# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health and social care directorate

## Quality standards and indicators

## Briefing paper

**Quality standard topic:** Fertility problems

**Output:** Prioritised quality improvement areas for development.

**Date of Quality Standards Advisory Committee meeting:** 10th March 2014

## Contents

# 1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for fertility problems. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

## *1.1 Structure*

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

## *1.2 Development source*

The key development source(s) referenced in this briefing paper is:

- Fertility. NICE clinical guideline 156 (2013).
- Dietary interventions and physical activity interventions for weight management before, during and after pregnancy. NICE public health guidance 27 (2010).

# 2 Overview

## *2.1 Focus of quality standard*

This quality standard will cover 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.

## *2.2 Definition*

Infertility is when a couple cannot conceive (get pregnant) despite having regular unprotected sex. In recommendation 1.2.13.4 of CG156 it states that ‘Healthcare professionals should define infertility in practice as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.’ Recommendation 1.2.13.5 defines when formal investigation for the majority of people should commence as ‘A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner’.

## 2.3 Incidence and prevalence

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. The main causes of infertility in the UK are (percent figures indicate approximate prevalence):

- 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 disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also play a role.

In 2011, 48,147 women had a total of 61,726 cycles of IVF or IVF with intracytoplasmic sperm injection (ICSI) and 2,087 women had a total of 4,091 cycles of donor insemination (DI). Four in ten (40.3%) IVF treatment cycles were funded by the NHS in 2011 and six in ten (59.7%) were funded privately. For DI 17.9% of cycles were funded by the NHS in 2011 and 82.1% were funded privately.

In cycles (NHS and privately funded) which started in 2011[1] a total of 89,648 embryos were transferred during the course of fertility treatment which started in 2011:

- 30,337 fresh embryos were transferred during IVF treatment
- 40,340 fresh embryos were transferred during ICSI treatment[2]
- 17,635 thawed embryos which had previously been frozen were transferred

## 2.4 Management

Given the range of causes of fertility problems, the provision of appropriate investigations is critical. These investigations include semen analysis; assessment of ovulation, tubal damage and uterine abnormalities; and screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella.

Once a diagnosis has been established, treatment falls into 3 main types:

- medical treatment to restore fertility (for example, the use of drugs for ovulation induction)
- surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis)

[1] HFEA (2013) Fertility treatment in 2011: Trends and figures. http://www.hfea.gov.uk/104.html
[2] 401 embryos were transferred during treatment involving both IVF *and* ICSI.

- assisted reproduction techniques (ART) – any treatment that deals with means of conception other than vaginal intercourse. It frequently involves the handling of gametes or embryos.

The NICE pathway provides further background about the management of fertility problems.

## *2.5 National Outcome Frameworks*

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 |
|---|---|
| 4 Ensuring that people have a positive experience of care | ***Improvement areas***<br>**Improving people's experience of outpatient care**<br>4.1 Patient experience of outpatient services |

# 3 Summary of suggestions

## *3.1 Responses*

In total 20 stakeholders (including 4 specialist committee members) responded to the 2-week engagement exercise (13/01-27/01/2014). One stakeholder (NHS England) confirmed that they had no comments to make at the engagement stage.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 2 for further consideration by the Committee.

Full details on the suggestions provided are given in appendix 3 for information.

**Table 2 Summary of suggested quality improvement areas**

| Suggested area for improvement | Stakeholders |
|---|---|
| **Initial advice and investigations in primary care (4.1)**<br>High quality initial advice and investigations in the primary care setting. Assessment and information about modifiable factors such as weight loss or weight gain, alcohol intake, smoking. | Association of Biomedical Andrologists<br>British Fertility Society<br>Gloucestershire Royal Hospital NHS Foundation Trust |
| **Appropriate use of ovarian stimulation drugs (4.2)**<br>Prescribing clomifene citrate or letrozole in primary care. | Gloucestershire Royal Hospital NHS Foundation Trust |
| **Prompt referral to specialist services (4.3)**<br>People experiencing delays in referral to specialist services and the negative impact on patient management and treatment outcomes. Women aged 36 and over highlighted as a particular group who require prompt referral and access. | Gloucestershire Royal Hospital NHS Foundation Trust<br>Merck Serono<br>SCM |
| **Variation in funding: definition of 'full cycle of IVF' (4.4)**<br>Commissioners either unaware of or intentionally not commissioning services which deliver a 'full cycle' of IVF as defined in CG156. | Ferring Pharmaceuticals Ltd.<br>Infertility Network UK<br>Merck Serono<br>National Infertility Awareness Campaign<br>Progress Educational Trust<br>SCM |
| **Variation in funding: number of cycles of IVF (4.5)**<br>Variation in funding of IVF: women under 40 years<br>Variation in funding of IVF: women aged 40-42 years | Infertility Network UK<br>National Infertility Awareness Campaign<br>Progress Educational Trust<br>SCM |

| Suggested area for improvement | Stakeholders |
|---|---|
| | Infertility Network UK<br>National Infertility Awareness Campaign<br>SCM |
| **Appropriate use of ICSI (4.6)**<br>Discrepancy between the observed rate of male factor infertility and the reported use of ICSI. | Infertility Network UK<br>National Infertility Awareness Campaign<br>Progress Educational Trust<br>SCM |
| **Monitoring ovulation induction (4.7)**<br>Stakeholders reported that not all fertility clinics have robust protocols in place for preventing, diagnosing and managing ovarian hyperstimulation syndrome. | Human Fertilisation and Embryology Authority<br>Royal College of Nursing<br>SCM |
| **Single embryo transfer (4.8)**<br>Multiple pregnancy represents significant risks to the mother's and baby's health and that single embryo transfer is key to reducing the rate of multiple pregnancy. Appropriate approach where people do not have access to the 3 cycles of IVF (when the woman is aged under 40 years). | Human Fertilisation and Embryology Authority<br>Infertility Network UK<br>National Infertility Awareness Campaign<br>Progress Educational Trust<br>Royal College of Nursing<br>SCM |
| **Laboratory quality assurance (4.9)**<br>Need for improved quality control (QC) systems within laboratories which provide assisted reproduction procedures. | Ferring Pharmaceuticals Ltd.<br>Royal College of Nursing<br>SCM<br>British Fertility Society<br>Association of Biomedical Andrologists |
| **Counselling (4.10)**<br>Importance of counselling services being made available to those people who are undergoing fertility treatment, fertility preservation or gamete donation. | British Fertility Society<br>Cardiff Fertility Studies Research Group<br>Cardiff University<br>Infertility Awareness Campaign<br>Infertility Network UK<br>Progress Educational Trust<br>Royal College of Nursing<br>SCM |
| **Fertility preservation for people with cancer (4.11)**<br>Cryopreservation is not always offered promptly to people diagnosed with cancer. | Association of Biomedical Andrologists<br>British Fertility Society<br>Human Fertilisation and Embryology Authority<br>SCM |

| Suggested area for improvement | Stakeholders |
|---|---|
| **Additional suggestions - out of scope, no supporting recommendations, do not meet technical criteria for statement development (4.12)**<br><br>Benchmarking services to establish transparent national comparisons<br>Audit areas of uncertain quality including primary care initial infertility investigations, mild ovarian stimulation in secondary care and use of gonadotropins.<br>Data for patients about outcomes of fertility providers<br>Lesbian and bisexual women's experience of fertility services<br>Staffing levels<br>Training and competencies<br>Validation of a patient satisfaction questionnaire | |

# 4 Suggested improvement areas

## *4.1 Initial advice and investigations in primary care*

### 4.1.1 Summary of suggestions

Stakeholders highlighted the importance of people who present with difficulties conceiving receiving high quality initial advice and investigations (such as screening for chlamydia). Stakeholders highlighted that in primary care people should receive an assessment of and information about modifiable factors such as weight loss or weight gain, alcohol intake, smoking, folic acid intake, prescribed and recreational drug use. Stakeholders reported that changing such behaviours can improve natural conception rates and improve the effectiveness of fertility treatments. Appropriate advice and lifestyle modifications prior to referral would avoid disappointments in people referred and avoid delay in definitive treatment.

There was a general theme from stakeholders that fertility treatment focuses primarily on the woman, and one stakeholder specifically highlighted that lifestyle factors are not always considered for men, thereby leading to people needing to undergo sometimes unnecessary invasive fertility treatments.

### 4.1.2 Selected recommendations from development source

Table 3 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 3 to help inform the Committee's discussion.

**Table 3 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Initial advice and investigations in primary care | **1.2 Initial advice to people concerned about delays in conception**<br><br>NICE CG156 Recommendations 1.2.3.1, 1.2.3.2, 1.2.3.3, 1.2.4.1, 1.2.4.2, 1.2.4.3, 1.2.4.4, 1.2.5.1, 1.2.6.1, 1.2.6.2, 1.2.6.3, 1.2.6.4, 1.2.7.1, 1.2.8.1, 1.2.9.1, 1.2.10.1, 1.2.11.1, 1.2.12.1<br><br>**1.3 Investigation of fertility problems and management strategies**<br>NICE CG156 Recommendations 1.3.11.1, 1.3.12, 1.3.12.1, 1.3.13, 1.3.13.1, 1.3.13.2, 1.3.13.3 |

| | |
|---|---|
| Initial advice and investigations in primary care | **Preparing for pregnancy: women with a BMI of 30 or more.**<br><br>NICE PH27, recommendation 1, bullet 3: |

**Initial advice to people concerned about delays in conception**

NICE CG156 Recommendations 1.2.3.1, 1.2.3.2, 1.2.3.3, 1.2.4.1, 1.2.4.2, 1.2.4.3, 1.2.4.4, 1.2.5.1, 1.2.6.1, 1.2.6.2, 1.2.6.3, 1.2.6.4, 1.2.7.1, 1.2.8.1, 1.2.9.1, 1.2.10.1, 1.2.11.1, 1.2.12.1

1.2.3 Alcohol

1.2.3.1 Women who are trying to become pregnant should be informed that drinking no more than 1 or 2 units of alcohol once or twice per week and avoiding episodes of intoxication reduces the risk of harming a developing fetus. **[2004]**

1.2.3.2 Men should be informed that alcohol consumption within the Department of Health's recommendations of 3 to 4 units per day for men is unlikely to affect their semen quality. **[2004, amended 2013]**

1.2.3.3 Men should be informed that excessive alcohol intake is detrimental to semen quality. **[2004]**

1.2.4 Smoking

1.2.4.1 Women who smoke should be informed that this is likely to reduce their fertility. **[2004]**

1.2.4.2 Women who smoke should be offered referral to a smoking cessation programme to support their efforts in stopping smoking. **[2004]**

1.2.4.3 Women should be informed that passive smoking is likely to affect their chance of conceiving. **[2004]**

1.2.4.4 Men who smoke should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking will improve their general health. **[2004]**

1.2.5 Caffeinated beverages

1.2.5.1 People who are concerned about their fertility should be informed that there is no consistent evidence of an association between consumption of caffeinated beverages (tea, coffee and colas) and fertility problems[1]. **[2004]**

1.2.6 Obesity

1.2.6.1 Women who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive. **[2004, amended 2013]**

1.2.6.2 Women who have a BMI of 30 or over and who are not ovulating should be informed that losing weight is likely to increase their chance of conception. **[2004, amended 2013]**

1.2.6.3 Women should be informed that participating in a group programme involving exercise and dietary advice leads to more pregnancies than weight loss advice alone. **[2004]**

1.2.6.4 Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility. **[2004, amended 2013]**

1.2.7 Low body weight

1.2.7.1 Women who have a BMI of less than 19 and who have irregular menstruation or are not menstruating should be advised that increasing body weight is likely to improve their chance of conception. **[2004]**

1.2.8 Tight underwear

1.2.8.1 Men should be informed that there is an association between elevated scrotal temperature and reduced semen quality, but that it is uncertain whether wearing loose-fitting underwear improves fertility. **[2004]**

1.2.9 Occupation

1.2.9.1 Some occupations involve exposure to hazards that can reduce male or female fertility and therefore a specific enquiry about occupation should be made to people who are concerned about their fertility and appropriate advice should be offered. **[2004]**

1.2.10 Prescribed, over-the-counter and recreational drug use

1.2.10.1 A number of prescription, over-the-counter and recreational drugs interfere with male and female fertility, and therefore a specific enquiry about these should be made to people who are concerned about their fertility and appropriate advice should be offered. **[2004]**

1.2.11 Complementary therapy

1.2.11.1 People who are concerned about their fertility should be informed that the effectiveness of complementary therapies for fertility problems has not been properly evaluated and that further research is needed before such interventions can be recommended. **[2004]**

1.2.12 Folic acid supplementation

1.2.12.1 Women intending to become pregnant should be informed that dietary supplementation with folic acid before conception and up to 12 weeks' gestation reduces the risk of having a baby with neural tube defects. The recommended dose is 0.4 mg per day. For women who have previously had an infant with a neural tube defect or who are receiving anti-epileptic medication or who have diabetes (see Diabetes in pregnancy, NICE clinical guideline 63), a higher dose of 5 mg per day is recommended. **[2004, amended 2013]**

**Investigation of fertility problems and management strategies**

NICE CG156 Recommendations 1.3.11.1, 1.3.12, 1.3.12.1, 1.3.13, 1.3.13.1, 1.3.13.2, 1.3.13.3

1.3.11 Susceptibility to rubella

1.3.11.1 Women who are concerned about their fertility should be offered testing for their rubella status so that those who are susceptible to rubella can be offered vaccination. Women who are susceptible to rubella should be offered vaccination and advised not to become pregnant for at least 1 month following vaccination. **[2004, amended 2013]**

1.3.12 Cervical cancer screening

1.3.12.1 To avoid delay in fertility treatment a specific enquiry about the timing and result of the most recent cervical smear test should be made to women who are concerned about their fertility. Cervical screening should be offered in accordance with the national cervical screening programme guidance. **[2004]**

1.3.13 Screening for *Chlamydia trachomatis*

1.3.13.1 Before undergoing uterine instrumentation women should be offered screening for *Chlamydia trachomatis* using an appropriately sensitive technique. **[2004]**

1.3.13.2 If the result of a test for *Chlamydia trachomatis* is positive, women and their sexual partners should be referred for appropriate management with treatment and contact tracing. **[2004]**

1.3.13.3 Prophylactic antibiotics should be considered before uterine instrumentation, if screening has not been carried out. **[2004]**

**Changing behaviour**

NICE PH27, recommendation 1, bullet 3, Preparing for pregnancy: women with a BMI of 30 or more.

GPs, dietitians and other appropriately trained health professionals should advise, encourage and help women with a BMI of 30 or more to reduce weight before becoming pregnant. They should explain that losing 5–10% of their weight (a realistic target) would have significant health benefits[3] and could increase their chances of becoming pregnant. Further weight loss, to achieve a BMI within the healthy range (between 24.9 and 18.5 kg/m2) should also be encouraged, using evidence-based behaviour change techniques. Losing weight to within this range may be difficult and women will need to be motivated and supported.

### 4.1.3 Current UK practice

No current practice information identified.

[3] This is an edited extract from a recommendation that appears in 'Obesity'. NICE clinical guideline 43.

## *4.2 Appropriate use of ovarian stimulation drugs*

### 4.2.1 Summary of suggestions

One stakeholder highlighted that people with unexplained infertility are sometimes prescribed clomifene citrate or letrozole (ovarian stimulation drugs) in primary care. Instead these patients should be referred to specialist services where more definitive treatment can be commenced.

### 4.2.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

**Table 4 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Prompt referral to specialist services | **Unexplained infertility**<br>NICE CG156 Recommendation 1.8.1.1 (key priority for implementation) and 1.8.1.2 |

**Unexplained infertility**

NICE CG156 Recommendation 1.8.1.1 (key priority for implementation)

Do not offer oral ovarian stimulation agents (such as clomifene citrate, anastrozole or letrozole) to women with unexplained infertility. **[new 2013]**

NICE CG156 Recommendation 1.8.1.2

Inform women with unexplained infertility that clomifene citrate as a stand-alone treatment does not increase the chances of a pregnancy or a live birth. **[new 2013]**

### 4.2.3 Current UK practice

No current practice information identified.

## *4.3 Prompt referral to specialist services*

### 4.3.1 Summary of suggestions

Also see section on cryopreservation, which includes access (including referral) to cryopreservation service for people undergoing cancer treatment which may affect their future fertility.

Stakeholders highlighted that some people experiencing fertility problems experience delays in referral to specialist services, which has a negative impact on patient management and treatment outcomes. This was a general theme and stakeholders also highlighted women aged 36 and over as a particular group who require prompt referral and access because fertility declines with age.

### 4.3.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

**Table 5 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Prompt referral to specialist services | **Defining infertility**<br>NICE CG156 Recommendation 1.2.13.5 (key priority for implementation) and 1.2.13.7 (key priority for implementation) |

**Defining infertility**

NICE CG156 Recommendation 1.2.13.5 (key priority for implementation)

A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. **[new 2013]**

NICE CG156 Recommendation 1.2.13.7 (key priority for implementation)

Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:

- the woman is aged 36 years or over

- there is a known clinical cause of infertility or a history of predisposing factors for infertility. **[new 2013]**

### 4.3.3 Current UK practice

No current practice information identified.

## *4.4 Variation in funding: definition of 'full cycle of IVF'*

### 4.4.1 Summary of suggestions

Stakeholders highlighted that some commissioning organisations are either not aware of the definition of 'full cycle' within the updated NICE CG156 or take deliberate action not to commission services which deliver the full cycle of IVF due to financial constraints. Mechanisms for limiting an IVF cycle reported by stakeholders include limiting a cycle to the transfer of fresh embryos only or imposing a cap on the number of frozen embryos transferred. Stakeholders reported that these restrictions limit a woman's chance of conceiving and force people to access private fertility treatment in order to have the frozen embryos transferred to the woman.

Those areas which commission the recommended number of cycles of IVF (see section 4.5) do not always commission the full cycle.

### 4.4.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

**Table 6 Specific areas for quality improvement**

| Suggested quality improvement area | Suggested source guidance recommendations |
|---|---|
| Variation in funding: definition of 'full cycle of IVF' | **Criteria for referral for IVF**<br>NICE CG156 Recommendation 1.11.1.2 (key priority for implementation) |

**Criteria for referral for IVF**

NICE CG156 Recommendation 1.11.1.2 (key priority for implementation)

Inform people that normally a full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). **[new 2013]**

### 4.4.3 Current UK practice

National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England

The report does not present a breakdown of which CCGs commission services to provide a full cycle in line with CG156 recommendation 1.11.1.2 (key priority for implementation), but in relation to this definition the report includes the following:

‘The majority of CCGs audited adhered to this principle, some were found to have limited the number of frozen embryo cycles to two or one. A few others were found to offer no funding for frozen embryo cycles.’ Section 4.3, paragraph 2, page 12.

CCG policies

During the engagement process several stakeholders submitted a hyperlink to a CCG policy which is not in line with the definition of a full cycle of IVF in CG156 recommendation 1.11.1.2 (key priority for implementation). Buckinghamshire CCGs, East Berkshire CCGs, West Berkshire CCGs and Oxfordshire CCG (which appears to consist of 10 clinical commissioning groups) have adopted an interim policy for implementation from 1 April 2013 which acknowledges the publication of CG156 in February 2013 and defines one cycle of IVF as:

‘one fresh cycle including ovulation induction, egg retrieval, fertilisation and implantation, and includes appropriate diagnostic tests, scans and pharmacological therapy. Berkshire, Buckinghamshire and Oxfordshire Clinical Commissioning Groups will not fund any subsequent frozen cycles using stored embryos.’ Page 2 of Interim Policy Statement 11f: Assisted Conception Services[4].

[4] Interim policy statement 11f accessed 24/02/2014

## *4.5 Variation in funding: number of cycles of IVF*

### 4.5.1 Summary of suggestions

Stakeholders reported that some commissioning organisations are restricting access to IVF by applying local criteria such as limiting the number of IVF cycles that women are able to access, imposing a minimum and upper age limit for IVF, only considering childless children for IVF or imposing minimum waiting time thresholds. Stakeholders highlighted particular concerns regarding the number of cycles of IVF that are available to women who are aged under 40 years or aged 40-42 years.

Variation in funding of IVF: women under 40 years

Stakeholders reported that some commissioning organisations are restricting access to IVF by intentionally not commissioning services that deliver 3 full cycles of IVF to women aged under 40 who meet the criteria specified in NICE CG156.

Variation in funding of IVF: women 40-42 years

Stakeholders reported that some commissioning organisations are restricting access to IVF by intentionally not commissioning services that deliver 1 full cycle of IVF to women aged 40-42 who meet the criteria specified in NICE CG156.

