Fertility problems

NICE quality standard

Draft for consultation

May 2014

Introduction

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

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

For more information see the overview.

Why this quality standard is needed

Fertility problems exist when a woman cannot conceive (get pregnant) despite having regular unprotected vaginal intercourse at and around the time of ovulation or artificial insemination. Fertility (NICE clinical guideline 156) 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
- fewer multiple births
- live births in women receiving treatment for infertility.

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	***Improvement areas*** **Reducing deaths in babies and young children** 1.6 ii Neonatal mortality and stillbirths
4 Ensuring that people have a positive experience of care	***Overarching indicator*** 4a Patient experience of primary care in GP services 4b Patient experience of hospital care ***Improvement areas*** 4.5 Improving women and their families' experience of maternity services

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 high-quality services for people with fertility problems 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.

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 written and verbal advice on the impact that lifestyle can have on their chances of getting pregnant, including factors such as smoking, alcohol, obesity and recreational drug use.

Statement 2. People are referred for specialist consultation if they have not conceived after 1 year of unprotected vaginal intercourse or earlier if there is a known clinical cause, a history of predisposing factors for infertility or the woman is aged 36 years or over.

Statement 3. People are offered counselling before, during and after investigations and treatment for fertility problems, irrespective of the outcome.

Statement 4. Services analysing semen samples use methods and reference values in accordance with the World Health Organization laboratory manual for the examination and processing of human semen.

Statement 5. Women aged under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) are offered 3 full cycles of in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI).

Statement 6. Women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) are offered 1 full cycle of in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

Statement 7. People 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.

Statement 8. Services that evaluate the quality of embryos use the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Statement 9. Women having in vitro fertilisation (IVF) have 1 or 2 embryos transferred according to the age of the woman (or the age of the donor if donor eggs are used), the cycle number and the quality of the embryos.

Statement 10. People of reproductive age preparing to have treatment for cancer that is likely to give them fertility problems are offered cryopreservation.

Questions for consultation

Questions about the quality standard

Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?

Question 2 If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Quality statement 1: Lifestyle advice

Quality statement

People who are concerned that it is taking longer than expected to conceive are given written and verbal advice on the impact that lifestyle can have on their chances of getting pregnant, including factors such as smoking, alcohol, obesity and recreational drug use.

Rationale

When people who are trying to have a baby are concerned that it is taking longer than expected, written and verbal advice should be given about changes that can be made to their lifestyle that can help. This information should be provided for both men and women. It should explain that smoking, drinking alcohol, obesity and recreational drug use can have an impact on their chances of getting pregnant.

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 information on the impact of smoking, alcohol, obesity and recreational drug use.

Data source: Local data collection.

Process

Proportion of people presenting for the first time who are concerned that it is taking longer than expected to conceive who are given advice on the impact that lifestyle changes can have on the chances of getting pregnant that includes smoking, alcohol, obesity and recreational drug use.

Numerator – the number in the denominator given advice on the impact that lifestyle changes can have on the chances of getting pregnant that includes smoking, alcohol, obesity and recreational drug use.

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

Data source: Local data collection. Data can be collected using NICE clinical guideline 156 clinical audit tool for Fertility: people concerned about delays in conception.

Outcome

People who are concerned that it is taking longer than expected to conceive feel informed about factors that may reduce the likelihood of conception.

Data source: Local data collection.

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

Service providers (primary and secondary care services) ensure that written and verbal information about the impact of lifestyle changes on fertility is available to share with people who are concerned that it is taking longer than expected to conceive.

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

Commissioners (clinical commissioning groups) ensure that primary and secondary care providers give written and verbal information about the impact of lifestyle changes on fertility when people 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 longer than expected to become pregnant are given written and verbal information on how their lifestyle can affect their chances of getting pregnant, especially if they smoke, drink alcohol, use recreational drugs or are overweight.

Source guidance

- Fertility (NICE clinical guideline 156), recommendations 1.2.3, 1.2.4, 1.2.6 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 they have not conceived after 1 year of unprotected vaginal intercourse, or earlier if there is a known clinical cause, a history of predisposing factors for infertility or the woman is aged 36 years or over.

