have them discarded at the facility.”
18. Mrs A told HDC that she and her husband planned to take the embryos to her mother’s grave.
19. On 25 October 2017, Mr and Mrs A completed the return slip advising of their decision, and circled option “1”. On the enclosed “Consent to Discard Frozen Embryos” form, Mrs A selected the option:
- “Please inform us when embryos are ready for collection & **we will collect**⁶ from the clinic within 14 days of notification or clinic staff will dispose in the usual way.”
20. Mrs A provided her current mobile number and email address on the form for the fertility clinic to contact her.
21. On 13 December 2017, the Extended Storage Coordinator telephoned Mrs A, who informed the fertility clinic that she had posted the consent to discard forms and was not applying for an extension for storage.
22. The forms were received by the fertility clinic on 23 January 2018.

⁴ Emphasis in original.

⁵ A ministerial committee that reviews, determines, and monitors applications for assisted reproductive procedures and human reproductive research.

⁶ Emphasis in original.

Embryo discard and disposal⁷

23. Fertility Associates told HDC that “the processes involved in discarding embryos are robust and require two embryologists to check throughout the discard process”.
24. The lead embryologist, Mr B, and a colleague began processing Mrs A’s request on 9 July 2018. They both checked that the names, dates of birth, and signatures on the “Consent to Discard Frozen Embryos” form matched those on the consent form associated with freezing the embryos, as per the usual process. They documented that they had done this by signing the completed “Consent to Discard Frozen Embryos” form.
25. Mr B told HDC that on 16 July 2018, after the 10-year expiry date, he and his colleague removed Mrs A’s three embryos from storage. Once the straws⁸ had thawed, the embryos were cut into a tube, labelled with Mrs A’s and Mr A’s names, and left in the laboratory for collection. Mr B made a note in Mrs A’s medical record the same day that stated: “Frozen and stored embryos discarded today as per patient request.”
26. Mr B stated:
- “If [a] patient request[s] their embryos to be returned or collected, once ready for collection, we call the patient to inform them to collect from clinic or advise them that we have couriered their embryos. Normally I would document this on their file however on this occasion it appears that I did not document making the call.
- If the embryos requested to be collected or returned are not collected within 14 days, they are disposed in the usual way.”
27. Subsequently, Mrs A and her husband’s embryos were disposed of in the usual way, by incineration. However, the disposal was not documented in Mrs A’s medical record. The fertility clinic stated that it has no record of when the straws were disposed of after awaiting collection, as this is not something that it usually records.
28. There is no documentation either on the “Consent to Discard Frozen Embryos” form, or in Mrs A’s medical records, regarding Mrs A being contacted to collect the embryos.
29. Fertility Associates told HDC:
- “Because of the time between the discarding in July 2018 and [Mrs A’s] call in October 2019, the embryology staff cannot recall whether a call had been made immediately after discarding, and unfortunately nothing was recorded on the forms, as there was no section on the form in which to record calls which are made. We therefore cannot be sure whether our staff attempted to contact [Mrs A] at the time, but must admit to the possibility that they did not.”

⁷ “Disposal” in this case refers to placing the embryos in a biological waste bag, for collection and incineration.

⁸ Embryo straws are flexible or rigid clear tubes used for freezing and storing human embryos.

30. Mrs A does not recall being contacted by the fertility clinic when her embryos were ready for collection. She noted that since the beginning of 2018, her voice message recording on her mobile phone has requested that the caller not leave a message, and instead email or text. She stated:

“If a voicemail had been left, I would not have listened to it. A voicemail is not an appropriate way to advise someone that they need to collect emotionally valuable material within a limited timeframe.”

31. The call data from Mrs A’s phone (requested by HDC from her telecommunications provider) shows that Mrs A did not receive a call from the fertility clinic at any point in the month of July 2018.

Subsequent events

32. Mrs A told HDC that she contacted the clinic once or twice in 2018, wondering what was happening, but received no reply. She is confident that she called at least once and left a message. The fertility clinic told HDC that it has no record of these communications in its system.
33. On 3 May 2019, Mrs A sent an email to the fertility clinic requesting an update on the whereabouts of her embryos. The email stated:

“About 16 months ago I completed a form to allow my embryos to come out of the freezer. I ticked the box saying I would like to collect them. I was told I would be contacted to collect them. I have been meaning to get in touch because I don’t think I’ve been contacted yet!”

