

Fertility problems

Quality standard

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This standard is based on CG156.

This standard should be read in conjunction with QS55, QS53, QS47, QS22, QS15, QS143 and QS172.

Introduction

This quality standard covers the assessment and treatment of fertility problems in:

- people with explained or unexplained infertility
- people preparing for cancer treatment who may wish to preserve their fertility.

For more information see the [Fertility problems overview](#).

Why this quality standard is needed

Fertility problems exist when a woman cannot conceive (get pregnant) despite having regular unprotected vaginal intercourse, or artificial insemination, at and around the time of ovulation. [Fertility](#) (NICE guideline CG156) recommends that in practice, healthcare professionals should define infertility in terms of the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. The main causes of infertility in the UK (with approximate prevalence given as a percentage) are:

- unexplained infertility (no identified male or female cause) (25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

In about 40% of cases, fertility disorders are found in both the man and the woman.

The quality standard is expected to contribute to improvements in the following outcomes:

- singleton births
- multiple births
- live births
- incidence of anxiety and/or depression.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following outcomes framework published by the Department of Health:

- [NHS Outcomes Framework 2014/15](#)

Table 1 shows the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 [NHS Outcomes Framework 2014/15](#)

Domain	Overarching indicators and improvement areas
1 Preventing people from dying prematurely	<p><i>Improvement areas</i></p> <p>Reducing deaths in babies and young children</p> <p>1.6 ii Neonatal mortality and stillbirths</p>

Patient experience and safety issues

Ensuring that care is safe and that people have a positive experience of care is vital in a high-quality service. It is important to consider these factors when planning and delivering services relevant to fertility.

NICE has developed guidance and an associated quality standard on patient experience in adult NHS services (see the NICE pathway on [patient experience in adult NHS services](#)), which should be considered alongside this quality standard. They specify that people receiving care should be treated with dignity, have opportunities to discuss their preferences, and be supported to understand their options and make fully informed decisions. They also cover the provision of

information to patients. Quality statements on these aspects of patient experience will not usually be included in topic-specific quality standards. However, recommendations in the development source(s) for quality standards that impact on patient experience and are specific to the topic will be considered during quality statement development.

Coordinated services

The quality standard for fertility specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole fertility care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to people experiencing fertility problems.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality fertility service are listed in [Related quality standards](#).

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating people with fertility problems should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard. Quality statements on staff training and competency are not usually included in quality standards. However, recommendations in the development source(s) on specific types of training for the topic that exceed standard professional training will be considered during quality statement development.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting people with fertility problems. If appropriate, healthcare professionals should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care.

List of quality statements

Statement 1. People who are concerned that it is taking longer than expected to conceive are given advice on the impact that lifestyle can have on their chances of getting pregnant.

Statement 2. People are referred for specialist consultation if the woman has not conceived after 1 year of intercourse or after 6 cycles of artificial insemination, or earlier in certain circumstances.

Statement 3. People who are having problems conceiving are offered counselling before, during and after investigation and treatment for their fertility problems.

Statement 4. Services analysing semen samples use methods and reference values in accordance with the most recent World Health Organization laboratory manual.

Statement 5. Women aged under 40 years who meet the criteria for in vitro fertilisation (IVF) are offered 3 full cycles of IVF.

Statement 6. Women aged 40–42 years who meet the criteria for IVF are offered 1 full cycle of IVF.

Statement 7. Women having IVF are offered intracytoplasmic sperm injection (ICSI) only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Statement 8. Women having IVF have 1 or 2 embryos transferred according to the woman's or donor's age, the cycle number and the quality of the embryos.

Statement 9. People preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation.

Quality statement 1: Lifestyle advice

Quality statement

People who are concerned that it is taking longer than expected to conceive are given advice on the impact that lifestyle can have on their chances of getting pregnant.

