

Feedback form

Please provide your contact details below.

Name:	Barbara Holland & Barbara Robson
If this feedback is on behalf of an organisation, please name the organisation:	Federation of Women's Health Councils Aotearoa – New Zealand
Please provide a brief description of the organisation if applicable:	The Federation of Women's Health Councils Aotearoa – New Zealand (FWHC) is a national umbrella organisation of women's health councils, women's health groups, and individual women throughout New Zealand. The Federation has a commitment to providing a powerful voice for women consumers of health and disability services, and to act as a public good advocate in matters that affect their well-being interests and those of their family/whanau.
Address/email:	fedwhc@xtra.co.nz
Interest in this topic (e.g. user of fertility services, health professional, researcher, member of public):	Public interest

Please refer to page v for information about:

- Publication of feedback on ACART's website
- Official Information Act requests – possible release of you feedback
- Official Information Act requests – possible release of you name and contact details

We will acknowledge all feedback.

- ☐ I **request** that my feedback be withheld in full or part from publication on ACART's website. (If you wish a part to be withheld, please clearly indicate which part.)
- ☐ I **do not** give permission for my name to be published on ACART's website.
- ☐ I **do not** give permission for my contact details to be published on ACART's website.

If you consider that your feedback, or your name and contact details (if you are submitting on behalf of an organisation), should be withheld under the Act, please state the reasons here:

FWHC agrees to our submission being publicly disclosed.

Questions for response

Question 1

Refer to sections 3 and 4.

- (a) Do you agree with ACART's assessment of the known risks and benefits to health associated with the use of cryopreserved ovarian tissue to restore ovarian function?

Yes ☒ No ☐

Please give reasons for your views.

FWHC agrees that NZ women should have the choice (with fully informed consent) to seek to have her own cryopreserved ovarian tissues reintroduced to her body and have this procedure undertaken within NZ (presuming her current health status indicates this is a viable option).

FWHC does recognise these are still early days in terms of being able to assess risks of future outcomes and women must be clearly told this. We simply don't know yet whether there will be associated risks for any epigenetic changes arising from interference of the ovarian tissues arising from removal/cryopreservation or their reintroduction to the mother or the potential transgenerational impact on any subsequent offspring.

- (b) Are there any risks and/or benefits associated with the use of cryopreserved ovarian tissue to restore ovarian function that ACART has not identified or assessed?

Yes ☐ No ☒

If yes, please list below.

FWHC notes this is still experimental treatment for which we have minimal longer term data.

We must be careful not to overhype the picture that this new workaround for a disease treatment pathway option does not imply any guarantees that future desired outcomes will follow, and most importantly will not produce assurance against the introduction of additional / currently unknown future risks. Most certainly however it gives young people, especially, a prospect of potentially desirable future outcomes and we agree that women should not have to travel overseas to access this treatment procedure.

There will always be a risk that the woman's expectations exceed the supporting evidence of a successful outcome in terms of restoring endocrine function long term and/or restoring her fertility such that she is able to produce offspring (should she wish for that outcome).

Question 2

Refer to section 4.

- (a) Do you agree with ACART's conclusion that the risks associated with the use of cryopreserved ovarian tissue to restore ovarian function falls within a level that is acceptable in New Zealand?

Yes ☐ No ☒

Please give reasons for your views.

In general we give a qualified tick to agreeing re-implantation of cryopreserved ovarian tissue becomes an acceptable procedure in NZ for most cases.

BUT

FWHC especially has grave concerns at this point in time about allowing use of cryopreserved ovarian tissue in women who have had blood borne diseases such as leukaemia, or lymphatic cancers, even if the woman is deemed to be in remission. It is not just that reintroduction of the tissue might cause reintroduction of the disease of concern (lurking/hidden cancer cells) but the messaging within the cell tissue that has caused the cancer tumour to arise in the first place that remains worrisome.

Allowing for cryopreservation of the ovarian tissue to be stored does give these women a potential future option for transplantation should the evidence support this consideration, but currently we do not believe the risk/benefit ratio indicates it is safe to do so. We note that Denmark does not allow for this to happen for women with leukaemia given the paucity of international evidence in this particular regard. We believe NZ should also follow this precautionary precedent.

