NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE guidelines

Equality and health inequalities assessment (EHIA) template

Fertility problems (update)

The considerations and potential impact on equality and health inequalities have been considered throughout the guidance development, maintenance and update process according to the principles of the NICE equality policy and those outlined in Developing NICE guidelines: the manual.

This EHIA relates to:

Fertility problems: assessment and treatment

Appendix [X]: equality and health inequalities assessment (EHIA)

NICE guideline NGXXX on fertility problems

STAGE 1. Surveillance review

Not done for this guideline update.

STAGE 2. Informing the scope

See Equality Impact Assessment (EIA1) from August 2022 on the guideline website.

STAGE 3. Finalising the scope

See Equality Impact Assessment 2 (EIA2) from November 2022 on the guideline website.

STAGE 4. Development of guideline or topic area for update

Fertility problems (update)

Date of completion: 11.04.2025

Focus of guideline or update: assessment and treatment of health-related fertility problems

4.1 From the evidence syntheses and the committee's considerations thereof, what were the main equality and health inequalities issues identified? Were any **further** potential issues identified (in addition to those identified during the scoping process) or any gaps in the evidence for any particular group?
1) Protected characteristics outlined in the Equality Act 2010 *Age* The committee agreed that female/maternal age is the main predictive factor for fertility outcomes. (See recommendations 1.2.3 and 1.3.6 in the draft guideline.) In evidence review J, which looked at clinical prediction models on achieving live birth, age was included as a key predictive factor. Age was a particularly relevant variable in the economic analysis based on the prediction models that looked at the cost-effectiveness of the number of IVF cycles to be offered in the NHS. Based on the cost-effectiveness analysis, the committee agreed that IVF is a cost-effective treatment to people under 42 years but not for those 42 or over. Furthermore, based on the cost-effectiveness analysis, the committee agreed that people aged 40 to 41 years should be

offered 1 full cycle of IVF whereas people under 40 could be offered more IVF cycles. (See section 1.9 in the draft guideline.) Committee acknowledged that this means that people may be excluded from IVF treatment or receive fewer cycles of IVF treatment based on their age. However, the committee thinks there is sufficiently robust cost-effectiveness evidence to justify this decision to ensure public funds are used appropriately, in a manner that is reasonable and proportionate to the scale of the benefit. (See rationale and impact section for section 1.9 in the draft guideline and evidence review J for further details.)

Age was also an important consideration for the evidence review on fertility preservation (evidence review R) because sperm, oocyte or embryo preservation is only possible for people of reproductive age. The evidence review also looked for evidence on ovarian tissue and testicular tissue preservation, relevant particularly for pre-pubertal people needing fertility preservation for medical indications (for example before cancer treatment). Some evidence was identified on ovarian tissue preservation but evidence on testicular tissue preservation was very limited. The recommendations made by the committee are not restricted by age (see section 1.14 in the draft guideline).

Based on the evidence review protocols agreed with the committee, the analysis was done according to age in evidence reviews E, G, I, V, W and Y if such data was available because the committee anticipated age might influence the outcomes. However, in the end, age did not play an important role in the results and did not influence recommendations based on these reviews. In all other evidence reviews (apart from evidence review J covered earlier), subgroup analyses according to age were only planned and performed when such data was available, if serious heterogeneity (inconsistency between the studies) was observed in the meta-analyses because it was thought that age of the study populations may influence the outcomes. However, where this was done, age did not explain the heterogeneity and did not influence recommendations.

Disability
Disability was discussed particularly in relation to people who are not able to have vaginal intercourse to conceive due to a clinically diagnosed physical disability or psychosexual problem. This population was not specified in any evidence reviews in this update.

Gender reassignment
Gender reassignment was particularly considered in relation to fertility preservation (evidence review R), because some treatments for gender dysmorphia or as part of gender transition process can impact fertility. Some evidence specific to trans people was identified in evidence review R. In general, in line with the guideline scope, the guideline is only applicable to anyone with a health-related fertility problem (as defined in the scope), regardless of their gender identity, or anyone who may require interventions to

preserve fertility because of high risk of fertility problems due to clinical conditions or medical or surgical interventions.

