Human Fertilisation & Embryology Authority

Commissioning guidance for fertility treatment

ACE The Association of Clinical Embryologists

British Fertility Society

Royal College of Nursing

Royal College of Obstetricians & Gynaecologists

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About this guidance

This guidance is intended for use by clinical commissioning groups (CCGs) to support them in commissioning fertility services for their local population and implementing the NICE guidelines on fertility treatment. It is produced by the Human Fertilisation and Embryology Authority (HFEA), the national regulator of fertility clinics, in conjunction with the main professional bodies, British Fertility Society, Association of Clinical Embryologists, Royal College of Obstetricians and Gynaecologists, and Royal College of Nursing to assist CCGs in using available resources to make evidence-based clinical commissioning decisions.

We recognise that CCGs face many competing priorities. This guidance aims to promote more consistent and better quality commissioning decisions across the UK, improve the cost-effectiveness of healthcare resources and deliver the significant public health benefits that are possible through accessing fertility treatment. The National Institute for Health and Care Excellence's (NICE) clinical guidance on diagnosing and treating fertility problems should be referred to.

A benchmark price for IVF has been published in 2019 by NHS Improvement which will help to guide how much you are spending on IVF treatment in your area.

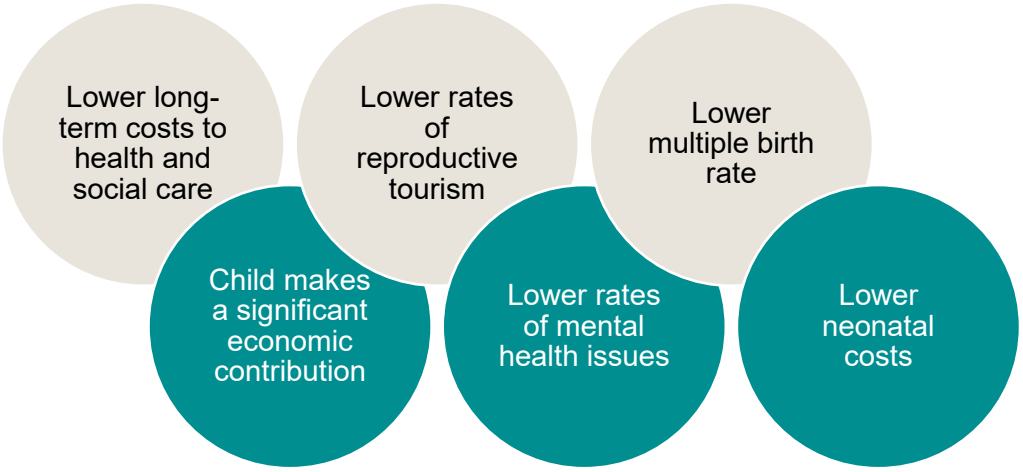
Why commission fertility treatment?

Infertility is a recognised medical condition which can have a real impact on individuals' mental health. Failure to address infertility and commission appropriate treatments can lead to a significant economic burden on the health sector. Infertility affects one in seven heterosexual couples in the UK.

Commissioning fertility treatment can have positive economic effects because it:

- Reduces rates of mental health issues relating to infertility in couples, and the costs associated with this.
- Reduces the incidence of multiple births, which can be very costly to neonatal services and long-term health and social care services.
- Reduces reproductive tourism, where people travel abroad for fertility treatment, which often leads to health complications or multiple births absorbed by the NHS.
- Generates long-term financial gain, as the resultant child makes a significant contribution to the economy.

Effective commissioning of IVF treatment is cost effective for CCGs



Poorly commissioned IVF treatment can increase costs for CCGs.

"[We expect] all those involved in commissioning infertility treatment services to be fully aware of the importance of having regard to the National Institute for Health and Care Excellence (NICE) fertility guidelines." (DHSC)

"Effective commissioning contributes to the NHS Outcomes Framework Indicator 1c. Neonatal mortality and stillbirths." (NICE)

Reducing multiple births

Multiple births are the single biggest risk to the health of women and babies undergoing IVF. In 2008, around one in four IVF births were multiples, compared with about 1% from natural conception. Over the last decade, the HFEA has worked with patients and professionals to reduce multiple birth rates to 10% which was reached in 2017.

The increased risks to the mother include miscarriage, pregnancy induced hypertension, pre-eclampsia, gestational diabetes and caesarean section with the result being that maternal mortality is 2.5 times greater. Most of the health problems of twins can be explained by their frequent prematurity and their lower gestational weight.