Rationale

Lifestyle factors, including body weight, smoking, alcohol and recreational drug use can have an impact on people's chances of getting pregnant. People who are trying to have a baby and are concerned it is taking longer than expected, should be given written and verbal advice about changes that can be made to their lifestyle that can help. This information should be provided for both men and women. Positive outcomes from lifestyle change interventions may reduce the need for onward referrals.

Quality measures

Structure

Evidence of local arrangements to ensure that people who are concerned that it is taking longer than expected to conceive are given written and verbal advice on the impact that lifestyle (including body weight, smoking, alcohol and recreational drug use) can have on their chances of getting pregnant.

Data source: Local data collection.

Process

Proportion of people who are concerned that it is taking longer than expected to conceive who are given written and verbal advice on the impact that lifestyle (including body weight, smoking, alcohol and recreational drug use) can have on their chances of getting pregnant.

Numerator – the number in the denominator given written and verbal advice on the impact that lifestyle (including body weight, smoking, alcohol and recreational drug use) can have on their chances of getting pregnant.

Denominator – the number of people who are concerned that it is taking longer than expected to conceive.

Data source: Local data collection. NICE [clinical audit tool](#) for fertility: people concerned about delays in conception: audit standard 1b.

Outcome

People who are concerned that it is taking longer than expected to conceive feel informed about the impact that lifestyle can have on their chances of getting pregnant.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and public health practitioners, and commissioners

Service providers (such as primary care, fertility, pre-conception advice and gynaecology services) ensure that written information about the impact of lifestyle on fertility is available to share with people who are concerned that it is taking longer than expected to conceive.

Healthcare professionals and public health practitioners give written and verbal information about the impact of lifestyle on fertility to people who are concerned that it is taking longer than expected to conceive.

Commissioners (clinical commissioning groups and NHS England area teams) ensure that primary, secondary, community and specialist fertility care providers give written and verbal information about the impact of lifestyle on fertility to people who are concerned that it is taking longer than expected to conceive.

What the quality statement means for patients

People who are concerned that it is taking them longer than expected to become pregnant are given advice (both spoken and in writing) on how their lifestyle can affect their chances of getting pregnant, especially if they smoke, drink alcohol, use recreational drugs or are over or underweight.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendations 1.2.3.1–3, 1.2.4.1–4, 1.2.6.1–4 and 1.2.10.1.

Equality and diversity considerations

Information given about fertility problems should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with fertility problems should have access to an interpreter or advocate if needed.

Quality statement 2: Referral for specialist consultation

Quality statement

People are referred for specialist consultation if the woman has not conceived after 1 year of intercourse or after 6 cycles of artificial insemination, or earlier in certain circumstances.

Rationale

Over 80% of women aged under 40 years will conceive within 1 year if they have regular unprotected vaginal intercourse at and around the time of ovulation. If they do not conceive after 1 year, or after 6 cycles of artificial insemination, they should be referred to specialist services to decide if more support is needed. Women aged 36 years or over and people with a known clinical cause or history of predisposing infertility factors should be offered an earlier referral (before 1 year) because of the impact of these factors on fertility. Delays in referral to specialist services can have a negative impact on patient care and treatment outcomes.

Quality measures

Structure

Evidence of local arrangements to ensure that referral pathways are in place for specialist consultation when women have not conceived after 1 year of intercourse or after 6 cycles of artificial insemination, or earlier in certain circumstances.

Data source: Local data collection.

Process

a) Proportion of people (women aged 35 years or under and men) who are referred for specialist consultation if the woman has not conceived after 1 year of intercourse or after 6 cycles of artificial insemination, when there is no known clinical cause or history of predisposing factors for infertility in the woman or man.

Numerator – the number in the denominator who are referred for specialist consultation.

Denominator – the number of people (women aged 35 years or under and men) who have not conceived after 1 year of intercourse or after 6 cycles of artificial insemination and there is no known clinical cause or history of predisposing factors for infertility in the woman or man.