Pregnancy and maternity
N/A

Race
The committee discussed the issue that donated sperm or oocytes from people from ethnic minorities are less available. However, this was not directly relevant to any evidence reviews conducted for this update.

Religion or belief
The committee discussed that some people may object to IVF because of reasons related to religion or belief. This was particularly relevant in discussions related to evidence review G on surgery for tubal disease, evidence review I on tubal catheterisation, and evidence review K on assisted reproduction techniques.

Sex
Fertility problems affect all sexes. Throughout the development of the guideline, any discussion of fertility problems and assisted reproduction techniques always included consideration for both female and male factors.
It should be noted that by virtue of how human reproduction works, sperm and egg are needed to conceive and a uterus is needed to carry the embryo/fetus.

Sexual orientation
For same-sex female couples to conceive will mean using either artificial insemination (including intrauterine insemination, IUI) or in vitro fertilisation (IVF) with donor sperm. Same-sex male couples may involve a surrogate, using either IVF (with a donated egg or the surrogate's egg) or artificial insemination including IUI (if using surrogate's egg), to conceive. Currently people in same-sex relationships using ART (including IUI and IVF) to conceive are often expected to self-fund these. While the majority of opposite-sex couples conceive through unprotected vaginal sexual intercourse, some also use artificial insemination or IVF to conceive for various reasons, particularly when they have health-related fertility problems.

There has been some confusion over the 2013 NICE guideline CG156 on how it applies to people in same-sex relationships. The 2013 guideline scope was limited to people who have a possible pathological problem (physical or psychological) to explain their infertility and gave special consideration for people in same sex relationships who have unexplained infertility after donor insemination. However, people in same-sex relationships without any mention of a 'pathological problem' or 'unexplained infertility after donor insemination' were included in a recommendation 1.9.1.1 in the 2013

guideline CG156: “Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse:

- people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm
- people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
- people in same-sex relationships. [new 2013]”

This meant that there was some confusion and inconsistency in interpretation of the NICE recommendations for same-sex couples regardless of their fertility.

In terms of same-sex male couples, CG156 Full guideline document from 2013 states on page 77: “Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy using the sperm of one partner, the latter being the usual way that male couples will be able to have a baby in which one of them will be a genetic parent. The Scope specified that surrogacy was not to be covered in this guideline. However, when a pregnancy does not occur through surrogacy after an appropriate period of time (equivalent to the 12 months with vaginal intercourse or 6 cycles of AI for other people) there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment.”

The updated guideline, as defined in the 2022 guideline scope, specifically covers health-related fertility problems. The 2022 guideline scope on page 4 defines people with health-related fertility problems as “those who have a known health-related impediment to fertility, or those who do not achieve a pregnancy:

- after 12 months of regular unprotected sexual intercourse or
- after 6 cycles of artificial insemination.”

So people without a health-related fertility problem, as defined in the scope, are not within the remit of the guideline. However, anyone with a health-related fertility problem, as defined in the scope, is, regardless of their sexual orientation and whether or not they are using a surrogate. For same sex couples, this means that they would be within the remit of the guideline if they have:

- a previously known health-related impediment to fertility
- a health-related impediment to fertility of which they become aware of before or during attempting to conceive through assisted reproductive techniques
- not conceived after 6 cycles of artificial insemination.

2) *Socioeconomic deprivation (for example, variation by area deprivation such as Index of Multiple Deprivation, National Statistics Socio-economic Classification, employment status, income)*

The committee discussed that people without a known health-related fertility problem who are using artificial insemination to conceive are currently often expected to self-fund intrauterine insemination. This can exclude people who cannot afford it and/or lead to more informal methods of artificial insemination being used. It should be noted that, according to the guideline scope, this guideline only covers health-related fertility problems. Therefore, people without health-related fertility problems are not within the remit of the guideline. It should also be noted that, if people using artificial insemination to conceive have not conceived after 6 cycles of artificial insemination, they would be considered, according to the scope, to have a health-related fertility problem and would therefore be within the remit of this guideline.

