

Engagement Report

Topic details

Title of service specification policy or Fertility policy statement: Allogeneic Ovarian

Fertility preservation for service users with ovarian tissue who are at high/very high risk

of infertility and cannot store mature eggs.

Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm.

Fertility and endocrine restoration using

cryopreserved ovarian tissue.

Programme of Care: Women and Children

Clinical Reference Group: Specialised Women's

URN: 1867

1. Summary

This report summarises the feedback NHS England received from stakeholder engagement about the above service specifications.

2. Background

The three service specifications describe an integrated single fertility preservation programme for service users at high risk/very high risk of infertility and endocrine failure. They describe how the overall programme will be delivered through an integrated hub and spoke model, through a hospital based clinical service and a tissue establishment that can cryopreserve ovarian and testicular tissue. The service specifications also describe the service user pathway for fertility and endocrine restoration using cryopreserved ovarian tissue.

The service is specifically for service users who are at high or very high risk of reproductive and endocrine failure and cannot store mature eggs or sperm. Access to the service is based on a risk of infertility and not on any specific patient group or diagnoses.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The three service specifications were sent to stakeholder testing on the 31 October 2022 which lasted until the 14 December 2022.

Respondents were asked the following consultation questions:

- 1 Are the inclusion eligibility criteria in the service specifications clear and concise?
- 2 Are the exclusion criteria clear in the service specifications clear and concise?
- 3 Is the service aim clear and concise?
- 4 Is the service description clear and concise?
- 5 Is the model of service delivery clear and concise?
- 6 Are the patient pathways clear?
- 7 The service specifications make reference to consent, are the statements clear and concise?
- 8 Do you support the Equality and Health Inequalities Impact Assessment?
- 9 Please declare any conflict of interests relating to this document or service area.

4. Engagement Results

Eight responses were received:

- 3 Group responses
- 5 individual responses

All of the responses received were supportive of the three service specifications, there was support for the equality and health inequalities impact assessment and there were no declarations of any conflict of interests.

Confirmation has been received from the 13Q assessment process that no further public consultation is required.

5. How has feedback been considered?

The comments received were considered by the Service Specification Working Group at two separate meetings (31 January 2023 and 7 March 2023) to enable full consideration of the comments received and as part of the process to support a decision on whether any changes to the service specifications should be made.

The following areas were raised during engagement:

Clarification required about: -

- Age thresholds
- Risk threshold criteria
- Tumour cell contamination
- Guidance on surgical techniques
- HTE licence and ISO quality requirements
- Funding and workload modelling
- The role of the proposed Expert Clinical Panel and funding to support it
- The number of Hubs and Spokes required to deliver the service.
- The pathways listed in the specifications
- Follow up data clarification
- Whether there is a need to include male fertility and andrological urologist in the model
- Whether the model would create a duplication of roles, given the fact that HTE licence requirements will have to be in place and are specific in terms of licence requirements
- Tissue storage length.
- Whether the titles of the draft service specifications are describing the service adequately.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

A number of changes have been made to the service specification to improve clarity and content/specification requirements. The changes are listed in Appendix A alongside comments received.

The 13Q assessment has been completed following stakeholder testing. Confirmation has been received that no further consultation is required.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No