Data source: Local data collection. Data can be collected using the NICE [clinical audit tool](#) for fertility: people concerned about delays in conception: audit standard 3.

b) Proportion of people who are referred for specialist consultation within 1 year of identification of fertility problems when there is a known clinical cause in the woman or man, a history of predisposing factors for infertility or the woman is aged 36 years or older.

Numerator – the number in the denominator who are referred for specialist consultation within 1 year of identification of fertility problems.

Denominator – the number of people who have not conceived and have a known clinical cause, a history of predisposing factors for infertility or the woman is aged 36 years or older.

Data source: Local data collection. Data can be collected using the NICE [clinical audit tool](#) for fertility: people concerned about delays in conception: audit standard 4.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (primary care, secondary care and specialist fertility services) ensure that referral pathways are in place so that people who have not conceived are referred for specialist consultation after 1 year of intercourse or 6 cycles of artificial insemination, or earlier depending on the presence of known infertility factors and the age of the woman.

Healthcare professionals refer people for specialist consultation if they have not conceived after 1 year of intercourse or 6 cycles of artificial insemination, or earlier depending on the presence of known infertility factors and the age of the woman.

Commissioners (clinical commissioning groups and NHS England area teams) ensure that there is sufficient capacity within specialist services and that agreed pathways and referral criteria are in place for people who have not conceived to be referred for specialist consultation after 1 year of intercourse or 6 cycles of artificial insemination, or earlier depending on the presence of known infertility factors and the age of the woman.

What the quality statement means for patients

People finding it difficult to get pregnant are referred for specialist advice and tests if they have been trying for a year or longer or have had 6 cycles of artificial insemination (which is the direct

insertion of sperm into a woman's womb or the neck of the womb). If they have a known problem that might affect their fertility or the woman is aged 36 years or older, they should be referred earlier.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendations 1.2.13.5, 1.2.13.6 and 1.2.13.7 (key priorities for implementation).

Definitions of terms used in this quality statement

Circumstances for earlier referral

An earlier referral should be offered if there is a known clinical cause of infertility in the woman or man, a history of predisposing factors for infertility (such as amenorrhoea, oligomenorrhoea, pelvic inflammatory disease or undescended testes) or the woman is aged 36 years or over. [[Fertility](#) (NICE guideline CG156), recommendation 1.2.13.7]

Specialist consultation

Assessment, investigation or treatment in secondary or tertiary care services (for example, urology departments, gynaecology departments or fertility clinics). [Expert opinion]

Quality statement 3: Counselling

Quality statement

People who are having problems conceiving are offered counselling before, during and after investigation and treatment for their fertility problems.

Rationale

People experiencing fertility problems should be offered counselling because fertility problems themselves, and the investigation and treatment for fertility problems, can cause emotional stress.

Quality measures

Structure

Evidence of local arrangements to ensure that people who are having problems conceiving are offered counselling before, during and after investigation and treatment for their fertility problems in secondary or tertiary care.

Data source: Local data collection.

Process

a) Proportion of people who are having problems conceiving and who are having investigations for fertility problems in secondary or tertiary care who receive counselling.

Numerator – the number in the denominator who receive counselling.

Denominator – the number of people who are having problems conceiving and who are having investigations for their fertility problems in secondary or tertiary care.

Data source: Local data collection.

b) Proportion of people who are having problems conceiving and who are having treatment for fertility problems in secondary or tertiary care who receive counselling.

Numerator – the number in the denominator who receive counselling.

Denominator – the number of people who are having problems conceiving and who are having treatment for their fertility problems in secondary or tertiary care.

Data source: Local data collection.

c) Proportion of people who are having problems conceiving and who have received treatment for fertility problems in secondary and tertiary care who receive counselling.

Numerator – the number in the denominator who receive counselling.

Denominator – the number of people who are having problems conceiving and who have received treatment for fertility problems in secondary or tertiary care.

Data source: Local data collection.

