Fertility Associates Limited

A Report by the
Deputy Health and Disability Commissioner

(Case 20HDC00586)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a man in his forties by a Fertility Associates Limited clinic. In particular, it concerns the storage of his sperm samples.

2. In April 2018, the man and his partner began the IVF process with Fertility Associates, with the intention of using the man's stored sperm to conceive a baby. Once his partner's egg retrieval was completed, the next step in the fertilisation process was to retrieve the man's sperm samples from storage so that they could be thawed and used to fertilise the eggs. However, when attempting to retrieve the sperm from storage, the clinic was unable to locate his samples.

3. Fertility Associates commenced an internal investigation, which found that the last time it was known that the man's sperm samples were in Fertility Associates' possession was in 2011, which was the last time a physical audit of the banks occurred at the clinic. After investigating potential causes for the loss of the samples, Fertility Associates found it was most likely that the samples were lost when the storage bank holding the samples was decommissioned, and that the loss occurred because staff did not follow policy.

Findings

4. Having carefully considered the evidence presented by Fertility Associates' internal investigation, the Deputy Commissioner concluded that there was insufficient information available to make conclusions regarding the most likely cause of the loss of the man's samples.

5. Whilst the Deputy Commissioner acknowledged that Fertility Associates' policies (including its bank decommissioning policy) may have been appropriate, she considered that there were shortcomings in other record-keeping and audit systems that could have enabled Fertility Associates to pinpoint how the loss of the man's samples occurred.

6. The Deputy Commissioner also found that the presence of a policy was insufficient basis on which to conclude that adequate safeguards were in place to prevent the loss from occurring, as staff need to be aware of the policy and supported to follow it, and there needs to be adequate monitoring in place to identify any gaps. The Deputy Commissioner considered that there was no evidence of which staff were involved, what steps were in place to ensure that they had the necessary skills and training, and how the policy was monitored.

7. Whilst the Deputy Commissioner acknowledged that loss of samples is a rare and devastating risk to assisted reproductive technologies, she considered that it was Fertility Associates' responsibility to ensure the safe storage of samples in its possession. She was critical that Fertility Associates lost the man's sperm samples, and that its systems failed both to prevent the loss from occurring, and to identify how the loss occurred.

8. The Deputy Commissioner considered that Fertility Associates has a responsibility through both its staff and its processes to provide a reasonable standard of care to consumers. As a

service, it failed to safeguard the man's samples, and that was a failure for which it was directly responsible. The Deputy Commissioner found that Fertility Associates did not provide services to the man with reasonable care, and therefore breached Right 4(1) of the Code.

Recommendations

9. The Deputy Commissioner acknowledged the changes that Fertility Associates had made since these events, and that it had already provided the man and his partner with an apology. She recommended that in addition, Fertility Associates report to HDC on any decommissioned banks within that 12-month period, and provide details of the audit documentation in relation to the decommissioning, to show that the relevant processes were followed; engage an expert in the field of cryogenic storage facility management to review Fertility Associates' systems and processes to identify any storage risks that are not mitigated sufficiently; and provide evidence of its updated sample storage consenting documentation.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided by Fertility Associates Limited. The following issue was identified for investigation:

- *Whether Fertility Associates Limited provided Mr A with an appropriate standard of care between 2011 and 2018 (inclusive).*

11. This report is the opinion of Deputy Health and Disability Commissioner Dr Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

12. The parties directly involved in the investigation were:

Mr A	Consumer
Fertility Associates Limited	Provider/fertility company

13. Further information was received from the Clinic Manager, Ms B.

14. Independent 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. This report concerns the care provided to Mr A, in his forties, by a Fertility Associates Limited clinic (the clinic). In particular, it concerns the storage of Mr A's sperm samples.

16. As a teenager, Mr A was diagnosed with cancer. Prior to undergoing chemotherapy,[1] a sample of Mr A's sperm was placed in storage in 1995. The storage was later purchased by Fertility Associates Limited (who remain the current owner).

17. Fertility Associates has 22 fertility clinic locations (including five treating clinics) across New Zealand. Its services include IVF,[2] donor/surrogate fertility procedures, and cryo-preservation.[3] Cryopreservation is available for reproductive cells[4] (such as eggs and sperm), fertilised embryos, and human tissue (such as ovarian tissue and testicular tissue).

18. Mr A's sperm samples were stored using cryopreservation. Sperm samples are stored in thin plastic straws that are sealed at each end and placed in a plastic container called a "goblet". Goblets are then stored in a cylindrical metal canister, which can hold 20–30 goblets. Canisters are stored in a storage tank called a "bank", which is filled with liquid nitrogen and can hold up to 20 canisters. Mr A's sample was split between 15 straws, all stored within the same goblet.

19. Sperm can be stored indefinitely in liquid nitrogen, but the Human Assisted Reproduction Technology Act 2004 (the HART Act)[5] imposes a 10-year limit on storage. Anything stored for over 10 years requires application to the Ethics Committee on Assisted Reproductive Technology (ECART) for extended storage. Mr A had applied to ECART for extended storage in 2014, and this was granted.

Fertility treatment — 2018

20. In April 2018, Mr A and his partner, Ms A, began the IVF process with Fertility Associates, with the intention of using Mr A's stored sperm and Ms A's ova (eggs) to conceive a baby.

21. The IVF process begins with treatment to stimulate the ovaries prior to extraction of the eggs. Each cycle of IVF requires a daily self-injection of hormones, and a second injection to trigger the maturation of the eggs. Alongside this, the patient is monitored with blood tests (to determine hormone levels) and trans-vaginal ultrasound scans.[6]

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[1] Treatment using drugs to stop the growth of cancer cells. Chemotherapy can impair fertility, including sperm production.
[2] In vitro fertilisation (IVF) is a procedure in which eggs are removed from the ovaries and combined with sperm outside the body to produce embryos. The embryos are grown in a laboratory for several days and then either placed into the uterus or frozen for future use.
[3] Cryopreservation is the use of very low temperatures to preserve living cells, tissues, and other biological samples.
[4] Gametes.
[5] https://www.legislation.govt.nz/act/public/2004/0092/latest/whole.html
[6] Scans to examine female reproductive organs.

22. On 25 May 2018, after completing her first IVF cycle, Ms A underwent a procedure at Fertility Associates to retrieve her eggs.[7] Out of the 16 eggs retrieved, five were found to be mature and suitable for use.

