

# Regulated Fertility Services: A commissioning aid

June 2009



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## 1. Purpose of the commissioning aid

- 1.1 Fertility services pose particular challenges for commissioners. These challenges arise from the diversity of providers involved, the social value judgements that sometimes need to be made in commissioning and the rapid pace of technological change.
- 1.2 This document is to assist NHS commissioners in developing their services. It sets out the background to fertility services, describes what they comprise and how they are accessed, and outlines an approach to commissioning them. It includes a spreadsheet model to assist commissioners in gauging likely levels of uptake.
- 1.3 Sections 3 to 6.8 are intended mainly to inform commissioners about the background and issues raised by this service. By contrast, sections 6.9 to 6.11, 7 and 8 provide guidance on what and how to commission.
- 1.4 The aid is designed to complement the World Class Commissioning cycle (refer to Annex A). It concentrates on those parts of the cycle where support to commissioners is likely to be most useful.

## 2. Summary

- Infertility is usually defined as failure to conceive after frequent unprotected sexual intercourse for two years in couples in the reproductive age group in the absence of known pre-existing causes of infertility. Its prevalence rises with age.
- It has several causes, but sometimes the cause in an individual couple cannot be diagnosed. Fertility in both sexes is reduced by smoking, excessive alcohol consumption and obesity. These lifestyle factors also diminish the effectiveness of some treatments for infertility.
- Infertility is managed in primary, secondary and tertiary care. Treatment may include counselling, lifestyle advice, drugs, surgery and in-vitro fertilisation (IVF).
- The majority of fertility treatment in the UK is statutorily regulated by the Human Fertilisation and Embryology Authority (HFEA).
- In 2004, the National Institute for Health and Clinical Excellence (NICE) published a clinical guideline on fertility. Other guidance has followed from the Department of Health.
- Commissioning fertility services raises issues not encountered in other clinical areas, and requires particular care.
- New interventions and new evidence needs to be considered in specifying what to commission.
- Commissioners should follow the principles of World Class Commissioning. This includes carrying out a thorough needs assessment, reviewing existing provision, and developing a service specification describing in detail the fertility service they wish to commission.
- Fertility services have been identified as suitable for full contestability via an open competitive tendering process. This aid assists commissioners in undertaking such a process.

### **3. Background**

3.1 This section sets out what infertility is and how it is caused, investigated and treated. It then describes the policy context within which fertility services are provided, and the main issues which arise for commissioners.

#### **3.2 Definition, epidemiology and causes of infertility**

- 3.2.1 Infertility is usually defined as failure to conceive after frequent unprotected sexual intercourse for two years in couples in the reproductive age group in the absence of known pre-existing causes of infertility. This definition is different from the treatment criteria in the NICE clinical guideline, because the guideline's aim is to define the point at which treatment should be offered. About 84% of couples in the general population will conceive within a year if they have sexual intercourse every two to three days and do not use contraception. This proportion rises to 92% at two years.
- 3.2.2 Women's fertility falls with age, and so the prevalence of infertility rises: from 5% for women aged from 25–29 years, through 9% at 30–34 years, to 20% at 35–39 years. Since fertility naturally declines markedly after a woman reaches the age of 40, this is often considered the upper limit of the reproductive age range for the purpose of defining infertility.
- 3.2.3 Infertility has several causes. Some completely preclude reproduction without treatment, while others make it less likely, but not impossible.
- 3.2.4 In about 30% of couples, the male partner is unable to produce or ejaculate enough normal sperm. About as commonly, problems are found with the female partner, such as a failure to ovulate (produce eggs) (about 10%) or a partial or complete blockage to the passage of the eggs from the ovary to the uterus where they can be fertilised (about 15%).
- 3.2.5 Problems are found with both partners in about 10% of couples, and in about 25% of cases no cause of infertility can be identified. Fertility in both sexes is reduced by smoking, excessive alcohol consumption and obesity. These lifestyle factors also diminish the effectiveness of some treatments of infertility.

#### **3.3 Outline clinical pathway, investigations and treatment**

- 3.3.1 Infertility is managed in primary, secondary and tertiary care. The first stage of management in primary care is usually lifestyle advice to increase the chances of conception occurring naturally. If this is not effective, initial investigations will often include semen analysis and assessment of the ovulatory cycle. If these are normal, tubal patency may be investigated on referral to hospital.
- 3.3.2 Commonly used treatments for ovulatory problems in secondary care include hormonal treatment to stimulate ovulation, often with oral drugs such as clomiphene. Tubal problems can sometimes be treated surgically, though often IVF is preferred. Several drug and surgical treatments are available for sperm problems. Drug treatment is also sometimes tried when no cause of infertility can be found.
- 3.3.3 Some couples with infertility who do not conceive with these first-line treatments may be offered intra-uterine insemination (IUI). Some couples will be considered for IVF, which is now responsible for about 1% of births in the UK. IVF involves:

- the use of drugs to switch off the natural ovulatory cycle;
- induction of ovulation with other drugs;
- monitoring the development of the eggs in the ovary;
- ultrasound-guided egg collection from the ovary;
- processing of sperm;
- mixing of eggs and sperm in the laboratory;
- use of progesterone to make the uterus receptive to implantation; and
- transfer of selected embryo(s) and freezing of those suitable but not transferred.