A report by the National Guideline Alliance about twin pregnancy costing (2018) found that:

- Multiple pregnancies are, on average, almost three times as expensive as single pregnancies.
- Much of the difference in costs between singleton and multiple pregnancies come from the need for emergency caesarean section, post neonatal death, admissions to neo-natal intensive care, and a range of other conditions, like cerebral palsy.
- A reduction of 10% in the twin pregnancy rate from its current level could lead to a saving of £15million to the NHS, which, though small in the context of NHS spend, is considerably in excess of what NICE regard as a significant resource impact.

Alongside this, there are also emotional and psychological costs to the families and children which can have a long-term impact. For these reasons, the HFEA and professional bodies encourage the use of a clinically effective single embryo transfer policy so that the aim of all IVF treatment is the birth of a single healthy child.

What is good commissioning?

Good commissioning is not about rushing to IVF

It is important explore alternative options rather than jumping straight to IVF treatment. However, it is equally important that there is no unnecessary delay in assessment and referral where clinically necessary. This is particularly important in fertility treatment because female fertility – and the success of IVF treatment – declines with age.

A woman of reproductive age who has not conceived after one 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 (NICE Clinical Guideline 156).

In 2017 there were around 54,700 patients who sought fertility treatment. There were approximately 70,000 cycles of IVF treatment and around 5,500 cycles of donor insemination treatment. For IVF treatments, about 40% were funded by the NHS (compared to around 16% of DI treatments).

At a time when many commissioners are looking for efficiency savings, effective commissioning is vital. A sustainable and realistic commissioning pathway will consist of a coordinated treatment pathway that covers investigations, emotional support and evidence-based treatment options. NICE offer an interactive flowchart of clinical pathways to support CCGs in developing cost effective IVF treatment pathways.

The benchmark prices, published in 2019, are on the NHS Improvement website.

Before IVF treatment

Advice on lifestyle changes

- Lifestyle factors, including body weight, smoking, alcohol and recreational drug use can have an impact on people's chances of getting pregnant. The NHS provides useful information about lifestyle factors that can affect fertility and ways to improve reproductive health.

Referral for specialist consultation

- Over 80% of women under 40 will conceive within one year if they have regular unprotected vaginal intercourse. If they do not conceive after one year, or after six cycles of artificial insemination, they should be referred to specialist services. Women aged 36 or over and people with a known clinical cause or history of predisposing infertility factors should be referred when they first visit their GP for advice.

People experiencing premature infertility are offered cryopreservation

- Some treatments for cancer can cause fertility problems. Cryopreservation (freezing) of men's sperm or women's oocytes or embryos may give people with cancer or other medical treatments causing premature infertility the option of trying to have children in the future.

During IVF treatment

Counselling before, during and after investigation and treatment

- Fertility problems themselves, and the investigation and treatment for fertility problems, can cause emotional stress. NICE Clinical Guideline 156 provides further details.

Semen analysis

- Semen analysis is the primary assessment tool for male fertility potential and should use methods in accordance with the most recent World Health Organisation laboratory manual. Male factor infertility is the most common reason why women seek treatment.

Women under 40 receive three full cycles of IVF

- Access to the appropriate number of full cycles of IVF for women who meet the criteria. IVF should be considered as an option only if expectant management and first line treatments for women have not led to a pregnancy.

Women aged 40–42 years who meet the criteria receive 1 full cycle of IVF

- Access to the appropriate number of full cycles of IVF for women who meet the criteria. IVF should be considered as an option only if expectant management and first line treatments for women have not led to a pregnancy.

Intracytoplasmic sperm injection (ICSI)

- Women having IVF receive ICSI only if there are severe deficits in semen quality, azoospermia, or if previous IVF treatment resulted in failed or very poor fertilisation.

A safe embryo transfer strategy

- An effective embryo transfer strategy minimises the chance of multiple pregnancies, which represent a significant health risk to mothers and babies. See the multiple birth section of this guidance.

Types of fertility treatment

There are a variety of treatments for infertility, and what is suitable for each individual will depend on their particular circumstances. A full IVF cycle, as defined by NICE guidelines, consists of one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

In vitro fertilisation (with patient or donor eggs)

IVF involves ovarian stimulation and then collecting a woman's eggs and fertilising them with sperm in the lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred into the woman's womb to hopefully continue to a pregnancy. Ideally one embryo is transferred to minimise the risk of multiple pregnancy. In older women, or those with poor quality embryos, two may be transferred, with a maximum of three in those over 40 years. It is best practice to freeze any remaining good quality embryos to use later in a frozen embryo transfer if the first transfer is unsuccessful.

In vitro fertilisation (with patient or donor eggs) with ICSI

IVF with intracytoplasmic sperm injection (ICSI) treatment is exactly the same as IVF. The only difference is that instead of mixing the sperm with the eggs and leaving them to fertilise in a dish, a skilled embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation when sperm quality is very poor as it bypasses any potential problems the sperm will have in actually penetrating into the egg.