### 4.5.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

**Table 7 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Variation in funding: IVF for women under 40 | **Criteria for referral for IVF**<br>NICE CG156 Recommendation 1.11.1.3 (key priority for implementation) |
| Variation in funding for IVF: women 40-42 years | **Criteria for referral for IVF**<br>NICE CG156 Recommendation 1.11.1.4 (key priority for implementation) |

**Criteria for referral for IVF**

NICE CG156 Recommendation 1.11.1.3 (key priority for implementation)

In women aged under 40 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), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. **[new 2013]**

NICE CG156 Recommendation 1.11.1.4 (key priority for implementation)

In 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), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:

- they have never previously had IVF treatment
- there is no evidence of low ovarian reserve (see recommendation 1.3.3.2)
- there has been a discussion of the additional implications of IVF and pregnancy at this age. **[new 2013]**

### 4.5.3 Current UK practice

National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England

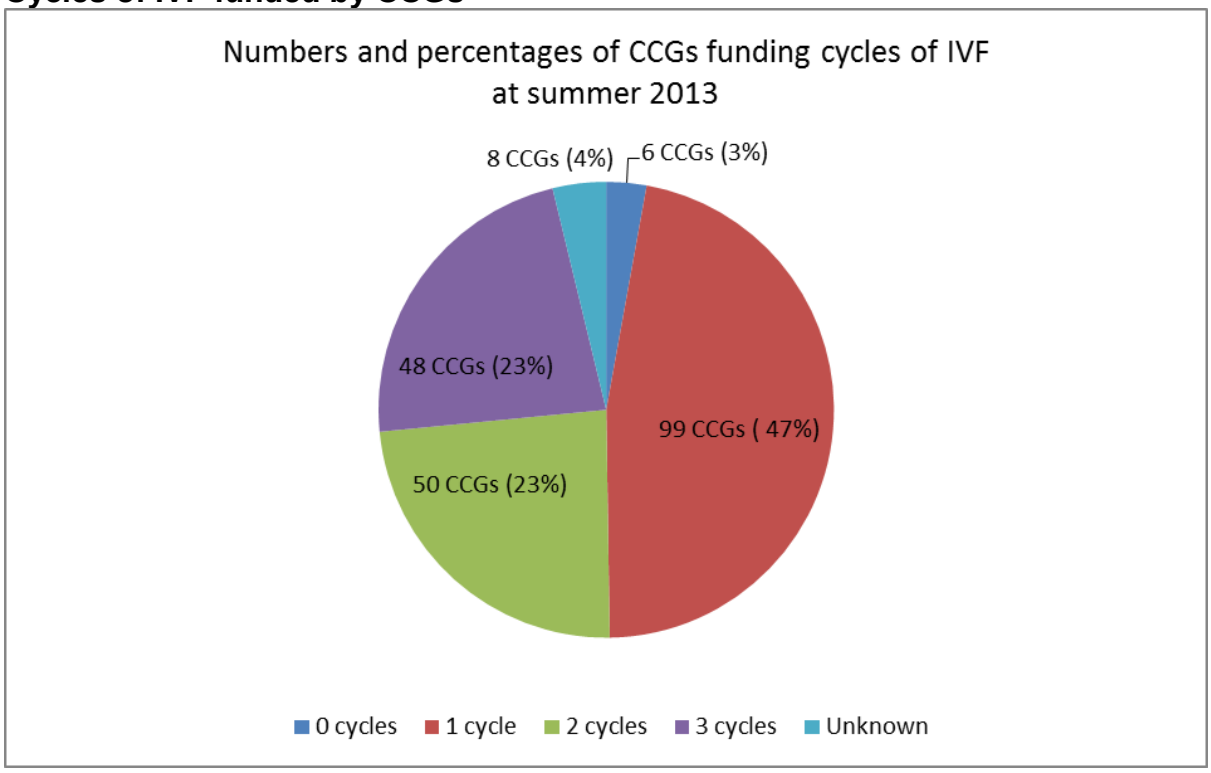
Throughout the summer of 2013, the National Infertility Awareness Campaign wrote to every CCG to ask for their policy on the provision of assisted conception services. These requests were followed-up with phone calls and emails. Although most CCGs responded (either individually or as groups of CCGs), in cases were CCGs did not respond NIAC searched CCG websites to try to establish current local policy. Of the 211 CCGs, NIAC sourced fertility policies for 204 CCGs. This report provides a snapshot of commissioning policies for the provision of fertility services. Policies may have been reviewed and updated in the interim.

CCG policies

During the engagement process several stakeholders submitted a hyperlink to a proposal for CCGs in East of England to reduce the number of cycles commissioned from 3 full cycles to 2 full cycles of IVF for women aged under 40 years[5].

[5] See Discussion paper for East of England CCGs proposing to reduce to 2 full cycles of IVF and include age range extension but not to adopt guidance on waiting time reduction. (accessed 24/02/2014)

**Cycles of IVF funded by CCGs**




Data extracted from appendix 1 of National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England.[6]

*Additional access criteria: Age*

The majority of CCGs have a lower limit threshold for IVF that requires the woman to be 23 years old before she will be considered for IVF treatment. Table 8 provides the breakdown for lower age limits.

**Table 8: Lower age limits imposed by CCGs for access to IVF**

| **Age criteria** | No lower limit | <23 years considered* | 23 years | 24 | 30 | Unknown | NA (No IVF funded) |
|---|---|---|---|---|---|---|---|
| **Number of CCGs** | 32 | 6 | 152 | 1 | 2 | 12 | 6 |
| **Percentage** | 15% | 3% | 72% | 0% | 1% | 6% | 3% |

*6 CCGs had a general policy of 23 years being the lower age criteria for access to IVF, but highlighted the CCG would consider individual requests for access to IVF for women aged under 23 years.

[6] It is not clear in the report why there are 7 CCGs which did not respond to the survey but there are 8 CCGs for which it is unknown if IVF cycles are funded.

Data extracted from appendix 1 of National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England.

The majority of CCGs have an upper age limit threshold for IVF which requires the woman to be less than 40 years of age to be considered for IVF treatment. Table 9 provides the breakdown for upper age limits.

**Table 9 Upper age limits imposed by CCGs for access to IVF**

| **Age criteria** | <35 | <36 | <37.5 | <39 | <40 | <42 | Unknown | NA (No IVF funded) |
|---|---|---|---|---|---|---|---|---|
| **Number of CCGs** | 17 | 1 | 2 | 5 | 161 | 7 | 12 | 6 |
| **Percentage** | 8% | 0% | 1% | 2% | 76% | 3% | 6% | 3% |

Data extracted from appendix 1 of National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England.

*Additional access criteria: Children from current or previous relationship*

The majority of CCGs stipulate that the people seeking fertility treatment must not have any children from either their current or previous relationship. Table 10 shows the breakdown by category.

**Table 10 shows the breakdown by category**

| **Criteria** | **Number of CCGs** | **Percentage** |
|---|---|---|
| No living children for both partners | 155 | 73% |
| One partner may (not from current relationship) | 15 | 7% |
| One partner may (not from current relationship, must not live with them) | 10 | 5% |
| Both partners (not from current relationship) | 1 | 0% |
| Not more than 4 combined from previous relationships | 7 | 3% |
| Unknown | 17 | 8% |
| NA (no funding for IVF) | 6 | 3% |

Data extracted from appendix 1 of National Infertility Awareness Campaign (January 2014) Fighting for funding: A report into the status of NHS fertility services in England.

*Additional access criteria: Lifestyle criteria*

In the report NIAC highlight that some CCGs also impose other restrictions such as smoking status and limitations based on a woman's BMI.

Human Fertilisation and Embryology Authority Fertility treatment in 2011[7].

The HFEA is the independent regulator of fertility treatment in the UK and their remit includes regulation of all NHS and private providers of fertility treatment. The HFEA collect data about every treatment cycle performed and around 60,000 fertility treatments are performed in UK licensed clinics annually. The HFEA have published an annual report about cycles of fertility treatment which started in 2010 and 2011.

The majority – almost two thirds – of women who received IVF treatment were aged 37 and under. There has been no change in the age distribution of women receiving IVF treatment since last year. Women having IVF treatment were on average 35.0 years old. The average length of time patients reported trying to conceive was 4.6 years (range 0 to 20 years). Women having DI treatment were on average 35.2 years old and had been trying to conceive for on average 4.0 years (range 0 to 20 years).

**Percentage of all IVF cycles performed, by age group, 2011**

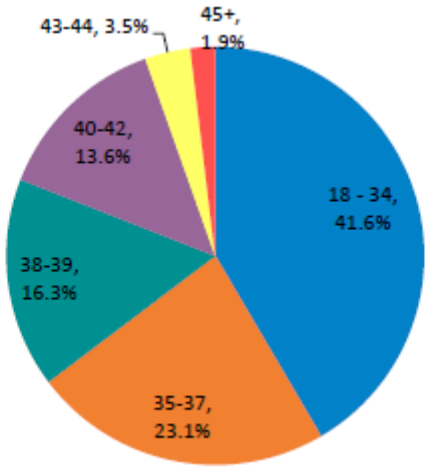



Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures page 12 (figure 2).

There is a general trend in the UK and elsewhere for women to have children slightly later in life and the HFEA collected data demonstrates the longer term trend in the age of women seeking fertility treatment reflects this. Since 1991 the average (mean) age of women being treated has increased by about 1 and half years for IVF, from 33.6 to 35.0, but by over 3 years for DI, from 31.9 to 35.2. However, over the shorter term (since around 2006), the average age for women having either type of treatment has actually remained steady.

[7] HFEA (2013) Fertility treatment in 2011: Trends and figures. http://www.hfea.gov.uk/104.html

**Average age of women treated with fresh IVF and DI, 1991 to 2011**

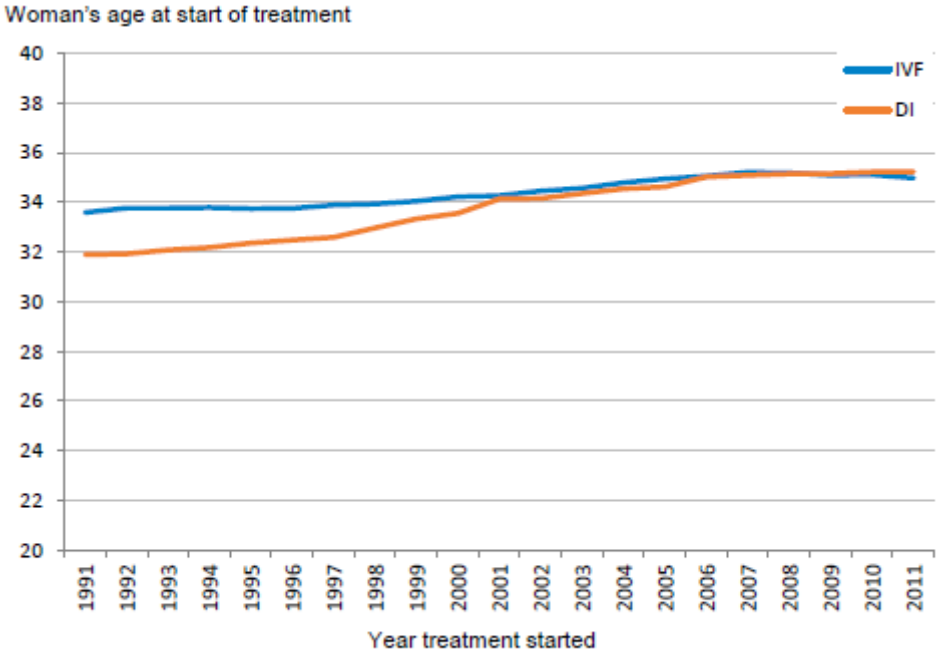



Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures page 37 (figure 20).

## *4.6 Appropriate use of ICSI*

### 4.6.1 Summary of suggestions

Stakeholders highlighted that the use of intracytoplasmic sperm injection (ICSI) in the UK is disproportionate to the number of patients with an identifiable need for this type of treatment. Stakeholders highlighted that incidence of male factor infertility in cases of fertility treatment is 30 to 40%. However, data from the HFEA shows that ICSI is used to treat 53% of all couples receiving fertility treatment in the UK. There is therefore a discrepancy between the observed rate of male factor infertility and the reported use of ICSI. Stakeholders also reported that the rates of cycles that feature ICSI vary widely from clinic to clinic, and region to region. Given these trends, it is important to ensure that the decision to use ICSI is based on clinical need.

### 4.6.2 Selected recommendations from development source

Table 11 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 11 to help inform the Committee's discussion.

**Table 11 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Appropriate use of ICSI | **Semen analysis**<br>NICE CG156 Recommendations 1.3.1.1<br><br>**Indications for intracytoplasmic sperm injection**<br>NICE CG156 Recommendations 1.13.1.1 |

**Semen analysis**

NICE CG156 Recommendations 1.3.1.1

1.3.1.1 The results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values[8]:

- 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

[8] Please note the reference ranges are only valid for the semen analysis tests outlined by the World Health Organization.

- 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. **[2004, amended 2013]**

**Indications for intracytoplasmic sperm injection**

NICE CG156 Recommendations 1.13.1.1

The recognised indications for treatment by ICSI include:

- severe deficits in semen quality
- obstructive azoospermia
- non-obstructive azoospermia.

In addition, treatment by ICSI should be considered for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation. **[2004]**

### 4.6.3 Current UK practice

Who needs ICSI? A nationwide survey on ICSI use[9]

A UK wide survey was undertaken to examine different criteria used and their effect on ICSI usage and treatment outcomes. Centres which offer ICSI were identified using the Human Fertilisation and Embryology Authority (HFEA) website. Questionnaires were then posted to all centres that offer the procedure. Each centre received the questionnaire twice; the first was sent to the HFEA person responsible and a month later, a follow-up questionnaire was sent to the centre's lead embryologist. Data were also extracted from the HFEA website. 71 centres were identified and questionnaires returned from 43 (61%). When deciding to use ICSI, 43 (100%) of centres used sperm count, 93% used sperm motility, 76% used sperm morphology and 72% used anti-sperm antibodies. All centres stated that they would offer ICSI after failed fertilisation with conventional IVF and 38% of centres offered ICSI on patient request. No centres reported using other criteria for selection. The absolute values chosen for each criterion varied hugely between centres. Compared with the 2010 World Health Organization (WHO) guidelines of normal semen analyses, 32% of centres used a higher count, 50% a higher motility and 59% a higher morphology. Based on the WHO criteria, 27% of centres would use ICSI for sperm that were normal by all WHO criteria. Between centres, no significant difference in ICSI fertilisation rates was found. However, there was a significant

[9] Jones J, Horne G and Fitzgerald C (2012) Who needs ICSI? A nationwide survey on ICSI use. *Human Fertility* 15 (3): 144-149.

negative correlation between increased ICSI usage and fertilisation rates by conventional IVF (p = 0.0058). Data obtained from the HFEA website failed to demonstrate an increase in live birth rate in centres using ICSI more frequently. Conclusion: ICSI usage varied widely, due to large differences in the ICSI selection criteria used, with many centres using ICSI for patients with normal semen parameters. Centres which used more ICSI did not report higher live birth rates. No evidence was found to suggest that higher ICSI usage increased overall fertilisation rates. These findings highlight the need for guidelines on when to use ICSI.

Human Fertilisation and Embryology Authority Fertility treatment in 2011[10]

When patients register with a clinic, information about the type of infertility they are seeking treatment for is collected and reported to the HFEA. The HFEA data is split into those receiving IVF and those receiving ICSI. About half (52.9%) of fresh IVF treatments in 2011 involved ICSI, a similar proportion to that seen in recent years (51.9% in 2010, 52.1% in 2009). The HFEA report that because ICSI involves the injection of a single sperm into an egg, it can be used in male factor infertility, for instance low sperm count, or low sperm motility. This is reflected in Figure 3, where the proportion of male factor infertility treated with ICSI is much greater than that by standard IVF. It is important to note that the information is recorded at the *start* of a woman or couple's treatment and it is possible that further problems become apparent during treatment (or in the case of unexplained infertility, a cause may be uncovered later on).

[10] HFEA (2013) Fertility treatment in 2011: Trends and figures. http://www.hfea.gov.uk/104.html

**Percentages of couples seeking standard IVF or ICSI treatment, by the reason they sought treatment, 2011**

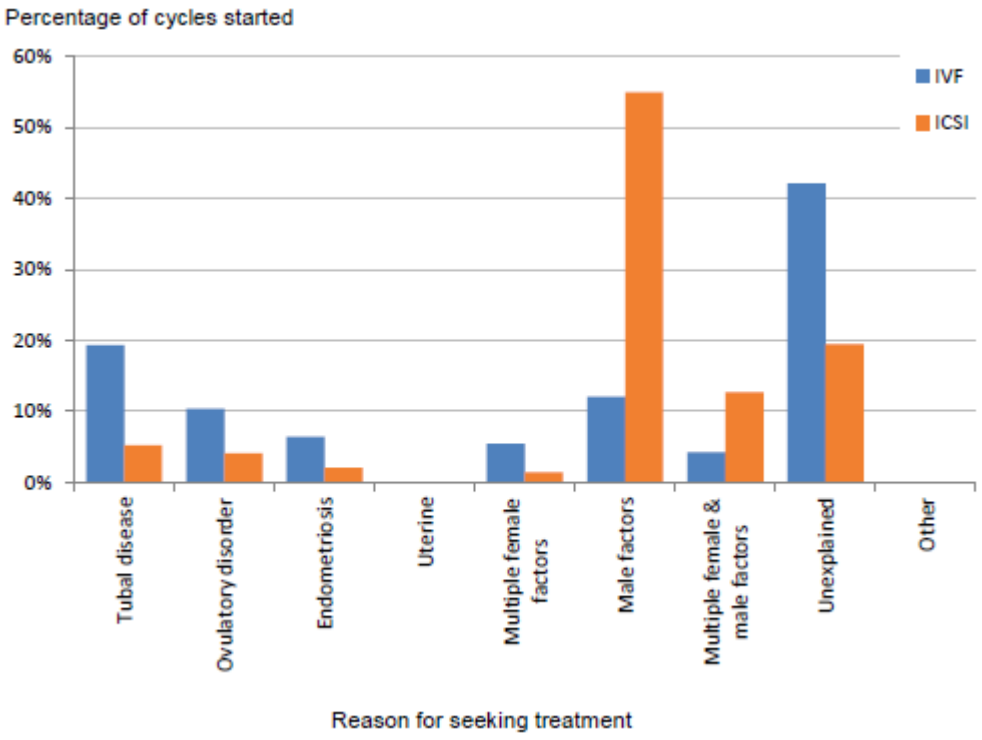



Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures page 13 (Figure 3).

## *4.7 Monitoring ovulation induction*

### 4.7.1 Summary of suggestions

Stakeholders reported that the use of gonadotrophins to superovulate the woman prior to ovulation confers a risk of ovarian hyperstimulation syndrome which can be life threatening to the patient. Fertility clinics should have protocols in place for preventing, diagnosing and managing ovarian hyperstimulation syndrome. Stakeholders reported that practice in this area is variable and varying strategies exist for recording events of / management of ovarian hyperstimulation syndrome within the centres currently treating patients who have undergone ovarian stimulation using gonadotrophins.

### 4.7.2 Selected recommendations from development source

Table 12 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 12 to help inform the Committee's discussion.

**Table 12 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Monitoring ovulation induction | **Monitoring ovulation induction during gonadotrophin therapy**<br>NICE CG156 Recommendations 1.5.4.2<br><br>**Triggering ovulation in IVF**<br>NICE CG156 Recommendations 1.12.4.3 |

**Monitoring ovulation induction during gonadotrophin therapy**

NICE CG156 Recommendations 1.5.4.2

Ovarian ultrasound monitoring to measure follicular size and number should be an integral part of gonadotrophin therapy to reduce the risk of multiple pregnancy and ovarian hyperstimulation. **[2004]**

**Triggering ovulation in IVF**

NICE CG156 Recommendations 1.12.4.3

Clinics providing ovarian stimulation with gonadotrophins should have protocols in place for preventing, diagnosing and managing ovarian hyperstimulation syndrome. **[2004]**

### 4.7.3 Current UK practice

Human Fertilisation and Embryology Authority Fertility treatment in 2011[11].

The HFEA is the independent regulator of fertility treatment in the UK and their remit includes regulation of all NHS and private providers of fertility treatment. The HFEA collect data about every treatment cycle performed and around 60,000 fertility treatments are performed in UK licensed clinics annually. The HFEA have published an annual report about cycles of fertility treatment which started in 2010 and 2011.

The report includes details of why some treatment cycles are abandoned and these are separated into two groups:

- Cycles that failed before the egg retrieval stage - 5.9% of cycles that failed during this stage did so because the woman's ovaries responded too much and there was a risk of this leading to ovarian hyperstimulation syndrome.

- Cycles that fail between the egg retrieval and embryo transfer stage – 43% of cycles that failed during this stage did so because of a risk of ovarian hyperstimulation syndrome. This was the most common reason for a cycle to fail in this stage and include 871 patients. In the report it is highlighted that risk of OHSS is not the same as a diagnosis, and identification of patients at risk of OHSS and subsequent failure of the cycle forms can reflect safe clinical management.

[11] HFEA (2013) Fertility treatment in 2011: Trends and figures. http://www.hfea.gov.uk/104.html

## *4.8 Single embryo transfer strategy*

### 4.8.1 Summary of suggestions

The single embryo transfer strategy is intended to minimise the chance of multiple and higher order pregnancies, by transferring only one embryo in specific clinical circumstances. Stakeholders have highlighted that multiple pregnancy represents significant risks to the mother's and baby's health. Stakeholders highlighted that the multiple pregnancy rate in the UK following fertility treatment is poorer than international counterparts, and stakeholders highlighted that the HFEA have set a national target of 10%. Reducing multiple pregnancy rates improves the outcomes for mothers and babies, and reduces the cost of caring for mothers and babies who have additional health and social care needs.

Of the 9 Stakeholders that highlighted the importance of national implementation of single embryo transfer, 4 also highlighted that this approach is not appropriate in circumstances where people do not have access to the 3 cycles of IVF (when the woman is aged under 40 years).

### 4.8.2 Selected recommendations from development source

Table 13 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 13 to help inform the Committee's discussion.

**Table 13 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Single embryo transfer strategy | **Embryo transfer strategies in IVF**<br>NICE CG156 Recommendation 1.12.6.5 (key priority for implementation), 1.12.6.7, 1.12.6.8 |

**Embryo transfer strategies in IVF**

NICE CG156 Recommendation 1.12.6.5 (key priority for implementation)

When considering the number of fresh or frozen embryos to transfer in IVF treatment:

- For women aged under 37 years:
    - In the first full IVF cycle use single embryo transfer.

  - In the second full IVF cycle use single embryo transfer if 1 or more top-quality embryos are available. Consider using 2 embryos if no top-quality embryos are available.
  - In the third full IVF cycle transfer no more than 2 embryos.

- For women aged 37–39 years:
  - In the first and second full IVF cycles use single embryo transfer if there are 1 or more top-quality embryos. Consider double embryo transfer if there are no top-quality embryos.
  - In the third full IVF cycle transfer no more than 2 embryos.

- For women aged 40–42 years consider double embryo transfer. **[new 2013]**

NICE CG156 Recommendation 1.12.6.7

No more than 2 embryos should be transferred during any one cycle of IVF treatment. **[new 2013]**

NICE CG156 Recommendation 1.12.6.8

Where a top-quality blastocyst is available, use single embryo transfer. **[new 2013]**

### 4.8.3 Current UK practice

Human Fertilisation and Embryology Authority Fertility treatment in 2011[12]

*Numbers of embryos transferred*

Women who have a good chance of becoming pregnant, and have several embryos available may choose to only have one embryo transferred in order to reduce the risk of a multiple pregnancy. This is known as elective single embryo transfer, or eSET. In 2011, as in 2010, two embryos (or double embryo transfer, DET) was still the most likely number to be transferred in each cycle; however, this proportion has decreased since 2010. Only around 1 in 6 women overall (16.8 %) received an eSET, and slightly more (18.7%) received a non-elective SET (i.e. only one embryo was available to transfer). A small proportion (4.3%) also received triple embryo transfer.