Outcome

People who are having problems conceiving feel supported throughout and after investigation and treatment for their fertility problems.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (secondary and tertiary care services) ensure that counselling services are available for people who are having problems conceiving before, during and after investigation and treatment for their fertility problems.

Healthcare professionals refer people who are having problems conceiving for counselling before, during and after investigations and treatment for their fertility problems.

Commissioners (clinical commissioning groups and NHS England area teams) ensure that counselling services are available before, during and after investigation and treatment for people with fertility problems, and that pathways and referral criteria are in place.

What the quality statement means for patients

People finding it difficult to get pregnant have the opportunity to see a counsellor before, during and after any tests or treatment for fertility problems.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendation 1.1.2.4.

Equality and diversity considerations

Good communication between healthcare professionals and people with fertility problems is essential. Care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with fertility problems should have access to an interpreter or advocate if needed.

Quality statement 4: Semen analysis

Quality statement

Services analysing semen samples use methods and reference values in accordance with the most recent [World Health Organization laboratory manual](#).

Rationale

Semen analysis is the primary assessment tool for male fertility potential. The accuracy of the result is dependent on following accredited methods of analysis that are regularly audited and subject to quality control. Variations in laboratory techniques significantly influence the reliability of the results of semen analysis. This may lead to a longer process for investigating male infertility, and possibly to inappropriate treatment.

Quality measures

Structure

Evidence of a quality assurance programme to ensure that services analysing semen samples use methods and reference values in accordance with the most recent World Health Organization laboratory manual.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (laboratory services) ensure that there is a quality assurance programme in place so that services analysing semen samples use methods and reference values in accordance with the most recent World Health Organization laboratory manual.

Healthcare professionals (such as scientists and laboratory technicians) analysing semen samples use methods and reference values in accordance with the most recent World Health Organization laboratory manual.

Commissioners (clinical commissioning groups) ensure that the laboratory services they use comply with the most recent World Health Organization laboratory manual.

What the quality statement means for patients

Men having their semen checked to measure the quantity and quality of their sperm have it tested by a laboratory that uses recommended methods to provide an accurate result.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendation 1.3.1.1.

Definitions of terms used in this quality statement

Reference values

The results of the semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values:

- semen volume: 1.5 ml or more
- pH: 7.2 or more
- sperm concentration: 15 million spermatozoa per ml or more
- total sperm number: 39 million spermatozoa per ejaculate or more
- total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility
- vitality: 58% or more live spermatozoa
- sperm morphology (percentage of normal forms): 4% or more.

The reference ranges are only valid for the semen analysis tests outlined by the World Health Organization.

[[Fertility](#) (NICE guideline CG156), recommendation 1.3.1.1]

Quality statement 5: IVF for women under 40 years

Quality statement

Women aged under 40 years who meet the criteria for in vitro fertilisation (IVF) are offered 3 full cycles of IVF.

Rationale

Access to the appropriate number of full cycles of IVF for women who meet the criteria for IVF will increase the likelihood of those women becoming pregnant. IVF should be considered as an option only if expectant management and first-line treatments for women have not led to a pregnancy. This staged approach to treatment supports the efficient and equitable use of healthcare resources.

Quality measures

Structure

Evidence of local arrangements to provide 3 full cycles of IVF for women aged under 40 years who meet the criteria for IVF.

Data source: Local data collection. National data on provision of IVF are available from the [Human Fertilisation and Embryology Authority](#).

Process

Proportion of women aged under 40 years who meet the criteria for IVF who are offered 3 full cycles of IVF.

Numerator – the number in the denominator who receive 3 full cycles of IVF.

Denominator – the number of women aged under 40 years who meet the criteria for IVF.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (specialist fertility services) ensure that policies are in place on provision of 3 full cycles of IVF for women aged under 40 years who meet the criteria for IVF.

Healthcare professionals (in specialist fertility services) adhere to policies on provision of 3 full cycles of IVF for women aged under 40 years who meet the criteria for IVF.