3) *Geographical area variation (for example, geographical differences in epidemiology or service provision- urban/rural, coastal, north/south)*

The decisions about provision and funding of fertility treatments are made locally by integrated care boards. The committee were aware of the variation in the ability to access to NHS-provided fertility treatments, particularly IVF, across different areas in England and in the UK as a whole. They discussed that in many areas NICE guideline recommendations are not followed and additional, stricter eligibility criteria are in place.

The committee acknowledged that there may be geographical variation in access to tubal surgery because it is only recommended to be done in centres with appropriate expertise. (See evidence review G.) The committee also acknowledged that there may be geographical variation in access to microscopic subinguinal surgical treatment for clinically detected varicocele because the procedure requires specialist expertise. (See evidence review X.)

4) *Inclusion health and vulnerable groups (for example, vulnerable migrants, people experiencing homelessness, people in contact with the criminal justice system, sex workers, Gypsy, Roma and Traveller communities, young people leaving care and victims of trafficking)*

These groups were not specified in evidence review protocols or discussed by the committee.

4.2 How have the committee's considerations of equality and health inequalities issues identified in EIA1, EIA2 and 4.1 been reflected in the guideline or update and any draft recommendations?

Overall, the guideline has been edited according to the current NICE style guide so that inclusive language is used.

Age

Recommendations on fertility preservation for medical indications (section 1.14) do not restrict according to age and specifically mention adolescents in recommendations 1.14.4 and 1.14.5. Recommendation 1.14.6 mentions pre-pubescent people and research recommendation 3 is specifically on pre- and peri-pubescent people. This is explained in the associated rationale section and further information is available in evidence review R.

Recommendations on access criteria for IVF (section 1.9) includes age as an access criterion for NHS-provided IVF, see recommendations 1.9.3, 1.9.4, 1.9.5 and 1.9.7. This was already the case in 2013 guideline CG156 where IVF was offered to people up 42 years of age. However, based on new cost-effectiveness analysis, the updated guideline advises that the upper age limit is restricted further so that people up to 41 years of age are eligible for IVF. Furthermore, the number of IVF cycles recommended depends on age (this was also the case in the 2013 guideline CG156), where people under 40 years may be offered more cycles than people who are 40 or 41 years. This is also based on the new cost-effectiveness analysis.

The committee agreed that the differential access to IVF treatment by age is justifiable based on the cost-effectiveness analysis which showed that overall IVF is not cost effective for those aged 42 or above. In rare scenarios where 1 cycle of IVF showed to be border-line cost-effective for 42-year-olds, limitations in the data, likely overestimation of IVF effectiveness due to assumptions made, or other factors, led to the committee to conclude that IVF is not a cost-effective treatment for people aged 42. Similarly, the committee agreed that the differing number of IVF cycles offered by age is justifiable based on the cost-effectiveness evidence. Across the different scenarios analysed, up to 6 cycles of IVF was found to be cost effective for under 40-year-olds, whereas for those 40 and over, the number of IVF cycles deemed cost effective was much lower, if at all. These are explained in the associated rationale section for section 1.9 and much more detail about the cost-effectiveness analysis, its findings and the committee's discussion are available in evidence review J.

Disability

Recommendations on unstimulated IUI (section 1.7) include populations who are not able to have vaginal intercourse to conceive due to a clinically diagnosed physical disability or psychosexual problem. These recommendations are from 2013 and new evidence was not reviewed to update these recommendations. However, these were amended to clarify the pathways for the different populations listed in the 2013 recommendations. See update information in Table 4 in the draft guideline document for further information.

Gender reassignment

Trans and non-binary people who are preparing for treatment for gender dysphoria or as part of gender transition process that is likely to impair their fertility are included within the recommendations on fertility preservation for medical indications (section 1.14) because

these recommendations are applicable to anyone with a medical indication for fertility preservation. See evidence review R for further information.

Religion or belief

Some people object to IVF for religious reasons and alternative treatment options are covered in recommendation 1.6.1 on tubal surgery, recommendation 1.6.2 on tubal catheterisation and recommendation 1.8.3 about considering IUI as an alternative to IVF. Further information is available from evidence reviews G, I and K.

