

[In Confidence]

Office of the Minister of Health
Chair, Cabinet Legislation Committee

Approval of the Human Assisted Reproductive Technology Amendment Order 2021

Proposal

1. I seek authorisation to submit the Human Assisted Reproductive Technology Amendment Order 2021 (the Order) to the Executive Council.

Relation to Government priorities

2. This paper relates to the Government priority of *Improving the wellbeing of New Zealanders and their families*. The Order will enable a medical procedure which will improve health outcomes and reproductive options.

Policy

3. The Order will declare that the re-implantation of cryopreserved ovarian tissue, back into the woman from whom it was removed, is an established procedure. This means it can be undertaken without needing approval from an ethics committee.
4. The Order will not change the current prohibition on cryopreserved ovarian tissue being implanted into a different woman.

Background

5. The Human Assisted Reproductive Technology Act (HART) Act 2004 governs the approval status of assisted reproductive procedures in New Zealand. Under HART there are two advisory committees that determine whether certain procedures may be performed. These are the Ethics Committee for Assisted Reproductive Technology (ECART) and the Advisory Committee on Reproductive Technology (ACART).
6. Under HART, reproductive procedures can be:
 - 6.1 prohibited;
 - 6.2 subject to moratorium;

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6.3 restricted and requiring ethical approval from ECART in accordance with guidelines issued by ACART; or

6.4 permitted as established procedures, without needing approval from ECART.

7. Under section 6 of HART, procedures can become established procedures by Order in Council made on the recommendation of the Minister of Health given after technical and ethical advice and a risk assessment tendered by ACART.
8. Ovarian tissue cryopreservation and transfer is a procedure undertaken to preserve ovarian function and fertility. Currently 26 countries, including Australia and the United Kingdom, allow for re-implantation of cryopreserved ovarian tissue into the woman from whom it was removed. It is usually used to preserve fertility in cancer patients prior to treatment.
9. Currently in New Zealand, ovarian tissue can lawfully be removed and cryopreserved as an established procedure, but cannot lawfully be re-implanted as it an assisted reproductive procedure and ACART has not issued guidelines for ECART to use in considering applications. ECART is not permitted to approve applications where ACART guidelines do not exist. Until now, the re-implantation of cryopreserved ovarian tissue has not been allowed because of limited evidence about the safety of the procedure. There were concerns that cancerous cells in the ovarian tissue might be transferred back to a patient who had been treated for cancer.
10. ACART assessed the safety of the procedure and, in 2017 advised the Minister of Health that there was now sufficient evidence of the safety of re-implanting cryopreserved ovarian tissue that it should be routinely permitted in New Zealand as an established procedure.
11. On 28 June 2017 the Cabinet Social Policy Committee [SOC-17-MIN-0072 refers] agreed that the re-implantation of cryopreserved ovarian tissue into the woman from whom it was removed should be declared an established procedure under section 6 of the Human Assisted Reproductive Technology Act 2004.
12. The Human Assisted Reproductive Technology Amendment Order 2021 will declare that the re-implantation of cryopreserved ovarian tissue, back into the woman from whom it was removed, is an established procedure. This procedure will therefore not require ECART approval.

Analysis

13. The procedure of Ovarian tissue cryopreservation and transfer has now been assessed as safe by ACART, following the process for an established procedure under HART. The procedure also has a variety of benefits to health.

Benefits of Ovarian tissue cryopreservation and transfer as an established procedure

14. Women and girls who undergo some cancer treatments, such as chemotherapy or radiotherapy, may experience loss of ovarian function and fertility. It is possible for ovarian tissue to be removed and cryopreserved, then later thawed and re-implanted into the woman from whom it was removed to restore fertility.
15. Ovarian tissue cryopreservation is a faster fertility preservation option than harvesting and freezing eggs (oocyte cryopreservation), meaning there is no delay in cancer treatment. Ovarian tissue cryopreservation is also the only option to preserve fertility and ovarian function in pre-pubescent girls.
16. In addition to restoring fertility, ovarian function and hormonal activity can be restored by re-implantation of ovarian tissue. This can be beneficial to other physiological processes such as:
 - 16.1 preventing early onset of osteoporosis and cardiovascular disease in young women;
 - 16.2 enabling pre-pubescent girls to undergo puberty at the appropriate age;
 - 16.3 preventing early onset menopause;
 - 16.4 reducing hormone therapies following types of chemotherapy.
17. As well as the use of ovarian tissue cryopreservation for cancer patients, this procedure has indications for other issues such as the treatment of other reproductive disorders such as premature ovarian failure, a condition where women go through early onset menopause, and as an elective alternative to oocyte cryopreservation. Fertility preservation treatments can also help transgender men who wish to preserve their fertility and for non binary people.