[12] HFEA (2013) Fertility treatment in 2011: Trends and figures. http://www.hfea.gov.uk/104.html

**Proportion of all embryo transfers (fresh and frozen), by number of embryos transferred, 2011**

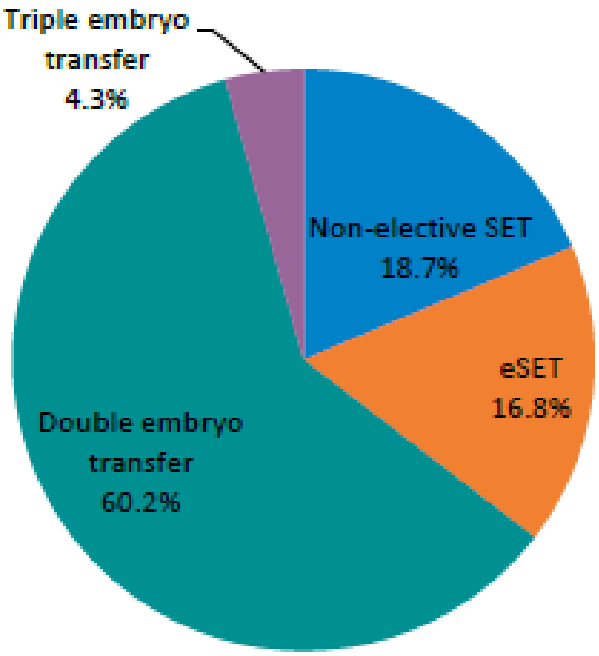



Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures, page 17 (figure 6).

*Rates of eSET by age group*

The HFEA data shows that the women in the age groups 18 to 34 and 35 to 37 have the highest proportion of eSETs and that eSET decreases with age.

**eSETs as a proportion of all embryo transfers performed, 2011**

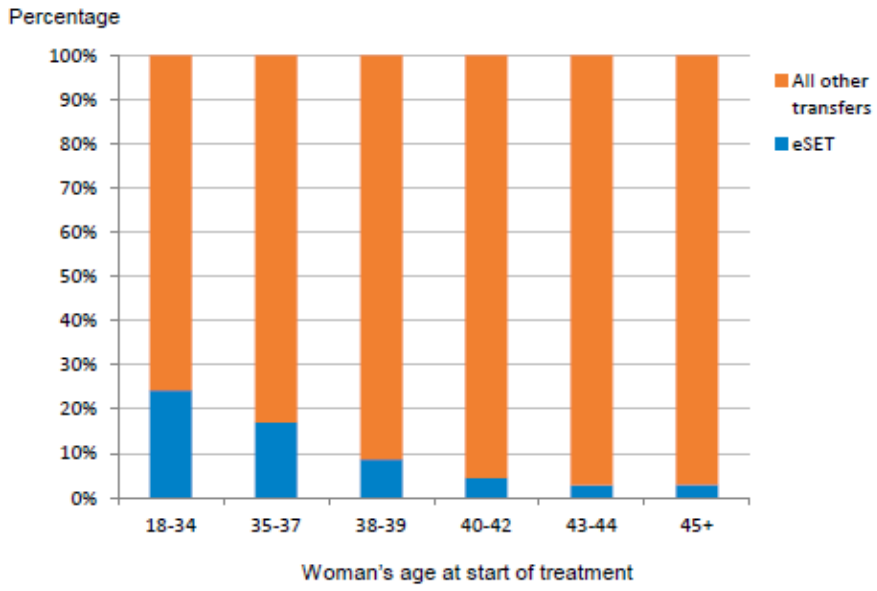


Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures, page 19 (figure 9).

**Percentage of embryo transfers which were eSET, January 2008 to June 2010**

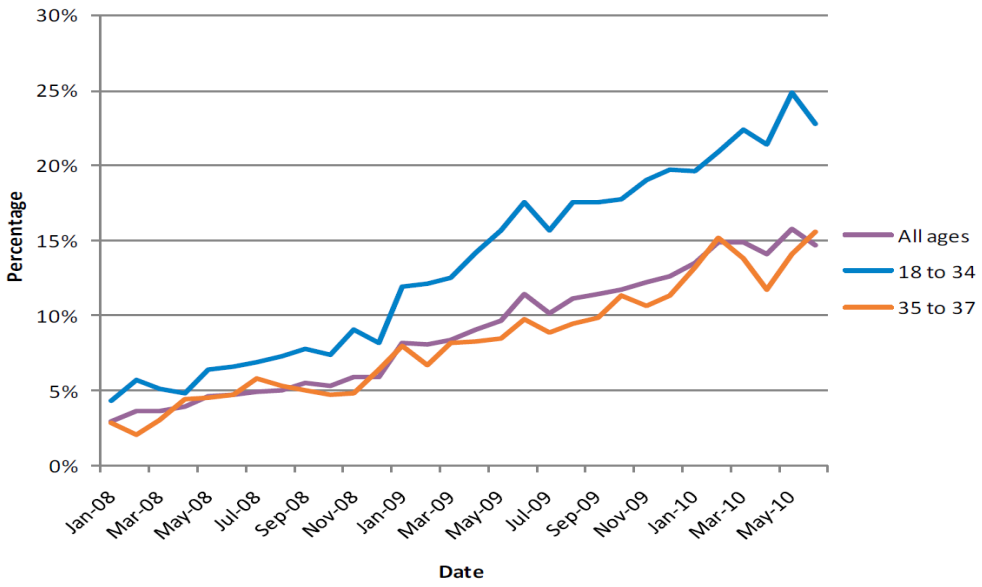



Figure taken from HFEA report Improving outcomes for fertility patients: Multiple births 2011 page 8 (figure 1).

*Stage of embryo development at transfer (cleavage or blastocyst)*

The HFEA data demonstrates that where eSET is implemented nearly two thirds of those transfers (65.1%) were of blastocysts, which represents an increase of around 8 percentage points on 2010. However, where two embryos are transferred nearly three quarters of transfers are of cleavage stage embryos, a similar proportion to that seen in 2010.

**Embryos transferred, as a percentage of all fresh embryos transferred, by whether the embryo was cleavage or blastocyst, 2011**

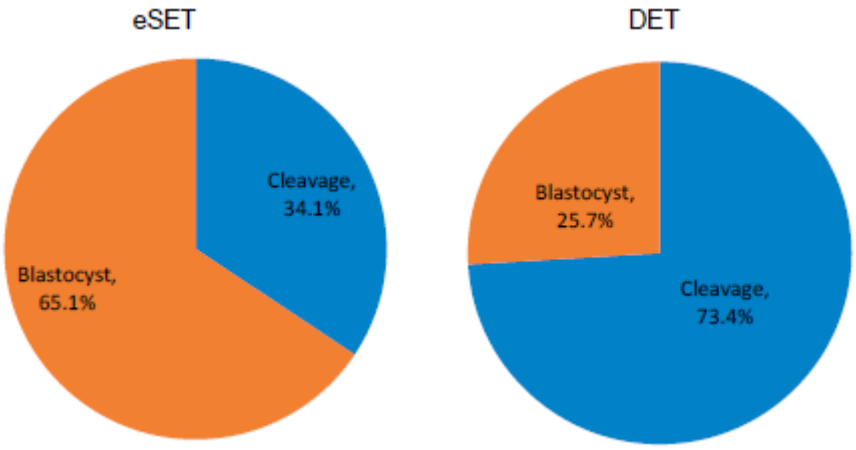



Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures, page 19 (figure 8).

*Multiple pregnancy rates*

The HFEA report that multiple pregnancies following single embryo transfer are rare and happen when the embryo splits in two, resulting in identical (monozygotic) twins. By receiving eSET, the risk of a multiple pregnancy is similar to that of all conceptions, which is 1.57%[13]. After the transfer of two cleavage stage embryos around a quarter of pregnancies confirmed by ultrasound were of two or more babies, but this is affected by the woman's age, and is highest in women aged 18-34 (around a third of pregnancies). Transferring two blastocysts at one time carries an even higher risk of multiple pregnancy than transferring two cleavage stage embryos, which is again affected by a woman's age and is highest in women aged 18-34 (just under half of pregnancies).

[13] Office for National Statistics, 2011, Statistical Bulletin: Live births in England and Wales by characteristics of birth www.ons.gov.uk/ons/dcp171778_241936.pdf. The ONS figures will contain multiple births after fertility treatment, as well as natural conceptions as they cover *all* recorded births in England and Wales.

**Multiple pregnancy rate (% of pregnancies), fresh own eggs, by stage and number of embryos transferred, 2011**

| | Stage: | Cleavage stage embryo | | Blastocyst stage embryo | |
|---|---|---|---|---|---|
| | Transfer type: | eSET | Double | eSET | Double |
| Age | 18 – 34 | 0.7% | 32.6% | 2.2% | 47.1% |
| | 35 – 37 | | 24.0% | | 37.2% |
| | 38 – 39 | | 19.8% | | 32.1% |
| | 40 – 42 | | 12.0% | | 21.5% |
| | 43 – 44 | | | | |
| | 45 + | | | | |
| | All ages | 0.7% | 26.7% | 2.2% | 38.9% |

Figure taken from HFEA (2013) Fertility treatment in 2011: Trends and figures, page 24 (table 9).

In the age groups 40-42, 43-44 and 45+ the figures are aggregated due to small numbers.

The multiple pregnancy rate has decreased between 2008 and the beginning of 2011. The decrease is most pronounced in women aged under 35, who saw the greatest increase in eSET (figure 1).

**Multiple pregnancy rates as an outcome of IVF treatment, 2008-2011**

| | Year | 2008 | 2009 | 2010 | 2011 |
|---|---|---|---|---|---|
| Age | 18 to 34 | 31.2% | 27.6% | 23.5% | 21.7% |
| | 35 to 37 | 25.0% | 23.5% | 22.7% | 20.4% |
| | All ages | 26.7% | 24.4% | 22.3% | 20.6% |

Figures taken from HFEA report Improving outcomes for fertility patients: Multiple births 2011 page 17 (table 4, data for 2008 and 2009) and HFEA report Fertility treatment in 2011: Trends and figures page 23 (table 8, data for 2010 and 2011)

*Policy and multiple birth rate from IVF*

In January 2009 the HFEA introduced a policy to promote eSET and minimise the risk of multiple births from IVF treatment. All clinics must have their own strategy around eSET, which sets out how they will lower their multiple birth rate to within a maximum rate set by the HFEA. The HFEA lowers the maximum multiple birth rate each year, after careful evaluation, towards an ultimate aim of a multiple birth rate of not more than 10% each year[14].

[14] HFEA Improving outcomes for fertility patients: Multiple births 2011

**The HFEA national targets for multiple pregnancy rates**

| Year | Target |
|---|---|
| **January – December 2008** | No target, acting as a benchmark |
| **January 2009 – March 2010** | No more than 24% multiple births |
| **April 2010 – March 2011** | No more than 20% multiple births |
| **April 2011 – March 2012** | No more than 15% multiple births |

In 2010 the HFEA set the target for the maximum multiple birth rate at 10%. This target came into effect in October 2012[15].

[15] See HFEA website for further details http://www.hfea.gov.uk/Multiple-births-after-IVF.html accessed 28th February 2014.

## *4.9 Laboratory quality assurance*

### 4.9.1 Summary of suggestions

Laboratory quality assurance: overarching

Stakeholders highlighted the need for improved quality control (QC) systems within laboratories which provide assisted reproduction procedures. This was a general theme that covers all laboratory procedures. Stakeholders also highlighted some specific areas of laboratory work in which there are particular quality improvement issues that relate to variable practices and quality assurance mechanisms. These areas include semen analysis (2 stakeholders), embryo selection and grading (3 stakeholders) and cryopreservation (2 stakeholders).

Stakeholders highlighted that semen analysis is the primary assessment tool for male fertility potential and precision 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 result of semen analysis. This may lead to a longer process in investigating male infertility, the offer of inappropriate treatment, and potentially over treatment.

In relation to embryo selection, stakeholders highlighted that to allow the most effective implementation of a single embryo transfer strategy it is essential to ensure that embryos with the best possible chance of implantation are identified and positively selected. By being able to confidently select the best embryo, embryologists can, with confidence transfer fewer embryos in most cases.

In relation to cryopreservation, stakeholders reported variation in the period of storage and suggested that some services have not implemented the recommendations in NICE CG156, which recommend a minimum storage period of 10 years, with case by case review thereafter. Stakeholders also reported that there is local variation in the provision of cryopreservation for sperm and oocytes, thereby causing a gender inequity in some localities. Stakeholders also highlighted other groups of people who may wish to preserve their fertility, such as people receiving treatment for rheumatoid arthritis and people with social reasons for delaying their family. These populations are outside of the scope of the underpinning evidence source NICE CG156.

### 4.9.2 Selected recommendations from development source

Table 14 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 14 to help inform the Committee’s discussion.

**Table 14 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Laboratory quality assurance: semen analysis | **Semen analysis**<br>NICE CG156 Recommendations 1.3.1.1 |
| Laboratory quality assurance: single embryo transfer | **Embryo transfer strategies in IVF**<br>NICE CG156 Recommendation 1.12.6.4 |
| Laboratory quality assurance: cryopreservation services | **Cryopreservation of semen, oocytes and embryos**<br>NICE CG156 Recommendations 1.16.1.9, 1.16.1.11, 1.16.1.12 and 1.16.1.13 |

**Semen analysis**

NICECG156 Recommendation 1.3.1.1

The results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values[2]:

- 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. [2004, amended 2013]

**Embryo transfer strategies in IVF**

NICE CG156 Recommendation 1.12.6.4

Evaluate embryo quality, 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 (see figure 3). **[new 2013]**

**Figure 3 (as referred to in recommendation 1.12.6.4) UK NEQAS embryo morphology scheme**


## Embryo Morphology Scheme

Cleavage stage embryo grading system

| | | |
|---|---|---|
| **Blastomere Number** | | |
| **Blastomere Size** | 4 = | Regular, even division |
| | 3 = | <20% difference (blastomere diameter) |
| | 2 = | 20-50% difference |
| | 1 = | >50% difference *Hardarson et al 2001* |
| **Fragmentation** | 4 = | 10% fragmentation by volume |
| | 3 = | 10-20% |
| | 2 = | 20-50% |
| | 1 = | >50% *van Royen et al 2003* |

Blastocyst grading system

| | | |
|---|---|---|
| **Expansion Status** | 6 = | Hatched blastocyst; the blastocyst has evacuated the ZP |
| | 5 = | Hatching blastocyst; trophectoderm has started to herniate through the ZP |
| | 4 = | Expanded blastocyst: blastocoele volume now larger than that of the early embryo, ZP very thin. |
| | 3 = | Full blastocyst; blastocoele completely fills the embryo |
| | 2 = | Blastocyst; blastocoele more than half the volume of the embryo, some expansion in overall size, ZP beginning to thin |
| | 1 = | Early blastocyst; blastocoele less than half the volume of the embryo, little or no expansion in overall size, zona pellucida (ZP) still thick |
| **ICM Grading** | 5 = | ICM prominent, easily discernible and consisting of many cells, cells compacted and tightly adhered together |
| | 4 = | Cells less compacted so larger in size, cells loosely adhered together, some individual cells may be visible |
| | 3 = | Very few cells visible, either compacted or loose, may be difficult to completely distinguish from trophectoderm |
| | 2 = | Cells of the ICM appear degenerate or necrotic |
| | 1 = | No ICM cells discernible in any focal plane |
| **Trophectoderm** | 3 = | Many small identical cells forming a continuous trophectoderm layer |
| | 2 = | Fewer larger cells; may not form a completely continuous layer |
| | 1 = | Sparse cells; may be very large, very flat or appear degenerate |

*(Modified for UK NEQAS Embryo Morphology Scheme 2010 from Cutting et al, Elective Single Embryo Transfer: Guidelines for Practice. British Fertility Society and Association of clinical Embryologists. Human Fertility, September 2008; 11(3): 131–146)*

## Cryopreservation of semen, oocytes and embryos

NICE CG156 Recommendation 1.16.1.9

Use freezing in liquid nitrogen vapour as the preferred cryopreservation technique for sperm. **[new 2013]**

NICE CG156 Recommendation 1.16.1.11

In cryopreservation of oocytes and embryos, use vitrification instead of controlled-rate freezing if the necessary equipment and expertise is available. **[new 2013]**

NICE CG156 Recommendation 1.16.1.12

Store cryopreserved material for an initial period of 10 years. **[new 2013]**

NICE CG156 Recommendation 1.16.1.13

Offer continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility. **[new 2013]**

### 4.9.3 Current UK practice

No current practice data identified.

## *4.10 Counselling*

### 4.10.1 Summary of suggestions

Stakeholders highlighted the importance of counselling services being made available to those people who are undergoing fertility treatment, fertility preservation or gamete donation. Counselling services were highlighted by stakeholders as being patchy, often poorly commissioned and poorly monitored. Stakeholders highlighted that there are particular groups of people for whom specialist fertility counselling is particularly important; people donating gametes (6 stakeholders), people receiving treatment with donated gametes (6 stakeholders), people undergoing fertility preservation (3 stakeholders) men with a diagnosis of azoospermia (2 stakeholders) and people with a diagnosis of a genetic condition which has implications for their chances of conception and having a healthy child (1 stakeholders).

### 4.10.2 Selected recommendations from development source

Table 15 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 15 to help inform the Committee's discussion.

**Table 15 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Counselling | **Psychological effects of fertility problems**<br>NICE CG156 Recommendation 1.1.2.2, 1.1.2.3, 1.1.2.4 and 1.1.2.5.<br><br>**Indications for donor insemination – Information and counselling**<br>NICE CG156 Recommendation 1.14.2.2<br><br>**Screening of sperm donors**<br>NICE CG156 Recommendation 1.14.3.2<br><br>**Oocyte donation and 'egg sharing'**<br>NICE CG156 Recommendation 1.15.3.2 and 1.15.3.3 |

**Psychological effects of fertility problems**

NICE CG156 Recommendation 1.1.2.2

People who experience fertility problems should be informed that they may find it helpful to contact a fertility support group. **[2004]**

NICE CG156 Recommendation 1.1.2.3

People who experience fertility problems should be offered counselling because fertility problems themselves, and the investigation and treatment of fertility problems, can cause psychological stress. **[2004]**

NICE CG156 Recommendation 1.1.2.4

Counselling should be offered before, during and after investigation and treatment, irrespective of the outcome of these procedures. **[2004]**

NICE CG156 Recommendation 1.1.2.5

Counselling should be provided by someone who is not directly involved in the management of the individual's and/or couple's fertility problems. **[2004, amended 2013]**

**Indications for donor insemination – Information and counselling**

NICE CG156 Recommendation 1.14.2.2

Couples considering donor insemination should be offered counselling from someone who is independent of the treatment unit regarding all the physical and psychological implications of treatment for themselves and potential children. **[2004]**

**Screening of sperm donors**

NICE CG156 Recommendation 1.14.3.2

All potential semen donors should be offered counselling from someone who is independent of the treatment unit regarding the implications for themselves and their genetic children, including any potential children resulting from donated semen. **[2004]**

**Oocyte donation and 'egg sharing'**

NICE CG156 Recommendation 1.15.3.2

Oocyte recipients and donors should be offered counselling from someone who is independent of the treatment unit regarding the physical and psychological

implications of treatment for themselves and their genetic children, including any potential children resulting from donated oocytes. **[2004]**

NICE CG156 Recommendation 1.15.3.3

All people considering participation in an 'egg-sharing' scheme should be counselled about its particular implications. **[2004]**

### 4.10.3 Current UK practice

No current practice data identified.

## *4.11 Fertility preservation for people with cancer*

### 4.11.1 Summary of suggestions

Fertility preservation for people with cancer: prompt access to cryopreservation

Stakeholders reported the need to ensure that people who could benefit from fertility preservation, in particular people diagnosed with cancer whose family is not yet complete, are given the opportunity to promptly access cryopreservation services. Stakeholders reported that cryopreservation is not always offered promptly to people diagnosed with cancer, either because of a delay in offering referral or a delay in an appointment being made available in the fertility service.

One stakeholder also highlighted the importance of ensuring the people are able to store their gametes as oocytes or semen, rather than as embryos. This means that should relationships change, a man and woman have the opportunity to access their own gametes in the future.

### 4.11.2 Selected recommendations from development source

Table 15 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 15 to help inform the Committee's discussion.

**Table 15 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Fertility preservation for people with cancer: prompt access to cryopreservation | **Defining infertility**<br>NICE CG156 Recommendations 1.2.13.8<br><br>**Cryopreservation of semen, oocytes and embryos**<br>NICE CG156 Recommendations 1.16.1.8 and 1.16.1.10 |

**Defining infertility**

NICE CG156 Recommendations 1.2.13.8

Where treatment is planned that may result in infertility (such as treatment for cancer), early fertility specialist referral should be offered. **[2004, amended 2013]**

**Cryopreservation of semen, oocytes and embryos**

NICE CG156 Recommendation 1.16.1.8

Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. **[new 2013]**

NICE CG156 Recommendation 1.16.1.10

Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if:

- they are well enough to undergo ovarian stimulation and egg collection **and**
- this will not worsen their condition **and**
- enough time is available before the start of their cancer treatment. **[new 2013]**

### 4.11.3 Current UK practice

National survey of oncologist current knowledge, practice and attitudes[16]

A national online survey was conducted with 100 oncologists. Oncologists saw fertility preservation as mainly a woman's issue and 87% of oncologists expressed a need for further information about fertility preservation methods and 23% reported that they had never consulted a fertility preservation guideline. Most reported discussing fertility preservation with patients and 38% supported this with written patient information and 1/3 reported that they did not usually refer patients who had questions about fertility preservation to a specialist service.

[16] Adams E and Watson E (2013) Fertility preservation in cancer survivors: a national survey of oncologists' current knowledge, practice and attitudes. *British Journal of Cancer*. 108, p1602-1616.

## *4.12 Additional suggestions*

### 4.12.1 Summary of suggestions

The following additional suggestions were made by stakeholders:

- Benchmarking services to establish transparent national comparisons
- Audit areas of uncertain quality including primary care initial infertility investigations, mild ovarian stimulation in secondary care and use of gonadotropins.
- Data for patients about outcomes of fertility providers
- Lesbian and bisexual women’s experience of fertility services
- Staffing levels
- Training and competencies
- Validation of a patient satisfaction questionnaire

These areas are either out of scope, have no supporting recommendations or do not meet technical criteria for statement development.