Commissioners (clinical commissioning groups) should commission sufficient capacity within specialist fertility services to provide 3 full cycles of IVF for women aged under 40 years who meet the criteria for IVF.

What the quality statement means for patients

Women under 40 finding it difficult to get pregnant who have been trying for 2 years or longer or have had 12 cycles of artificial insemination (which is the direct insertion of sperm into a woman's womb or the neck of the womb) are offered 3 full cycles of IVF. A full cycle of IVF involves collecting eggs and sperm, fertilising the eggs outside the woman's body, and placing 1 or 2 fertilised eggs (embryos) into the womb to start a pregnancy.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendation 1.11.1.3 (key priority for implementation).

Definitions of terms used in this quality statement

Criteria for IVF for women aged under 40 years

Women aged under 40 years should be offered 3 full cycles of IVF if they have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (including 6 or more by intrauterine insemination). The use of intracytoplasmic sperm injection (ICSI) should not preclude the provision of the appropriate number of IVF cycles. [[Fertility](#) (NICE guideline CG156), recommendation 1.11.1.3]

Full cycle of IVF

A full cycle should include 1 episode of ovarian stimulation and the transfer of any resultant fresh

and frozen embryo(s). [[Fertility](#) (NICE guideline CG156)]

Any previous full cycle, whether self- or NHS-funded, should count towards the total of 3 full cycles offered by the NHS. [[Fertility](#) (NICE guideline CG156)], recommendation 1.11.1.6]

Equality and diversity considerations

The existence of living children should not be a factor that precludes the provision of fertility treatment.

The statements include reference to specific age groups. This is to promote effective care because age was found to be the only robust factor in determining IVF success.

The statement focuses on people who have a possible pathological problem to explain their infertility. It includes women in same-sex relationships and women with or without a partner having artificial insemination.

Quality statement 6: IVF for women aged 40–42 years

Quality statement

Women aged 40–42 years who meet the criteria for in vitro fertilisation (IVF) are offered 1 full cycle of IVF.

Rationale

The overall chance of having a live birth after IVF treatment falls with rising female age and also decreases as the number of unsuccessful cycles increases. Access to the appropriate number of full cycles of IVF for women who meet the criteria for IVF will increase the likelihood of those women becoming pregnant. IVF should be considered as an option only if expectant management and first-line treatments for women have not led to a pregnancy. This staged approach to treatment supports the efficient and equitable use of healthcare resources.

Quality measures

Structure

Evidence of a locally agreed policy on provision of 1 full cycle of IVF for women aged 40–42 years who meet the criteria for IVF.

Data source: Local data collection. National data on provision of IVF and intracytoplasmic sperm injection (ICSI) are available from the [Human Fertilisation and Embryology Authority](#).

Process

Proportion of women aged 40–42 years who meet the criteria for IVF who are offered 1 full cycle of IVF.

Numerator – the number in the denominator who receive 1 full cycle of IVF.

Denominator – the number of women aged 40–42 years who meet the criteria for IVF.

Data source: Local data collection.

What the quality statement means for service providers, healthcare

professionals and commissioners

Service providers (specialist fertility services) ensure that policies are in place on provision of 1 full cycle of IVF for women aged 40–42 years who meet the criteria for IVF.

Healthcare professionals (in specialist fertility services) adhere to policies on provision of 1 full cycle of IVF for women aged 40–42 years who meet the criteria for IVF.

Commissioners (clinical commissioning groups) should commission sufficient capacity within specialist fertility services to provide 1 full cycle of IVF for women aged 40–42 years who meet the criteria for IVF.

What the quality statement means for patients

Women aged 40 to 42 finding it difficult to get pregnant who have been trying for 2 years or longer or they have had 12 cycles of artificial insemination (which is the direct insertion of sperm into a woman's womb or the neck of the womb) are offered 1 full cycle of IVF if all of the following apply:

- they have never had IVF before
- tests show that their ovaries would respond normally to fertility drugs
- they have discussed the risks of IVF and becoming pregnant at this age with their doctor.