Intrauterine insemination (IUI) or donor insemination

IUI is a type of fertility treatment in which the best quality sperm are separated from sperm that are sluggish or non-motile. This sperm is then placed directly in the womb. This can either be performed with the woman's partner's sperm (IUI) or donor sperm (known as donor insemination or DI). Sometimes ovarian stimulation is used in conjunction with IUI.

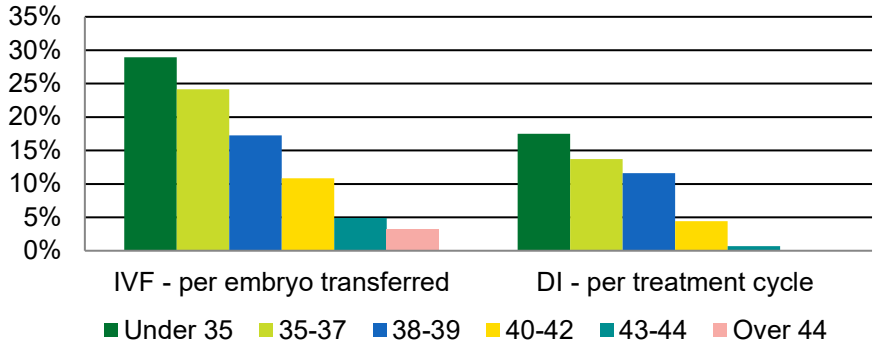
How successful is fertility treatment?

Success rates depend on the age of the patient, the cause of infertility, and other patient-specific factors such as lifestyle (eg, body weight and smoking status). The most important factor in predicting the success of fertility treatment is age: birth rates from fertility treatment fall with increasing female (or egg donor's) age.

National statistics give an indication of success rates across the whole country and are not adjusted based on a patient's (or donor's) age or for each specific type of fertility problem.

For clinic level success rates across the UK, see the HFEA's Choose a Fertility Clinic.

Birth rate (%) by patient age, 2017



Who should be able to access fertility treatment?

Access restrictions to fertility treatment should only be in place for clinical reasons which are supported by evidence, and any restrictions based on social value judgments should be in keeping with local policies on decision-making and ethical frameworks. CCGs may wish to restrict access based on either partner being sterilised.

NICE's fertility guideline clinical access restrictions

Female age

Women under 40 should be offered three full cycles of IVF treatment - women aged 40-42 should be offered one full cycle of IVF treatment if they have normal ovarian reserve for their age.

Number of previous treatment cycles

Each previous cycle, whether NHS funded of privately funded, should count towards the NICE recommendation.

Body mass index

Women should have a BMI of 19-30 kg/m2 before commencing assisted reproduction.

Alcohol intake

Women should reduce their consumption of alcohol to less than six units per week.

Smoking

Women and their partners should be non-smokers.

Key points to commission cost-effective fertility treatment

Women under 40 should receive three full cycles of IVF.

Women aged 40–42 who meet the criteria should receive one full cycle of IVF.

(NICE CG156)

Use the HFEA's **Choose a Fertility Clinic** to find the clinic that's right for your population. You can search by location, size, NHS provision and see sucess rates and patient feedback.

'Birth rates per embryo transferred' is a measure of a clinic's success rates and it allows you to make a fair comparison between clinics. Use the HFEA's **Choose a Fertility Clinic** to compare local clinics' success rates.

For some people, having twins may seem like a wonderful thing, but multiple pregnancies are much less safe for both mother and babies. The HFEA have set a target for all clinics to have a multiple birth rate of 10% or lower.

Additional resources

The HFEA (Human Fertilisation and Embryology Authority)

The HFEA provides free, clear and impartial information to all affected by fertility treatment. We are the UK Government's independent regulator overseeing fertility treatment and research.

Resources for commissioners include:

- Choose a Fertility Clinic: Explore clinics in your locality by proximity, eligibility criteria, patients' feedback, inspection reports and the clinic's birth and multiple birth rates: www.hfea.gov.uk/choose-a-clinic/
- Explore fertility treatments: Our website provides information on all the different treatments available: www.hfea.gov.uk
- Statistics and publications: We produce many publications about the work we do, from our annual fertility treatment report to patient leaflets and corporate publications: www.hfea.gov.uk/about-us/publications
- Clinic level data for individual CCGs can be provided by the HFEA on request to support evidence-based decision-making.

NICE (National Institute for Health and Care Excellence)

NICE Clinical Guideline 156 covers diagnosing and treating fertility problems. It aims to reduce variation in practice and improve the way fertility problems are investigated and managed. NICE has also produced tools and resources to help you put this guideline into practice: https://www.nice.org.uk/guidance/cg156 and https://www.nice.org.uk/guidance/cg156/resources.