## Appendix 1: Key priorities for implementation (CG156)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

**Defining infertility**

- A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. **[new 2013]**
- Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:
    - the woman is aged 36 years or over
    - there is a known clinical cause of infertility or a history of predisposing factors for infertility. **[new 2013]**

**Unexplained infertility**

- Do not offer oral ovarian stimulation agents (such as clomifene citrate, anastrozole or letrozole) to women with unexplained infertility. **[new 2013]**
- Offer IVF treatment (see recommendations 1.11.1.3–4) to women with unexplained infertility who have not conceived after 2 years (this can include up to 1 year before their fertility investigations) of regular unprotected sexual intercourse. **[new 2013]**

**Intrauterine insemination**

- For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse:
    - do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF)
    - advise them to try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered. **[new 2013]**

**Criteria for referral for IVF**

- Inform people that normally a full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian

stimulation and the transfer of any resultant fresh and frozen embryo(s). **[new 2013]**

- In women aged under 40 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), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. **[new 2013]**
- In 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), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:
    - they have never previously had IVF treatment
    - there is no evidence of low ovarian reserve (see recommendation 1.3.3.2)
    - there has been a discussion of the additional implications of IVF and pregnancy at this age. **[new 2013]**

**Embryo transfer strategies in IVF**

- When considering the number of fresh or frozen embryos to transfer in IVF treatment:
    - For women aged under 37 years:
        - In the first full IVF cycle use single embryo transfer.
        - In the second full IVF cycle use single embryo transfer if 1 or more top-quality embryos are available. Consider using 2 embryos if no top-quality embryos are available.
        - In the third full IVF cycle transfer no more than 2 embryos.
    - For women aged 37–39 years:
        - In the first and second full IVF cycles use single embryo transfer if there are 1 or more top-quality embryos. Consider double embryo transfer if there are no top-quality embryos.
        - In the third full IVF cycle transfer no more than 2 embryos.
    - For women aged 40–42 years consider double embryo transfer. **[new 2013]**

- Where a top-quality blastocyst is available, use single embryo transfer. **[new 2013]**

## Appendix 2: Glossary

Terms in this glossary have been adapted from the 'Information for the public' version of CG156 or the full guideline produced alongside CG156.

### *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.

### *Assisted reproduction*

Treatments that enable people to conceive without having sexual intercourse. Methods include intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), donor insemination and egg donation.

### *Blastocyst*

An embryo, 5 or 6 days after fertilization.

### *Cryopreservation*

The freezing and storage of embryos, sperm or eggs for future use in IVF treatment cycles. The technique of controlled rate slow freezing is well established; vitrification is a newer ultra-rapid freezing process.

### *Donor insemination*

The placement of donor sperm into the vagina, cervix or womb.

### *Egg*

The female reproductive cell. A woman usually produces 1 egg in a normal monthly cycle.

### *Embryo*

A fertilised egg.

### *Fallopian tubes*

The pair of tubes leading from a woman's ovaries to her womb. The fallopian tube is where fertilisation of the egg by a sperm takes place in natural conception.

### *Gamete*

A mature haploid male or female germ cell which is able to unite with another of the opposite sex in sexual reproduction to form a zygote (Oxford online dictionary).

### *Gonadotrophins*

Hormones that a woman can take to stimulate her ovaries to produce eggs. They can be given during ovulation induction and ovarian stimulation. In men they can be used to stimulate sperm production.

### *Intracytoplasmic sperm injection (ICSI)*

A variation of in vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.

### *In vitro fertilisation (IVF)*

A technique by which eggs are collected from a woman and fertilised outside her body. One or 2 of the embryos created are then transferred to the womb. If one of them attaches successfully, it results in a pregnancy.

### *Intracervical insemination*

A procedure in which sperm is placed into a woman's cervix (the neck of the womb) to help her conceive.

### *Intrauterine insemination*

A procedure in which sperm is placed inside a woman's womb to help her conceive.

### *Multiple pregnancy*

A pregnancy in which the woman is carrying more than one baby. Multiple pregnancies carry higher health risks for both the mother and the babies.

### *Oocyte*

A cell in an ovary which may undergo meiotic division to form an ovum (Oxford online dictionary).

### *Ovarian stimulation*

The use of gonadotrophins to stimulate the ovaries to produce more than 1 egg at once as part of IVF treatment.

### *Ovarian hyperstimulation syndrome*

A potentially serious condition that occurs when the ovaries 'over-react' to fertility drugs.

### *Ovaries*

Two small organs in a woman's reproductive system which produce follicles and eggs.

### *Ovulation*

The process by which the ovaries produce eggs. In a woman's natural cycle, ovulation occurs when a mature egg is released from the ovary each month.

### *Ovulation induction*

The use of fertility drugs to control or stimulate a woman's ovulation.

### *Semen*

The fluid containing sperm that is produced by a man during ejaculation.

### *Sperm*

The male reproductive cell, which fertilises a woman's egg.

### *Surgical sperm recovery*

A minor surgical procedure to obtain sperm from the testicles in men who cannot ejaculate or have a blockage in the flow of sperm from their testicles.

## Appendix 3: Suggestions from stakeholder engagement exercise

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
|---|---|---|---|---|
| SCM 1 | Parity in NHS funding for fertility treatment | It is neither acceptable nor fair that patients in some areas of the UK have access to different levels of funding for NHS fertility treatment than others. Ideally, availability of NHS funded care should be comparable across the country. | The impact of the revised NICE guidelines (2013) has not yet been fully established however it appears that the inclusion of women 40-42 for one full cycle of treatment and the reduction from 36 to 24 months infertility duration for referral, if adopted will contribute a significant new cost pressure to NHS resources as a result of which treatment provisions may be reduced. CCG commissioning in some areas may be over a very small catchment area and this is very likely to lead to disparity in provision nationally and on a more local (and hence acute) level. | NICE Fertility Guidelines, 2013<br>INUK ongoing survey of NHS funding availability<br>http://www.infertilitynetworkuk.com/information/niac/commissioning_of_infertility_services<br>In house review of NHS funded treatment performed in 2012 by Cambridge IVF (see attached document). |
| SCM 1 | Improvements in embryo selection for transfer | To allow the most effective implementation of a single embryo transfer strategy it is essential to ensure that embryos with the best possible implantation are identified and positively selected. | Technology plays a major role in the provision of effective fertility laboratory services. There are a number of key developmental indicators which, when considered collectively will enable embryologists to select the best single embryo (or 2 embryos for transfer). By being able to confidently select the best embryo, embryologists can, with confidence transfer fewer embryos in most cases. This results in lower multiple birth rates meaning the risks to both the mother, pregnancy and resultant offspring are reduced and represents a cost saving to the NHS as unnecessary multiple births represent a significant resource drain | Numerous publications on the effectiveness of time-lapse mophometric embryo analysis systems.<br>www.oneatatime.org.uk |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | both to neonatal critical care and later in life where multiple births result in long term health consequences for mothers and / or children. | |
| SCM 1 | Improved quality of diagnostic semen analysis | Diagnostic semen analysis is performed in many district general hospitals, private fertility clinics and tertiary NHS centres / teaching hospitals. The quality of the analysis varies dramatically and there is no nationally adopted guideline for ensuring effective semen analysis despite having a well established national EQA scheme in place. | Not performing semen analysis to an accepted best practice standard can lead to misdiagnosis and over use of invasive procedures such as intra-cytoplasmic sperm injection (ICSI) which is an additional cost pressure to the NHS and also to self funding patients.<br>Current advances in automation using reputable computer assisted semen analysis (CASA) systems, where fully validated in situ is an option to minimise the margin of human error in semen analysis further and as such should be considered as a robust alternative to manual semen assessment. | WHO laboratory manual for the examination and processing of human semen Fifth edition http://www.who.int/reproductivehealth/publications/infertility/9789241547789/en/<br>NICE Fertility Guidelines, 2013 Reference Paper http://www.sciencedirect.com/science/article/pii/S001502820804781X<br>Recommended contributing expert for this topic – Dr Mathew Tomlinson |
| SCM 1 | Improved availability of fertility preservation services for women | At present women wishing to preserve their fertility have very limited options to store their gametes or ovarian tissue effectively and most have to rely on storing embryos meaning they are committed to a man and his continued consent to the storage and use of the created embryos | It can be argued that it is discriminatory that a care pathway to preserve fertility for women does not exist that allows a women to preserve her fertility as an individual. Egg and ovarian tissue storage is not available at all in some areas of the country and where it is, it is still regarded as an experimental science whilst it is established practice in other countries in Europe and across the world. Women may have to rely on the contribution of sperm from a male partner to allow them to fertilise eggs and store resultant embryos which, although highly | NICE Fertility Guidelines, 2013. Discussion Paper - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2921283/<br>Evidence from cases presented and challenged in law under the HFEA act (2008, as amended). For example, the Natalie Evans case - http://news.bbc.co.uk/1/hi/health/4779876.stm<br>Cryopreservation options - http://www.cancerresearchuk.org/cancer-help/about- |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | effective does leave the women at risk of not being able to use her stored genetic material should her relationship with the 'father' of the embryos break down. | cancer/treatment/chemotherapy/fertility/womens-fertility-and-chemotherapy |
| SCM 1 | Improved ovarian stimulation strategies | The use of gonadotrophins to superovulate the woman prior to ovulation confers a risk of ovarian hyperstimulation syndrome (OHSS). This risk can be reduced using a well constructed stimulation regime with defined intervention points to minimise the risk of OHSS which can be life threatening to the patient. What is more, evidence exists to suggest that egg quality and quantity do not share a linear relationship and to some extent, less is actually more. | In any healthcare environment the starting point is to do no harm. There is a significant risk of harm or death to the patient. IVF Clinics should have robust protocols in place to avoid OHSS where possible and to minimise its effect in situations where its onset to some extent cannot be avoided. Although clear guidelines exist the number of cases of OHSS is still higher than it needs to be and this can only be attributed to miss-management of patients during the stimulatory phase of their treatment.<br><br>A conservative approach to stimulation may prove beneficial as recent published evidence has suggested that in cases where more than 10 eggs are collected the resultant embryo quality is not likely to increase over those cycles where 8 eggs were collected indicating that a stimulation regime which puts patients at risk of OHSS to increase egg yield may in fact not be reflected in embryo quality and ultimate treatment outcome. | NICE Fertility Guidelines, 2013.<br>Severe OHSS – Death: http://news.bbc.co.uk/1/hi/health/4440573.stm<br>Best Practice Document (UK) - http://www.rcog.org.uk/files/rcog-corp/GTG5_230611.pdf<br>Best Practice Document (Canada) – http://sogc.org/wp-content/uploads/2013/01/gui268CPG1111E_000.pdf<br>Reference Paper - http://informahealthcare.com/doi/abs/10.1080/14647270601111239<br>Reference Paper - http://www.journals.elsevierhealth.com/periodicals/ycuog/article/S0957-5847%2805%2900004-1/abstract<br>Recommended contributing expert – Mr Raj Mathur, Consultant Gynaecologist, Cambridge IVF, Addenbrooke's Hospital.<br>Reference Paper - http://humrep.oxfordjournals.org/content/20/3/588.full |
| Stonewall | Key area for quality improvement 1 | The HFEA 2008 and Equality Act 2010 both mean lesbians cannot be discriminated against when accessing services – | There is widespread variation and knowledge on whether same-sex couples are entitled to fertility treatment (and therefore whether CCG's fund same-sex | Infertility Network UK's database of CCG's demonstrates the limited number of CCG's who have a clear policy on same-sex couples |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | Driving up clinicians knowledge on providing fertility treatment to same-sex couples | including fertility services. | couples seeking treatment in line with NICE 2013 guidance). | seeking treatment, if they meet the requirements as set out in NICE Guidelines 2013.<br><br>http://www.infertilitynetworkuk.com/niac_2/ccg_details |
| Stonewall | Key area for quality improvement 2<br><br>Patient Experience | Despite legal protections for lesbians and bisexual women, many still report negative experiences of accessing healthcare.<br><br>Patient experience is a key driver in the NHS at the moment and all groups' experience needs to be considered – especially those who often discrimination. | 50 per cent of lesbians have had a negative experience of healthcare in the past year, and many report poor reactions from a range of clinicians when seeking to access fertility treatment. | Stonewall's Prescription for Change (www.stonewall.org.uk/lesbianhealth) demonstrates the wide range of poor experiences. Additionally Stonewall's briefing on experiences of the NHS provides information on typical experiences http://www.healthylives.stonewall.org.uk/lgb-health/briefings/experiences.aspx |
| Gloucestershire Royal Hospital NHS Foundation Trust | Key area for quality improvement 1 Patients with fertility problems – at secondary care | It's a common problem involving approximately 7% couples needing help in some form to conceive. The emotional stress is an issue and in certain cases time is of essence. Hence care by a specialist team is very important to avoid any delays in the intervention. | This service is poor and variable.<br>On many occasions patients are seen by generalists whereby the adequate expertise is not always present. This delays the referral being made to the specialist team which has negative impact on the patient management as well as treatment outcome. | NICE-Fertility Guidelines CG156<br>1.1.3.1 People who experience fertility problems should be treated by a specialist team because this is likely to improve the effectiveness and efficiency of treatment and is known to improve people's satisfaction with treatment. |
| Gloucestershire Royal Hospital NHS Foundation Trust | Key area for quality improvement 2<br><br>Initial advice to | High BMI above 30 and smoking are important and identified risk factors in sub fertility. It's also been recognised to affect the | Patients wait long enough to be seen in the specialist clinics not been given the right pre conception advice. Appropriate advice and life style modifications prior to referral would avoid disappointments in | NICE CG156 – Guideline 1.2 |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | couples concerned about delay in conception before referral to secondary care | miscarriage rates as well as compromise the success of assisted conception treatment modalities | couples referred and avoid delay in definitive treatment. | |
| Gloucestershire Royal Hospital NHS Foundation Trust | Key area for quality improvement 3<br><br>Ovulation induction drugs like clomifene citrate or letrozole to be prescribed by fertility specialists | Clomifene is an important drug in the management of sub fertility associated with anovulation. Also the indications and duration of treatment is quite specific as it has long term sequalae on patient's health. | This service is poor whereby GPs/ non-specialist prescribe clomifene to patients with unexplained infertility or with anovulation with different doses and variable duration. This compromises the care whereby patients could have been offered a more definitive treatment considering the whole picture. | NICE CG156- guideline 1.8.1<br>Do not offer oral ovarian stimulation agents (such as clomifene citrate, anastrozole orletrozole) to women with unexplained infertility.<br>For women who are taking clomifene citrate, do not continue treatment for<br>longer than 6 months – guideline 1.5.2.4 |
| Gloucestershire Royal Hospital NHS Foundation Trust | Key area for quality improvement 4<br>General practitioners at primary care level should do the basic fertility investigations before referral to specialists at secondary care | Given the range of causes of fertility problems, the provision of appropriate investigations is critical. These investigations include semen analysis; assessment of ovulation, and screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella. | This has benefits for the service in increased efficiency and capacity as well as the service users reducing the number of appointments and the associated inconvenience. | NICE CG156 - Guideline1.3 |
| NHS England | Thank you for the opportunity to comment on the engagement exercise for the above quality standard I wish to confirm that NHS England has no substantive comments to make regarding this consultation. | | | |
| British Fertility Society | Equitable funding for fertility | It is widely known that funding for fertility treatment is different | Lack of appropriate funding has led to inaccessibility for many who cannot afford | The Infertility Network UK<br>Primary Care Trusts Liaison |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | treatment. | throughout the UK. NICE guidance since 2004 has made specific recommendations regarding funding which have been variously qualified by sequential commissioners along with so called social criteria which may be used to exclude patients from treatment.<br><br>In addition the lack of national tariffs may have led to discrepancies in commissioning based on differences in calculating fees to commissioners as opposed to actual per cycle costs. The attempts to produce national tariffs were abandoned in 2012. | to fund themselves, and an opaque mixture of services through NHS and non-NHS centres.<br><br>Lack of equitable funding and exclusion of services from the NHS results in dissatisfaction for both patients and providers alike.<br><br>The production of appropriate national tariffs would contribute to a more equitable approach. | Project 2009-2012 Final Report on Findings April 2011 - October 12: http://www.infertilitynetworkuk.com/niac_2/ccg_details<br>NICE Fertility Guidelines 2004<br><br>NICE Fertility Guidelines 2013<br><br>Commissioning Fertility services Factsheet. NHS Commissioning Board Feb 2013<br><br>Final report of the Expert Group on Commissioning NHS Infertility Provision. DoH Jan 2010 |
| British Fertility Society | Fertility preservation for patients undergoing cancer treatment | Chemotherapy and radiotherapy treatments given to treat cancer (and some other chronic conditions e.g. rheumatoid arthritis) can lead to infertility. It needs to be offered at the point of diagnosis and any sperm, eggs or embryos placed in storage should be kept for 10 years in the first instance to guard against relapse. Storage beyond 10 years should be provided in cases where infertility persists or the patient | Many studies have shown that:<br><br>(a) Oncologists have poor awareness of fertility issues and do not offer fertility preservation appropriately;<br><br>(b) Patients have a poor understanding of fertility issues at the point of diagnosis and rely on the support of health professionals to facilitate fertility preservation;<br><br>(c) Young female cancer patients are particularly unhappy with the information | Pacey, A.A., & Eiser, C. 2011 Banking sperm is only the first of many decisions for men: what healthcare professionals and men need to know. Human Fertility, 14, 208-217.<br><br>Gilbert, E., Adams, A., Mehanna, H., Harrison, B., Hartshorne, G.M. (2010) Who should be offered sperm banking for fertility preservation? A survey of UK oncologists and haematologists. Annals of Oncology, 22, 1209- |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
|---|---|---|---|---|
| | | is too young to have considered use at that stage. | provided and access to fertility preservation services;<br><br>(d) Information provided on-line about sperm banking (there is no data on egg and embryo banking) is of poor quality and could be improved.<br><br>(e) As in Point 1 above funding for fertility preservation is extremely variable and often discrepant for male and female procedures. NICE 2013 has made guidance regarding proper funding for fertility preservation in particular recommending that it should not be influenced by the social criteria that are often applied to fertility funding albeit that that might have an impact on subsequent gamete or embryo use.<br><br>Therefore there is significant scope for improvement concerning how fertility preservation services are delivered. | 1214.<br><br>Eiser, C., Arden-Close, E,. Morris, K., Pacey, A.A. (2011) The legacy of sperm banking: How fertility monitoring and disposal of sperm are linked with views of cancer treatment. Human Reproduction, 26, 2791-2798.<br><br>Peddie VL, Porter MA, Barbour R, Culligan D, MacDonald G, King D, Horn J, Bhattacharya S. (2012) Factors affecting decision making about fertility preservation after cancer diagnosis: a qualitative study. *BJOG* 119, 1049-1057.<br><br>Merrick, H., Wright, E., Pacey, A.A., Eiser, C. (2012) Finding out about sperm banking: what information is available online for men diagnosed with cancer? Human Fertility, 15, 121-128.<br><br>Yeomanson DJ, Morgan S, Pacey AA. (2013) Discussing fertility preservation at the time of cancer diagnosis: Dissatisfaction of young females. *Pediatr Blood Cancer,* 60, 1996-2000.<br><br>NICE Fertility Guidelines 2013 |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
|---|---|---|---|---|
| British Fertility Society | Primary Care role and patient pathway | Primary care roles in management of infertility relate to providing good health for fertility and pregnancy information, identification of relevant fertility issues and for prompt referral to expert centres. | Ensuring that couples are well informed at an early stage about how they can optimise general health and wellbeing for fertility and pregnancy, must be considered standard in primary care and later reinforced. This includes smoking, alcohol, weight management, folic acid supplementation, cervical screening etc.<br><br>In addition timely referral to expert centres must be made to avoid undue delay in undertaking full investigation and moving to effective fertility treatment. Progress through the patient pathway should not be measured differently to other medical problems. | NICE Fertility Guidelines 2004<br><br>NICE Fertility Guidelines 2013<br><br>Standards of Care of the Infertile BFS/RCOG Joint Document 2006 |
| British Fertility Society | Multiple pregnancy in treatments not licensed by HFEA | The risks of twin and higher order pregnancy are well known. In IVF treatments there has been significant reduction in twin pregnancy rates following the introduction of elective single embryo transfer policies in selected patients.<br><br>There are currently no specific restrictions for ovulation induction treatments to ensure that multiple pregnancies are avoided as far as possible. | Whilst higher order pregnancies are uncommon, twin pregnancies remain a significant risk of ovulation induction treatment. Unmonitored or poorly monitored cycles aimed at maximising pregnancy rates increase the risk of multiple pregnancies; untenable practice when IVF multiples are being minimised where possible. As ovulation induction is not licensed through the HFEA regulatory authority, unless linked to a licensed treatment such as intrauterine insemination, national monitoring/standards do not currently exist.<br><br>A standard for acceptable twin rates for | NICE Fertility Guidelines 2013<br><br>http://www.oneatatime.org.uk |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | such treatments should be established, monitored and maintained by centres/practitioners offering such treatment. | |
| British Fertility Society | Provision of specialist infertility counselling – implications and therapeutic.<br>Before treatment with donor gametes<br>Before donating gametes | Preparation for parenthood sessions, for people seeking treatment with donor gametes, ensure they are fully informed of all the social, legal and ethical implications of having a donor conceived child. including telling children from an early age that they are donor conceived in order to promote the long term psychological wellbeing of donor conceived offspring.<br>Donors potentially make a life long commitment when they donate their gametes. It is important that donors are fully informed about this commitment and given the opportunity to explore the implications of donation for them, their partner and any future children. | The HFEA Code of Practice requires clinics to offer implications counselling in a number of circumstances before consent to treatment or donation is obtained. Implications counselling is a routine part of the treatment pathway in some clinics, but not all. Introducing a key quality standard that states that patients undergoing donor treatment will receive implications counselling (including preparation for parenthood) routinely as part of their treatment and be offered therapeutic counselling where appropriate, will ensure that patients are given the opportunity to fully consider the implications of treatment/donation before they consent.<br>Similarly there is a risk to the long-term psychological health of the donor, their families and any donor-conceived offspring if donors are inadequately prepared for the potential consequences of their donation. Implications counseling should be a demonstrable part of the individual's pathway to donation. | Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. Recommendation 'As a matter of good professional practice, clinics should provide counselling sessions as part of the routine series of appointments attended by prospective parents. An additional support session later in pregnancy or after the birth of the child should also routinely be offered.'<br>Policy and Practice paper: Wilde et al 'Family building using donated gametes and embryos in the UK: Recommendations for policy and practice on behalf of the British Infertility Counselling Association and the British Fertility Society in collaboration with the Association of Clinical Embryologists and the Royal College of Nurses Fertility Nurses Forum' Posted online on December 13, 2013.<br>Routine counselling advocated by for example:<br>Donor Conception network, the |

| Stakeholder | Key area | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | | National Gamete Donation Trust and the Infertility Network UK. The British Infertility Counselling Association Guidelines for Good Practice (2012)<br>HFEA Code of Practice (8th edition)<br>Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. Recommendation 'Clinics should ensure that sessions with a counsellor are scheduled as part of a routine series of appointments that donors attend before deciding whether or not to donate. Where donors have partners, clinics should strongly encourage partners to attend these sessions.' |
| British Association of Urological Surgeons (BAUS) | Key area for quality improvement 1 Surgical sperm Retrieval; Microdissection Testicular sperm extraction for sperm retrieval in men with non obstructive azoospermia. | Sperm recovery can be achieved by a number of methods for non obstructive azoospermia The microsurgical technique (mTESE) has been shown to be superior in sperm retrieval rates to that of TESA or conventional TESE in a number of studies. Patients are offered a wide variety of surgical techniques to obtain sperm in the UK, with no uniformity in clinical practice. mTESE has | A number of studies have demonstrated that the sperm retrieval rates in men undergoing m Tese are superior to those undergoing TESA or conventional TESE. Men with NOA are currently offered a substandard surgical procedure with a potential reduction in the chances of achieving paternity. Most centres within the UK are not offering this validated surgical technique. | Outcome of microdissection TESE compared with conventional TESE in non-obstructive azoospermia: a systematic review. Deruyver Y, Vanderschueren D, Van der Aa F. Andrology. 2014 Jan;2(1):20-4. doi: 10.1111/j.2047-2927.2013.00148.x. Epub 2013 Nov 6 |