23. Once Ms A's egg retrieval had been completed, the next step in the fertilisation process was to retrieve Mr A's sperm samples from storage so that they could be thawed, in order to be used to fertilise Ms A's eggs. However, when attempting to retrieve Mr A's sperm from storage, the clinic was unable to locate his samples.

24. Mr A was notified of this by telephone immediately, at 1.21pm on 25 May 2018. During the call, Fertility Associates requested permission to cryopreserve Ms A's eggs while they completed a more thorough search of the storage banks at the clinic. This was agreed to by Mr A and Ms A.

25. From 25 May 2018 to 2 June 2018, a full search was completed of all the banks in the clinic, and this confirmed that the samples were no longer in storage. Fertility Associates noted that during this time, Mr A and Ms A were offered support by their Fertility Associates counsellor and doctor, including several long and detailed conversations providing further information.

26. On 2 June 2018, Fertility Associates confirmed with Mr A that the clinic had lost his sperm samples, and advised him of his options going forward. These included an offer of a testicular biopsy (a micro-surgical procedure) to check whether Mr A had any remaining viable sperm, or the provision of donor sperm to use with Ms A's eggs. Mr A and Ms A declined the offer of donor sperm, but Mr A underwent the biopsy in October 2018. Unfortunately, the procedure did not find any remaining sperm that could be used.

Fertility Associates' internal investigation

27. Once it had been confirmed that Mr A's samples had been lost, Fertility Associates undertook an internal investigation to determine when and how the samples went missing.

28. Fertility Associates told HDC that the last time it was known that Mr A's sperm samples were in Fertility Associates' possession was in 2011, which was the last time a physical audit of the banks occurred at the clinic.

29. Physical auditing[8] was conducted periodically by Fertility Associates at its clinics around New Zealand until July 2010, when it moved to "auditing by exception" (for example, when a sample was not where it should be when it came to be used, or when a bank was decommissioned (retired)[9]). Fertility Associates considers that because auditing requires

[7] This is done using a transvaginal ultrasound machine to identify follicles (small fluid-filled sacs inside a woman's ovaries). A needle is then inserted through the vagina wall and into the follicle to extract the fluid (which contains the eggs). The fluid is examined under a microscope, and the eggs removed and placed in a culture dish to be either frozen or mixed with sperm with the goal of creating embryos. Egg retrieval is day surgery, usually completed under light sedation and pain relief.

[8] An inventory check of all goblets containing frozen genetic material.

[9] Fertility Associates decommissions its banks once they have been in use for 15 years. It stated that where possible, when a bank is decommissioned, the canisters inside are moved to a new bank, which is given the

removal of samples from the liquid nitrogen storage, the risk of damaging[10] the viability of samples is too high to undertake frequent physical audits. Fertility Associates noted the significant number of samples it holds[11] compared to the unlikely event of lost samples.

30. Fertility Associates acknowledged that in its guidelines for good practice in IVF laboratories, the European Society of Human Reproduction and Embryology (ESHRE) recommends undertaking regular physical inventories (see Appendix C). However, Fertility Associates told HDC that there is other authority explaining why this is not universally accepted, nor adopted by Fertility Associates. Fertility Associates provided HDC with an article from the *Journal of Assisted Reproduction and Genetics* (a publication based in the USA), which notes that spot checking of random samples is less desirable than spot checking of samples scheduled for discard, as the viable samples will be exposed to temperature change (see Appendix C). Fertility Associates highlighted that the article found that regular thawing events (such as thawing samples for treatment or for discarding) provide an excellent source of spot check verifications, and that the risk–benefit of performing complete or partial inventories must be seriously assessed.

31. Fertility Associates also told HDC that it is not aware of any guidelines that suggest checking the location of samples before beginning a procedure that uses frozen samples.

32. Fertility Associates' investigation found that there were two possible times when Mr A's samples could have been handled between the physical audit in 2011 and the discovery of the missing sample in May 2018 — in 2015 when the storage bank containing Mr A's sperm samples was decommissioned, and in 2017, when the canister that stored Mr A's samples was emptied and the goblets inside were relocated.

33. After consideration and investigation into other possible causes for the loss of Mr A's samples, Fertility Associates concluded that an accidental discard of Mr A's sperm during the bank decommission in 2015 was most likely. However, there are no contemporaneous records to confirm that Mr A's samples were present in the storage bank when it was decommissioned in 2015, so this cannot be confirmed as the cause of the loss.

34. Fertility Associates has a policy titled "5844.55 — Liquid Nitrogen Bank Audit", which guides the process for decommissioning a storage bank after 15 years of use. This policy was introduced in 2010 following an incident in 2006 where an embryo goblet was retained at the bottom of a retired bank and the samples perished. The relevant excerpts of the May

same name as the old bank to avoid changing information records. Fertility Associates told HDC that its decommissioning process is undertaken to reduce the chance of bank failure caused by metal fatigue, as the welding around the neck of storage banks can be affected by the repeated temperature changes from –196°C liquid nitrogen and room temperature. Metal fatigue can result in small cracks in the bank that changes the internal temperature, which can cause complete loss or decreased viability of samples.

[10] Once samples are in a temperature above –55°C, they will be damaged irreversibly and no longer viable for fertilisation (unless thawed completely for use).

[11] Fertility Associates currently stores approximately 20,000 goblets of frozen genetic material.

2013 version of the policy, which was in place at the time of events, are set out in Appendix B.

35. The policy helps staff to avoid sample damage when transferring samples to a new bank, and requires a check that all samples have been removed from the decommissioned bank and placed in the new one. The policy outlines that two staff members should be involved — one to check the goblets in the original canister and the other to record the presence or absence of each goblet against a printed list of bank contents for the bank that is being decommissioned. An inventory audit is needed for the contents of the bank that is being decommissioned and of the new bank. The policy states that the decommissioning process is complete when the electronic database and the paper records are both updated to record the exact location of each goblet.

36. Banks are upended to check that no goblets have escaped from their canisters and become stuck at the bottom of the bank. This can sometimes happen if goblets float in the liquid nitrogen and become lodged at the bottom of the bank under the "false bottom" that normally holds canisters in position. Fertility Associates noted that while goblets becoming stuck at the bottom of the bank is uncommon, it does happen an estimated one to two times per year. Usually the goblets can be retrieved with a metal "grabber" if the movement is noticed.

37. However, neither an inventory nor upending of the bank were recorded to have occurred in 2015 when the bank holding Mr A's samples was decommissioned. Fertility Associates told HDC that while its Essential Record policy requires that it keep records made by its internal auditors for seven years, it had not been its practice to retain the inventory check (or "audit") when a bank was retired. This meant that it was not possible for Fertility Associates to audit that the inventory that was required when the bank was decommissioned actually occurred.