Rationale

Over 80% of people will conceive within 1 year if the woman is aged less than 40 years and they have regular unprotected vaginal intercourse at and around the time of ovulation. If they do not conceive after 1 year, 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 known impact of these factors on fertility. Delays in referral to specialist services can have a negative impact on patient management and treatment outcomes.

Quality measures

Structure

Evidence of local arrangements to ensure that referral pathways are in place for specialist consultation when couples have not conceived after 1 year of unprotected vaginal intercourse, or earlier if there is a known clinical cause, a history of predisposing factors for infertility or the woman is aged 36 years or over.

Data source: Local data collection.

Process

a) Proportion of couples (where woman is aged 35 years or younger) referred for specialist consultation if they have not conceived after 1 year of unprotected vaginal intercourse when there is no known clinical cause or history of predisposing factors for infertility.

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

Denominator – the number of couples (where woman is aged 35 years or younger) with no known clinical cause or history of predisposing factors for infertility who have not conceived after 1 year of unprotected vaginal intercourse.

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

b) Proportion of couples referred for specialist consultation when they have not conceived with unprotected vaginal intercourse and have a known clinical cause, history of predisposing factors for infertility or the woman is aged 36 years or older.

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

Denominator – the number of couples who have not conceived with unprotected vaginal intercourse and have a known clinical cause, 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 (clinical audit standard 4).

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

Service providers (primary care services) ensure that referral pathways are in place so that people who have not conceived with unprotected vaginal intercourse are referred for specialist consultation within appropriate timeframes depending on the presence of known infertility factors and the age of the woman.

Healthcare professionals refer people who have not conceived with unprotected vaginal intercourse for specialist consultations within appropriate timeframes depending on the presence of known infertility factors and the age of the woman.

Commissioners (clinical commissioning groups and NHS England local area teams) ensure that there is sufficient capacity within specialist services and check that agreed pathways and referral criteria are in place for people who have not conceived

with unprotected vaginal intercourse 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. If they have a known problem that might affect their fertility or the woman is aged 36 or older they should be referred earlier.

Source guidance

- Fertility (NICE clinical guideline 156), recommendations 1.2.13.5 and 1.2.13.7 (key priorities for implementation).

Definitions of terms used in this quality statement

Specialist consultation

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

Predisposing factors

These include amenorrhoea (absent periods), oligomenorrhoea (irregular or infrequent periods), pelvic inflammatory disease or undescended testes.

Quality statement 3: Counselling

Quality statement

People are offered counselling before, during and after investigations and treatment for fertility problems, irrespective of the outcome.

Rationale

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

Quality measures

Structure

Evidence of local arrangements to ensure that people are offered counselling before, during and after investigations and treatment for fertility problems, irrespective of the outcome.

Data source: Local data collection.

Process

Proportion of people who are offered counselling before, during and after an investigation or treatment for fertility problems.

Numerator – the number in the denominator who are offered counselling before, during and after.

Denominator – the number of people undergoing investigation or treatment for fertility problems.

Data source: Local data collection.

Outcome

People feel supported throughout investigations and treatment for fertility problems.

Data source: Local data collection.

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

Service providers (primary, secondary and tertiary care services) ensure that counselling services are available for people undergoing investigations and treatment for fertility problems.

Healthcare professionals offer referral for counselling before, during and after investigations and treatment for fertility problems, irrespective of the outcome.

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

What the quality statement means for patients

People undergoing investigation or treatment for fertility problems are offered counselling at all stages.

Source guidance

- Fertility (NICE clinical guideline 156), 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 World Health Organization laboratory manual for the examination and processing of human semen.

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 in investigating male infertility, the offer of inappropriate treatment, and potentially over treatment.

Quality measures

Structure

Evidence of a quality assurance programme to ensure services analysing semen samples use methods and reference values in accordance with the World Health Organization laboratory manual for the examination and processing of human semen.

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 to ensure compliance with the World Health Organization laboratory manual for the examination and processing of human semen.