A full cycle of IVF involves collecting eggs and sperm, fertilising the eggs outside the woman's body, and placing 1 or 2 fertilised eggs (embryos) into the womb to start a pregnancy.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendation 1.11.1.4 (key priority for implementation).

Definitions of terms used in this quality statement

Criteria for IVF for women aged 40–42 years

Women aged 40–42 years should be offered 1 full cycle of IVF if they have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (including 6 or more by intrauterine insemination) and have never had IVF treatment before, have no evidence of low ovarian reserve (when a woman doesn't have many eggs left) and have had a

discussion of the additional implications of IVF and pregnancy at this age. The use of ICSI should not preclude the provision of the appropriate number of IVF cycles. [[Fertility](#) (NICE guideline CG156), recommendation 1.11.1.4].

Full cycle of IVF

A full cycle should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). [[Fertility](#) (NICE guideline CG156)]

Equality and diversity considerations

The existence of living children should not be a factor that precludes the provision of fertility treatment.

The statements include reference to specific age groups. This is to promote effective care because age was found to be the only robust factor in determining IVF success.

The statement focuses on people who have a possible pathological problem to explain their infertility. It includes women in same-sex relationships and single women having artificial insemination.

Quality statement 7: Intracytoplasmic sperm injection

Quality statement

Women having in vitro fertilisation (IVF) are offered intracytoplasmic sperm injection (ICSI) only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Rationale

ICSI is a technique in which a single sperm is injected into an egg to achieve fertilisation. It is sometimes used in addition to IVF and improves the chances of conception. However, given the added resources involved, its use should be determined by clinical need.

Quality measures

Structure

Evidence of local arrangements to ensure that ICSI is offered only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Data source: Local data collection.

Process

Proportion of women having IVF with ICSI because of severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or because previous IVF treatment resulted in failed or very poor fertilisation.

Numerator – the number in the denominator having ICSI because of severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or because previous IVF treatment resulted in failed or very poor fertilisation.

Denominator – the number of women having IVF with ICSI.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (specialist fertility services) ensure that policies are in place to offer ICSI to women having IVF only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Healthcare professionals (in specialist fertility services) offer ICSI to women having IVF only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Commissioners (clinical commissioning groups) monitor the use of ICSI for women having IVF in the services they commission.

What the quality statement means for patients

Women having IVF are offered an additional procedure to improve their chances of getting pregnant only if problems with the sperm mean that it is unlikely to fertilise the egg without it, or if there was poor or no fertilisation with IVF in the past. The procedure involves injecting a sperm directly into the egg and is called intracytoplasmic sperm injection (ICSI for short).

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendation 1.13.1.1.

Definitions of terms used in this quality statement

Severe deficits in semen quality

Low quality sperm identified through comparison of sperm analysis results to the reference values in the [World Health Organization laboratory manual](#). [Expert opinion]

Intracytoplasmic sperm injection (ICSI)

A procedure sometimes used in addition to IVF, which involves injecting a single sperm into the inner cellular structure of an egg. [[Fertility](#) (NICE guideline CG156)]

Non-obstructive azoospermia

No sperm in the ejaculate due to testicular failure. [Adapted from [Fertility](#) (NICE guideline CG156)]

Obstructive azoospermia

The testes produce sperm as normal but a blockage prevents entry to the ejaculate. [Adapted from [Fertility](#) (NICE guideline CG156)]

Quality statement 8: Number of embryos transferred

Quality statement

Women having in vitro fertilisation (IVF) have 1 or 2 embryos transferred according to the woman's or donor's age, the cycle number and the quality of the embryos.

Rationale

An effective embryo transfer strategy minimises the chance of multiple pregnancies following IVF and improves the outcome of IVF with the birth of more single, healthy babies. Multiple pregnancies represent a significant health risk to mothers and babies.

