Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Loss of sperm sample highlights poor standard of record-keeping and audit systems
20HDC00586

The Deputy Health and Disability Commissioner Dr Vanessa Caldwell has found Fertility Associates breached the Code of Health and Disability Services Consumers' Rights (the Code) in providing fertility services to a male consumer.

Following chemotherapy some years prior, the man had placed a sample of sperm in storage in a facility later bought by Fertility Associates. However, the clinic was later unable to find the sperm samples during the IVF process with the man and his partner. A testicular biopsy confirmed that the man had no remaining sperm that could be used for IVF.

Fertility Associates undertook an internal investigation and found that the last time the man's sperm samples were known to be in its possession was seven years prior. After considering potential causes for the loss, Fertility Associates concluded the samples were most likely lost because staff did not follow policy and undertake an inventory check when the storage bank holding the samples was decommissioned.

After careful consideration of the evidence, Dr Caldwell concluded that due to poor record keeping there was insufficient information to make a conclusion regarding the most likely cause of the sample loss. She acknowledged that Fertility Associates' policies may have been appropriate but pinpointed shortcomings in record-keeping and audit systems that could have assisted identification of how the samples were lost.

Dr Caldwell found the presence of a policy was an insufficient basis to conclude that adequate safeguards were in place to prevent the loss of the samples. Staff needed to be aware of the policy and supported to follow it, and there needed to be adequate monitoring in place to identify gaps. Dr Caldwell noted that Fertility Associates were unable to identify 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.

Dr Caldwell found Fertility Associates breached Right 4(1) of the Code for failing to provide services with reasonable care and skill.

"I acknowledge that loss of samples is a rare and devastating risk to assisted reproductive technologies, however, I am critical that Fertility Associates lost the man's sperm samples, and that its systems were unable to provide evidence of how or when the loss occurred," she said. "Fertility Associates has a responsibility to ensure the safe storage of samples in its possession and to have robust systems in place to prevent loss occurring ".

Since the complaint, Fertility Associates has undertaken a number of actions, including:

- Apologising to the man and his partner.
- Implementing the practice of splitting patient samples between multiple locations for fertility preservation samples in certain circumstances.
- Introducing a new policy that requires all working documents relating 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 investigations into any future lost samples.
- Updating its auditing tool for retiring storage banks, and including reporting on retired banks as part of routine auditing.
- Changing its policies to require an incident report to be raised when any sample is not in the location recorded in its record.

Dr Caldwell acknowledged that Fertility Associates has already apologised to the man and his partner. She also recommended that they:

- Report to HDC on any decommissioned banks and provide details of audit documentation to show that the relevant processes were followed.
- Engage an expert in the field of cryogenic storage facility management to review its systems and processes to identify any storage risks that are not mitigated sufficiently.
- Provide evidence that its sample storage consenting documentation has been updated to inform consumers of its physical auditing processes and the possibility of sample loss.
- Store samples over 10 years of age in designated banks, and verify the presence of stored samples before the owner is asked if they intend to extend storage.

22 May 2023

Editor's notes

The full report of this case will be available on HDC's website. Names have been removed from the report to protect privacy of the individuals involved in this case.

The Commissioner will usually name providers and public hospitals found in breach of the Code, unless it would not be in the public interest, or would unfairly compromise the privacy interests of an individual provider or a consumer.

More information for the media, including HDC's naming policy and why we don't comment on complaints, can be found on our website here.

HDC promotes and protects the rights of people using health and disability services as set out in the Code of Health and Disability Services Consumers' Rights (the Code).

In 2021/22 HDC made 402 recommendations for quality improvement and providers complied with 98% of those recommendations.

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