38. Fertility Associates told HDC that it accepts that a physical audit and inventory check should have been completed. Fertility Associates surmised that during the decommissioning process, Mr A's goblet (containing all 15 straws of his samples) had likely sunk to the bottom of the bank. It stated that had its auditing procedure been followed, it is likely that the goblet could have been retrieved.

39. Fertility Associates provided a statement from the Clinic Manager, Ms B. Ms B was employed at the clinic when the bank that had held Mr A's samples was retired in 2015, although she said that she was not involved in the process of retiring the bank. Ms B stated that the embryologists who participated in retiring that bank no longer work at Fertility Associates, although Fertility Associates did not provide any documentation to confirm which staff members were involved in the decommissioning process. Ms B said that it is her opinion that the previous clinic owners did not have a policy of retiring old banks, as many old banks were retired soon after Fertility Associates purchased the clinic. For this reason, Ms B considers that staff may have followed a process used by the previous owners to move samples from one bank to another, rather than following Fertility Associates' policy for decommissioning banks.

40. Internal auditing of liquid nitrogen bank use was scheduled and undertaken in 2014 and 2016, and documents titled "Liquid Nitrogen Bank and Shipper Audit" from 2014 and 2016 were provided to HDC. Fertility Associates told HDC that there are no records from 2015, as audits occur every alternate year. The audits undertaken in 2014 and 2016 both document that the Liquid Nitrogen Bank Audit policy was followed. The 2014 and 2016 audits both record "yes" next to "Procedure 5844.55 followed". The 2014 audit states that the auditor asked colleagues to read the protocol and confirm that it was followed in a recent audit. The 2016 audit states that the audit was completed by the auditor verbally going through the 5844.55 process with Ms B. These audits were completed later in the year (rather than contemporaneously when the banks were decommissioned), with staff being asked to recall whether the policy had been followed in retrospect.

41. During its investigation into the loss of Mr A's samples, Fertility Associates noted that when the canister that stored Mr A's samples was emptied and the goblets relocated in September 2017, there was no record of Mr A's goblet being relocated in the data change log of the medical system. Fertility Associates told HDC that this indicates that Mr A's samples were not present on this date, and further indicates the likelihood of them having been lost when the bank was decommissioned in 2015.

Possible other causes for loss

42. Whilst Fertility Associates considers the most likely cause of the loss to be accidental discard when the bank was decommissioned, it provided HDC with alternative possible causes of loss that were considered following its internal investigation.

43. Fertility Associates told HDC that there is no paperwork indicating that Mr A's samples would have been discarded due to wrong calculation of the expiry date.

44. Fertility Associates also told HDC that it is unlikely that the sample was mistaken for another and discarded owing to misreading of the name on the samples, as a review of discarded samples records did not show any names similar to Mr A's.

45. Accidental discard due to ambiguous labelling was also considered unlikely, as codes of donor samples that were discarded in early 2015 were reviewed and none were similar to Mr A's. Fertility Associates told HDC of one other case of a lost sperm sample in its clinics due to accidental discard of a sample that had been transferred to the clinic from overseas and therefore had unfamiliar labelling. While Mr A's samples were labelled differently to standard labelling because they had been banked in 1995, the lack of donor codes that were similar to Mr A's surname meant that Fertility Associates considered it would be an unlikely scenario for accidental discard to occur in this way.

46. Fertility Associates assured both Mr A and HDC that the likelihood of the samples having been used mistakenly by another patient is the least likely possible cause for loss, because of the extra steps required in sample identification when samples are used for treatment. Treatment requires sample identification checks by two people, and in some treatments such as IVF, two-person checks are repeated at multiple stages of the treatment.

Further information

Fertility Associates

47. Fertility Associates met with Mr A and Ms A, along with Mr A's father, on 6 June 2018 at the clinic. Fertility Associates apologised for the loss, and explained the process of its search, alongside possible causes of loss. Mr A, Ms A, and Mr A's father were shown the facilities where samples were kept, and had a meeting to give them the opportunity to ask any remaining questions. Fertility Associates told Mr A that the costs of sperm storage would be refunded, and also offered the option of testicular biopsy or treatment using donated sperm. Mr A was also provided with access to Fertility Associates' counsellor.

48. Fertility Associates participated in a professionally facilitated mediation with Mr A, which resulted in a legal settlement. I note the acknowledgement by Fertility Associates of the loss suffered by Mr A and Ms A, and the steps taken by Fertility Associates to provide redress.

49. During the search for Mr A's samples in 2018, multiple discrepancies were found between the physical stored samples and the electronic database, and these were followed up by Fertility Associates over the course of a few months. Some of the discrepancies were a result of changes in the electronic database, including before Fertility Associates had purchased the clinic. A total of 249 goblets were identified for follow-up. Fertility Associates told HDC that it was a lesson on the extra scrutiny needed when acquiring a clinic, and the potential risks of permitting gradual cultural change.

Mr A

50. Mr A told HDC that this experience has been devastating for him and his family. He said that egg retrieval was a "long and difficult process" that his partner, Ms A, undertook. Although he complained to Fertility Associates directly and engaged in mediation, he explained to HDC that he still has "concerns about Fertility Associates' processes, including their procedures for storing samples and their policy for responding to serious adverse events". Mr A expressed that he wants to ensure that Fertility Associates has storing practices and policies that will give peace of mind to other people storing their samples with Fertility Associates.

51. Mr A is pleased that HDC's investigation has been able to provide him with additional information about his samples and Fertility Associates' processes.

Responses to provisional opinion

Mr A

52. Mr A was given the opportunity to comment on the "information gathered" section of the provisional opinion.

53. Mr A told HDC that prior to mediation, he told Fertility Associates that he thought it would be a good idea to undertake a physical check of samples before starting the IVF process. Mr A explained that this would have saved him and Ms A a lot of stress and anxiety if they had found out about the loss prior to starting treatment. Fertility Associates' clinical documents show that Ms A experienced anxiety and stress around the medical procedures she underwent during the IVF process (such as the ultrasounds), in some cases necessitating

rescheduling of appointments because certain procedures, including scans and smears, were unable to be completed.

Fertility Associates

Breach finding

54. Fertility Associates submitted that it is open to HDC to accept the findings of its own internal investigation and conclude on the balance of probabilities that Mr A's samples were lost in 2015 because the Liquid Nitrogen Bank Audit Policy was not followed by its staff. It submitted that the alternative explanations for loss are unlikely. Fertility Associates considers that there is no evidence that its investigation was in any way lacking, and therefore no basis for HDC to dispute its findings.

