Engagement report

Topic details

Title of policy or policy statement: Pre-implantation genetic testing of embryos at significant risk of serious genetic conditions

Programme of Care: Women and Children's

Clinical Reference Group: Specialised Women's

URN: 2122

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

People in the general population who have, or are carriers for, a serious genetic condition, may want to avoid passing the condition on to their children.

For people in this position, the technique pre-implantation genetic testing (PGT) in conjunction with in vitro fertilisation (IVF) can be an option. IVF involves obtaining eggs and a sperm sample and combining them in a laboratory and allowing the embryo to develop. IVF is usually used to help people with fertility problems have a baby. PGT involves checking these IVF embryos to see if they have inherited the genetic condition in question. Only those that are found not to have inherited the genetic condition are transferred into the female. As the embryos need to be tested in a laboratory, a person undergoing PGT needs to use IVF, even if they do not have any fertility problems (Royal College of Obstetricians & Gynaecologists, 2022).

The Human Fertilisation and Embryology Authority (HFEA) regulates fertility treatment and research using human embryos. Only genetic conditions that are approved by the HFEA can be tested for. Currently, the HFEA has approved over 600 genetic conditions for which PGT may be performed in the UK.

The HFEA must ensure PGT is carried out only where there is a 'significant risk' that a child born with the condition in question would have, or could develop, a 'serious' medical condition (HFEA, 2022). The seriousness of a condition is assessed on: age of onset; if the condition and/or symptoms are life-limiting or reduce life expectancy; quality of life; and, availability, efficacy and invasiveness of any treatment.

The policy proposition is proposed as an update to the current NHS England, routinely commissioned, clinical commission policy *Pre-implantation Genetic Diagnosis E01/P/a*. The updated policy proposition aligns with the updated NICE guidelines on eligibility for IVF: *NICE [CG156] Fertility Problems: assessment and treatment*, in particular with regards to eligibility criteria for age and body mass index (BMI). The updated policy proposition increases the upper age limit for females undergoing PGT to under 43 years

of age at the time of treatment. In place of a BMI threshold the updated policy proposition requires a comprehensive assessment of fertility. The updated policy proposition has also removed having an unaffected child from the current relationship as one of the exclusion criteria. The updated policy proposition would widen access to PGT and is expected to have a positive impact on health equity.

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 policy proposition was sent for stakeholder testing from 24th March 2023 to 7th April 2023. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following consultation questions:

- The policy proposition proposes increasing the upper age limit for females receiving PGT treatment to under 43 years of age at the time of treatment from the current criteria of under 40 years of age at the time of treatment. Do you support this increase in age limit?
- This policy proposition proposes removing the current limits on treatment relating to Body Mass Index (BMI) which prevents women with a BMI over 30 or under 19 from accessing treatment. It proposes replacing BMI limits with a comprehensive fertility assessment by the PGT fertility team prior to starting PGT treatment. Fertility assessment involves ovarian reserve testing and semen analysis. Do you support this policy proposal to remove BMI limits?
- This policy proposition proposes that couples who already have a child unaffected by a genetic condition but meet the rest of the criteria will now be offered PGT treatment, by removing the current exclusion. Do you support the policy proposal to offer the option of PGT to these parents?
- Do you believe that there will be any positive or negative impacts on patient care as a result of implementing this policy? If so, what are they?
- Have you read the full evidence review?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give publication details.
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Assessment present a true reflection of the patient and carers lived experience of the condition?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.
- Do you have any potential conflict of interest relating to this document or service area?

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

Engagement Results

17 responses were received:

- 8 organisations
- 9 individuals

3. Are you replying on behalf of an organisation?

More Details Insights

Yes	8
No	9



6. I am responding as an individual

More Details

Patient	0
Carer / family member of a pati...	0
Clinician	5
Academic	2
Other	1



All respondents supported the increase in age limit:

7. The policy proposes increasing the upper age limit for females receiving PGT treatment to **under 43 years of age at the time of treatment** from the current criteria of under 40 years of age at the time of treatment.

   Do you support this increase in the age limit?

More Details Insights

Yes	16
No	0
Other	0



14 of the respondents (82%) supported the proposed removal of BMI limits:

9. This policy proposes removing the current limits on treatment relating to Body Mass Index (BMI) which prevents women with a BMI over 30 or under 19 from accessing treatment. It proposes replacing BMI limits with a **comprehensive fertility assessment** by the PGT fertility team prior to starting PGT treatment. Fertility assessment involves ovarian reserve testing and semen analysis.

   Do you support this policy proposal to remove BMI limits?

More Details Insights

Yes	14
No	3
Other	0



16 of the respondents (94%) supported the proposal to remove the current exclusion criteria for couples who already have a child unaffected by a genetic condition but who meet the rest of the eligibility criteria:

11. This policy proposes that couples who already have a child unaffected by a genetic condition but meet the rest of the criteria will **now be offered the option of PGT treatment**, by removing the current exclusion.

Do you support the policy proposal to offer the option of PGT to these parents?

More Details Insights

Yes	16
No	1
Other	0



In line with the 13Q assessment it was deemed that further public consultation was not required.

4. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Women and Children's PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
The general consensus was that there was enough evidence to support this policy proposition. All respondents, with the exception of one organisation, had read the full evidence review. One individual and two organisations responded to the question regarding any additional evidence that should have been considered in the evidence review. One individual cited a percentage related to the misdiagnosis. This was not referenced. One organisation commented 'size of family' only, with no further clarifying information or references. A further organisation commented saying that the evidence review is 'comprehensive and made the best use of published studies, which are of variable quality.'	All comments were noted. The response to the comments received regarding the evidence was that the policy proposition is based on the published evidence returned in the independent evidence review. No changes were made to the policy proposition or supporting documents as a result of these comments.
Patient Impact Assessment (PIA)	

With the exception of one organisation, all respondents felt that the PIA presented a true reflection of the patient and carers lived experience of the condition. One organisation commented 'could consider affect on existing conditions'. Another individual commented that due to the 600 conditions currently licensed for PGD, the PIA does not present a true reflection of each of them individually.	All comments were noted. The PIA has been completed by the patient public voice (PPV) representatives on the policy working group. It is intended to focus on the collective impact of the intervention (PGT) on more than 600 conditions which are currently approved for PGT by the HFEA. The PIA is constrained by a word limit.
EHIA (Transport Costs)	
All respondents supported the EHIA with the exception of one respondent who commented that they had not reviewed it. Key themes raised by stakeholders in this document related to the impact of potential travel and accommodation costs incurred as a result of travelling to one of the 5 commissioned PGT centres.	These comments were noted. The EHIA acknowledges that people living in deprived areas, or those living in remote, rural and island locations may be impacted due to limited ability to travel to services. It is the responsibility of the service provides to ensure processes are in place to ensure equitable access to, and continued engagement with, services.
Eligibility criteria (number of treatment cycles according to age)	
Three respondents provided comments on the age limit in relation to number of treatment cycles permitted at a given age. This mainly related to wording in the policy proposition and the need to provide further clarity in this area. It was acknowledged by all respondents that increasing the upper age limit was favourable and would improve equity of access to PGT.	These comments were considered by the PWG and changes were made to the wording of the policy proposition (on p.5) as detailed in the table below.
Eligibility criteria (BMI)	
Four respondents provided comments on the removal of BMI limits from the eligibility criteria. One respondent commented that the removal of BMI limits would have a negative impact as they felt that retention of BMI was a level of positive lifestyle change. No supporting evidence was given. One organisation commented that leaving individual clinicians to determine clinical risk for individual patients would	These comments were considered by the PWG who were clear that BMI on its own should not be used as a surrogate for fertility and/or clinical risk. The policy proposition removes BMI as part of the eligibility criteria and instead replaces this with a comprehensive assessment of fertility. This is based on the published, peer-reviewed evidence returned in the independent evidence review and aligns with the updated NICE guidelines *[CG156]: Fertility problems: assessment and treatment.*

lead to inequity of access and risk patients being unhappy. Two respondents commented on the need to retain an upper limit on BMI due to associated clinical risks.	This is expected to increase equity of access. An amendment was made to the footnotes accompanying the patient pathway in the policy proposition to make it clear that the medical consultation will include an individualised assessment of the clinical risks of undergoing PGT treatment. The wording is detailed in the table below.
Eligibility criteria (removal of 'unaffected child' from exclusion criteria)	
One respondent commented that they supported the removal of having an unaffected child from the exclusion criteria. However, the respondent wanted further clarification on whether an untested child counts as unaffected.	This commented was noted. Having an unaffected/untested child is no longer mentioned in the eligibility criteria and is therefore not applicable to include in the policy proposition.
Transfer of embryos and ovarian reserve	
One organisation commented on the number of embryos transferred per cycle, and also the potential adoption of criteria for reduced ovarian reserve.	This was noted by the PWG but it was felt that no changes to the policy proposition were required as a result of these comments.
Funding Mechanisms and Data Collection	
Two respondents commented on funding and data collection as detailed in the policy. Comments relating to data collection focused on timing and utilisation of data collection. The comment related to funding mechanisms related to review of the current tariff.	These comments were noted. The data collection requirements and funding are referenced in the policy proposition. Following review with the PWG, no changes to these sections are required as a result of this comments.

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

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

Policy Proposition	Detail of Change	Page Number
Clarification on wording for number of cycles by age.	Individual/s who have previously self-funded PGT will be entitled to NHS treatment according to the following criteria. Where the female is aged less than 40 years and meets the inclusion criteria, they will be entitled	5

	to up to three cycles of PGT. Where the female is aged 40-42 years and meets the inclusion criteria, they will be entitled to one cycle of PGT if there has been a discussion of the additional implications and risks of PGT and pregnancy at this age. Any suitable unaffected frozen embryos from self-funded PGT must be used before undergoing an NHS funded PGT cycle. Where individual/s have previously self-funded an IVF cycle without PGT, any suitable frozen eggs or embryos can be used in an NHS funded PGT cycle. This will **not** include a new round of egg collection and will count as 1 cycle.	
Clarification to patient pathway via insertion of new footnote on 'comprehensive fertility assessment'	'The medical consultation includes an assessment of the clinical risks of undergoing PGT treatment for the individual patient; the level of risk may be such that a patient is assessed as not medically fit for work-up'.	6

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

No.