Healthcare scientists analysing semen use methods and reference values in accordance with the World Health Organization laboratory manual for the examination and processing of human semen.

Commissioners (clinical commissioning groups) ensure that the laboratory services they use comply with the World Health Organization laboratory manual for the examination and processing of human semen.

What the quality statement means for patients

Men having their semen checked have it tested by a laboratory that uses standard methods to give an accurate result.

Source guidance

- Fertility (NICE clinical guideline 156), recommendation 1.3.1.1.

Definitions of terms used in this quality statement

Reference values

The results of 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.

[NICE clinical guideline 156 recommendation 1.3.1.1]

Quality statement 5: IVF for women under 40 years

Quality statement

Women aged under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) are offered 3 full cycles of in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI).

Rationale

Access to the correct number of full cycles of IVF depending on the age of the woman increases the likelihood of pregnancy for people who have not conceived within 2 years. This will ensure provision of in vitro fertilisation (IVF) treatment is clinically and cost effective.

Quality measures

Structure

Evidence of local arrangements to provide 3 full cycles of IVF, with or without ICSI, for women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination).

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

Process

Proportion of women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) who are offered 3 full cycles of IVF, with or without ICSI.

Numerator – the number in the denominator offered 3 full cycles of IVF, with or without ICSI.

Denominator – the number of women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination).

Data source: Local data collection.

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

Service providers (specialist secondary or tertiary care fertility services) ensure that policies are in place on provision of 3 full cycles of IVF, with or without ICSI for women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination).

Healthcare professionals within specialist secondary or tertiary care fertility services adhere to policies on provision of 3 full cycles of IVF, with or without ICSI for women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination).

Commissioners (clinical commissioning groups) should commission sufficient capacity within specialist secondary or tertiary care fertility services to provide 3 full cycles of IVF, with or without ICSI for women under 40 years who have not conceived after 2 years of regular unprotected vaginal intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination).

What the quality statement means for patients

Women under 40 years who have been trying to get pregnant through regular unprotected sexual intercourse for 2 years or who have not become pregnant after 12 cycles of artificial insemination (at least 6 of which were by intrauterine insemination) are offered 3 full cycles of IVF.

Source guidance

- Fertility (NICE clinical guideline 156), recommendations 1.11.1.3 and 1.11.1.6 (key priorities for implementation).

Definitions of terms used in this quality statement

Artificial insemination

A procedure that involves directly inserting sperm into a woman's womb or cervix (the neck of the womb) to help her conceive. [NICE clinical guideline 156: Information for the public]

Full cycle

A full cycle should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). [NICE clinical guideline 156]

Any previous full cycle, whether self- or NHS-funded, should count towards the total of 3 full cycles offered by the NHS. [NICE clinical guideline 156 recommendation 1.11.1.6]

Intrauterine insemination

Clinical delivery of sperm into the uterine cavity. [NICE clinical guideline 156]

In vitro fertilisation

In vitro fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body. Usually, 1 or 2 resulting embryos are then transferred to the womb with the aim of starting a pregnancy. [NICE clinical guideline 156]

Equality and diversity considerations

In Fertility (NICE clinical guideline 156), the existence of living children is not a factor that precludes the provision of fertility treatment.

CG156 includes recommendations that relate to specific age-groups. The guideline development group found that age was the only robust factor in determining IVF success, and hence recommendations about access to IVF therapy have been made on the basis of age.

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

Quality statement

Women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) are offered 1 full cycle of in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

Rationale

The overall chance of a live birth following IVF treatment falls with rising female age and decreases as the number of unsuccessful cycles increases. Access to the correct number of full cycles depending on the age of the woman will ensure provision of in vitro fertilisation (IVF), with or without intracytoplasmic sperm injection (ICSI), is clinically and cost effective .

Quality measures

Structure

Evidence of local agreed policy on provision of 1 full cycle of IVF, with or without ICSI, for women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

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 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) who are offered 1 full cycle of IVF, with or

without ICSI, provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

Numerator – the number in the denominator offered 1 full cycle of IVF, with or without ICSI.