55. Fertility Associates stated that the independent advice received from Professor Chapman did not indicate that Fertility Associates' systems had failed to meet the expected standard. It stated that on the contrary, Professor Chapman found that its policies and procedures were "appropriate". Fertility Associates considers that a finding that its systems were in breach of the Code is inconsistent with Professor Chapman's advice.

56. Fertility Associates also stated that HDC cannot find it directly responsible for the loss of Mr A's samples on the basis that it had an organisational obligation to provide reasonable care, as this would mean that every service level provider would be directly responsible for every breach of the Code. Fertility Associates also submitted that HDC cannot work backwards from an adverse outcome (as occurred in Mr A's case) to assume a breach of the Code.

57. Fertility Associates stated that no system can prevent all human error, and that it would be unreasonable for HDC to expect perfection. It submitted that similarly to other areas of medicine such as Radiology, "it is provable from data and well established that a certain error rate is inevitable". It stated that thankfully, that rate is very low for assisted reproduction technologies.

58. In summary, Fertility Associates submitted that it does not accept that there were any higher-level organisational failures in relation to the loss of Mr A's samples that could be attributed directly to Fertility Associates. It does not accept that it is directly liable for any systems failures causing or contributing to the loss of Mr A's samples, and submitted that it can be held vicariously liable only for the failure of its staff to follow the Liquid Nitrogen Bank Audit Policy.

Frequency of audits and checks prior to fertility treatments

59. Fertility Associates told HDC that it remains of the view that the risks involved in conducting regular physical audits or pre-procedure checks outweigh the benefits. Fertility Associates provided HDC with three expert advice reports to advise on the current global standards and practices of inventory and auditing of cryogenically stored genetic material.

60. I acknowledge the opinions of the three experts provided by Fertility Associates, who all stated that, in their opinion, the risk of doing a full audit of frozen samples outweighs the

benefits. I accept that there is not a universally accepted standard about the nature of auditing.

61. Fertility Associates told HDC that any advice it receives in the future in relation to physical auditing and pre-procedure checks will be considered carefully. If the science becomes such that Fertility Associates is convinced that the benefits of physical auditing or pre-procedure checks outweigh the risks, Fertility Associates will change its approach. Fertility Associates said that in the meantime, it will be explicit with patients about its current approach.

Opinion: Fertility Associates Limited

Care provided to Mr A — breach

62. 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). Fertility Associates also has a duty of care to ensure that samples stored with it are kept safe.

63. Prior to undergoing chemotherapy, Mr A's sperm samples were stored by a company that later was purchased by Fertility Associates. When Mr A and his partner attempted to access the sperm to have a baby, it was discovered that the stored samples had been lost.

64. Following confirmation that Mr A's samples could not be found in the clinic, Fertility Associates commenced an internal investigation into the events and explored potential explanations for the loss.

65. The last time it was known that Mr A's samples were in Fertility Associates' possession was in July 2011, which was the last time a physical audit of banks occurred at the clinic, when Fertility Associates purchased the clinic from the previous owners. Fertility Associates found that between this time and the discovery of the missing samples in May 2018, there were two possible times where Mr A's samples could have been handled — in 2015 when the storage bank containing Mr A's sperm samples was decommissioned, and in 2017, when the canister that stored Mr A's samples was emptied and the goblets inside were relocated.

66. Fertility Associates also considered alternative explanations for the loss, including the samples being discarded due to an incorrect expiry date or ambiguous labelling, being mistaken for another sample leading to discard, or accidental use due to mistaken identity.

67. Of these scenarios, Fertility Associates found that the most likely point in time that the samples were lost was when the original storage bank was decommissioned and samples were moved to a new bank.

68. In 2015, the storage bank containing Mr A's sample was decommissioned as a safety precaution, as it had been in use for a total of 15 years. When decommissioning this bank, Fertility Associates was required to follow the steps in its policy "5844.55 — Liquid Nitrogen

Bank Audit" (see Appendix B). The policy outlines that there should be an audit of the contents of the bank being decommissioned, and the contents of the new bank. It also requires that the bank should be physically turned upside down to check for any goblets that have sunk to the bottom of the bank. The policy requires two people to complete the audit during the decommissioning of the bank.

69. However, neither an inventory nor upending of the bank were recorded to have occurred in 2015 when the bank holding Mr A's samples was decommissioned. Fertility Associates has surmised that during the decommissioning process, Mr A's goblet (containing all 15 straws of his samples) had likely sunk to the bottom of the bank. As support for this proposition, Fertility Associates noted that when the canister that stored the samples was emptied and the goblets relocated in 2017, there was no record of Mr A's goblet being relocated in the data change log of the medical system. Fertility Associates considers that this indicates that Mr A's samples were not present in 2017, and further indicates the likelihood of them being lost in 2015.

70. Fertility Associates told HDC that a physical audit and inventory check should have been completed, and that if this had occurred in line with policy, Mr A's samples could have been identified as missing at the time of the bank being decommissioned, and recovered before any damage occurred.

71. Fertility Associates has submitted that it is open to me to accept the findings of its internal investigation and conclude on the balance of probabilities that Mr A's samples were lost in 2015 because the Liquid Nitrogen Bank Audit Policy was not followed by its staff. It has stated that the other alternative explanations for loss are unlikely, and there is no evidence that its investigation was in any way lacking, meaning there is no basis to dispute the investigation's findings.

72. I have carefully considered the evidence presented by Fertility Associates' internal investigation, and the likelihood of the alternative scenarios. In my view, the investigation was thorough and commenced within an appropriate time from the discovery of the loss. I acknowledge that Fertility Associates considers that Mr A's samples were most likely lost following the decommissioning of the storage bank in 2015, and that the loss resulted from the failure of one or two of its staff members to follow policy. Fertility Associates is entitled to draw this conclusion from its internal investigation. However, I do not accept that there is sufficient evidence to conclude that it is more likely than not that the loss of Mr A's samples occurred in this way.