Sexual orientation

The guideline does not suggest access to fertility treatment based on sexual orientation. Rather, it provides criteria based on whether people are seeking to conceive through unprotected vaginal sex or artificial insemination. Therefore, the 2013 recommendations on unstimulated intrauterine insemination (section 1.7 in new guideline, section 1.9.1 in CG156) which previously mentioned ‘same-sex couples’ have been amended so that ‘same-sex couples’ have been taken out (see recommendation 1.7.1 in new guideline). In the absence of a known health-related impediment to fertility, people using artificial insemination to conceive are not within the remit of the guideline but if pregnancy has not been achieved after 6 cycles of artificial insemination, they are considered to have a health-related fertility problem. They are, therefore, within the remit of the guideline, as defined in the 2022 guideline scope. So the recommendation was amended to clarify this (see recommendation 1.7.2 in the new guideline). See further information in update information table 4 of the draft guideline document. NICE acknowledges that those using artificial insemination to conceive will include female same-sex couples and so there may be an argument that they are disadvantaged or at least in a different position in general from opposite-sex couples who may be able to have unprotected vaginal sex to conceive. NICE considers that position to be justifiable and a proportionate means of achieving the aim of providing services for health-related fertility problems.

HIV

At scope consultation, stakeholders suggested that people with HIV may be subject to stigma and unnecessary restrictions when accessing fertility treatment, and that the current guideline recommendations may be out of step with current understanding of the transmissibility of HIV. This is documented in the EIA2. No new evidence was reviewed in relation to the recommendations specific to HIV and so these recommendations were not updated. However, the committee did agree to delete some of the recommendations from the 2013 guideline that they considered out of date, particularly in relation to the current understanding of the transmissibility of HIV, as noted by the stakeholders (the 2013 recommendations 1.3.10.3, 1.3.10.6 and 1.3.10.7, see update information table 3 for more information). Additionally, a 2013 recommendation on unstimulated IUI was

amended not to specify men with HIV as those requiring sperm washing, because most men with HIV would no longer require sperm washing (see recommendation 1.7.1).

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4.3 Could any draft recommendations potentially increase inequalities?
Recommendations 1.9.3, 1.9.4, 1.9.5 and 1.9.7 recommend restricting access to IVF according to age, based on cost-effectiveness evidence detailed in evidence review J. This was already the case in the 2013 guideline CG156. However, the age at which NICE recommends access to IVF has been reduced by one year in this guideline update. The scope of the guideline made it clear that the update would look at "predictive factors and models for the success of assisted reproduction techniques (ART) to inform recommendations on criteria for access to treatments". Because age is a key predictive factor for fertility, criterion based on age was expected in the updated recommendations. See recommendations 1.2.3 and 1.3.6 in the draft guideline.

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4.4 How has the committee's considerations of equality and health inequalities issues identified in EIA1, EIA2 and 4.1 been reflected in the development of any research recommendations?
Research recommendation 3 is specific to prepubertal and peripubertal males undergoing medical treatment, or have a medical condition, that is likely to impair their fertility.

3

4.5 Based on the equality and health inequalities issues identified in EIA1, EIA2 and 4.1, do you have representation from relevant stakeholder groups for the guideline or update consultation process, including groups who are known to be affected by these issues? If not, what plans are in place to ensure relevant stakeholders are represented and included?
A wide range of organisations have registered as stakeholders. To further ensure that relevant stakeholders are represented the NICE Public Involvement Adviser has been asked to encourage more LGBTQ+ organisations to register.

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4.6 What questions will you ask at the stakeholder consultation about the impact of the guideline or update on equality and health inequalities?
No specific questions will be asked.

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6 Completed by developer ____Maija Kallioinen_____

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8 Date_____11.04.2025_____

Approved by committee chair _____Fergus Macbeth_____

Date _____ 02.06.2025_____

Approved by NICE quality assurance lead ___Sara Buckner_____

Date_____16.06.2025_____