- (b) Please note any other comments below.

Question 3

Refer to section 4.

- (a) Has ACART identified all the relevant areas to monitor the use of cryopreserved ovarian tissue to restore ovarian function?

Yes ☐ No ☒

Please give reasons for your views.

We definitely support a NZ database for ongoing monitoring of outcomes, and including that of any offspring born subsequent to reinstatement of a woman's cryopreserved tissues.

There would need to be some additional controls around allowing for inclusion of NZ women's data in an international database. We presume the numbers of NZ women for whom this procedure is a desirable option is small overall and they would all benefit from the wider learning derived from a larger evidence-based pool. However, NZ women must be given the option about whether their data is sent overseas or not, and their consent for this separately recorded. Further, they should not be denied access to treatment on the basis of any refusal to have their data outcomes shared internationally. Where there are children conceived subsequent to the re-implantation of ovarian tissue treatment data sharing affects more than just the mother who has undergone the treatment – it affects the children as well.

How is the situation being managed at present where NZ women undergo the re-implantation of cryopreserved ovarian tissue procedure in other countries, i.e. where is their related data held and what controls do they exercise over who it is shared with? Current information flows in this regard are not clear to FWHC.

- (b) Are there any other areas ACART should monitor?

Yes ☒ No ☐

Please give reasons for your views.

Stage and site of cancer and any associated treatments. This may well indicate a cut-off point for whether reinstatement for cryopreserved tissue is a recommended intervention for certain types of cases in future.

Question 4

Refer to section 5.

- (a) Has ACART identified all the ethical issues relevant to the use of cryopreserved ovarian tissue to restore ovarian function?

Yes ☒ No ☐

Please give reasons for your views.

- (b) Do you agree with ACART's ethical analysis that there are no significant ethical issues associated with the use of cryopreserved ovarian tissue to restore ovarian function?

Yes ☐ No ☒

Please give reasons for your views.

FWHC believes there is significant potential for expanded experimental 'treatment creep' should NZ start allowing for cryopreservation of young person's tissue to be used as a backstop option against conditions such as osteoporosis. We do not support this potential future use option.

Question 5

Refer to section 6.

- (a) Do you agree that the use of cryopreserved ovarian tissue to restore ovarian function should become an established procedure?

Yes ☒ No ☐

Please give reasons for your views.

FWHC notes the conversation around the intended purpose being an intervention with the potential for restoring ovarian function, especially subsequent to iatrogenic disruption of this function.

There would be a significant benefit from (potentially) restoring endocrine function for the woman's general physical wellbeing; restoring fertility potential is another layer of benefit. Of course, this all depends on the woman's age and prior family stage, as well as her disease stage at the time of considering cryopreservation in the first place, let alone considering whether this excised tissue should be reused following her disease treatment and (hopeful) recovery. Only the woman concerned will be able to answer that QALY matter.

- (b) Please note any other comments below.

Question 6

Refer to section 6.

Do you agree with ACART's position that the scope for the use of cryopreserved ovarian tissue to restore ovarian function be limited to the woman from whom the tissue was excised, for her own treatment?

Yes ☒ No ☐

Please give reasons for your views.

FWHC is adamantly opposed to any potential for women to embark on a journey that enables them to have their ovarian tissue preserved for later use just because there might be a future need/benefit arising, eg where a woman delays childbearing for social/economic reasons; or to counter increased risks to her future hormonal or fertility wellbeing through other personally adopted behaviours such as smoking uptake or risky alcohol consumption (both known carcinogenic factors).

Question 7

Refer to section 6.

Do you have any further comments to share with ACART?

FWHC would like to know about the following matters:

- a) If/when re-implantation of cryopreserved ovarian tissue becomes standard practice within NZ what criteria will be used / how will limits be determined for who will be eligible to undergo this procedure?
- b) Will the re-implantation procedure be publicly funded?
- c) Who will do the outcomes monitoring?
- d) Will the private sector also be able to treat women who seek to have their cryopreserved tissues grafted back in and are willing to pay for it privately, and will these women have the same rules of limitation applied as those who come through the publicly funded pathway?