73. I reiterate the following information, which demonstrates the difficulty in reaching such a conclusion:

a) There are no contemporaneous records to confirm that Mr A's samples were present in the storage bank when it was decommissioned in 2015.

b) While neither an inventory nor upending of the bank was recorded to have occurred in 2015, this is not necessarily because it did not occur. Fertility Associates did not keep inventory records from bank decommissioning at the time, meaning it is not possible

for Fertility Associates to determine whether or not an inventory took place. The absence of record-keeping means that it also is not possible to determine whether or not the staff undertaking the bank decommissioning followed the Liquid Nitrogen Bank Audit Policy. Even if staff had followed the policy and undertaken an inventory check, Fertility Associates would not hold the inventory records to prove that this occurred.

c) Fertility Associates' internal process audit systems since 2015 have been unable to identify whether the Liquid Nitrogen Bank Audit Policy was followed correctly in 2015. While internal auditing of liquid nitrogen bank use was undertaken in 2014 and 2016 and relevant records provided to HDC, Fertility Associates could not provide records for 2015 because audits occur every alternate year.

d) Even if a process audit of compliance with the Liquid Nitrogen Bank Audit Policy had taken place in 2015, the absence of inventory records means that Fertility Associates would not have been able to confirm that the inventory that was required when the bank was decommissioned actually occurred. The information provided by Fertility Associates with respect to the 2014 and 2016 audits indicates that its method of determining compliance was to ask staff to read the Liquid Nitrogen Bank Audit Policy and confirm that it was followed. The audits were not completed at the time of bank decommissioning, and relied on staff recalling in retrospect whether the policy had been followed.

e) Fertility Associates has not provided any evidence to confirm which staff members were involved in the decommissioning process. However, Ms B stated that the embryologists who completed the process no longer work at Fertility Associates. As Fertility Associates is unable to identify the relevant staff, it is not possible to ask the staff whether they complied with the Liquid Nitrogen Bank Audit Policy. I also note that even if the staff could be identified, their recollection of the specific bank decommission in 2015 is unlikely to be reliable in the absence of any contemporaneous documentation.

f) The fact that Mr A's samples were not recorded as having been relocated in September 2017 alongside the other samples that were relocated from the same bank does not mean that Mr A's samples were lost in 2015. In my view, this simply means that Mr A's samples were lost sometime between 2011 (when the last physical audit was undertaken at the clinic) and 2017.

74. On the basis of the above, I consider that there is insufficient information available to suggest that the loss of Mr A's samples most likely occurred as a result of a failure by Fertility Associates' staff to follow the Liquid Nitrogen Bank Audit Policy, and this casts doubt on the findings of Fertility Associates' internal investigation. In my view, the loss of Mr A's samples could have resulted from any of the scenarios investigated by Fertility Associates.

75. I received advice from Professor Michael Chapman, an obstetrician and gynaecologist and Clinical Director of IVF Australia — Southern Sydney. Professor Chapman advised that he could not pinpoint the time at which the samples were lost, and Fertility Associates' "detailed review" (its internal investigation) failed to identify when the samples were lost.

76. Professor Chapman told HDC that the loss of 15 straws "would seem significantly below 'adequate care'". However, Professor Chapman also noted that such a loss is an extremely rare event, and the loss was unintentional, and he suspects that a rare mishandling of specimens occurred. Overall, Professor Chapman considered that the loss was a "moderate degree of substandard care".

77. Considering the factors that led to this departure from the standard of care, Fertility Associates submitted that the opinion received from Professor Chapman did not find that its systems departed from the accepted standard. To the contrary, Fertility Associates stated that Professor Chapman found its policies to be "appropriate". Fertility Associates considers that any finding that its systems were in breach of the Code would be inconsistent with Professor Chapman's advice.

78. I accept that Professor Chapman was asked to advise on the adequacy of the policies and procedures in place at Fertility Associates, and he stated that "the current policies are appropriate".

79. However, I would first note that the presence of a policy is insufficient basis on which to conclude that adequate safeguards were in place to prevent the loss from occurring. Having a policy, however well worded, is not enough — staff need to be aware of it and supported to follow it, and adequate monitoring should be in place to identify any gaps. In this case, there is no evidence of which staff were involved, what steps were in place to ensure that they had the necessary skills and training, and how it was monitored.

80. I note that Professor Chapman also stated that "clearly the systems of record keeping and audit [had] failed". I agree. In my view, although Fertility Associates' policies (including the Liquid Nitrogen Bank Audit Policy) may have been appropriate, there were shortcomings in other record-keeping and audit systems that could have enabled Fertility Associates to pinpoint how the loss of Mr A's samples occurred.

81. If it had been Fertility Associates' practice to retain records of inventory checks from bank decommissioning processes, and to undertake process audits to review those inventory checks to ensure that the Liquid Nitrogen Bank Audit Policy had been followed, Fertility Associates would have been better placed to identify whether Mr A's samples were lost during the bank decommissioning process in 2015. As a result, Fertility Associates also would have been better placed to identify any problems with the Liquid Nitrogen Bank Audit Policy, or staff compliance with the policy, in order to learn from the error in Mr A's case and prevent future recurrences more effectively.

82. Fertility Associates informed HDC that it has introduced a policy that requires all working documents pertaining to the retirement of a bank to be retained for seven years, to allow Fertility Associates to check that an audit was completed at the decommissioning stage, and to assist in any investigations if there are further incidents of lost samples (see the "Changes made" section below). In my view, this policy change demonstrates Fertility Associates' recognition that there were shortcomings in its record-keeping practices and ability to undertake process audits and investigations at the time Mr A's samples were lost. I

recognise that even if the record-keeping and process audit systems I have described had been in place at the time of events, this does not necessarily mean that the loss of Mr A's samples would not have occurred. Because it is not possible to identify how the loss of Mr A's samples occurred, unfortunately this means that it has not been possible for this investigation to examine whether Fertility Associates' systems could have been improved in any way to prevent the loss from occurring in the first place. I appreciate that this must be disappointing for Mr A.

83. However, what I can conclude is that it was Fertility Associates' responsibility to ensure the safe storage of samples in its possession. The samples were lost, and Fertility Associates was unable to pinpoint how or when they were lost within a large window of almost seven years in which Mr A's samples were not recorded to have been sighted. Fertility Associates has submitted that there were no higher-level organisational failures in relation to the loss of Mr A's samples that could be attributed directly to Fertility Associates. I disagree. Fertility Associates' systems failed both to prevent the loss from occurring, and to identify how the loss occurred. This was substandard care that had a devastating outcome for Mr A and Ms A, and in my view is suggestive of systemic failures. Whilst I acknowledge that loss of samples is a rare and devastating risk to assisted reproductive technologies, I am nonetheless critical that Fertility Associates lost Mr A's sperm samples, and that its systems were unable to provide evidence of how or when the loss occurred. Fertility Associates has a responsibility through both its staff and its processes to provide a reasonable standard of care to consumers. As a service, it failed to safeguard Mr A's samples, and that is a failure for which it is directly responsible. Accordingly, I find that Fertility Associates did not provide services to Mr A with reasonable care, and therefore breached Right 4(1) of the Code.[12]

Frequency of audits and checks prior to fertility treatments — other comment

84. In July 2010, Fertility Associates moved from regular physical auditing of samples to "auditing by exception". This meant that regular physical audits did not occur, and checks that samples were present were not carried out prior to patients beginning fertility treatment. Fertility Associates expressed concern that implementing either of these processes would increase unnecessary handling of samples and therefore risk damaging sample viability.