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| | | now been clearly defined as the Gold Standard for surgical sperm retrieval in non-obstructive azoospermia worldwide. | | |
| British Association of Urological Surgeons (BAUS) | Key area for quality improvement 2 Evaluation of all male patients with subfertility by a Urologist. | The European Association of Urology Guidelines 2013 advocate that a Urologist should examine any man with fertility problems for Uro-genital abnormalities. A diagnosis is mandatory before starting appropriate therapy and to identify potential health issues and treatable conditions in the male partner. | There is currently a wide variance in clinical standards in the UK. The male partner is often not evaluated by the Urologist which can result in potential Urological problems untreated or remaining undetected. Furthermore, potentially correctable conditions such eg varicocele, obstructive azoospermia may be missed or not treated reducing the chances of either natural conception or improving the outcome from ART. | European Association of Urology Guidelines on Male Infertility; Eur Urol. 2012 Aug;62(2):324-32 |
| National Infertility Awareness Campaign | Cycles of IVF/ICSI offered to eligible patients<br><br>and also within this,<br><br>Definition of a 'full cycle'. | Three cycles of IVF/ICSI have been shown by NICE to be the most clinically and cost-effective number to offer eligible patients.<br><br>In order to maximise clinical outcomes, it is essential that this recommendation be implemented uniformly across the country.<br><br>A cap on the number of frozen embryos transfer events as part of a cycle has a direct, negative, effect on the likelihood of a successful outcome. Therefore, | The recommendations contained within the NICE guideline on fertility are intended to inform the commissioning decisions of local commissioners, yet too often they are ignored or implemented in a piecemeal fashion. This is perhaps more common for fertility treatment than any other NHS service.<br><br>The 2004 and 2013 NICE guidelines on fertility recommended that three full cycles of IVF be provided to eligible couples. Ever since the first guideline's publication, NIAC has been working to increase adherence amongst commissioners. Significant progress has | *'Holding back the IVF* Revolution' a report looking at variations in provision for couples seeking IVF/ICSI treatment by the All Party Parliamentary Group on Infertility (2011), accessible here: http://www.garethjohnsonmp.co.uk/uimages/File/appg_IVF_report.pdf<br><br>*'Assisted Conception Needs Assisted Implementation*', NIAC 2013 audit of CCG fertility service provision: http://www.infertilitynetworkuk.com/uploaded/NIAC/Assisted%20Conception |

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| | | the definition of a cycle also needs to be reiterated to commissioners, as this is often misinterpreted or misused. | been made but even now, a decade on from 2004, variations in provision are still widespread.<br><br>In 2011 the All Party Parliamentary Group on Infertility published a report entitled 'Holding Back the British IVF Revolution'. The report highlighted the fact that over 70% of Primary Care Trusts (PCTs) were not providing the recommended three cycles of IVF treatment to eligible couples.<br><br>Two years later in 2013, NIAC conducted an audit of England's CCGs and found that despite the transition to GP-led commissioning, provision remained largely similar to that in 2011 with 50% of CCGs offering one cycle, 25% offering two cycles and a further 25% offering three cycles. Six CCGs offered no funding whatsoever.<br><br>Since the audit took place, a number of CCGs within the East of England (the region that made up the bulk of CCGs providing three cycles) have reconsidered their joint policy and are now actively considering a reduction to two cycles.<br><br>NIAC routinely writes to those commissioners that have suspended or reduced funding for fertility treatment. As | %20Needs%20Assisted%20Implementation.pdf<br><br>Paper circulated to East of England CCGs recommending a reduction to two cycles (2013): http://www.norwichccg.nhs.uk/publications-policies/doc_download/232-item-9-specialist-fertility-treatments<br><br>West Norfolk CCG Governing Body document recommending reduction to two cycles (October 2013): http://www.westnorfolkccg.nhs.uk/sites/default/files/pdf/Agenda%20Item%2011.1%20WNCCG%20GB%20Papers%2031.10.13%20IVF%20Local%20Policy.pdf<br><br>Norwich CCG Governing Board paper stating that West Norfolk CCG, North Norfolk CCG and South Norfolk CCG all support a reduction in cycles offered to two (see agenda item 9): http://www.norwichccg.nhs.uk/agendas-and-papers/cat_view/1-public/3-agendas-and-papers/10-2013/16-november<br><br>Press release from North East Essex CCG stating that |

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| | | | a matter of course, we quote the recommendations contained within the 2013 NICE guideline. Many CCGs acknowledge the guideline and express their regret at not being able to 'afford' three full cycles, whilst others simply state that the guideline is not mandatory.<br><br>Given the direct correlation between the number of cycles provided and the likelihood of a successful clinical outcome, NIAC is of the opinion that 'cycles offered' is the single most important area in need of quality improvement. Furthermore, we believe that this standard, if adopted, should be transposed into the CCG Outcome Indicator set as soon as possible in order to both encourage adherence at a local level and increase the capacity for oversight at a national level (currently neither the Department of Health or NHS England collect data on the number of cycles commissioned by each CCG).<br><br>Definition of a cycle<br><br>As evidenced above, variation in IVF cycles offered is widespread. Even in those areas that fund just one cycle of treatment, this is not always a full cycle as defined by NICE. | commissioners had decided to reduce the number of IVF cycles offered to two: http://www.neessexccg.nhs.uk/News%20and%20Events/News/Current%20News/483.html<br><br>Definition of a cycle<br><br>Policy from the following CCGs offering just one fresh cycle of IVF/ICSI with no funding for frozen embryos:<br>Aylesbury Vale Clinical Commissioning Group<br>Bracknell and Ascot Clinical Commissioning Group<br>Chiltern Clinical Commissioning Group<br>Newbury and District Clinical Commissioning Group<br>North and West Reading Clinical Commissioning Group<br>Oxfordshire Clinical Commissioning Group<br>South Reading Clinical Commissioning Group<br>Slough Clinical Commissioning Group<br>Windsor, Ascot and Maidenhead Clinical Commissioning Group<br>Wokingham Clinical Commissioning Group |

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| | | | In some cases CCGs offer the recommended fresh cycle followed by all available (viable) frozen embryos. In other CCGs, the number of frozen embryo transfers varies and can even be excluded from funding altogether. Not only does this adversely affect treatment outcomes but it also raises important ethical questions that have yet to be resolved. For example, is it right to offer a service whereby the NHS creates and freezes embryos using public money only to later deny access using public money?<br><br>This is another key area in need of quality improvement and should be included in forthcoming guidance as a quality statement. | Available at: http://www.oxfordshireccg.nhs.uk/wp-content/uploads/2013/04/PS11-Assisted-Conception.pdf<br><br>Policy of three full cycles from the following CCGs:<br>Newcastle North and East CCG<br>Newcastle West CCG<br>North Tyneside CCG<br>Northumberland CCG<br>Darlington CCG<br>Durham Dales, Easington and Sedgefield CCG<br>North Durham CCG<br>Cumbria CCG<br><br>Available here: http://www.cumbriaccg.nhs.uk/about-us/key-policies/policies/commissioning/value-based-clinical-commissioning-policies-cumbria-final-dec-2013.pdf |
| National | Use of ICSI | As per the NICE guideline, ICSI | The incidence of male factor infertility in | HFEA 2011 trend data on the use |

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| Infertility Awareness Campaign | | should be considered in cases of: severe deficits in semen quality; obstructive azoospermia; non-obstructive azoospermia; and for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation. Yet recent data suggests that the use of ICSI in the UK is disproportionate to the number of patients with an identifiable need for this type of treatment.<br><br>Given that CCGs often cite the costs of IVF/ICSI treatment as the number one obstacle to implementing NICE's recommendations in full, strategies designed to make efficiency savings should be prioritised as a means of freeing up additional resources for subsequent reinvestment in the service | cases of fertility treatment is only 30 to 40%, however, data from the HFEA shows that ICSI is now used to treat 53% of all couples receiving fertility treatment in the UK. There is therefore a discrepancy between the observed rate of male factor infertility and the reported use of ICSI.<br><br>Given these trends, it is important to ensure that the decision to use ICSI is based on clinical need and that it is not viewed as a form of security against fertilisation failure.<br><br>ICSI is also a more expensive treatment for the patient, the clinic and the Department of Health. From a purely cost-effective point of view, it is difficult to justify its use in patients that do not require it. | of ICSI: http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf |
| National Infertility Awareness Campaign | Female Age Criteria for IVF/ICSI | Female Age criteria for IVF/ICSI treatment varies widely across the country depending on the CCG in question. A quality statement on age criteria is necessary in order to help reduce unwarranted variation in | Despite the longstanding recommendation by NICE that couples should be offered three full cycles of IVF/ICSI if the female partner is aged under 40, a number of CCGs operate a more restrictive age range, typically limiting referrals to those couples where | Policy from the following CCGs offering just one fresh cycle of IVF/ICSI to couples where the female partner must be aged under 35:<br>Aylesbury Vale CCG<br>Bracknell and Ascot CCG |

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| | | access to fertility services and encourage uniform compliance from commissioners. | the female partner is aged under 35.<br><br>In addition, many CCGs are not adhering to the new age extension recommended by NICE in February 2013 (one cycle of IVF/ICSI to eligible couples where the female partner is aged between 40-42). NIAC's audit of CCGs found that just 5 CCGs had implemented this age extension by the Summer of 2013 (individual CCG data available via Infertility Network UK website).<br><br>Several others have yet to remove the lower age limit of 23.<br><br>NIAC acknowledges that the definition of 'childlessness' falls outside the scope of NICE guidance however it should be noted that this definition also varies from area to area and it is currently being used as a means of further reducing the number of referrals i.e. neither partner can have a child from a previous relationship. | Chiltern CCG<br>Newbury and District CCG<br>North and West Reading CCG<br>Oxfordshire CCG<br>South Reading CCG<br>Slough CCG<br>Windsor, Ascot and Maidenhead CCG<br>Wokingham CCG<br>Available here:<br>http://www.oxfordshireccg.nhs.uk/wp-content/uploads/2013/04/PS11-Assisted-Conception.pdf<br><br>Policy from another set of CCGs offering IVF/ICSI to couples where the female partner must be aged under 35:<br><br>North Hampshire CCG<br>South East Hampshire CCG<br>North East Hampshire and Farnham CCG<br>West Hampshire CCG<br>Fareham and Gosport CCG<br>Southampton City CCG<br>Portsmouth City CCG<br><br>Available at:<br>http://www.porthosp.nhs.uk/Downloads/Maternity/IVF%20Referral%20Form%20July%202013.docm |

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| National Infertility Awareness Campaign | Single Embryo Transfer | Single Embryo Transfer (eSET) strategies have a positive, demonstrable effect on the number of multiple pregnancies. Multiple pregnancies have higher rates of mortality and morbidity for mothers and babies which also result in considerable costs to maternity and, neonatal services as well as longer term health care if the babies survive but have disabilities.<br><br>Given that CCGs often cite the costs of IVF/ICSI treatment as the number one obstacle to implementing NICE's recommendations in full, strategies designed to make efficiency savings should be prioritised as a means of freeing up additional resources for subsequent reinvestment in the service. | NIAC supports measures that reduce the risk of multiple pregnancies. It is encouraging to see that the HFEA policy on reducing multiple births from IVF is having an impact but this needs to continue with centres and patients supported with the use of elective single embryos transfers where appropriate. I It is essential that commissioners understand the reasons for the need to adopt a clinically appropriate policy of eSET.<br><br>An example of where eSET may not be clinically appropriate would be if CCG funding arrangements only allowed for one cycle of IVF treatment. Any such strategy should therefore be balanced.<br><br>This is particularly pertinent given the aim of the Human Fertilisation and Embryology Authority and other professional bodies to achieve a 10% multiple birth rate target. | www.oneatatime.org.uk |
| National Infertility Awareness Campaign | Provision of specialist infertility counselling routinely for patients in the | A diagnosis of azoospermia or very low ovarian reserve is devastating news for most people. An early therapeutic intervention ensures that | There is currently no counselling provision at the stage of diagnosis of absolute infertility and patients can usually only access specialist infertility counselling once they have become a | Bak CW, Seok HH, Song SH, Kim ES, Her YS, Yoon TK. J Androl. 2012 Hormonal imbalances and psychological scars left behind in infertile men. |

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| | following circumstances:<br>After diagnosis of azoospermia and very low ovarian reserve<br>Before treatment with donor gametes<br>Before donating gametes<br>Before provision of fertility preservation treatment in oncology patients | patients are supported in coming to terms with the fact that they will not be able to have their own genetic children. Early intervention also ensures that people get the information they need on the available options for family building. Preparation for parenthood sessions, for people seeking treatment with donor gametes, ensure they are fully informed of all the social, legal and ethical implications of having a donor conceived child. These sessions, conducted by specialist infertility counsellors, also inform patients of best practice regarding telling children from an early age that they are donor conceived and ensure patients are informed of suitable ways of doing this in order to promote the long term psychological wellbeing of donor conceived offspring. Donors potentially make a lifelong commitment when they donate their gametes due to legislation that enables donor-conceived adult offspring to apply to the HFEA for identifiable information about | patient in an infertility clinic. This is sometimes too late, as couples attending infertility clinics are only those who have made a decision to pursue treatment with donor gametes. This neglects a significant proportion of people struggling to come to terms with this diagnosis who do not have access to specialist counselling. The psychological impact of a diagnosis of male or female absolute infertility is well known and supported in the research. Early therapeutic intervention could prevent later onset of anxiety and depression in these patients. This quality standard is relevant for primary and secondary care providers. (2, 3,4) General Comment: HFEA Code of Practice requires clinics to offer counselling in a number of circumstances before consent to treatment or donation is obtained. Counselling is becoming a routine part of the treatment pathway in some clinics, but not all. Introducing a key quality standard that states that all patients in the circumstances outlined here (and gamete donors) will receive counselling routinely as part of their treatment, will ensure that more patients are given the opportunity to fully consider the implications of treatment/donation before they consent.<br>The provision of pre-treatment implications counselling sessions needs | Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. Recommendation ‘As a matter of good professional practice, clinics should provide counselling sessions as part of the routine series of appointments attended by prospective parents. An additional support session later in pregnancy or after the birth of the child should also routinely be offered.’<br>(2,3) Policy and Practice paper: Wilde et al 'Family building using donated gametes and embryos in the UK: Recommendations for policy and practice on behalf of the British Infertility Counselling Association and the British Fertility Society in collaboration with the Association of Clinical Embryologists and the Royal College of Nurses Fertility Nurses Forum' Posted online on December 13, 2013.<br>(2,3) Routine counselling advocated by for example: Donor Conception network, the National Gamete Donation Trust and the Infertility Network UK.<br>(2,3,4) The British Infertility Counselling Association |

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| | | their donor. It is important that donors are fully informed about this commitment and given the opportunity to explore the implications of donation for them, their partner and any future children.<br>Similarly to above, all patients seeking fertility preservation prior to treatment for cancer should routinely see a specialist counsellor to enable them to fully explore their options. Decisions are made about fertility preservation at a time when people are in considerable distress. It is important that patients are supported to make the best choice they can to give them a chance of having children in the future. | improving to ensure that all clinics refer patients routinely for counselling and give sufficient information to patients on the importance of attending such sessions. 'Preparation for parenthood sessions' are a routine part of treatment in some clinics but not all. It is important to establish the quality standard that all patients should routinely have implications counselling before consenting to treatment with donor gametes.<br>As above, pre-donation counselling does not routinely take place in all clinics before donation. Therefore not all donors will have fully considered the implications before consenting to donate. There is a risk to the long-term psychological health of the donor, their families and any donor-conceived offspring if donors are inadequately prepared for the potential consequences of their donation.<br>Currently, not all patients requiring fertility preservation are routinely referred to a specialist infertility counsellor. Receiving good information and support at this critical time is essential to ensure cancer survivors are given the best possible chance of having a family post treatment and are supported in dealing with the prospect of future infertility as a result of cancer or cancer therapies. | Guidelines for Good Practice (2012)<br>(2,3,4) HFEA Code of Practice (8th edition)<br>Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. Recommendation 'Clinics should ensure that sessions with a counsellor are scheduled as part of a routine series of appointments that donors attend before deciding whether or not to donate. Where donors have partners, clinics should strongly encourage partners to attend these sessions.'<br>Journal of Clinical Oncology: Loren, Alison W., et al. "Fertility Preservation for Patients with Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update" (Full-text. Published online ahead of print: May28 2013)<br>http://jco.ascopubs.org/content/early/2013/05/24/JCO.2013.49.2678.full.pdf+html<br>www.macmillan.org.uk information about fertility preservation for patients |

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| SCM 2 | Key area for quality improvement 1<br><br>Ensuring people feel supported to manage their condition | Pain of infertility is exacerbated by isolation. This involves both the female and male partners. The kind of choices these couple may have to make for their care can be bewildering in many situations. This leads to stress, social maladjustment, psychological disorders and psychiatric morbidity | Availability of local support group and professional counselling services will reduce stress, loss of libido, the risk of broken relationships and psychological disorders through a process of mental and emotional adjustment. | QS 15<br>QS 47<br>CG 156 SECTION 4.3<br>The HFEA Code of Practice |
| SCM 2 | Key area for quality<br><br>improvement 2 Infertility investigation in the male | Male factor infertility is encountered in 50% of couples (the sole cause in 20% of infertile couples and is contributing factor in another 25-30% of infertile couples). Semen analysis in the primary assessment tool of male fertility potential. Precision 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 result of semen analysis. This may lead to a longer process in investigating male infertility, the offer of inappropriate treatment, and potentially over treatment. Not all laboratories offering semen analysis are accredited to carry out this work and are not taking part in a national quality control process. | WHO laboratory manual for the examination and processing of human semen. 5th Edition, 2010. Part III.<br><br>CG 156 SECTIONs 6.1, 6.2 |
| SCM 2 | Key area for quality improvement 3<br><br>Managing Male infertility | Although male factor infertility is the sole or a contributory factor in 50% of infertile couples, the bulk of infertility management (investigation and treatment) focuses on the female. Some cases of male factor infertility could be corrected by changing | Access to reproductive medicine specialists who are skilled in dealing with male factor infertility is an essential part of the quality of the care offered because: Like women, men deserve to know the cause of their infertility be it related to life style, hormonal, genetic or idiopathic cause. | CG 156 SECTIONs 6.1, 6.2<br><br>Alukal JP, Lipshultz LI. Why treat the male in the era of assisted reproduction? Semin Reprod Med. 2009; 27:109-14 |

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| | | life style issues, or through medical or surgical treatment. In doing so natural fertility may be regained, thus sparing men (and couples) more invasive and expensive treatments. This is only achievable through adequate assessment and, when appropriate, treatment instead of rushing all subfertile men indiscriminately to assisted reproductive techniques. | Couples need to make informed decision regarding their treatment as male factor infertility may be transmitted to male children<br>This facilitate genetic counselling should a recognised genetic condition is found to be the underlying cause of infertility as it is the case in the infertility-type of cystic fibrosis gene mutation.<br>This ensures that specialist treatment is offered to cases where natural fertility may be regained thus sparing men (and couples) more invasive and expensive treatments (testicular biopsies, IVF/ICSI). | |
| SCM 2 | Key area for quality improvement 4<br><br>Safety: A low incidence of multiple pregnancies by adopting a clear policy for single embryo transfer | Replacing two or more embryos is associated with unacceptable incidence of multiple pregnancy rate (including twins and high order multiple pregnancy), which exceeds 25% of pregnant women.<br><br>Multiple pregnancy is associated with increased risk of miscarrying the pregnancy, delivering prematurely, small babies, congenital abnormalities and neurological deficit and death of newly borne babies. In addition maternal complications and death are increased. | A low incidence of multiple pregnancies by adopting a clear policy for single embryo transfer to address:<br>The high incidence of loss of undelivered babies, which should be viewed as failed treatment.<br>The prohibitive financial cost of looking after babies born prematurely and neurologically damaged babies, which has a negative impact on resources both clinical and social. | CG 156 SECTION 15.7<br><br>The HFEA Code of Practice |

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| SCM 2 | Key area for quality improvement 5<br><br>Effectiveness and safety: Audited embedded bedded infertility management for quality assurance | Clinical audit is highly developed in assisted reproductive units to meet HFEA requirements for regular reporting of activity by licensed IVF centres. Clinical audit remains scares in 1ry and secondary infertility care. Data on the effective use of resources in primary care to investigate infertility, the compliance with NICE guidelines in using mild ovarian stimulation in secondary care, and the safety of the use of gonadotropins in conjunction GnRH agonists of antagonists for IVF are examples of clinic audits that does not make it in the selected audit topic in many care delivery organizations | A strong program of clinical audit based on standards derived from CG 156 offers:<br>Reassurance that Guideline recommendations based on best clinical evidence true influence clinical care.<br>The means to identify areas of substandard infertility care or care associated with risk.<br>Insight into the effective use of resources<br>The opportunity to construct an action plan to address areas of substandard care. Improvements achieved are verified through re-audit (complete audit cycle-Closing the loop) | NICE policy on audit.<br>The whole of CG 156. |
| SCM 3 | Key area for quality improvement 1<br><br>Female Age Criteria for IVF/ICSI | The age of the female is a key factor for successful treatment. The NICE Guideline published in 2013 recommends that 3 full cycles of IVF/ICSI should be funded for couples where the female is aged up to 39 inclusive and one cycle for couples where the female is aged between 40 and 42 subject to additional criteria. As always, the decision was based | Some CCGs have implemented more limiting criteria in relation to the age of the female – for example only funding treatment for couples where the female is 35 years old and under.<br><br>Many CCGs have not implemented the new recommendations in the Fertility Guideline published in 2013 i.e. one cycle for couples where the age of the female is between 40 and 42. Nor have they removed the lower age limit of 23 which | In February 2007 Infertility Network UK published the results of a survey of the Primary Care Trusts (PCTs) in place at the time. Data on the varying female age criteria being employed by PCTs at the time can be found in the report attached to the covering email.<br><br>In 2012 Infertility Network UK (I N UK) published its final report on |