The NHS

The NHS provides information on fertility problems, including advice on the causes of fertility problems and lifestyle factors that can contribute to fertility problems, diagnosis and treatment options: https://www.nhs.uk/conditions/infertility/

This Clinical Commissioning Policy (N-SC/037) outlines the pathway and criteria for access to assisted reproduction techniques such as IVF and ICSI for Armed Forces couples: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/11/n-sc037.pdf

Association of Clinical Embryologists (ACE)

ACE is the professional body for embryologists www.embryologists.org.uk

British Fertility Society (BFS)

The BFS is dedicated to promoting expert medical practice in fertility treatment based on scientific evidence: https://britishfertilitysociety.org.uk

Royal College of Nursing (RCN)

The RCN represents nurses and the nursing profession: www.rcn.org.uk

Royal College of Obstetricians and Gynaecologists (RCOG)

The RCOG is the professional body for anyone working in the field of obstetrics and gynaecology (O&G): www.rcog.org.uk

Key terms and definitions

The table below provides some useful definitions of key terminology that may be used when commissioning fertility treatment. More useful definitions and information on various forms of fertility treatment and services can be found from our website at www.hfea.gov.uk.

Term	Definition
Abandoned cycle with IVF / ICSI	Prior to egg retrieval, usually due to a lack of response (where fewer than three mature follicles are present) or conversely if there has been an excessive response to gonadotrophins and the patient is at risk of severe ovarian hyperstimulation syndrome (OHSS). One abandoned cycle does not count towards the number of commissioned cycles.
Assisted reproduction	The collective name for treatments designed to lead to conception by means other than sexual intercourse, which include intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and donor insemination (DI).
Blastocyst	Blastocyst stage embryos are selected on day five of their development (or on day six if they have not developed by day five).
Cleavage	Cleavage stage embryos are selected on day one or day two of their development
Clinical pregnancy	A pregnancy diagnosed by ultrasonographic visualisation of one or more gestational sacs. It includes ectopic pregnancy. Note: multiple gestational sacs are counted as one clinical pregnancy.
Cryopreservation	The freezing and storage of embryos, sperm or eggs for future use in IVF treatment cycles.
Donor insemination	DI is a type of fertility treatment in which high quality donor sperm is used when either the male partner has no sperm or for lesbian couples. This sperm is then injected directly into the womb (IUI).
Embryo transfer	The procedure in which one or more embryos are placed in the uterus.
Fertilisation	The union of an egg and sperm.
Full cycle	This term is used to define a full IVF treatment, comprising of one episode of ovarian stimulation and the transfer of any resultant fresh embryo(s). Where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos may be transferred to the patient as a frozen cycle and be included within the 'full cycle'. All frozen embryos from a previous cycle should be used before a further IVF cycle is initiated. Storage of frozen embryos will be routinely funded for one year unless the provider has agreed an alternative as part of a pathway agreement.

	Legally they can be stored for up to 10 years, other than in exceptional circumstances Any costs relating to the continued storage of embryos beyond this will ordinarily be the responsibility of the couple.
Infertility / Subfertility	In practice, infertility is defined as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.
Intracytoplasmic sperm injection	IVF with ICSI treatment is similar to standard IVF. However, instead of mixing the sperm with the eggs and leaving them to fertilise in a dish, a skilled embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation as it bypasses any potential problems the sperm will have in penetrating into the egg.
Intrauterine insemination	IUI is a type of fertility treatment in which the best quality sperm are separated from sperm that are sluggish or non-motile. This sperm is then placed directly in the womb. This can either be performed with the woman's partner's sperm (IUI) or donor sperm (known as donor insemination or DI). Sometimes ovarian stimulation is used in conjunction with IUI.
In vitro fertilisation	IVF involves ovarian stimulation and then collecting a woman's eggs and fertilising them with sperm in the lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred back to the woman's womb to hopefully continue to a pregnancy. Ideally one embryo is transferred to minimise the risk of multiple pregnancy. In older women, or those with poor quality embryos, two may be transferred with a maximum of three in those over 40 years. It is best practice to freeze any remaining good quality embryos to use later on in a frozen embryo transfer if the first transfer is unsuccessful.
Ovarian Hyper-Stimulation Syndrome (OHSS)	A condition in which the ovarian response to stimulation results in clinical problems, including abdominal distension, dehydration and potentially serious complications due to thrombosis and lung and kidney dysfunction. It is more likely in women who are excessively sensitive to medicines used for ovarian stimulation.
Ovarian stimulation	Stimulation of the ovary to achieve growth and development ovarian follicles.
Unsuccessful cycle of IVF/ ICSI	Includes failure of fertilisation, failure of cleavage of embryos and failure to conceive following transfer of embryos. An unsuccessful cycle counts towards the number of commissioned cycles.

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