85. Professor Chapman advised HDC that auditing by exception has been common practice in past years owing to the magnitude of auditing in commercial clinics, combined with the risk of damage to samples. However, he noted that freezing equipment has improved, and quality standards have changed over time, which would mean that full audits are expected today. Professor Chapman said that had full audits been performed, the loss of Mr A's samples could have been identified sooner.

86. Professor Chapman also advised that the failure to identify the loss until Mr A sought to use the samples was a significant failure of good practice due to what were less rigorous audit processes than are in place today. I understand Professor Chapman to mean that he would

[12] Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill.

expect developments in today's technology to allow for more rigorous audits than Fertility Associates was conducting at the time of these events.

87. Fertility Associates disagreed with Professor Chapman's statements, commenting that the risk of damage to samples caused by physical audits is the same as it ever was, as the physical audit methods have not changed. However, Fertility Associates stated that electronic inventory systems have improved over time, which means that inventory errors are less likely.

88. Fertility Associates submitted that there is no consensus regarding suitable inventory audit procedures for IVF laboratories. Fertility Associates acknowledged that ESHRE recommends regular physical inventories. However, the article provided to HDC by Fertility Associates from the *Journal of Assisted Reproduction and Genetics* (a US publication) notes that spot checking of random samples is less desirable than spot checking of samples scheduled for discard, as on the former approach the viable samples will be exposed to temperature change.

89. Fertility Associates told HDC that full regular auditing is not industry standard, and would be time and resource intensive. Fertility Associates provided advice from three experts in the field on current global standards and practices of inventory and auditing of cryogenically stored genetic material. Their collective view is that there is no global standard or best practice supporting regular physical auditing of cryogenic samples, and the risk of undertaking audits outweighs the benefits.

90. Fertility Associates also told HDC that it is not aware of any guidelines that suggest checking the location of samples before beginning a procedure that uses frozen samples. Fertility Associates denies that declining to check a sample before beginning IVF could be considered a failure of good practice, as this would expose the sample to an increased risk of damage. Fertility Associates commented that pre-procedure checks would require its organisation to complete approximately 40,000 additional checks over a 10-year period. Between its five treating clinics nationwide, this would result in approximately 15–16 additional checks weekly in each clinic. It noted that every single check gives rise to the risk of a mistake and/or damage to the sample through temperature change.

91. Fertility Associates told HDC that after careful deliberation, it has decided that auditing by exception best protects its patients' interests.

92. I have carefully considered Fertility Associates' submissions on this matter. I acknowledge that there is inherent risk in completing physical audits, and that it is in the consumer's best interests to minimise exposure of samples to temperature change. I also acknowledge that there are very few New Zealand-based guidelines that give direction on how genetic material should be stored. The HART Act 2004[13] gives guidance on how long samples can be stored, what kind of samples can be stored, and what they can be used for, but it does not detail day-to-day checks and balances that individual providers should undertake.

[13] https://www.legislation.govt.nz/act/public/2004/0092/latest/whole.html.

93. While Fertility Associates and its experts have referred to relevant European and American guidance (Appendix C), I accept that this does not present a global standard regarding suitable audit procedures for IVF laboratories:

a) The ESHRE Guidelines for Good Practice in IVF Laboratories (2008) stated that "an annual audit of stored gametes and embryos must be carried out" involving "cross referencing contents with storage records".

b) The ESHRE Revised Guidelines for Good Practice in IVF Laboratories (2015) provide that a periodic inventory of the contents of a cryobank, including cross-referencing contents with storage records, is "recommended".

c) The ASRM Committee Opinion (2020) notes that "storage tank inventories are usually performed only when needed rather than on a regularly scheduled basis", and annual physical inventories "are not routine since their benefit may be outweighed by the risk of inadvertent compromise of cryo-preserved samples due to the fragile nature of these samples …".

d) The *Journal of Assisted Reproduction and Genetics* Best Practice Guidelines for ART Labs (2019) provide that regular random sampling of samples (i.e., monthly or quarterly) is less desirable to spot checking during regular thawing events and discarding procedures, as it may "unnecessarily expose viable samples to brief but possible changes in temperature". In addition, I accept from the expert reports provided by Fertility Associates that there is no consensus view between these experts and my independent advisor that physical auditing or pre-procedure checks is a quality standard required of Fertility Associates.

94. On this basis, I accept Fertility Associates' position that its preferred practice of auditing by exception does not fall below industry standards.

95. Notwithstanding this, I find it concerning that a sample may not be checked for such a long period of time, as occurred in this case. There was a gap of over six years between the physical audit in July 2011 when Fertility Associates took ownership of the clinic (in which Mr A's samples were noted as present), and the audit following the identification of Mr A's missing samples in May 2018. Had the loss been identified earlier, Ms A would not have had to undergo the IVF process, including egg retrieval, without having a viable sample of sperm for fertilisation. I acknowledge the significant effect that fertility treatments such as IVF have on patients, as these are sensitive and invasive medical procedures. Ms A had been involved in treatment for a long period of time, and, in my view, the serious effects of these treatments should be considered and balanced against the risk of damaging samples.

96. Further, the audit in May 2018 was undertaken only once Mr A requested his samples — rather than as a scheduled audit — and it revealed not only Mr A's samples as missing but a number of other discrepancies in the electronic inventory that have since been updated against the audit. Fertility Associates has a duty of care over the samples it stores, and a gap of six years between visually sighting a sample results in limited knowledge not only of the location of the sample, but of its existence entirely.

97. I also note that consumer awareness of risks to their samples whilst in storage is an important aspect of informed consent. Consumers who pay for their genetic material to be stored should have full knowledge that regular auditing does not occur, and therefore delayed discovery of loss is a potential risk. Similarly, if Fertility Associates were to change its systems to complete more regular audits, I would expect a consent form to disclose the potential risks to viability associated with completing physical checks on stored samples. While Fertility Associates' stance is that physical audits and pre-procedure checks will put samples at risk, consumers are not given the opportunity to assess this risk and weigh up options of starting fertility treatment without a check being completed.