Quality measures

Structure

Evidence of local arrangements to implement an agreed embryo transfer strategy in which 1 or 2 embryos are transferred according to the woman's or donor's age, the cycle number and the quality of the embryos.

Data source: Local data collection.

Process

a) Proportion of IVF cycles in which embryo transfers are carried out in line with Fertility (NICE guideline CG156) (see also the definitions section below).

Numerator – the number in the denominator carried out in line with Fertility (NICE guideline CG156).

Denominator – the number of embryo transfers in IVF cycles.

Data source: Local data collection. Data can be collected using the NICE [clinical audit tool](#) for fertility: embryo transfer strategies: audit standards 4–7.

Outcome

a) Proportion of embryo transfers that are elective single embryo transfers.

Data source: Local data collection. National data on elective single embryo transfers are available from the [Human Fertilisation and Embryology Authority](#).

b) Number of IVF treatments resulting in multiple pregnancy.

Data source: Local data collection. National data on multiple pregnancy rates following IVF treatment are available from the [Human Fertilisation and Embryology Authority](#).

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (specialist fertility services) ensure that systems are in place to monitor the number of embryos transferred during IVF cycles.

Healthcare professionals (in specialist fertility services) transfer the appropriate number of embryos during IVF, taking into account the woman's or donor's age, the cycle number and the quality of the embryos.

Commissioners (clinical commissioning groups) ensure that the services they commission have policies in place on embryo transfer strategies that take into account the woman's or donor's age, the cycle number and the quality of the embryos.

What the quality statement means for patients

Women having IVF have 1 or 2 embryos transferred into their womb, depending on the woman's age (or the donor's age), the number of IVF treatments she has had and the quality of the embryos.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendations 1.12.6.5, 1.12.6.8 (key priorities for implementation), 1.12.6.6 and 1.12.6.7.

Definitions of terms used in this quality statement

Embryo transfer according to age, cycle number and quality of embryos

The number of embryos transferred should be determined by the age of the woman, cycle number and quality of embryos as follows.

Age	Cycle	Quality of embryos ¹	Number of embryos to transfer
Under 37	1st	N/A	1
Under 37	2nd	1 or more top-quality embryos available	1
Under 37	2nd	If no top-quality embryos are available	No more than 2
Under 37	3rd	N/A	No more than 2
37–39	1st or 2nd	1 or more top-quality embryos available	1
37–39	1st or 2nd	If no top-quality embryos are available	No more than 2
37–39	3rd	N/A	No more than 2
40–42	N/A	N/A	No more than 2
N/A	N/A	Top-quality blastocyst available	1
¹ Embryo quality is evaluated at both cleavage and blastocyst stages, according to the Association of Clinical Embryologists (ACE) and UK National External Quality Assessment Service (UK NEQAS) for Reproductive Science Embryo and Blastocyst Grading schematic.			

[Adapted from *Fertility* (NICE guideline CG156)]

Equality and diversity considerations

The existence of living children should not be a factor that precludes the provision of fertility treatment.

Quality statement 9: Cryopreservation before cancer treatment

Quality statement

People preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation.

Rationale

Some treatments for cancer can cause fertility problems. Cryopreservation of men's sperm or women's oocytes or embryos may give people with cancer the option of having children in the future.

Structure

Evidence of local arrangements to ensure that people preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation.

Data source: Local data collection.

Process

a) Proportion of males having treatment for cancer that is likely to result in fertility problems who receive sperm cryopreservation.

Numerator – the number in the denominator who receive sperm cryopreservation.

Denominator – the number of males having treatment for cancer that is likely to result in fertility problems.

Data source: Local data collection.

b) Proportion of females having treatment for cancer that is likely to result in fertility problems who receive oocyte or embryo cryopreservation.

Numerator – the number in the denominator who receive oocyte or embryo cryopreservation.