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| | | on both clinical and cost effectiveness. However, the eligibility criteria being used by CCGs across England in relation to the age of the female vary enormously resulting in inequity. | was in the previous guideline. The audit performed by NIAC in 2013 showed that only 5 CCGs had done so at that time. | the Primary Care Trusts Liaison Project 2009-2012 funded by a grant from the Department of Health. See http://www.infertilitynetworkuk.com/uploaded/Primary%20Care%20Trusts%20Liaison%20Project%202009-2012.pdf The report showed that the NICE guideline was still not being fully implemented across England, including the female age criteria. |
| SCM 3 | Key area for quality improvement 2<br><br>Ensure that ICSI treatment is only used when clinically appropriate | Data from the Human Fertilisation & Embryology Authority (HFEA) indicates show that 53% of couples undergoing assisted reproduction treatment have ICSI. The NICE guideline 2013 states that ICSI should be considered in cases of: severe deficits in semen quality; obstructive azoospermia; non-obstructive azoospermia; and for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation. The number of patients having ICSI does not equate with the number of | Male infertility accounts for 30-40% of people experiencing difficulties in conceiving, yet 53% of couples undergoing assisted reproduction have ICSI. There is therefore an inconsistency between the rate of male factor infertility and the reported use of ICSI.<br><br>It is important to ensure that the decision to use ICSI is based on clinical need. ICSI is also a more expensive treatment for the patient, the clinic and the Department of Health and therefore it is more cost effective if it is only used where appropriate and as recommended in the NICE Guideline. | HFEA 2011 trend data on the use of ICSI: http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf |

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| | | couples where the male partner is diagnosed with male infertility as described above.<br><br>ICSI is more expensive than IVF and is an area where savings could be made to the NHS if we can ensure that only those who need ICSI access it and those that don't have IVF. CCGs would be able to provide more cycles of IVF and therefore would increase full implementation of the NICE guideline and improve the quality of the treatment being provided. | | |
| SCM 3 | Key area for quality improvement 3<br><br>3 full cycles of IVF/ICSI should be to all eligible patients as recommended by NICE | In both the 2004 and 2013 NICE Fertility guideline, the recommendation relating to how many cycles should be funded by the NHS has been that 3 full cycles should be made available to those patients who fulfil the eligibility criteria.<br><br>This recommendation was based on both clinical and cost effectiveness – in other words offering eligible patients the best chance of achieving a pregnancy and having a family. | Funding for IVF/ICSI is notorious for being cited as an area of treatment which suffers from "a postcode lottery" whereby it totally depends on where you live as to whether you can access NHS funded treatment. This inequity has been in place since even before the publication of the original NICE guideline in 2004 and still exists.<br><br>Currently 73% of CCGs fall short of the NICE guideline recommendation of providing 3 full cycles of IVF/ICSI to eligible couples. 49% only offer one cycle of treatment and some of these do not | In February 2007 Infertility Network UK published the results of a survey of the Primary Care Trusts (PCTs) in place at the time. Of the 151 PCTs covered by the responses, 98 (64.9%) indicated that they were funding one cycle of IVF per couple. 21.2% of PCTs responded that they were funding up to 2 cycles of IVF per couple. And just 4.6% of PCTs were funding up to 3 cycles of IVF per couple. 9.3% did not fund IVF; did not respond to the question; or did not provide details of the number |

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| | | In order to maximise clinical outcomes, it is essential that this recommendation be implemented uniformly across the country.<br><br>Many CCGs are only funding A cap on the number of frozen embryos transfer events as part of a cycle has a direct, negative, effect on the likelihood of a successful outcome. Therefore, the definition of a cycle also needs to be reiterated to commissioners, as this is often misinterpreted or misused. | fund a full cycle and only fund one fresh cycle forcing patients from the NHS into the private sector to access any frozen embryos created during that fresh cycle) i.e. they are not providing a full cycle as defined by the NICE guideline. 24% of CCGs offer two cycles and only 24% offer three cycles. | of cycles funded. I have attached the report compiled based on the results of the survey to the covering email.<br><br>In 2008 the Department of Health performed a survey of Primary Care Trusts on the provision of IVF in England which showed that in 2008/09 27% funded 3 cycles; 23% funded 2 cycles; 25% funded 1 full cycle and 22% funded just one fresh cycle. I have attached the results of the survey to the covering email.<br><br>In 2012 Infertility Network UK (I N UK) published its final report on the Primary Care Trusts Liaison Project 2009-2012 funded by a grant from the Department of Health. See http://www.infertilitynetworkuk.com/uploaded/Primary%20Care%20Trusts%20Liaison%20Project%202009-2012.pdf The report showed that the NICE guideline was still not being met across the whole of England. Whilst funding had improved during the course of the project, there was still huge |

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| | | | | variation in the number of cycles being<br>funded by PCTs with the majority funding just one or two cycles and a<br>minority funding 3 cycles.<br><br>It also showed that eligibility criteria for fertility treatment still varied across PCT areas and were not in line with NICE Clinical Guideline Recommendations. Differences included requiring the partner to meet BMI and age limits.<br><br>An audit of CCGs in 2013 performed by the National Infertility Awareness Campaign (NIAC) showed that patients needing IVF are no better off than they were in 2011, despite the National Institute for Health and Care Excellence (NICE) updating its guideline on fertility earlier this year, and the transition to a new commissioning system.<br>NIAC's 2013 audit – the first to look nationally at CCG commissioning of fertility services - found that 73% fell short of the NICE guideline recommendation of providing 3 full cycles of |

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| | | | | IVF/ICSI to eligible couples.<br><br>Of the 198 CCGs that funded IVF/ICSI treatment:<br><br>• 49% only offered one cycle of treatment<br>• 24% offered two cycles<br>• 24% offered three cycles*<br><br>*rounded percentages<br><br>See http://www.infertilitynetworkuk.com/uploaded/NIAC/Assisted%20Conception%20Needs%20Assisted%20Implementation.pdf |
| SCM 3 | Key area for quality improvement 4<br><br>Embryo transfer strategy and single embryo transfer | Multiple pregnancy is the single biggest risk to the health and welfare of patients and children born from fertility treatment. It can lead to both short and long-term health problems, and places a financial burden on the health service.<br><br>Transferring one embryo in patients most at risk of conceiving a multiple pregnancy will give children born from IVF the best possible start in life, by reducing their chances of being born as a twin. | I repeat, multiple pregnancy is the single biggest risk to the health and welfare of patients and children born from fertility treatment leading to both short and long term health problems and a cost to the NHS.<br><br>NHS commissioners play a vital role in supporting the use of single embryo transfer (SET) in clinics. Providing funding for three full cycles of IVF, including follow-on frozen embryo transfers, makes a real difference in encouraging patients to have SET.<br><br>If a couple are only able to access NHS | HFEA multiple births policy change announcement (Nov 2013): http://www.hfea.gov.uk/8342.html<br><br>HFEA website on single embryo transfer with information for commissioners, health professionals and patients. http://www.oneatatime.org.uk/<br><br>HFEA aim and policy on single embryo transfer is to achieve a 10% multiple birth rate. http://www.oneatatime.org.uk/471.htm |

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| | | The costs to the NHS in terms of multiple pregnancies and the cost impact of neonatal care which many of them need due to premature births for example are significant. By reducing the number of multiple births and therefore making savings elsewhere would be a more cost-effective use of CCG resources which would aid those CCGs who are currently not fully implementing the NICE guideline in terms of the number of cycles they fund and who they fund it for. | funding for just one cycle they are understandably reluctant to accept single embryo transfer. | I N UK factsheet for patients on Single Embryo Transfer: http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/I%20N%20UK%20SET%20Patient%20Factsheet%20July%202013.pdf<br><br>Infertility Network UK factsheet on single embryo transfer for health professionals: http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/I%20N%20UK%20SET%20HP%20Factsheet%20July%202013.pdf |
| SCM 3 | Key area for quality improvement 5<br><br>Provision of specialist infertility counselling routinely for all those affected by difficulties in conceiving | All HFEA-licensed clinics have to provide an opportunity to talk to a counsellor about the implications of the suggested treatment before consent. Counselling aims to help patients to understand exactly what the treatment will involve and how it might affect them and those close to them - now and in the future. Counselling on the implications of treatment is especially important for those considering using donated sperm, eggs or embryos or surrogacy arrangements - all of | The NICE Fertility Guideline 2013 makes the following recommendations in relation to counselling:<br><br>People who experience fertility problems should be informed that they may find it helpful to contact a fertility support group. [2004]<br>People who experience fertility problems should be offered counselling because fertility problems themselves, and the investigation and treatment of fertility problems, can cause psychological stress. [2004]<br>Counselling should be offered before, during and after investigation and | HFEA Code of Practice: http://www.hfea.gov.uk/code.html<br><br>The British Infertility Counselling Association (BICA) have produced guidelines for good practice for infertility counselling which is available from their website at http://www.bica.net/books/guidelines-good-practice-infertility-counselling |

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| | | which involve complicated issues. Patients need time to explore how they feel, to consider the needs and legal rights of donor-conceived children and to talk about whether this is going to be the right decision for them.<br><br>Counselling can give patients the opportunity to talk freely and openly without being judged; the chance to explore feelings; sensitive issues that are troubling them and help in understanding the factors that may be contributing to their difficulties and support in finding their own solutions and new ways of coping.<br><br>Counselling can provide emotional support before, during or after fertility treatment. Most people find that infertility and assisted conception treatments are stressful. Counselling can be especially useful in helping patients to work through the emotions they may experience before, during and after treatment. This may | treatment, irrespective of the outcome of these procedures. [2004]<br><br>Currently only those clinics licensed to provide IVF/ICSI and regulated by the HFEA are legally obliged to provide access to a counsellor for their patients. However, there is currently no counselling provision at the stage of diagnosis in primary or secondary care. The emotional impact of infertility is not only on patients undergoing licensed treatments such as IVF yet there is no requirement for patients who are perhaps undergoing ovarian stimulation such as clomid to have the opportunity to access counselling should they require it. | |

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| | | be when they first find out they have fertility problems, when they are waiting for results, if their treatment isn't successful, or if they are both having to come to terms with the fact that there is no further suitable treatment for them to try. | | |
| Human Fertilisation and Embryology Authority | Fertility preservation | Fertility preservation is the effort to help patients retain their fertility, or ability to procreate, by storing eggs, sperm, testicular tissues or ovarian tissue.<br><br>Prospective patients may wish to preserve their fertility for several reasons.<br><br>• To delay having children for social reasons.<br><br>• To allow treatment of a medical condition which may affect future fertility.<br><br>• To allow storage of eggs, sperm or embryos prior to cancer treatment. | Increasing awareness amongst practitioners to ensure that patients who could benefit from fertility preservation are given the opportunity. Ensuring screening requirements are adhered to so the material stored can be used when needed. | Few clinics store ovarian tissue from licensing information available. |
| Human Fertilisation | The patient pathway from GP | To ensure patients are fully informed regarding their | When patients first experience problems with their fertility the first point of call is | |

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| and Embryology Authority | to the fertility clinic | possible treatment pathways | likely to be their GP. Therefore GPs' understanding of commissioning arrangements and treatment options is crucial in order for patients to understand their potential treatment pathway and to ensure they are directed down the right route as quickly as possible. | |
| Human Fertilisation and Embryology Authority | Reducing the rate of multiple births following IVF and aligning commissioning of fertility treatment with best practice regarding reducing multiple birth rates | The single biggest risk of fertility treatment is multiple pregnancy.<br><br>While it is important to reduce the risk of multiple births however, t is also important that commissioning policies don't jeopardise the risk of a successful outcome by restricting clinicians' freedom to choose the most appropriate treatment pathway for their patients eg, by mandating single embryo transfer for all patients | In 2009, the HFEA launched a campaign called One at a Time (www.oneatatime.org.uk) to inform patients and clinics about the risk associated with multiple births and the steps that be taken to avoid them without significantly damaging success rates.<br>Since 2009, the overall multiple births rate has reduced from 24% to close to 15%. Clinics are now working towards a new target of 10%, a level achieved in a number of other countries such as Sweden.<br>The decision on the number of embryos to transfer should be a clinical judgement taken on a case-by-case basis. | www.oneatatime.org.uk |
| Human Fertilisation and Embryology Authority | Success rates | It's important that patients are able to access accurate data about the likely outcomes of their treatment options. | If patients are empowered to make choices regarding their fertility, it is important for hospitals to be responsible in how they promote their services.<br><br>NHS fertility units should not be promoting success rates out of context. | The HFEA provides success rate data for individual clinics on its website: Choose A Fertility Clinic http://guide.hfea.gov.uk/guide/ |
| Human Fertilisation and | Safety of drug regimes used to stimulate a | Over stimulation of a woman's ovaries can lead to the development of life threatening | If clinicians are motivated to adhere to professional body guidelines in relation to stimulatory regimes this could reduce the | patient information on our website about risks/OHSS for background information |

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| Embryology Authority | woman's ovaries | complication – ovarian hyper-stimulation syndrome | incidence and associated risks of OHSS. | http://www.hfea.gov.uk/fertility-basics.html |
| Infertility Network UK | Key area for quality improvement 1<br><br>Female Age Criteria for IVF/ICSI | The age of the female is a key factor for successful treatment. The NICE Guideline published in 2013 recommends that 3 full cycles of IVF/ICSI should be funded for couples where the female is aged up to 39 inclusive and one cycle for couples where the female is aged between 40 and 42 subject to additional criteria. As always, the decision was based on both clinical and cost effectiveness. However, the eligibility criteria being used by CCGs across England in relation to the age of the female vary enormously resulting in inequity. | Some CCGs have implemented more limiting criteria in relation to the age of the female – for example only funding treatment for couples where the female is 35 years old and under.<br><br>Many CCGs have not implemented the new recommendations in the Fertility Guideline published in 2013 i.e. one cycle for couples where the age of the female is between 40 and 42. Nor have they removed the lower age limit of 23 which was in the previous guideline. The audit performed by NIAC in 2013 showed that only 5 CCGs had done so at that time. | In February 2007 Infertility Network UK published the results of a survey of the Primary Care Trusts (PCTs) in place at the time. Data on the varying female age criteria being employed by PCTs at the time can be found in the report attached to the covering email.<br><br>In 2012 Infertility Network UK (I N UK) published its final report on the Primary Care Trusts Liaison Project 2009-2012 funded by a grant from the Department of Health. See http://www.infertilitynetworkuk.com/uploaded/Primary%20Care%20Trusts%20Liaison%20Project%202009-2012.pdf The report showed that the NICE guideline was still not being fully implemented across England, including the female age criteria. |
| Infertility Network UK | Key area for quality improvement 2<br><br>Ensure that ICSI treatment is only | Data from the Human Fertilisation & Embryology Authority (HFEA) indicates show that 53% of couples undergoing assisted reproduction treatment have | Male infertility accounts for 30-40% of people experiencing difficulties in conceiving, yet 53% of couples undergoing assisted reproduction have ICSI. There is therefore an inconsistency between the rate of male factor infertility | HFEA 2011 trend data on the use of ICSI: http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf |

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| | used when clinically appropriate | ICSI. The NICE guideline 2013 states that ICSI should be considered in cases of: severe deficits in semen quality; obstructive azoospermia; non-obstructive azoospermia; and for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation. The number of patients having ICSI does not equate with the number of couples where the male partner is diagnosed with male infertility as described above.<br><br>ICSI is more expensive than IVF and is an area where savings could be made to the NHS if we can ensure that only those who need ICSI access it and those that don't have IVF. CCGs would be able to provide more cycles of IVF and therefore would increase full implementation of the NICE guideline and improve the quality of the treatment being provided. | and the reported use of ICSI.<br><br>It is important to ensure that the decision to use ICSI is based on clinical need. ICSI is also a more expensive treatment for the patient, the clinic and the Department of Health and therefore it is more cost effective if it is only used where appropriate and as recommended in the NICE Guideline. | |
| Infertility Network UK | Key area for quality improvement 3 | In both the 2004 and 2013 NICE Fertility guideline, the recommendation relating to how many cycles should be funded | Funding for IVF/ICSI is notorious for being cited as an area of treatment which suffers from "a postcode lottery" whereby it totally depends on where you live as to | In February 2007 Infertility Network UK published the results of a survey of the Primary Care Trusts (PCTs) in place at the time. |

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| | 3 full cycles of IVF/ICSI should be to all eligible patients as recommended by NICE | by the NHS has been that 3 full cycles should be made available to those patients who fulfil the eligibility criteria.<br><br>This recommendation was based on both clinical and cost effectiveness – in other words offering eligible patients the best chance of achieving a pregnancy and having a family. In order to maximise clinical outcomes, it is essential that this recommendation be implemented uniformly across the country.<br><br>Many CCGs are only funding A cap on the number of frozen embryos transfer events as part of a cycle has a direct, negative, effect on the likelihood of a successful outcome. Therefore, the definition of a cycle also needs to be reiterated to commissioners, as this is often misinterpreted or misused. | whether you can access NHS funded treatment. This inequity has been in place since even before the publication of the original NICE guideline in 2004 and still exists.<br><br>Currently 73% of CCGs fall short of the NICE guideline recommendation of providing 3 full cycles of IVF/ICSI to eligible couples. 49% only offer one cycle of treatment and some of these do not fund a full cycle and only fund one fresh cycle forcing patients from the NHS into the private sector to access any frozen embryos created during that fresh cycle) i.e. they are not providing a full cycle as defined by the NICE guideline. 24% of CCGs offer two cycles and only 24% offer three cycles. | Of the 151 PCTs covered by the responses, 98 (64.9%) indicated that they were funding one cycle of IVF per couple. 21.2% of PCTs responded that they were funding up to 2 cycles of IVF per couple. And just 4.6% of PCTs were funding up to 3 cycles of IVF per couple. 9.3% did not fund IVF; did not respond to the question; or did not provide details of the number of cycles funded. I have attached the report compiled based on the results of the survey to the covering email.<br><br>In 2008 the Department of Health performed a survey of Primary Care Trusts on the provision of IVF in England which showed that in 2008/09 27% funded 3 cycles; 23% funded 2 cycles; 25% funded 1 full cycle and 22% funded just one fresh cycle. I have attached the results of the survey to the covering email.<br><br>In 2012 Infertility Network UK (I N UK) published its final report on the<br>Primary Care Trusts Liaison Project 2009-2012 funded by a |

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| | | | | grant from the Department of Health. See http://www.infertilitynetworkuk.com/uploaded/Primary%20Care%20Trusts%20Liaison%20Project%202009-2012.pdf The report showed that the NICE guideline was still not being met across the whole of England. Whilst funding had improved during the course of the project, there was still huge variation in the number of cycles being funded by PCTs with the majority funding just one or two cycles and a minority funding 3 cycles.<br><br>It also showed that eligibility criteria for fertility treatment still varied across PCT areas and were not in line with NICE Clinical Guideline Recommendations. Differences included requiring the partner to meet BMI and age limits.<br><br>An audit of CCGs in 2013 performed by the National Infertility Awareness Campaign (NIAC) showed that patients needing IVF are no better off than they were in 2011, despite the National Institute for Health and |

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| | | | | Care Excellence (NICE) updating its guideline on fertility earlier this year, and the transition to a new commissioning system.<br>NIAC's 2013 audit – the first to look nationally at CCG commissioning of fertility services - found that 73% fell short of the NICE guideline recommendation of providing 3 full cycles of IVF/ICSI to eligible couples.<br><br>Of the 198 CCGs that funded IVF/ICSI treatment:<br><br>• 49% only offered one cycle of treatment<br>• 24% offered two cycles<br>• 24% offered three cycles*<br><br>*rounded percentages<br><br>See http://www.infertilitynetworkuk.com/uploaded/NIAC/Assisted%20Conception%20Needs%20Assisted%20Implementation.pdf |
| Infertility Network UK | Key area for quality improvement 4<br><br>Embryo transfer strategy and single | Multiple pregnancy is the single biggest risk to the health and welfare of patients and children born from fertility treatment. It can lead to both short and long-term health problems, and | I repeat, multiple pregnancy is the single biggest risk to the health and welfare of patients and children born from fertility treatment leading to both short and long term health problems and a cost to the NHS. | HFEA multiple births policy change announcement (Nov 2013): http://www.hfea.gov.uk/8342.html<br><br>HFEA website on single embryo |

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| | embryo transfer | places a financial burden on the health service.<br><br>Transferring one embryo in patients most at risk of conceiving a multiple pregnancy will give children born from IVF the best possible start in life, by reducing their chances of being born as a twin.<br><br>The costs to the NHS in terms of multiple pregnancies and the cost impact of neonatal care which many of them need due to premature births for example are significant. By reducing the number of multiple births and therefore making savings elsewhere would be a more cost-effective use of CCG resources which would aid those CCGs who are currently not fully implementing the NICE guideline in terms of the number of cycles they fund and who they fund it for. | NHS commissioners play a vital role in supporting the use of single embryo transfer (SET) in clinics. Providing funding for three full cycles of IVF, including follow-on frozen embryo transfers, makes a real difference in encouraging patients to have SET.<br><br>If a couple are only able to access NHS funding for just one cycle they are understandably reluctant to accept single embryo transfer. | transfer with information for commissioners, health professionals and patients. http://www.oneatatime.org.uk/<br><br>HFEA aim and policy on single embryo transfer is to achieve a 10% multiple birth rate. http://www.oneatatime.org.uk/471.htm<br><br>I N UK factsheet for patients on Single Embryo Transfer: http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/I%20N%20UK%20SET%20Patient%20Factsheet%20July%202013.pdf<br><br>Infertility Network UK factsheet on single embryo transfer for health professionals: http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/I%20N%20UK%20SET%20HP%20Factsheet%20July%202013.pdf |
| Infertility Network UK | Key area for quality improvement 5<br><br>Provision of specialist infertility | All HFEA-licensed clinics have to provide an opportunity to talk to a counsellor about the implications of the suggested treatment before consent. Counselling aims to help | Key area for quality improvement 5<br><br>Provision of specialist infertility counselling routinely for all those affected by difficulties in conceiving | All HFEA-licensed clinics have to provide an opportunity to talk to a counsellor about the implications of the suggested treatment before consent. Counselling aims to help patients to understand exactly |