34. Mr B called Mrs A on 7 May 2019, when he returned to work from leave. Mrs A did not answer, and Mr B left a voicemail message asking her to call back. Mr B documented the call in Mrs A’s medical records as: “Called [Mrs A] to discuss disposed embryos from storage, no answer, left message to call back.”
35. Mrs A did not check the voicemail message, and did not call back.
36. On 17 October 2019, Mrs A rang the 0800 number and was informed that her embryos had been disposed of in July 2018.

Further information

37. Fertility Associates told HDC that it is truly sorry that this situation occurred, and can assure Mrs A and her husband that this is not its usual practice. Fertility Associates stated that a review of its incident database, which covers all Fertility Associates clinics, showed that there has not been a similar case involving frozen embryos or sperm over the past 10 years. Fertility Associates said that around 3% of its patients reach the ten-year storage limit, and that the vast majority of embryos are used by patients within the ten years. Fertility Associates stated that of those patients who reach ten years, around 20–25% request the return of their embryos.

38. At the time of these events, Fertility Associates had in place a policy (dated June 2011) for “Discarding Frozen Embryos and Sperm”. There was nothing specific in the policy about contacting the patient to collect the embryos, or regarding documentation of any contact. There was also no space on the consent form to check off or document that the patient had been contacted to collect the embryos.
39. Fertility Associates told HDC that it discussed the incident and looked for ways to reduce the chance of a similar event happening again, and made the following changes:
1. The laboratory procedure for “Discarding Frozen Gametes, Embryos & Ovarian Tissue” was updated in November 2019, soon after the incident occurred, to be explicit about the communication needed to tell patients that a discarded sample is ready for collection, or has been sent by courier.
 2. Written, email, and telephone communication with patients who would like their embryos to be returned has been formalised. Calls are recorded in the patient’s medical history, or a copy of the letter or email sent is attached to the patient’s medical history. Letters or emails to patients about collection of samples are created and recorded within the patient management system.
 3. Rows have been added to the staff checklist on the “Consent to Discard Frozen Embryos” form (as well as the equivalent consent forms for sperm and eggs), as prompts to ensure that all steps of the procedure are done.
40. Fertility Associates stated that among its routine internal audits, it reviews consent forms and the consent process annually, which leads to regular improvements to the consent process and documentation. Fertility Associates told HDC:

“We believe we communicated clearly with [Mrs A and her husband] regarding the process of discard and the intent to discard and had clear direction from them that they wished their embryos to be removed from storage. We are truly sorry that they were not then made aware when that happened and were therefore not given the opportunity to collect their embryos.

We have taken their concerns very seriously, as has been shown by the update of our forms. I would like to again sincerely apologise to [Mrs A and her husband] regarding this failure of communication and for the distress this matter has caused them.”

Responses to provisional opinion

41. Mrs A was provided with the opportunity to comment on the “information gathered” section of the provisional opinion, and had no comments to make.
42. Fertility Associates was provided with the opportunity to comment on the provisional opinion, and its comments have been included in the report where relevant.