98. Finally, while I acknowledge that it was resource intensive, a complete physical audit of the clinic was completed after Mr A's samples were discovered missing. This took eight days (from 25 May to 1 June).

99. Fertility Associates has noted that any advice it receives in the future will be considered carefully, and if the science becomes such that it is convinced that the benefits outweigh the risks, it will change its approach. In the meantime, Fertility Associates has expressed a willingness to be explicit with patients about its current approach. I consider this to be appropriate.

Changes made since events

100. During mediation, Mr A raised the idea of spreading samples from the same owner across different banks, to ensure that even if bank failure occurs, it does not result in complete loss. This is recommended practice in the UK (although not in the US or Europe). Fertility Associates told HDC that splitting patient samples between multiple locations has already been implemented for fertility preservation samples where there is more than one goblet of material per patient.

101. Following these events, Fertility Associates introduced a new policy that requires all working documents pertaining to the retirement of a bank to be retained for seven years, to allow Fertility Associates to check that an audit was completed at the decommissioning stage, and to assist in any investigations if there are further incidents of lost samples.

102. Fertility Associates has also added a question to the liquid nitrogen audit tool that asks whether the bank has been retired according to the revised procedure. Fertility Associates advised that it updated its auditing tool in March 2021, and routine auditing now involves reporting on decommissioned banks.

103. Fertility Associates also changed its policies to require an incident report to be raised when any sample is not in the location recorded on the MediTEX cryo-record.

104. In addition, samples with extended ECART storage (making them over 10 years of age) are now stored in designated banks or canisters, and the presence of stored samples is verified before the clinic contacts the owner to ask if they intend to extend storage.

Recommendations

105. I acknowledge that Fertility Associates has already apologised to Mr A and Ms A at their meeting in June 2018. I consider this to be appropriate.

106. I recommend that Fertility Associates:

a) Within 12 months of the date of this report, report to HDC on any decommissioned banks within that 12-month period, and provide details of the audit documentation in relation to the decommissioning, to show that the relevant processes were followed.

b) Within six months of the date of this report, engage an expert in the field of cryogenic storage facility management to review Fertility Associates' systems and processes to identify any storage risks that are not mitigated sufficiently, and report back to HDC on the consideration given to any changes in light of this review.

c) In response to the provisional recommendations, Fertility Associates agreed to include the following wording as part of its sample storage consenting documentation:

> "Straws containing sperm, eggs or embryos may be handled while stored for various reasons, such as when retiring a bank or moving samples to a different bank location. Loss of samples during handling and moving has also been reported. There is a very small risk that handling could sometimes reduce the viability of frozen samples despite the care taken, so the clinic minimises handling and therefore does not do regular physical inventory audits of its banks. This means we would likely not know about the loss of a sample until the time of its intended use."

I recommend that within three months of the date of this report, Fertility Associates provide evidence that the above wording has been included by sending HDC an updated copy of its sample storage consenting documentation.

Follow-up actions

107. I have given careful consideration to whether Fertility Associates should be referred to the Director of Proceedings, and in particular have considered the public interest in ensuring that appropriate proceedings are taken where that public interest requires.

108. I consider the matter finely balanced. Although a rare event, this was substandard care with a devastating outcome for Mr A and Ms A, exacerbated by Fertility Associates' inability to identify exactly how or when the error occurred. In addition, I am mindful that Fertility

Associates, as the largest provider of this service in New Zealand, has some responsibility to develop and uphold the appropriate standards of care their consumers would expect. However, I also acknowledge that Fertility Associates has engaged in a restorative process and financial settlement with Mr A in efforts to redress his loss, and has made changes to its policies and processes in response to these events. While I have serious concerns about the identified failures in this case, I consider that the public interest in accountability can be met by my breach opinion, and the further recommendations I have outlined. With that in mind, a referral will not be made.

109. A copy of this report with details identifying the parties removed, except Fertility Associates Limited and the advisor on this case, will be sent to HealthCERT, and it will be advised of the name of the clinic.

110. A copy of this report with details identifying the parties removed, except Fertility Associates Limited and the advisor on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from Professor Michael Chapman (MBBS, MD, FRCOG, FRANZCOG, CREI):

"**Case of [Mr A]:**

This report provided on the request of the HDC.

In preparation of this report I have reviewed the extensive policies and procedures of Fertility Associates. I also have been provided with the results of the investigation undertaken to attempt to locate the semen samples of [Mr A].

In summary, this man had sperm frozen from a single sample in 1995 prior to treatment for cancer. There were 15 straws registered as being frozen. Over the ensuing years of storage in liquid nitrogen, these straws were allegedly transferred on a number of occasions from one canister to another. There are various reasons for the need to transfer, usually related to the upgrading of the canisters to ensure good sealing of the contents, or increase in size to deal with increased samples.

Over this time the ownership of the containers moved as clinics changed hands. On at least three occasions the audits of the contents of the containers were apparently undertaken. However it was not until 2018 that it became clear that [Mr A's] samples were not in the container as expected. The detailed review of the course of events fails to identify when the samples were lost.

Opinion

The loss of the storage samples for this man has meant that while he had hoped to have a genetically related child, this is now not possible. This assumes that he has lost all testicular function as the result of his chemotherapy.

Clearly the systems of record keeping and audit have failed. It would appear that the most recent audit on the transfer to Medifex, the loss of the samples was not detected. But this may not be the only time that the loss was missed. It cannot be determined when this occurred.

From my experience of over thirty years of sperm freezing, this is not the first occasion I have been involved in loss of samples albeit only on two previous occasions in that time. They were some years ago. They were associated with changes in the storage of the samples from one canister to another.

It was always a risk since the straws, which sit in each goblet, are light in weight and as the goblet is plunged into the liquid nitrogen, the straws can be displaced and float out, unknown to the technician. The equipment in 1995 was not fully fit for purpose at the time, being derived from veterinary experience where the loss of frozen samples was less important.

The equipment has improved since that time.

The other improvements have been quality control. Such steps as double checking by the scientists are now mandatory as can be seen in the extensive policies and procedures. Such rare events as this case are far less likely.

However I often use the aircraft industry as an example of the development of stringent checking processes which have reduced plane disasters but despite these procedures, planes still crash. No system is foolproof.

Professor Michael Chapman."

The following further advice was obtained from Professor Chapman:

"In response to your further questions, please see below.