Timing and 28-day Rule

18. It is proposed that all amendments to the Order come into force on 17 May 2021. This requires the amendments to be gazetted on or before 19 April 2021 with Executive Council approval on or before 12 April 2021.
19. No waiver of the 28-day rule is sought, the Order will comply with the 28-day rule.

Compliance

20. The Human Assisted Reproductive Technology Amendment Order 2021 complies with each of the following:
 - 20.1 the principles of the Treaty of Waitangi;
 - 20.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;

- 20.3 the principles and guidelines set out in the Privacy Act 1993;
- 20.4 relevant international standards and obligations; and
- 20.5 the Legislation Design and Advisory Committee's *LAC Guidelines on the Process and Content of Legislation* (2014 edition).

- 21. Section 6 of the Human Assisted Reproductive Technology Act 2004 requires that established procedures are made by Order in Council on the recommendation of the Minister of Health, given after advice tendered by ACART. In tendering advice to the Minister, ACART must provide the Minister with a report that sets out certain information and analysis.
- 22. These requirements have been met and I now seek agreement for re-implantation of cryopreserved ovarian tissue, back into the woman from whom it was removed, be made an established procedure through the Human Assisted Reproductive Technology Amendment Order 2021.

Regulations Review Committee

- 23. There are no grounds for the Regulations Review Committee to draw the regulations to the attention of the House of Representatives under Standing Order 319.

Certification by Parliamentary Counsel

- 24. The draft regulations are certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

Impact analysis

- 25. An impact analysis is not required as the proposal has no or only minor impacts on businesses, individuals, or not for profit entities. In addition, an impact analysis is not required because the required analysis has been previously undertaken by ACART. Treasury has granted an impact analysis exemption on these grounds.

Consultation

- 26. The Ministry of Justice and the Department of the Prime Minister and Cabinet have been consulted.
- 27. ACART has undertaken the necessary public consultation to advise the Ministry of Health that re-implantation of cryopreserved ovarian tissue into the same woman should be an established procedure. Overall, submitters (including the fertility sector) were supportive of the proposed amendments.

Communications

- 28. The Ministry of Health will communicate these changes directly to stakeholders. The Ministry of Health website will also be updated.

Proactive Release

29. This paper will be proactively released with any necessary redaction within 30 business days of a final decision by the Executive Council.

Recommendations

The Minister of Health recommends that the Cabinet Legislation Committee:

1. **note** that on 28 June 2017 the Cabinet Social Policy Committee agreed that the re-implantation of cryopreserved ovarian tissue into the woman from whom it was removed should be declared an established procedure under section 6 of the Human Assisted Reproductive Technology Act 2004 [SOC-17-MIN-0072 refers];
2. **note** that the Human Assisted Reproductive Technology Order 2021 will give effect to the decision referred to in recommendation one, above;
3. **note** that Section 6 of the Human Assisted Reproductive Technology Act 2004 requires that established procedures are made on the recommendation of the Minister given after advice tendered by the Advisory Committee on Assisted Reproductive Technology;
4. **note** the advice of the Minister of Health that this requirement has been met;
5. **note** that the Human Assisted Reproductive Technology Amendment Order 2021 will come into force on 17 May 2021;
6. **authorise** the submission of the Human Assisted Reproductive Technology Amendment Order 2021 to the Executive Council.
7. **authorise** a commencement date of 17 May 2021 for the Order.

Authorised for lodgement

Hon Andrew Little

Minister of Health