Opinion: Fertility Associates Holdings Limited — breach

43. 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) — that is, the health services provided by Fertility Associates must be of an appropriate standard, and it must have in place adequate systems, policies, and processes. Whilst Mrs A's initial IVF services were provided to her by the public hospital, these services were outsourced in 2015, and the fertility clinic took over the service of storing and caring for Mrs A's three remaining embryos.
44. On 25 October 2017, Mrs A completed the "Consent to Discard Frozen Embryos" form, as her embryos were due to reach their legal expiry date on 15 July 2018. On the form, Mrs A requested that the fertility clinic discard the frozen material, but chose the option for the fertility clinic to inform her when the embryos were ready for collection. She told HDC that she and her husband planned to take the embryos to her mother's grave.
45. The fertility clinic is unable to confirm whether any attempt was made to contact Mrs A to inform her that her embryos were ready for collection prior to disposing of them. There is no documentation on the "Consent to Discard Frozen Embryos" form, or in Mrs A's medical records, regarding Mrs A being contacted to collect the embryos. Mrs A does not recall being contacted when her embryos were ready for collection. In addition, call data from Mrs A's phone shows that she did not receive a call from the fertility clinic at any point in the month of July 2018. Having considered the evidence, I am satisfied on the balance of probabilities that the fertility clinic did not contact Mrs A to inform her that the embryos were ready for collection.
46. At the time of these events, Fertility Associates had in place a policy for "Discarding Frozen Embryos and Sperm". However, there was nothing specific in the policy about contacting the patient to collect the embryos, or regarding the documentation of any contact. There was also no space on the consent form to check off or document that the patient had been contacted to collect the embryos. Fertility Associates told HDC that if a patient requests the return or collection of embryos, its usual process is to call the patient once the embryos are ready to be collected from the clinic, or call to advise the patient that the embryos have been couriered. This process was not followed in this case, for which I am critical.
47. In my view, Fertility Associates needed to have in place a more effective system to ensure that the important step of contacting patients once their reproductive material was ready for collection was not missed. Whilst I acknowledge the changes that Fertility Associates has made subsequently, I am critical that these processes were not in place at the time of these events, and that there was nothing in its policy or on the consent forms to remind staff to contact the patient and to record that they had done so.
48. Right 7(9) states that every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a healthcare procedure. In this case, I am satisfied that Fertility Associates gave Mrs A the

right to make this decision, and she decided to have the embryos returned to her. However, the lack of an effective system at the fertility clinic resulted in the failure to return the embryos.

49. Mrs A was entitled to have her embryos returned to her if she chose that option. In my view, as well as the storage of the embryos, the return of these embryos to Mrs A at her request was part of the service that the fertility clinic was providing to Mrs A. As identified above, no attempt was made to contact Mrs A to let her know that the embryos were ready for collection, and subsequently they were not returned, and were disposed of against Mrs A's request. The return of her embryos was clearly of significant importance to Mrs A, and her wishes should have been respected. This did not occur, and was an undeniable omission by the fertility clinic. Accordingly, I find that Fertility Associates failed to provide services to Mrs A with reasonable care and skill, and breached Right 4(1)⁹ of the Code.
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Recommendations

50. I acknowledge the changes that Fertility Associates has made in response to these events. In addition to these changes, I recommend that Fertility Associates:
- a) Randomly audit a total of 30 "Consent to discard" forms (for frozen gametes, embryos, or ovarian tissue) over a three-month period to confirm that the consumer's request has been acted upon on each occasion, and, where the consumer wished to have their reproductive material returned to them, that they were informed when the material was ready for collection or couriering. The audit should also encompass whether or not the communication was documented appropriately, as per Fertility Associates' new process.
- The results of the audit are to be sent to HDC within six months of the date of this report. Where the results do not show 100% compliance, Fertility Associates should consider what further improvements could be made to its system, and advise HDC of those improvements.
- b) Further update its laboratory procedure for "Discarding Frozen Gametes, Embryos & Ovarian Tissue" to include the requirement to document the call, email, or letter sent to the patient advising that their reproductive material is ready for collection or couriering. This is to be completed within three months of the date of this report.
 - c) Provide its staff with training on the updated laboratory procedure for "Discarding Frozen Gametes, Embryos & Ovarian Tissue". Evidence that this has been done is to be sent to HDC within three months of the date of this report.

⁹ Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

- d) Provide Mrs A and her husband with a written apology for the breach of the Code identified in this report. The apology is to be sent to HDC within two weeks of the date of this report, for forwarding.
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Follow-up actions

51. A copy of this report with details identifying the parties removed, except the name of Fertility Associates Holdings Limited will be sent to the Ministry of Health, the Health Quality & Safety Commission, New Zealand Fertility Plus, Repromed, and the District Health Board. The Ministry of Health and the District Health Board will be advised of the name of the clinic.
52. A copy of this report with details identifying the parties removed, except the name of Fertility Associates Holdings Limited, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.