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| | counselling routinely for all those affected by difficulties in conceiving | patients to understand exactly what the treatment will involve and how it might affect them and those close to them - now and in the future. Counselling on the implications of treatment is especially important for those considering using donated sperm, eggs or embryos or surrogacy arrangements - all of which involve complicated issues. Patients need time to explore how they feel, to consider the needs and legal rights of donor-conceived children and to talk about whether this is going to be the right decision for them.<br><br>Counselling can give patients the opportunity to talk freely and openly without being judged; the chance to explore feelings; sensitive issues that are troubling them and help in understanding the factors that may be contributing to their difficulties and support in finding their own solutions and new ways of coping.<br><br>Counselling can provide | | what the treatment will involve and how it might affect them and those close to them - now and in the future. Counselling on the implications of treatment is especially important for those considering using donated sperm, eggs or embryos or surrogacy arrangements - all of which involve complicated issues. Patients need time to explore how they feel, to consider the needs and legal rights of donor-conceived children and to talk about whether this is going to be the right decision for them.<br><br>Counselling can give patients the opportunity to talk freely and openly without being judged; the chance to explore feelings; sensitive issues that are troubling them and help in understanding the factors that may be contributing to their difficulties and support in finding their own solutions and new ways of coping.<br><br>Counselling can provide emotional support before, during or after fertility treatment.<br>Most people find that infertility and assisted conception treatments |

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| | | emotional support before, during or after fertility treatment. Most people find that infertility and assisted conception treatments are stressful. Counselling can be especially useful in helping patients to work through the emotions they may experience before, during and after treatment. This may be when they first find out they have fertility problems, when they are waiting for results, if their treatment isn't successful, or if they are both having to come to terms with the fact that there is no further suitable treatment for them to try. | | are stressful. Counselling can be especially useful in helping patients to work through the emotions they may experience before, during and after treatment. This may be when they first find out they have fertility problems, when they are waiting for results, if their treatment isn't successful, or if they are both having to come to terms with the fact that there is no further suitable treatment for them to try. |
| Association of Biomedical Andrologists | Engaging men in a patient-centred way at their point of contact (the Andrology laboratory) | Patient-centred care should involve men as well as women but men's masculinity and working practices lead them to not seek medical interventions as readily as women. This means that they often do not attend GP or fertility clinic appointments. When they do, are often ignored and feel as if they are an accessory rather than an involved individual in the fertility process.<br>Engaging men at the point where they have to be present | Male factor infertility is solely responsible for 30% of fertility problems and jointly responsible for another 30% along with female factor. Yet fertility clinics are led by gynaecologists and male-related issues are not deeply explored in many cases.<br>However, the importance of government guidance on diet, smoking, alcohol, drugs and exercise applies to men as well as women, and financial savings may be made where men's sperm quality may be improved by lifestyle changes to the point where fertility treatments become unnecessary. | (Adamchak & Adebayo, 1987; Adelusi et al., 1998; Agarwal et al., 2008; Agbaje et al., 2007; Akre et al., 2010; Anderson et al., 2010; 2004; Birenbaum-Carmeli & Inhorn, 2009; Brugh et al., 2003; Carmeli & Birenbaum-Carmeli, 1994; Cousineau & Domar, 2007; Culley et al.; Dancet et al., 2011; Daniels, 2006; de Visser & Smith, 2006; de Visser et al., 2009; Dhillon et al., 2000; Dudgeon & Inhorn, 2003; Dunphy et al., 1991; Edelmann & Connolly, 2000; Ellis, 2012; Fahami et al., 2010; Ford, 2002; Fraga et al., 1996; |

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| | | (ie when providing the semen sample) is a cost effective way of disseminating health information and ensuring that the male is at least contributing as much as he can to their couple's fertility journey. | Financial savings may also be made through understanding and resolving sexual and erectile difficulties, access issues, diagnosis of disease states (infection, genetic disorders, retrograde ejaculation, etc). The evidence shows that men don't want this to be in gynaecology clinics. The Andrology laboratory is an underutilised resource dedicated solely to male reproduction. | Hammarberg et al., 2010; Hammond et al., 1990; Hinton & Miller; Imeson & McMurray, 1996; Inhorn, 2004; Inhorn, 2007a; Inhorn, 2007b; Inhorn, 2009; Morrison et al., 2007; Owens & Read, 1984; Shand, 2007; Sherrod, 2006; Showell et al., 2011; Skakkebaek et al., 1994; Weber et al., 2002; Wegner et al., 2010; White & Witty, 2009; White et al., 2006; Wilkes et al., 2009; Williams et al., 2009; Wirtberg et al., 2007; Wischmann & Thorn; Wu, 2011; Zitzmann et al., 2003; Zorn et al., 2008) |
| Association of Biomedical Andrologists | Fertility Preservation | Oncology patients receive differing levels of access to sperm banking and varying experiences. | Currently there is no defined set of eligibility criteria for sperm storage. Information about storage is given by the referring clinician. Levels of awareness and willingness to give this information vary considerably.<br>Staff engaged in the preservation of fertility should have received specific training in: understanding and dealing with the different client groups; providing information and taking consent; laboratory methods; long term cryostorage including competence in the use of cryogenic storage equipment; risk analysis and storage review.<br>Centres engaged in fertility preservation should understand and have continual dialogue with referring centres in order to | Tomlinson MJ, Kohut T, Hopkisson JF and Lemberger RJ Routine sperm banking for testicular cancer patients should be performed both before and after orchidectomy. In Press BJMSU.<br><br>Pacey A, . Merrick, H, Arden-Close E, Morris K., Tomlinson, M, Wright, E. Rowe R, & Eiser, C (2012). Monitoring fertility (semen analysis) by cancer survivors who banked sperm prior to cancer treatment. Human Reproduction 27, 3132-3139 |

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| | | | provide a service which adequately meets their needs and the needs of the patient.<br>Laboratory methods for fertility preservation should follow best practice guidance as published by the ABA 2013.<br>Patient pathways, information and facilities should take account of the special needs of different client groups including adolescents<br>Semen analysis carried out pre-freeze and post thaw should be performed in an accredited laboratory which adopts methods which demonstrably reduce the level uncertainty associated with the measurement.<br>Methods used to cryopreserve and thaw sperm should have been demonstrated as effective, either by performing regular post thaw audit or by demonstrating the quality of donor sperm treatment units produced by the same service using the same procedures.<br>Sperm storage review should take into account the risk associated with physical audit and the potential for damage to stored material.<br>Sperm storage review and specimen disposal should take into account the risks associated with: consent expiry; the wishes of the individual; the needs of individual; the needs of the partner; future capacity and cost of providing the service. | Tomlinson MJ and Morroll D (2008). Risks associated with cryopreservation: a survey of assisted conception units in the UK and Ireland*. Human Fertility, 11, 33-42. |

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| Association of Biomedical Andrologists | Review of funding mechanism for oncology storage. | Currently funding for storage of frozen sperm is determined by the local Trust. This results in an inequality of care and can leave patients and/or relatives having to make decisions about funding or continued storage whilst still undergoing treatment or while coping with bereavement. | Each Trust currently has its own funding criteria. The change in HFEA guidelines allowing samples to be stored for a total of 55 years needs to be supported with guidance on how to manage long term sperm storage and its associated costs. | Funding in England is controlled by each Trust. In Wales patients now getting 10 years centrally funded by WHSSC, then reviewed by clinical need. |
| Association of Biomedical Andrologists | What constitutes the minimum level of investigation for male infertility (semen analysis). | There is no defined standard as to what constitutes a diagnostic semen analysis. It is left up to the testing laboratory to determine which tests are appropriate to determine fertility. | Testing for male infertility should meet a minimum standard. Semen analysis should be carried out in an accredited laboratory which adopts methods which demonstrably reduce the level of uncertainty associated with semen parameter measurements. Laboratories which use non-recommended methods and do not support their work with appropriate QC and validation should not be allowed to act as the local diagnostic service. | Throughout the UK, Diagnostic semen analyses are performed in a variety of laboratory environments both within the NHS and the private sector. There is no mandatory accreditation of these laboratories and the level of testing performed is highly variable.<br>Bailey E, Fenning NR, Chamberlain S, Devlin L, Hopkisson JH and Tomlinson MJ (2007). Validation of sperm counting methods using Limits of Agreement. *Journal of Andrology,* 28, 364-373 .<br><br>*Tomlinson MJ, Harbottle SJ, Woodward B and Lindsay K. Association of Biomedical Andrologists (ABA). Guidelines for good practice version 3.* |

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| | | | | *Tomlinson MJ and Harbottle SJ (in press).* Facilities and Resources for the Andrology Service: In A Practical Guide to Setting Up an IVF Lab, Varghese A, Sjoblem P and Jayaprakasan K. Jaypee Medical Publishers<br><br>Tomlinson, MJ, Naeem A, Jayaprakasan K, Jayaprakasan R, Simpson, T, Newton T, Pooley K, Hopkisson J and Pridmore (2010). Validation of a novel computer assisted sperm analysis (CASA) system employing multi-target tracking algorithms. Fertility and Sterility Tomlinson MJ (2008) Managing risks associated with cryopreservation. Cryoletters, 29, 165-174. |
| Association of Biomedical Andrologists | Diagnosis and Treatment of Unexplained Infertility | NICE 2013 states that the case for IUI in the treatment of unexplained infertility is unclear because of a lack of evidence yet it is disregarded in favour of relatively invasive treatment for couples with no detectable pathology. | Within this patient group may be patients with psychosexual issues, physical problems with sexual intercourse, patients with retrograde ejaculation or even couples who are rarely together. Under new guidance these patients will receive IVF. Yet in the majority of clinics, 35-40% would be pregnant from a stimulated IUI. | Tomlinson MJ, Amissah-Arthur JB, Thompson KA, Kasraie J & Bentick B (1996). Prognostic indicators for IUI: Statistical model for IUI success. Human Reproduction. 11, 1892-1896. |
| Progress Educational Trust | Number of cycles of IVF/ICSI (intra-cytoplasmic sperm injection) offered to eligible patients | The NICE Guideline states that three cycles of IVF/ICSI is the most clinically and cost-effective number to offer to eligible patients. | The recommendations contained within the NICE guideline on fertility should inform the commissioning decisions of local commissioners, yet too often they are misunderstood, ignored and not fully | *'Holding back the IVF* Revolution' a report looking at variations in provision for couples seeking IVF/ICSI treatment by the All Party Parliamentary Group on Infertility |

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| | Clarification as to what a 'full cycle' is | In order to maximise clinical outcomes, the NICE recommendation of three full cycles of IVF/ICSI must be implemented.<br><br>Limiting the number of frozen embryo transfers which form part of a full cycle reduces the likelihood of a successful outcome. Further work needs to be done to improve commissioners' and GPs' understanding of the definition of a full cycle. | implemented.<br><br>The 2004 and 2013 NICE guidelines on fertility recommended that three full cycles of IVF be provided to eligible couples.<br><br>In 2011 the All Party Parliamentary Group on Infertility published a report entitled 'Holding Back the British IVF Revolution'. The report highlighted the fact that over 70% of Primary Care Trusts (PCTs) were not providing the recommended three cycles of IVF treatment to eligible couples.<br><br>In 2012 the National Infertility Awareness Campaign (NIAC) conducted a survey of fertility patients and found that only 49% of GPs appeared knowledgeable about the condition and the services available.<br><br>In 2013 NIAC conducted an audit of England's CCGs and found that despite the transition to GP-led commissioning, provision remained largely similar to that in 2011 with 50% of CCGs offering one cycle, 25% offering two cycles and a further 25% offering three cycles. Six CCGs offered no funding whatsoever.<br><br>Since the audit took place, a number of CCGs within the East of England (the | (2011),: http://www.garethjohnsonmp.co.uk/uimages/File/appg_IVF_report.pdf<br><br>*'Assisted Conception Needs Assisted Implementation*', NIAC 2013 audit of CCG fertility service provision: http://www.infertilitynetworkuk.com/uploaded/NIAC/Assisted%20Conception%20Needs%20Assisted%20Implementation.pdf<br><br>'Third of UK women entitled to IVF turned away by GPs, survey suggests' http://www.bionews.org.uk/page_170567.asp |

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| | | | region that made up the bulk of CCGs providing three cycles) have reconsidered their joint policy and are now actively considering a reduction to two cycles.<br><br>Given the direct correlation between the number of cycles provided and the likelihood of a successful clinical outcome, it is clear that the number of cycles offered and the understanding of what a 'cycle' is are important areas for quality improvement.<br><br>Information about the number of cycles provided should be captured and recorded in the CCG Outcome Indicator Set to both encourage compliance at a local level and improve oversight at a national level (neither the Department of Health nor NHS England collect data on the number of cycles commissioned by each CCG).<br><br>Clarification as to what a 'cycle' is<br><br>The problem of variation in the number of IVF or ICSI cycles offered is compounded because the cycle offered is not always a full cycle as defined by NICE.<br><br>The number of frozen embryo transfers carried out can vary according to the CCG with some excluding frozen embryo | |

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| | | | transfers from funding altogether. This impacts on the effectiveness of treatment. | |
| Progress Educational Trust | The overuse of intra-cytoplasmic sperm injection (ICSI) | The NICE guideline states that intra-cytoplasmic sperm injection (ICSI) should be considered in cases of: severe deficits in semen quality; obstructive azoospermia; non-obstructive azoospermia; and for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation.<br><br>However, recent data indicates that the use of ICSI in the UK is disproportionate to the number of patients with an identifiable need for this type of treatment.<br><br>CCGs often cite budget constraints and the cost of treatment as the main barriers to implementing NICE's recommendations in full. Limiting the use of ICSI to patients with a clinical indication for this type of treatment may be an expedient way to reduce unnecessary costs and allow for better compliance in the implementation of NICE's | In November 2013 Professor Lisa Jardine, chair of the Human Fertilisation and Embryology Authority (HFEA) criticised the overuse of intra-cytoplasmic sperm injection (ICSI). The same concern was voiced by Professor Andre Van Steirteghem in 2010 and Professor Rob Norman in 2009.<br><br>It has long been accepted that the incidence of male factor infertility in cases of fertility treatment is only 30 to 40% at most. However, data from the HFEA and the National Perinatal Statistics Unit shows that ICSI is now used to treat 53% of all couples receiving fertility treatment in the UK. There is a clear discrepancy between the observed rate of male factor infertility and the reported use of ICSI.<br><br>A survey of ICSI in the UK revealed its usage to range wildly – 21% to over 80% of patients being subjected to ICSI despite HFEA data failing to demonstrate an increased live birth rate in those centres that use ICSI more frequently. It is important to ensure that the decision to use ICSI is based on clinical need and that it is not viewed as a form of security against fertilisation failure. | HFEA 2011 trend data on the use of ICSI: http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf<br><br>Who needs ICSI? A nationwide UK survey on ICSI use September 2012, Vol. 15, No. 3 , Pages 144-149 (doi:10.3109/14647273.2012.720051) http://informahealthcare.com/doi/abs/10.3109/14647273.2012.720051<br><br>The cost effectiveness of intracyctoplasmic sperm injection (ICSI) Journal of Assisted Reproduction and Genetics Volume 24, Issue 12 , pp 571-577 DOI (10.1007/s10815-007-9175-0) http://link.springer.com/article/10.1007%2Fs10815-007-9175-0 |

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| | | recommendations. | ICSI is also a more expensive procedure for the patient, the clinic and the CCG. From a purely cost-effective point of view, it is difficult to justify its use in patients that do not have a clinical indication for it. | |
| Progress Educational Trust | Single Embryo Transfer | Single Embryo Transfer (eSET) policies have resulted in a reduction in the number of multiple pregnancies.<br><br>Multiple pregnancies give rise to increased health risks to both mothers and babies and can add significantly to the costs of both maternity and neonatal services.<br><br>The cost savings which eSET policies deliver to both maternity and neonatal services should be reinvested in the full implementation of the NICE Guideline. | Commissioners must understand the need to adopt a clinically appropriate policy of eSET and the importance of implementing NICE's recommendation of three full cycles of treatment.<br><br>An example of where eSET may not be clinically appropriate would be if CCG funding arrangements only allowed for one cycle of IVF treatment. Any such strategy should therefore be balanced. | "The impact of legally restricted embryo transfer and reimbursement policy on cumulative delivery rate after treatment with assisted reproduction technology", by K. Peeraer, S. Debrock, A. Laenen, P. De Loecker, C. Spiessens, D. De Neubourg, and T.M. D'Hooghe. *Human Reproduction* journal. doi:10.1093/humrep/det405. http://humrep.oxfordjournals.org/content/early/2013/11/24/humrep.det405.abstract |

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| Progress Educational Trust | Provision of specialist infertility counselling routinely for patients in the following circumstances:<br>After diagnosis of azoospermia and very low ovarian reserve<br>Before treatment with donor gametes<br>Before donating gametes<br>Before provision of fertility preservation treatment in oncology patients | A diagnosis of azoospermia or very low ovarian reserve is devastating news for most people. An early therapeutic intervention ensures that patients are supported in coming to terms with the fact that they will not be able to have their own genetic children. Early intervention also ensures that people get the information they need on the available options for family building. Preparation for parenthood sessions, for people seeking treatment with donor gametes, ensure they are fully informed of all the social, legal and ethical implications of having a donor conceived child. These sessions, conducted by specialist infertility counsellors, also inform patients of best practice regarding telling children from an early age that they are donor conceived and ensure patients are informed of suitable ways of doing this in order to promote the long term psychological wellbeing of donor conceived offspring. Donors potentially make a lifelong commitment when they | There is currently no counselling provision at the stage of diagnosis of absolute infertility and patients can usually only access specialist infertility counselling once they have become a patient in an infertility clinic. This is sometimes too late, as couples attending infertility clinics are only those who have made a decision to pursue treatment with donor gametes. This neglects a significant proportion of people struggling to come to terms with this diagnosis who do not have access to specialist counselling. The psychological impact of a diagnosis of male or female absolute infertility is well known and supported in the research. Early therapeutic intervention could prevent later onset of anxiety and depression in these patients. This quality standard is relevant for primary and secondary care providers. (2, 3,4) General Comment: HFEA Code of Practice requires clinics to offer counselling in a number of circumstances before consent to treatment or donation is obtained. Counselling is becoming a routine part of the treatment pathway in some clinics, but not all. Introducing a key quality standard that states that all patients in the circumstances outlined here (and gamete donors) will receive counselling routinely as part of their | Bak CW, Seok HH, Song SH, Kim ES, Her YS, Yoon TK. J Androl. 33(2):181-9 (2012) Hormonal imbalances and psychological scars left behind in infertile men. http://www.ncbi.nlm.nih.gov/pubmed/21546616<br><br>Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. http://www.nuffieldbioethics.org/sites/default/files/Donor_conception_report_2013.pdf<br><br>Recommendation 'As a matter of good professional practice, clinics should provide counselling sessions as part of the routine series of appointments attended by prospective parents. An additional support session later in pregnancy or after the birth of the child should also routinely be offered.'<br>(2,3) Policy and Practice paper: Wilde et al 'Family building using donated gametes and embryos in the UK: Recommendations for policy and practice on behalf of the British Infertility Counselling |

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| | | donate their gametes due to legislation that enables donor-conceived adult offspring to apply to the HFEA for identifiable information about their donor. It is important that donors are fully informed about this commitment and given the opportunity to explore the implications of donation for them, their partner and any future children.<br>All patients seeking fertility preservation prior to treatment for cancer should routinely see a specialist counsellor to enable them to fully explore their options. Decisions are made about fertility preservation at a time when people are in considerable distress. It is important that patients are supported to make the best choice they can to give them a chance of having children in the future. | treatment, will ensure that more patients are given the opportunity to fully consider the implications of treatment/donation before they consent.<br>The provision of pre-treatment implications counselling sessions needs improving to ensure that all clinics refer patients routinely for counselling and give sufficient information to patients on the importance of attending such sessions. 'Preparation for parenthood sessions' are a routine part of treatment in some clinics but not all. It is important to establish the quality standard that all patients should routinely have implications counselling before consenting to treatment with donor gametes.<br><br>As above, pre-donation counselling does not routinely take place in all clinics before donation. Therefore not all donors will have fully considered the implications before consenting to donate. There is a risk to the long-term psychological health of the donor, their families and any donor-conceived offspring if donors are inadequately prepared for the potential consequences of their donation.<br><br>Currently, not all patients requiring fertility preservation are routinely referred to a specialist infertility counsellor. Receiving good information and support at this | Association and the British Fertility Society in collaboration with the Association of Clinical Embryologists and the Royal College of Nurses Fertility Nurses Forum' Posted online on December 13, 2013. http://www.ncbi.nlm.nih.gov/pubmed/24329028<br>(2,3) Routine counselling advocated by for example: Donor Conception Network, the National Gamete Donation Trust and the Infertility Network UK.<br>(2,3,4) The British Infertility Counselling Association Guidelines for Good Practice (2012)<br>(2,3,4) HFEA Code of Practice (8th edition)<br>Nuffield Council on Bioethics Donor Conception: ethical aspects of information sharing 2013. Recommendation 'Clinics should ensure that sessions with a counsellor are scheduled as part of a routine series of appointments that donors attend before deciding whether or not to donate. Where donors have partners, clinics should strongly encourage partners to attend these sessions.' |

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| | | | critical time is essential to ensure cancer survivors are given the best possible chance of having a family post treatment and are supported in dealing with the prospect of future infertility as a result of cancer or cancer therapies. | Journal of Clinical Oncology: Loren, Alison W., et al. "Fertility Preservation for Patients with Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update" (Full-text. Published online ahead of print: May28 2013) http://jco.ascopubs.org/content/early/2013/05/24/JCO.2013.49.2678.full.pdf+html www.macmillan.org.uk information about fertility preservation for patients |
| Cardiff Fertility Studies Research Group Cardiff University | Reassurance given to women about the relationship between emotional distress and the outcome of a cycle of in vitro fertilisation. | Women worry that emotional distress (anxiety, depression) could reduce chances of conceiving with in vitro fertilisation. This can lead to self-blame when there is treatment failure.<br><br>There is good evidence that emotional distress is not associated with the outcome in one cycle of in vitro fertilisation. Evidence of stress effects when observed (over multiple cycles) are small, and limited. | NICE 2013 suggested that work stress can reduce conception, which may erroneously be generalised to the IVF context. | Please see:<br>Boivin, Griffiths, Venetis, BMJ 2011;342:d223<br>doi:<br>http://dx.doi.org/10.1136/bmj.d223<br><br>Matthiesen et al. Stress, distress and outcome of assisted reproductive technology (ART): a meta-analysis. Hum. Reprod. (2011) 26 (10): 2763-2776. doi: 10.1093/humrep/der246 |
| Cardiff Fertility Studies | Information given to women with | There is good and consistent evidence that emotional distress | Emotional distress in polycystic ovary syndrome is greater than in other infertile | Information given to women with polycystic ovary syndrome about |