Denominator – the number of women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) and have never previously had IVF treatment, have no evidence of low ovarian reserve and have had a discussion of the additional implications of IVF and pregnancy at this age.

Data source: Local data collection.

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

Service providers (specialist secondary or tertiary care fertility services) ensure that policies are in place on provision of 1 full cycle of IVF, with or without ICSI, for women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

Healthcare professionals within specialist secondary or tertiary care fertility services adhere to policies in place on provision of 1 full cycle of IVF, with or without ICSI, for women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

Commissioners (clinical commissioning groups) should commission sufficient capacity within specialist secondary or tertiary care fertility services to provide 1 full cycle of IVF, with or without ICSI, for women aged 40–42 years who have not

conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), provided they have never previously had IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.

What the quality statement means for patients

Women aged 40–42 years who have been trying to get pregnant through regular unprotected sexual intercourse for 2 years or who have not become pregnant after 12 cycles of artificial insemination (at least 6 or which were by intrauterine insemination) are offered 1 full cycle of IVF if they have never previously had IVF, their tests show that their ovaries would respond normally to fertility drugs and they have discussed with their doctor the additional risks of fertility treatment and pregnancy for women aged 40 years or older.

Source guidance

- Fertility (NICE clinical guideline 156), recommendation 1.11.1.4 (key priority for implementation).

Definitions of terms used in this quality statement

Full cycle

A full cycle should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). [NICE clinical guideline 156]

In vitro fertilisation

In vitro fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body. Usually, 1 or 2 resulting embryos are then transferred to the womb with the aim of starting a pregnancy. [NICE clinical guideline 156]

Low ovarian reserve

Ovarian reserve refers to how many eggs a women has left, and is used to provide an indication of how many eggs will be retrieved during ovarian stimulation in IVF. [Expert consensus]

Equality and diversity considerations

In Fertility (NICE clinical guideline 156), the existence of living children is not a factor that precludes the provision of fertility treatment.

CG156 includes recommendations that relate to specific age-groups. The guideline development group found that age was the only robust factor in determining IVF success, and hence recommendations about access to IVF therapy have been made on the basis of age.

Quality statement 7: Intracytoplasmic sperm injection

Quality statement

People 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 sometimes used in addition to IVF, and is a technique to inject a single sperm into an egg to achieve fertilisation. This will improve 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 secondary or tertiary care fertility services) ensure that agreed 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 because previous IVF treatment resulted in failed or very poor fertilisation.

Healthcare professionals within specialist secondary or tertiary care fertility services use ICSI for people 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 people having IVF in the services they commission.

What the quality statement means for patients

People having IVF are offered an additional procedure (called intracytoplasmic sperm injection) to inject the sperm directly into the egg only if problems with the sperm mean it is unlikely to fertilise the eggs without it or there was poor or no fertilisation of the eggs with previous IVF.

Source guidance

- Fertility (NICE clinical guideline 156), recommendation 1.13.1.1.

Definitions of terms used in this quality statement

Intracytoplasmic sperm injection (ICSI)

A variation of IVF in which a single sperm is injected into the inner cellular structure of an egg. [NICE clinical guideline 156]

In vitro fertilisation (IVF)

IVF is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body. Usually, 1 or 2 resulting embryos are then transferred to the womb with the aim of starting a pregnancy. [NICE clinical guideline 156]

Non-obstructive azoospermia

No sperm in the ejaculate due to testicular failure. [Adapted from NICE clinical guideline 156]

Obstructive azoospermia

The testes produce sperm as normal but a blockage prevents entry to the ejaculate. [Adapted from NICE clinical guideline 156]

Quality statement 8: Assessing embryo quality

Quality statement

Services that evaluate the quality of embryos use the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Rationale

Embryos with the best possible chance of implantation should be identified and positively selected for transfer as part of an embryo transfer strategy. Selecting the best embryos will reduce the need to transfer more than 1 embryo, leading to a decrease in the number of multiple pregnancies.