1. Whether adequate care was taken during the retirement of the bank holding [Mr A's] sperm straws in 2015, including whether an audit should have occurred following the transfer of [Mr A's] sample to a new bank;

The samples were lost at some point, but I cannot pinpoint that time. However the loss of 15 straws would seem significantly below 'adequate care'.

At each transfer of samples from one container to another, appropriate standard of care would be to audit the contents of each goblet being transferred.

2. Whether the loss of [Mr A's] sperm sample could have been identified at an earlier date;

Had full audits been performed, the loss could have been identified sooner.

3. Whether physical bank inventories should occur, and the adequacy of auditing 'by exception';

Because of the magnitude of the job and the risks of damaging specimens in removing single straws from the liquid nitrogen, audit by exception was common practice in the past. However, as quality standards have changed over time and freezing equipment improved, today full audits would occur.

4. The adequacy of the open disclosure process following the audit which identified [Mr A's] sperm sample was likely missing;

It would seem there was a delay in communicating the issue to [Mr A]. Given that the vast majority of sperm frozen in young patients is never accessed, it was standard practice to not immediately inform the patient of the loss of samples, waiting instead until the individual sought to use the sperm. Again current practice has changed and open disclosure in a timely manner should be the norm as soon as the issue arose. However there is a tradeoff of knowing the loss occurred and the psychological impact of knowing this versus the likelihood of it never wanting to be used. Once lost there is

little to offer other than sperm from another donor should pregnancy be sought. This would be the situation whether told earlier or later.

5. Whether [Mr A's] materials should have been stored across multiple banks;

Given the rarity of the loss of samples, it was and still would not be standard practice to spread the storage of samples.

6. The adequacy of the provided policies and procedures in place at Fertility Associates;

I believe the current policies are appropriate.

7. The adequacy of the changes made by Fertility Associates following the loss of [Mr A's] sample;

As above.

8. Any other matters in this case that you consider warrant comment;

Overall the loss of 15 straws of sperm is an extremely rare event. I cannot define when it actually occurred. Such a loss was unintentional, and I suspect a rare mishandling of specimens. The event was a moderate degree of substandard care. The failure to identify the loss until the patient sought the use of the sperm is a significant failure of good practice due to what were less rigorous audit processes than are in place today.

I hope these further comments are helpful. I am happy to clarify any points, should they be required.

Professor Chapman."

Appendix B: Fertility Associates Limited policy

5844. 55 Liquid Nitrogen Bank Audit Policy (May 2013)

Title:	Liquid Nitrogen Bank Audits
Purpose:	To ensure that samples are not retained in decommissioned banks
Scope:	Laboratory staff
Responsibility:	Laboratory Team Leader
Records:	Medtech, Frozen Asset Database (FAD)
References:	Liquid nitrogen hazard plan (7754.2)

Introduction

Auditing liquid nitrogen banks is undertaken by many ART units to reduce the risk of paper and computer records nor accurately recording bank contents. However, the physical act of checking the contents of banks increase the risk of samples experiencing temperature rises during checking. Also, the average duration of storage of embryos and many sperm samples is much shorter than the practical frequency of bank checking, reducing its usefulness.

On balance, Fertility Associates has decided not to undertake bank audits except after removing the contents of a bank about to be retired to a new bank.

Process

1. A bank audit should also be conducted on the new bank immediately after the contents have been transferred from an old bank being retired, before the old bank is allowed to warm up. Ideally, no samples should be withdrawn until the audit is complete.
2. The audit process requires two people.
3. The people doing the bank audit should wear eye protection against liquid nitrogen splashes, and closed footwear. (see Liquid nitrogen hazard plan, 7754.2).
4. A printed list of the bank contents of the retired bank at the date of retiring is obtained from the Frozen Assets Database.
5. An insulated container of a suitable size is filled with enough liquid nitrogen to fully immerse the metal canister of goblets from the tank to be audited.
6. One canister at a time is moved from the new bank to the insulated canister.
7. One person will check the goblets contained in the canister. The other person records presence or absence of a goblet against the printed list, and checks the goblet colours, script on the goblet and the number of straws contained in the goblet.
8. When the checking is complete for the whole bank, any discrepancies should be fully investigated using the original paper freezing records (masks), any previous audit notes, Medtech and the patient's paper file (if necessary), until the discrepancy is reconciled. The process is complete when the electronic database and paper records are updated to record the exact location of each goblet.

Appendix C: Relevant international guidance

European Society of Human Reproduction and Embryology (ESHRE) Guidelines for Good Practice in IVF Laboratories (2008)

…

12 Cryopreservation of Gametes and Embryos

…

12.9 An annual audit of stored gametes and embryos must be carried out, cross referencing contents with storage records

European Society of Human Reproduction and Embryology (ESHRE) Revised Guidelines for Good Practice in IVF Laboratories (2015)

…

12 Cryopreservation

…

12.6 A periodic inventory of the contents of the cryobank is recommended, including cross-referencing contents with storage records.

American Society for Reproductive Medicine, *Cryostorage of reproductive tissues in the in vitro fertilization laboratory: A Committee Opinion*

Inventory of Storage Tank

Storage tank inventories are usually performed only when needed rather than on a regularly scheduled basis. Annual physical inventories are not routine since their benefit may be outweighed by the risk of inadvertent compromise of cryo-preserved samples due to the fragile nature of these samples, especially vitrified embryos and oocytes. When a full cryostorage tank inventory is needed due to suspected loss of samples or discrepancies between the cryostorage records and the samples in the tank, the inventory should be conducted by laboratory personnel trained in handling cryopreserved tissue and a witness according to each program's policies and procedures.

…

Journal of Assisted Reproduction and Genetics (2019), *Comprehensive assessment of cryogenic storage risk and quality management concerns: Best practice guidelines for ART labs*

Sample management and inventory

…

A reliable inventory is based on an accurate recording of cryostorage location for each sample cryopreserved. Regular thawing events performed in an IVF laboratory provides an excellent source of spot check verifications when organized as a QC/QA process.

Furthermore, confirmation of sample locations relative to the routine process of discarding patient consented samples is another valuable spot check inventory resource that should be integrated into a QM plan. In addition to maintaining a daily QC log of sample disposition relative to their accuracy of location, random sampling (ID verification) of a given number of samples on a regular basis (monthly, quarterly) is a reassuring QC step in a comprehensive QM plan. The latter verification procedure is less desirable to thawing/discarding procedures, as it may unnecessarily expose viable samples to brief but possible changes in temperature …