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| Research Group Cardiff University | polycystic ovary syndrome about associated emotional aspects. | (anxiety, depression, low emotional quality of life) is associated with PCOS. | patient groups. However, this at-risk patient group is not identified in NICE 2013. | associated emotional aspects. |
| Cardiff Fertility Studies Research Group Cardiff University | Improve knowledge among staff of empirically validated tools to detect emotional distress and fertility related quality of life | Early detection of emotional needs improves possibility that these needs can be addressed during treatment. 22% of patients discontinue fertility treatment despite good prognosis and ability to cover costs. The main reason for discontinuation is the emotional burden of undergoing treatment, especially among those beginning treatment with anxiety and depression. | Fertility clinic staff report wanting to address psychosocial needs but lack methods to do so. NICE 2013 does not offer guidance on which patients should be referred or how best to measure impacts on quality of life in service evaluations. | Improve knowledge among staff of empirically validated tools to detect emotional distress and fertility related quality of life |
| Cardiff Fertility Studies Research Group Cardiff University | Offer a more diverse range of psychosocial support offered to patients before, during and after treatment. | Most patients express a need for psychosocial support before, during and after treatment and these can be satisfied in multiple methods that have been shown to be effective. These include online interventions, coping tools, information leaflets, staff empathy training, for example. Evidence suggests that non-counselling formats can be effective in meeting psychosocial needs. | NICE 2013 only recommended counselling as a way of satisfying patients' needs for emotional and psychological support (1.1.2.3-1.1.2.5). However, research shows that less than 15-20% of patients take up this offer, which means that the psychosocial needs of 80-85% of patients may not be addressed by this recommendation. | Boivin, J. Social Science and Medicine, 2003:57 (12), 2325-2341;<br>De Liz & Strauss Human Reproduction Vol.20, No.5 pp. 1324–1332, 2005; Hammerli et al. Human Reproduction Update, Vol.1, No.1 pp. 1–17, 2009. |
| Cardiff Fertility Studies | Ensuring all fertility clinic staff take | There is good evidence that patients value emotional | NICE 2013 recommended that patients should be offered counselling because | Please see:<br>Dancet et al. The patients' |

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| Research Group Cardiff University | responsibility for meeting psychosocial needs of patients | support from staff and that emotional support delivered by staff is effective in alleviating patient stress and distress. | the experience of infertility was associated with psychological stress (1.1.2.3) and that this counselling should be offered by someone independent from the clinic (i.e., not directly involved in management of patient care, see: 1.1.2.5). This recommendation does not take into account contra evidence that psychosocial support provided by staff is valued and effective. | perspective on fertility care: a systematic review. Hum Reprod Update. 2010 Sep-Oct;16(5):467-87. doi: 10.1093/humupd/dmq004. Epub 2010. |
| Ferring Pharmaceuticals Ltd. | Key area for quality improvement 1<br><br>A standard that can be used to underpin the grading of blastocysts and embryos. | Current NICE guidelines have adopted the Association of Clinical Embryologists (ACE/UK)<br>National External Quality Assessment Service (NEQAS) for Reproductive Science Embryo and Blastocyst Grading schematic.<br>The current terminology often used in embryo transfer strategies can lead to inconsistency between treatment centres to describe embryos and blastocyst grading. | While there are grading standards for blastocysts available, there is no agreed system for judging embryo quality, a point that is fundamental to the implementation of the NICE recommendations on decisions regarding single embryo transfer and double embryo transfer.<br>There is currently a knowledge gap on how to prioritize the individual parameters included in embryo scoring and a grading system could help to improve embryo selection and prediction of implantation and this would facilitate embryo selection for single embryo transfer rather than double embryo transfer. | UK NEQAS Reproductive Science – Embryo Morphology http://www.cmft.nhs.uk/media/327850/neqasgradingsystem.pdf<br><br>Fertility. NICE clinical guideline 156 (2013). |
| Ferring Pharmaceuticals Ltd. | Key area for quality improvement 2<br><br>National application of ISO | A quality control (QC) system is needed in ART units to assure reproducibility of all methods and competence in duties performed by the personnel.<br>The tools and principles that are used to measure quality in IVF | Such quality standards will constitute the minimal requirements for any laboratory offering ART, with the aim of also implementing a quality control system for all embryologists.<br>These will also have the advantage of eliminating the need for national bodies to | ESHRE guidelines for good practice in IVF laboratories. Committee of the Special Interest Group on Embryology of the European Society of Human Reproduction and Embryology. Gianaroli L, Plachot M, van Kooij |

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| | standards for good practice in IVF laboratories | laboratories and clinics are similar to other industries (ISO Norm 9001:2008 according to the ISO 9001:2000 regulation; ISO 14001:2004 regulation and the certification of a work health and safety system according to the OHSAS 18001:2007 regulation).<br>Adapting these tools to international standard infertility treatment has the advantage to unify national guidelines and develop a consensus on what quality measures are critical for quality measurement. | set country-specific regulations pertaining to quality.<br>It is essential to have a QC system to assure that everybody knows exactly how everything should be done. Furthermore, a QC system should bring about improvements such as making activities and procedures clearer to the staff and making the working methods more flexible. A common process is needed to document all routines and methods within the laboratory and describe these in a quality manual. This will also help to standardize the methods that embryologists use to perform their work in the laboratory. | R, Al Hasani S, Dawson K, DeVos A, Magli MC, Mandelbaum J, Selva J, van Inzen W. Hum Reprod. 2000 Oct;15(10):2241-6.<br><br>The application of quality systems in ART programs. Wikland M, Sjöblom C. Mol Cell Endocrinol. 2000 Aug 15;166(1):3-7. |
| Ferring Pharmaceuticals Ltd. | Key area for quality improvement 3<br><br>Validation of patient satisfaction questionnaire | ART measures of quality have focused mainly on effectiveness. Less attention has been paid to patients' perception of quality of care. A satisfied patient is one who understands their condition and its treatment, and feels that the best advice was given and the treatment, if indicated, was attempted with the best possible medical supervision and service. | Several studies have addressed the need to incorporate the patients' perspective into the overall care process provided by fertility centres, as well as the need for validated measurement instruments which are applicable to all sorts of infertility clinics. There have been little efforts to validate patient satisfaction questionnaires applicable to ART treatment.<br>Closer involvement of the patients and implementing a more patient focused approach will increase the quality of the services we provide. | Lentner E, Glazer G. Infertile couples' perceptions of infertility support-group participation. Health Care Women Int 1991;12:317–330.<br>Hojgaard A, Ingerslev HJ, Dinesen J. Friendly IVF: patient options. Hum Reprod 2001;16:1391–1396.<br>Schmidt L, Holstein BE, Boivin J, Tjornhoj-Thomsen T, Blaabjerg J, Hald F, Rasmussen PER, Nyboe Andersen A. High ratings of satisfaction with fertility treatment are common: findings from the Copenhagen Multi-centre Psychosocial Infertility (COMPI) |

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| | | | | Research Programme. Hum Reprod 2003;18:2638–2646. Haagen EC, Hermens RP, Nelen WL, Braat DD, Kremer J, Grol R. Subfertile couples' negative experiences with intrauterine insemination care. Fertil Steril 2008;89:809–816. |
| Ferring Pharmaceuticals Ltd. | Key area for quality improvement 4<br><br>Benchmark and audits | Few standards exist to compare IVF centers. IVF centres work in a very competitive environment and when assessing the performance of an IVF centre, benchmarking indicators and audits may be applied using quality standards to compare the quality of products and services. | Statistics / audits are an important measure of success, and should warrantee the correct reporting of results making it as transparent as possible, so that when they are compared with standard benchmarks from other centres, patients can be sure that the results are truly comparable, given different regulations, patient case mixes and plethora of types of treatments offered. | Alper, M.M., Brinsden, P.R., Fischer, R. and Wikland, M. (2002) Is your IVF programme good? Human Reproduction, 17, 8-10. |
| Ferring Pharmaceuticals Ltd. | Key area for quality improvement 5<br><br>To standardise the NICE definition of a full cycle | There is inconsistency in the provision of a full treatment cycle offered by the CCG – this can include provision of 1 fresh cycles, followed by all frozen embryos, or CCGs where embryos are frozen in the firsat cycle, but not available for use in subsequent cycles with public funding. | This raises important ethical questions and can adversely affect treatment outcomes. | Fertility. NICE clinical guideline 156 (2013). |
| Royal College of Nursing | Key area for quality improvement 1 Effectiveness of embryo/blastocyst | The effectiveness and timing of embryo/blastocyst transfer is recommended within the NICE Fertility guideline. | | NICE Fertility Guideline 2013 |

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| | transfers looking the number transferred and timing of transfer | | | |
| Royal College of Nursing | Key area for quality improvement 2 Ovarian hyperstimulation s yndrome (OHSS) – how many cases and severity and stimulation regimes | NICE Fertility clinical guidelines recommends that clinics providing ovarian stimulation with gonadotrophins should have protocols in place for preventing, diagnosing and managing ovarian hyperstimulation syndrome. | There exist varying strategies for the recording events of / management of OHSS within the Centres currently treating patients who have undergone Ovarian Stimulation using Gonadotrophin's.<br><br>Introducing a standardised evidenced based quality standard guideline will promote safety for all service users. | NICE Fertility Guideline 2013 |
| Royal College of Nursing | Key area for quality improvement 3 Effectiveness of cryopreservation | NICE Fertility Clinical guideline recommends the use of cryopreservation to store semen, oocytes and embryos. | Standardisation of quality guidelines | NICE Fertility Guideline 2013 |
| Royal College of Nursing | Key area for quality improvement 4 Number of elective single embryo transfers - Incidence of multiple pregnancy and if this is being reduced. | The target remains 10% as best practice even though this has been removed as a Licence Condition by the Human Fertilisation and Embryology Authority (HFEA). | | NICE Fertility Guideline 2013 |
| Royal College of Nursing | Key area for quality improvement 5 | Patients routinely see a counsellor before: treatment with donor gametes; donating | | NICE Fertility clinical guideline<br>Nuffield Council enquiry on information sharing in donor conception. |

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| | Offer and take up of counselling – a counsellor being a person with a professional qualification not directly involved in the management of treatment | gametes and before making decisions about fertility preservation to ensure they have had a suitable opportunity to explore the implications of treatment, donation and fertility preservation. | | Wilde, R, McTavish A, and Crawshaw M (2013) Recently published paper on behalf of BFS, BICA, ACE and RCN: Wilde et al *'Family building using donated gametes and embryos in the UK*: *Recommendations for policy and practice on behalf of the British Infertility Counselling Association and the British Fertility Society in collaboration with the Association of Clinical Embryologists and the Royal College of Nursing Fertility Nurses Forum* Human Fertility, Dec 2013, page 13 |
| Royal College of Nursing | Key area for quality improvement 6 Providing information - Comprehensive communication check list to support the patient's journey including expectant management | NICE Fertility guideline recommends the provision of information to the patient and spouse about the fertility cycle.<br><br>In clinical practice, we hear from patients of the challenges some experience during their fertility treatment journey.<br><br>The patient is required to attend fertility centre on a regular basis for each cycle. It is important that there is a standard around information on the commitment and expectations to help them prepare and plan both | It is important to support the patient and partner emotionally and consider steps to help them live as normal life as possible. Patients are told to carry on with life as usual and not alter their normal life for the treatment; however, what is sometimes not communicated to them or clarified is what is expected, for example if they are planning to be away within the cycle. If being away is going to be a problem then this should be communicated from the outset.<br><br>Regarding referral, the woman and her partner undergo many tests which get repeated once they get to the fertility centre. For them this may seem like a | |

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| | | financially and be aware of any life style changes. | waste of NHS resources, particularly where the reason for the repeated tests are not fully communicated. Some query the rationale for the initial hospital carrying out the test if the fertility centres are going to run same tests.<br><br>There should be a quality standard for communication for example checklist of the next stage of care and expectations so as to ensure that patients and their partners understand the processes and what is required of them. This will help with their emotional wellbeing, reducing anxiety and stress levels. | |
| Royal College of Nursing | Key area for quality improvement 7 Techniques to improve success rate<br>Support for weight management | NICE Fertility guidelines recommend techniques to improve success rate for fertility treatment<br>including endometriosis module. Obesity is evidently on the increase within the general population and could also be heightened due to stress. Providing structured programme of weight management support alongside established organisations could be beneficial to the assistance of conception. | Various techniques to improve success rates are used with limited evidence such as embryo glue, endometrial scratching, video incubator systems and embryo biopsy. Patients are paying lots of money for the extra procedures. A quality standard here would help ensure that they are adequately informed. Important to provide guidance through this journey with constant follow-up | NICE Fertility clinical guideline |
| Royal College of Nursing | Key area for quality improvement 8 | Ensuring data items collected by the HFEA this allows for long-term follow-up of children | By aiming for this follow up it can help shape and change assisted reproduction by encouraging long-term follow-up of | HFEA data collection<br>*'Family building using donated gametes and embryos in the UK'* |

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| | Data Collection | born as a result of assisted reproduction<br><br>Appropriate and precise data collection relevant for `Donor-Conceived' children to access relevant information. | children born as a result of assisted reproduction, better inform patients, donors and the general public and allow centres to focus on patient care. Patients often ask for evidence of abnormalities of assisted reproduction births. | (see above) |
| Royal College of Nursing | Key area for quality improvement 9 Training<br><br>Staffing Levels | Patients seek assistance for their fertility problems from practitioners whom are expected to be expert in delivering up-to-date evidenced based practise.<br><br>To ensure that all service users requiring treatment for their Fertility problems are seen within a timely fashion and by fully trained, knowledgeable, specialised practitioners. | This is key for quality standards, to ensure staff working within the auspices of their licence (issued from their regulatory body as well as the HFEA), are suitable persons to deliver activities under the licence/requirements.<br><br>Measured by appraisals, competencies, audits and training.<br><br>Patient treatments for their Fertility problems must not be additionally hampered by service providers that are unable to conduct professional adequate services due to short staffing issues. This could lead to increased waiting time, exacerbating anxiety levels. | ACE, BFS, NMC, RCN, HEFA, BICA<br><br>*'Family building using donated gametes and embryos in the UK'*<br><br>(see above) |
| Association of Clinical Embryologists | I am responding on behalf of the Association of Clinical Embryologists (ACE), our Chair Stephen Harbottle has responded separately and we fully support his comments and do not feel that there is anything further we wish to put forward as an association in a formal response except that we believe that consistency for staff training across all disciplines involved in delivering fertility care is essential. This is particularly relevant for scientist training with the evolution of the new MSC STP pathway. | | | |
| Merck Serono | Defining what is meant as one | The interpretation of what is considered one cycle of | The quality determinate for what is considered one cycle of treatment should | http://www.nice.org.uk/nicemedia/live/14078/62770/62770.pdf |

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| | cycle of treatment. | treatment is inconsistent across the England and Wales. It may be one fresh cycle, or a frozen cycle. This can have an effect on the success rates and equity of access for couples across different areas. | be based on the NICE CG156. "*Full cycle This term is used to define a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s)*." This would aid consistency, equity and quality of what the NHS expects to be delivered and the treatment that a patient would receive. | |
| Merck Serono | Male factor infertility | The consideration towards male factor infertility needs to be improved within the entire fertility pathway. Male infertility should be tested at the onset of a couple presenting and repeated within 3 months. This would improve a possible gender bias towards women's treatment and speed the referral time. If it is discovered earlier that it is a male infertility issue, the only recourse may be a direct referral to IVF. | Within CG156 "*Repeat confirmatory tests should ideally be undertaken 3 months after the initial analysis to allow time for the cycle of spermatozoa formation to be completed. However, if a gross spermatozoa deficiency (azoospermia or severe oligozoospermia) has been detected the repeat test should be undertaken as soon as possible*." A quality measure to support this recommendation of time between the 1st and second test could provide a more efficient decision process towards the needs of the couple | http://www.nice.org.uk/nicemedia/live/14078/62770/62770.pdf |
| Merck Serono | Faster referral times for infertile patients over 35. | It is well documented that biological age is a important determinate of fertility in females. Faster referral times and access to specialised treatment could improve the success rate in population who have more of a biological time | From the NICE guidelines CG156 "*Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:*<br>*- the woman is aged 36 years or over*<br>*- there is a known clinical cause of* | http://www.nice.org.uk/nicemedia/live/14078/62770/62770.pdf |

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| | | constraint. | *infertility or a history of predisposing factors for infertility*"<br>The number of referrals and waiting times could be improved in this population and be compared against average waiting times. | |
| SCM 4 | Key area for quality improvement 1<br><br>Single Embryo Transfer | The last ten years has seen significant advancements in the practice of assisted conception and IVF techniques – none more so than the now regular use of single embryo transfer (SET).<br><br>The knowledge that, on average, success rates in using SET are now equivalent to multiple embryo transfers (and exceed when looking at cumulative cycles data), plus the introduction of a regulatory requirement for each clinic to have its own in-house policy for SET along with national targets alongside this for reducing multiple births has seen one of the biggest single changes in clinical practice for a decade or more. | Unfortunately the regulators (HFEA) stance on this issue has been weakened by their recent response to a court ruling on a technical failing of an internal procedural process at the HFEA against a clinic considered to be failing against its obligations under this regulatory requirement.<br><br>The HFEA has now removed the ultimate penalty aligned to this particular requirement.<br><br>It is vital that, alongside the changes within the most recent NICE guidance on fertility where the recommendation that practitioners SHOULD use SET in specific circumstances, the message of SET as a significant driver for quality and safety in this treatment is reinforced through the quality guideline.<br><br>Good quality commissioning can play a key role here, and this would also reinforce the commissioner's position so that providers found to be lacking in their ethical approach to this vitally important | HFEA – One at a Time programme<br><br>Multiple Births Foundation – One at a Time website<br><br>NICE Fertility Guidance |

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| | | | clinical practice could be challenged through their contract. | |
| SCM 4 | Key area for quality improvement 2<br><br>Use of ICSI in IVF | NICE guidance is clear that ICSI has its place – in specific, diagnosed and diagnosable cases where male factor infertility is prominent in cause.<br><br>However, NICE is aware through the process used in developing the guidance, and other sources of info. also show, that the rates of cycles which feature ICSI vary widely from clinic to clinic, and region to region | This suggests two things (on the premise it cannot be explained by case mix alone) – 1. that ICSI rates is dependent on individual clinic practices and 2. that it is dependent on the quality of commissioning in an area.<br><br>A clear message in featuring as a priority quality measure would reinforce both positions – good clinical practice, and strengthened commissioning. | |
| SCM 4 | Key area for quality improvement 3<br><br>Provision of Counselling | The regulator requires the provision of counselling, and its benefits and necessity are acknowledged.<br><br>However – access, timeliness, type/ branch of counselling and quantity are far from specified and feature in few, if any, service specifications I am aware of – at least to any great degree or consequence.<br><br>We know that women come forwards for treatment later; | Provision is patchy clinic to clinic, so too access.<br><br>Though a regulatory requirement, the clinics need is merely to show provision.<br><br>It is under-regulated, under-measured (and likely unmeasured in many areas), and though some commissioners may be aware of its need those that do likely believe they are commissioning this by default of paying for a treatment to which counselling is required by regulation. Few specify its requirement or access/ provision levels. | |

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| | | often opt for seemingly dangerous/ high risk procedures; should expect an unsuccessful outcome; and can have a greater number of complications in later years too.<br><br>Access to high quality counselling, pre and post treatment is of the upmost importance. | | |
| SCM 4 | Key area for quality improvement 4<br><br>Waiting times<br><br>(by this I mean referral to treatment time, as opposed to the length of time it takes for a patient to move along their locally commissioned fertility pathway and eventually reach treatment in tertiary services.) | There are three key issues at play with regard to waiting times:<br><br>Commissioners who specify a minimum waiting time (disallowed by the Secretary of State for Health following the CCPs review of 2011, yet still in play);<br><br>Commissioners who 'cap' their contracts with providers annually – that is to say they stipulate that funding is only available for X number of cycles and so when patient Y arrives they are told they must wait until the following financial year for treatment; | 1. This practice was clearly disallowed by the SoS for health in 2011 and is against the NHS constitution.<br><br>In addition – tackling maximum waiting times is the priority, not managing minimum ones.<br><br>Also ruled as unacceptable by SoS for health, and a key feature of the constitution – indeed, where care cannot be provided locally within the maximum waiting times set (this would be 18-weeks RTT as fertility has never been listed as an exclusion and so 18-weeks applies though is never measured or enforced for this area of care) patients have the right to be offered care at an alternative | https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216681/dh_131089.pdf<br><br>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf |

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| | | Providers for whom the local commissioner has agreed to pay for any and all patients within a financial year, but the provider has a waiting list either due to capacity issues or due to prioritising private, fee paying patients above NHS referrals. | provider – including travelling abroad.<br><br>3. Where a commissioner has acceptable processes in place, that neither in breach of policy nor the constitution, and providers will be paid for all clinically eligible patients they see – then it seems unacceptable to me that NHS patients would be expected to wait longer than fee paying individuals – especially where this leads to a potentially lesser chance of success, say in a woman of older years, and where the provider fails in its duty to advise patients of their rights to choose an alternative provider (if their local commissioner provides for/ supports such a right in line with the constitution). | |
| SCM 4 | Key area for quality improvement 5<br><br>Rapid Access | There are two scenarios I believe need addressing here:<br><br>1. Those patients provided for within the most recent NICE guideline who are over 36 years of age and should be referred to a tertiary/ specialist provider swiftly;<br><br>And<br><br>2. Patients about to undergo treatment that has the potential to affect their fertility, for example cancer treatment, and | A clinical case is clear – as per the most recent clinical guideline – but local action is lacking.<br><br>Both clinical and ethical arguments are clear, plus there is the added complexity of differing pathways of care (Fertility vs. cancer, rheumatoid arthritis etc); different commissioners (CCGs for fertility, NHS England for specialist cancer care etc); and poor education of clinicians in all | |

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| | | for whom specific provision was made within the most recent NICE guidance.<br><br>In both cases I believe that almost one year after publication of the latest clinical guideline, local action and education is lacking and so a priority must be shown/ reinforced. | cases/ areas of care.<br><br>A clear quality statement on 'seamless pathways of care', collaborative commissioning between organisations, timely access to fertility preservation measures, and the education of clinicians is necessary. | |