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 NG256 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).

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.

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.

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.

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.

Completed by developer ____Maija Kallioinen_____

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_____

STAGE 5. Revisions and final guideline or update

(to be completed by the developer before guidance executive considers the final guideline or update)

Fertility problems (update)

Date of completion: 07/01/2025

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

5.1 How inclusive was the consultation process on the draft guideline in terms of response from groups (identified in box 2.2, 3.2 and 4.1) who may experience inequalities related to the topic?
We received consultation feedback from a wide range of stakeholder organisations, bringing different perspectives. These included NHS service providers, commissioning bodies, professional organisations, service user organisations, charities, national or regulatory bodies, academic/research organisations, private clinics and industry representatives. Service user organisations and charities are the most relevant respondents in terms of directly representing those who may experience inequalities related to the topic. However, many other respondents also brought perspectives to the consideration of equalities. None of the responding organisations were specific to particular cohorts or groups who may experience inequalities based on e.g. protected characteristics.

5.2 Have any **further** equality and health inequalities issues beyond those identified at scoping and during development been raised during the consultation on the draft guideline or update, and, if so, how has the committee considered and addressed them?
1) Protected characteristics outlined in the Equality Act 2010 (age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation) One stakeholder commented that “the first principles of care should be to equalize access to fertility both geographically and by protected characteristic. This will be particularly important for same sex couples, trans gendered people, older women and disabled people and people with long term health conditions.” We acknowledge this and indeed the aim to reduce health inequalities is principle 9 in NICE’s principles (Our principles | NICE). The committee carefully considered and agreed the recommendations based on this principle. But the recommendations also reflect the scope of the guideline which is specific to people with health-related fertility problems. Inequalities in access based on geographical location is discussed below.

One stakeholder commented about the need to recognise and consider age-related and ethnicity-related diversity and propensity to menstrual problems. While we acknowledge the comment, these were not within the scope of the guideline update and therefore have not been addressed.

In relation to recommendation 1.2.20, one stakeholder commented about the need to consider the impact of prescribed drugs on fertility, particularly for disabled women and women with mental ill health. The recommendation was not part of the guideline update. The committee agreed to amend the recommendation by providing some examples of commonly used prescribed over-the-counter or recreational drugs which may impact fertility but none of these are specifically related to disabilities or mental ill health.

In relation to recommendation 1.7.1, a stakeholder commented that the requirement for a clinical diagnosis of physical disability or psychosexual problem excludes those with self-reported difficulties or those unable to obtain a formal diagnosis. This recommendation was not part of the current update, although it has been amended by the committee to clarify the recommendation for whom unstimulated IUI should be offered. We acknowledge the issue raised by the stakeholder, but it was considered a reasonable criterion for NHS-funded fertility treatment. So no change has been made based on this comment.

One stakeholder commented that in recent years, Asian and black people have had lower birth rates than white people and people from a mixed ethnic background. We acknowledge this comment, but no change has been made to the guideline based on this.

Two stakeholders commented about the importance of access to services and appropriate information provision to people with learning disabilities, communication barriers and neurodiverse people. The guideline already refers to the foundational guideline about patient experience in adult NHS services, which covers many issues around person-centred, tailored approaches to communication, information sharing and care provision.

Several stakeholders raised the issue about lack of NHS-funded access to fertility treatments for same sex couples (both female and male) and LGBTQ+ communities in general. These considerations have been discussed in detail in previous EHIAs, particularly in EHIA stage 4. While we acknowledge these concerns, the guideline scope is clear that the population covered by the guideline is those with health-related fertility problems, regardless of their sexual orientation, relationship status or gender identity.