Quality measures

Structure

Evidence of local arrangements to ensure that services evaluate the quality of embryos according to the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Data source: Local data collection.

Process

Proportion of embryos evaluated for quality according to the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Numerator – the number in the denominator evaluated for quality according to the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Denominator – the number of embryos.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 3).

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

Service providers (laboratory services) ensure that systems are in place to monitor compliance with the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Healthcare scientists evaluate embryos for transfer according to the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

Commissioners (clinical commissioning groups) ensure that the services they commission evaluate quality of embryos for transfer according to the Association of Clinical Embryologists and UK National External Quality Assessment Service for Reproductive Science embryo and blastocyst grading scheme.

What the quality statement means for patients

People having IVF have the quality of their embryos checked by a laboratory that uses standard methods to give accurate results.

Source guidance

- Fertility (NICE clinical guideline 156), recommendation 1.12.6.4.

Quality statement 9: Number of embryos transferred

Quality statement

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

Rationale

An effective embryo transfer strategy minimises the chance of multiple and higher order pregnancies following IVF. Multiple pregnancies represent a significant risk to the mother's and baby's health.

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 age of the woman (or the age of the donor if donor eggs are used), the cycle number and the quality of the embryos.

Data source: Local data collection.

Process

a) Proportion of embryo transfers in the first full IVF cycle using eggs from a woman aged under 37 years in which a single embryo is transferred.

Numerator – the number in the denominator in which a single embryo is transferred.

Denominator – the number of embryo transfers in the first full IVF cycle using eggs from women aged under 37 years.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 4a).

b) Proportion of embryo transfers in the second full IVF cycle using eggs from women aged under 37 years in which a single embryo is transferred if 1 or more top-quality embryos are available.

Numerator – the number in the denominator in which a single embryo is transferred.

Denominator – the number of embryo transfers in the second full IVF cycle using eggs from women aged under 37 years where 1 or more top-quality embryos are available.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 4b).

c) Proportion of embryo transfers in the third full IVF cycle using eggs from women aged under 37 years in which no more than 2 embryos are transferred.

Numerator – the number in the denominator in which no more than 2 embryos are transferred.

Denominator – the number of embryo transfers in the third full IVF cycle using eggs from women aged under 37 years.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 4c).

d) Proportion of embryo transfers in the first or second full IVF cycle using eggs from women aged 37–39 years in which a single embryo is transferred if there are 1 or more top-quality embryos available.

Numerator – the number in the denominator in which a single embryo is transferred.

Denominator – the number of embryo transfers in the first or second full IVF cycle using eggs from women aged 37–39 years where 1 or more top-quality embryos are available.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standards 5a and 5b).

e) Proportion of embryo transfers in the third full IVF cycle using eggs from women aged 37-39 years in which no more than 2 embryos are transferred.

Numerator – the number in the denominator in which no more than 2 embryos are transferred.

Denominator – the number of embryo transfers in the third full IVF cycle using eggs from women aged 37–39 years.

f) Proportion of embryo transfers for women aged 40-42 years undergoing IVF treatment in which no more than 2 embryos are transferred.

Numerator – the number in the denominator in which no more than 2 embryos are transferred.

Denominator – the number of embryo transfers for women aged 40-42 years undergoing IVF treatment.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 6).

g) Proportion of embryo transfers for women (all ages) undergoing IVF where a top-quality blastocyst is available in which single embryo transfer is used.

Numerator – the number in the denominator where single embryo transfer is used.

Denominator – the number of embryo transfers for women (all ages) undergoing IVF where a top-quality blastocyst is available.

Data source: Local data collection. Data can be collected using the NICE clinical audit tool for Fertility: embryo transfer strategies (clinical audit standard 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 treatment 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 secondary or tertiary care fertility services) ensure that systems are in place to monitor the number of embryos transferred during IVF cycles.

Healthcare professionals transfer the appropriate number of embryos during IVF, taking into account the age of the woman (or the donor if donor eggs are used), 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.