Denominator – the number of females having treatment for cancer that is likely to result in fertility problems and:

- who are well enough to undergo ovarian stimulation and egg collection
- whose condition will not worsen with cryopreservation
- who have enough time before the start of their cancer treatment.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (specialist fertility services) ensure that agreed referral pathways are in place to provide cryopreservation to people who are preparing to have treatment for cancer that is likely to result in fertility problems.

Healthcare professionals (in specialist fertility services) offer cryopreservation to people preparing to have treatment for cancer that is likely to result in fertility problems.

Commissioners (clinical commissioning groups) ensure there is sufficient capacity within fertility services to provide cryopreservation for people preparing to have cancer treatment that is likely to result in fertility problems, with agreed referral pathways in place.

What the quality statement means for patients

People preparing to have treatment for cancer that is likely to result in fertility problems are given the option to preserve (freeze and store) their eggs or sperm for possible use in the future.

Source guidance

- [Fertility](#) (2013) NICE guideline CG156, recommendations 1.16.1.8 and 1.16.1.10.

Equality and diversity considerations

The existence of living children should not be a factor that precludes the provision of fertility treatment.

There should not be a lower age limit for cryopreservation for fertility preservation in people diagnosed with cancer.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its [Indicators for Quality Improvement Programme](#). If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's [What makes up a NICE quality standard?](#) for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in [Development sources](#).

Information for commissioners

NICE has produced [support for commissioning](#). This resource helps with quality improvement by providing information on key clinical, cost and service-related issues to consider during the commissioning process, and by signposting other implementation tools.

Information for the public

NICE has produced [information for the public](#) about this quality standard. Patients, service users and carers can use it to find out about the quality of care they should expect to receive; as a basis for asking questions about their care, and to help make choices between providers of social care services.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and [equality assessments](#) are available.

Good communication between healthcare professionals and people with fertility problems is essential. Treatment, care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with fertility problems should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards [Process guide](#).

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- [Fertility](#) (2013) NICE guideline CG156.

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- [Commissioning fertility services factsheet](#) (2013) NHS Commissioning Board.
- [HFEA Code of practice](#) (2013) Human Fertilisation and Embryology Authority.
- [HFEA Directions](#) (2009–2013) Human Fertilisation and Embryology Authority.

Definitions and data sources for the quality measures

- National data on provision of treatment for fertility problems are available from the [Human Fertilisation and Embryology Authority](#).
- NICE [clinical audit tools](#) for fertility: people concerned about delays in conception and fertility: embryo transfer strategies.

Related NICE quality standards

Published

- [Ectopic pregnancy and miscarriage \(2014\)](#) NICE quality standard 69.
- [Children and young people with cancer \(2014\)](#) NICE quality standard 55.
- [Anxiety disorders \(2014\)](#) NICE quality standard 53.
- [Heavy menstrual bleeding \(2013\)](#) NICE quality standard 47.
- [Multiple pregnancy \(2013\)](#) NICE quality standard 46.
- [Antenatal care \(2012\)](#) NICE quality standard 22.
- [Patient experience in adult NHS services \(2012\)](#) NICE quality standard 15.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 2. Membership of this committee is as follows:

Mr Barry Attwood

Lay member

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The following specialist members joined the committee to develop this quality standard:

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Update information

September 2016: Number of cycles of IVF corrected in the definitions section of statement 6.

About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the [quality standards process guide](#).

This quality standard has been incorporated into the NICE pathway on [fertility](#).

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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based

guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- [Association of Clinical Embryologists](#)
- [British Infertility Counselling Association](#)
- [Faculty of Sexual and Reproductive Healthcare](#)
- [Fertility Fairness](#)
- [Infertility Network UK](#)
- [Primary Care Women's Health Forum](#)
- [Royal College of General Practitioners](#)
- [Royal College of Obstetricians and Gynaecologists](#)
- [Royal College of Nursing](#)