There is generally little evidence specific to trans and non-binary people and it is not always clear if the study populations include them. The committee agreed that the recommendations in the guideline are applicable to trans and non-binary people but acknowledged that there may be additional aspects to their care and support that are not covered in the guideline. For example, discussions around potentially pausing gender-

affirming treatments during fertility treatments, or, for example, considerations related to a person with gender dysphoria needing to undergo invasive vaginal investigations or treatments. While the recommendations in the guideline generally apply to trans and non-binary people, it should also be noted that the guideline refers to the guideline on ovarian stimulation in IVF/ICSI by the European Society of Human Reproduction and Embryology (ESHRE) which does not refer to trans and non-binary people in the recommendations and does not use inclusive language in the same way as NICE guideline does. The committee agreed that the ESHRE recommendations referred to in the guideline are still applicable to trans and non-binary people.

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

No further issues were raised related to this dimension.

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

Geographical and ICB-level variation in access to IVF and/or fertility preservation services was raised by several stakeholders. We recognise the inequalities in access based on location and recognise that particularly in areas where access to NHS-funded services is limited based on local decisions, inequalities in personal wealth and ability to afford private care will lead to further inequalities in access. Equalities issues around geographical area variation have already been discussed in previous EHIAs. Local decisions about implementing NICE recommendations are not something we can influence. The NICE implementation teams will look for best practice examples and shared learning to support implementation of this guideline.

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)

No further issues were raised related to this dimension.

5.3 If any recommendations have changed after consultation, how could these changes impact on equality and health inequalities issues?

There were changes made to the recommendations because of the consultation process. Most of these changes won't have an impact on equality and health inequalities issues.

Stakeholders commented that for people using artificial insemination to conceive (for example female same-sex couples) and who have no known health-related fertility problems, the initial cycles of donor insemination are not NHS-funded. This financial barrier can lead to people seeking donor insemination through unregulated routes such as through websites or social media. The committee acknowledged the risks that this can bring, including safety issues with the donated sperm, and legal aspects of parenthood. It should be noted that the initial cycles of artificial insemination for those without known health-related fertility problems is outside the scope of this guideline. However, in response to these concerns, they decided to add the following recommendation to the guideline:

1.1.4 Advise people who are thinking about using donor sperm to conceive to have treatment in a licensed fertility clinic to ensure clinical safety and legal parenthood. [2026]

This recommendation addresses the safety and other concerns about unregulated donor inseminations. Although we recognise that the financial barriers to accessing safer donor insemination in regulated clinics remain, this is outside the scope of this guideline.

5.4 Following the consultation on the draft guideline and response to questions 4.1 and 5.2, have there been any further committee considerations of equality and health inequalities issues across the four dimensions that have been reflected in the final guideline?
No further issues were identified.

5.5 Please provide a summary of the key equality and health inequalities issues that should be highlighted in the guidance executive report before sign-off of the final guideline or update
Key equalities issues in the guideline relate to: • Geographical and ICB-level variation in access to IVF treatment, and to some extent access to fertility preservation, recognising that many ICBs are not implementing the guideline recommendations. • Differing routes for accessing IVF treatment for different cohorts of people depending on their method of conception. For couples trying to conceive through unprotected vaginal sexual intercourse with unexplained fertility problems, the

guideline recommends 2 years of expectant management before IVF treatment. For people using artificial insemination to conceive, 12 cycles of artificial insemination (of which at least 6 should be intrauterine insemination) are recommended before IVF treatment, unless there are contraindications or known causes of fertility problems. For the latter group, the initial 6 cycles of artificial insemination are not covered by the guideline and in current practice, people are expected to self-fund these. This can lead to inequalities in terms of:

  - the financial burden of needing to self-fund initial cycles of donor insemination compared to no financial burden for those trying to conceive through unprotected intercourse
  - the timeframe to access to IVF treatment: 2 years of expectant management for those trying to conceive through unprotected intercourse versus 12 cycles of artificial insemination for those relying on artificial insemination to conceive, which could, in theory, be achieved within 12 months.

- Age-related restrictions for accessing IVF treatment based on cost-effectiveness evidence.

Completed by developer	Maija Kallioinen
Date	07/01/2025
Approved by committee chair	Fergus Macbeth
Date	25/02/2026
Approved by NICE quality assurance lead	Sara Buckner
Date	30/01/2026