What the quality statement means for patients

Women having IVF have 1 or 2 embryos transferred into their womb, depending on the age of the woman (or the donor if donor eggs are used), the cycle number and the quality of the embryos.

Source guidance

- Fertility (NICE clinical guideline 156) recommendations 1.12.6.5 (key priority for implementation), 1.12.6.7 and 1.12.6.8 (key priority for implementation)

Definitions of terms used in this quality statement

In vitro fertilisation (IVF)

IVF is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body. Usually, 1 or 2 resulting embryos are then transferred to the womb with the aim of starting a pregnancy. [NICE clinical guideline 156]

Top-quality embryo or blastocyst

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. [NICE clinical guideline 156]

Quality statement 10: Cryopreservation prior to cancer treatment

Quality statement

People of reproductive age preparing to have treatment for cancer that is likely to give them fertility problems are offered cryopreservation.

Rationale

Some treatments for cancer can cause fertility problems. People with cancer who may want to have children in the future may benefit from cryopreservation, which may give them the option of having children later.

Quality measures

Structure

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

Data source: Local data collection.

Process

a) Proportion of males of reproductive age having treatment for cancer that is likely to give them fertility problems who are offered sperm cryopreservation.

Numerator – the number in the denominator offered sperm cryopreservation.

Denominator – the number of males of reproductive age having treatment for cancer that is likely to give them fertility problems.

Data source: Local data collection.

b) Proportion of females of reproductive age having treatment for cancer that is likely to give them fertility problems who are offered oocyte or embryo cryopreservation.

Numerator – the number in the denominator offered oocyte or embryo cryopreservation.

Denominator – the number of females of reproductive age having treatment for cancer that is likely to give them fertility problems and:

- are well enough to undergo ovarian stimulation and egg collection
- cryopreservation will not worsen their condition
- there is 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 secondary or tertiary care fertility services) ensure that agreed referral pathways are in place to provide cryopreservation to people of reproductive age who are preparing to have treatment for cancer that is likely to give them fertility problems.

Healthcare professionals in specialist secondary or tertiary care fertility services offer cryopreservation to people of reproductive age preparing to have treatment for cancer likely to give them fertility problems.

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

What the quality statement means for patients

People of reproductive age preparing to have treatment for cancer that is likely to give them fertility problems are given the option to freeze their eggs or sperm for possible use in the future.

Source guidance

- Fertility (NICE clinical guideline 156), recommendations 1.16.1.8 and 1.16.1.10.

Definitions of terms used in this quality statement

Cryopreservation

The freezing and storage of embryos, sperm or eggs for future use in IVF treatment cycles. [NICE clinical guideline 156]

Oocyte

An immature egg cell. [NICE clinical guideline 156]

Equality and diversity considerations

Young people should have adequate access to cryopreservation. NICE guideline 156 states that there should not be a lower age limit for cryopreservation for fertility preservation in people diagnosed with cancer.

Status of this quality standard

This is the draft quality standard released for consultation from 15 May to 12 June 2014. It is not NICE's final quality standard on fertility problems. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 12 June 2014. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the NICE website from October 2014.

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’.

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 on the NICE website.

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. NICE clinical guideline 156 (2013).

Policy context

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

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

Definitions and data sources for the quality measures

- National data on provision treatment for fertility problems are available from the Human Fertilisation and Embryology Authority.
- NICE clinical guideline 156 audit tools for people concerned about delays in conception and embryo transfer strategies.

Related NICE quality standards

Published

- Children and young people with cancer. NICE quality standard 55 (2014).
- Heavy menstrual bleeding. NICE quality standard 47 (2013).
- Multiple pregnancy. NICE quality standard 46 (2013).
- Antenatal care. NICE quality standard 22 (2012).
- Patient experience in adult NHS services. NICE quality standard 15 (2012).

In development

- Pain and bleeding in early pregnancy. Publication expected July 2014.
- Eating disorders. Publication expected October 2014.

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Obesity (adults).
- Obesity: prevention and management in adults.

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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Consultant Developmental Paediatrician, Guys and St Thomas NHS Foundation Trust

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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 for fertility.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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