3.3.4 More details of the treatments and the settings in which they are usually provided are in section 6.

### **3.4 Regulation and the role of the HFEA**

3.4.1 Fertility treatments and services covered by the Human Fertilisation and Embryology Act 1990,<sup>1</sup> as amended by the Human Fertilisation and Embryology Act 2008,<sup>2</sup> such as IVF and storage of gametes and embryos, are regulated by the HFEA ([www.hfea.gov.uk](http://www.hfea.gov.uk)). The HFEA oversees the use of gametes and embryos in these treatments and services and regulates all embryo research. It also licenses and inspects treatment clinics, other establishments carrying out activities covered by the Act, and research centres, and provides a range of detailed information for patients, professionals, the public and government.

3.4.2 The HFEA's activities have two particular implications for commissioners. Firstly, commissioners can use the data on the outcomes of IVF that the HFEA collects and publishes on its website to assist in assessing the relative performance of providers of IVF. The data require care in their interpretation, and the HFEA's website provides valuable guidance on this. Secondly, the rigour of the HFEA's processes of inspection and licensing, and their statutory basis, mean that commissioners can have a high degree of confidence in treatment centres in the UK.

### **3.5 NICE clinical guideline**

3.5.1 In 2004, the National Institute for Health & Clinical Excellence published a clinical guideline on the treatment of infertility ([www.nice.org.uk/guidance/CG11](http://www.nice.org.uk/guidance/CG11)). Key recommendations included:

- couples in which the woman is aged 23–39 years at the time of treatment and who have an identified cause for their fertility problems (such as azoospermia or bilateral tubal occlusion), or who have infertility of at least three years' duration, should be offered up to three stimulated cycles of IVF treatment; and
- to balance the chance of a live birth and the risk of multiple pregnancy and its consequences, no more than two embryos should be transferred during any one cycle of IVF treatment.

<sup>1</sup> [www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900037\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm)

<sup>2</sup> [www.opsi.gov.uk/acts/acts2008/Ukpga\\_20080022\\_en\\_1](http://www.opsi.gov.uk/acts/acts2008/Ukpga_20080022_en_1)

### **3.6 Department of Health advice**

3.6.1 Though strongly encouraged, adherence to NICE's clinical guidelines is not mandatory. Recognising that immediate implementation of the guideline on infertility would pose problems for the NHS, the then Health Secretary John Reid advised the NHS by means of Chief Executive Bulletin 207 (20–27 February 2004) that:

- the Department would be looking to primary care trusts (PCTs) who provide no IVF treatment to meet a minimum national level of provision of one cycle of IVF by April 2005; and
- in the longer term he would expect the NHS to make progress to full implementation.

3.6.2 In August 2008, Dawn Primarolo, the then Public Health Minister, wrote to PCTs and specialised commissioning groups. In her letter, she said that NICE was planning a review of its clinical guideline in 2010/11, but advised that commissioners should not delay implementing the guideline in the belief that it was about to be superseded. She also reiterated that references in the NICE clinical guideline to cycles of IVF should be interpreted as meaning full cycles, which are ones in which suitable fresh embryos are transferred and remaining suitable embryos are frozen, stored and subsequently transferred if required.

### **3.7 Multiple births minimisation strategy**

3.7.1 In 2006, the HFEA published an expert report on multiple births after IVF. Because twin births pose greater risks to mothers and infants than the birth of one baby, and give rise to higher NHS costs, the report recommended the introduction of elective single embryo transfer, an approach whereby couples at higher risk of giving birth to two or more babies have only a single embryo transferred. The HFEA's intention is to reduce the number of twin pregnancies without increasing the number of IVF cycles that do not result in a live birth.

3.7.2 In 2007, the HFEA announced that it would be working with professional groups to develop guidelines to identify couples suitable for elective single embryo transfer, and set a target for clinics to reduce their multiple pregnancy rates from the 2006 average of 23% to 10% by 2012. Clinics' rates of multiple pregnancies vary widely.

3.7.3 The following year, the HFEA Chief Executive wrote to directors of public health urging them to comply with NICE's clinical guideline. He pointed out that many couples were deterred from accepting elective single embryo transfer because only one NHS-funded cycle was available to them, especially if that was only a fresh cycle (i.e. there is no funding for the storage and/or transfer of any embryos resulting from, but not used in, the first cycle). They would accept the increased risk of a cycle failing if they knew it was not to be their only NHS-funded treatment.

3.7.4 In 2009, the HFEA Chief Executive wrote to directors of public health again, explaining that each IVF clinic was now required to have a multiple births minimisation strategy which described when elective single embryo transfer would be used. For 2009, the HFEA had set an upper limit of 24% for the proportion of births which are multiple, and would progressively reduce that to 10%. He urged PCTs not to set their own criteria for single embryo transfer, which might not reflect differences in casemix and technique as appropriately as the clinic's own. He wrote: "PCTs will wish to ensure



that their commissioning strategies are consistent with the HFEA's new Multiple Births policy. For example, your service specifications for IVF should recognise that different clinics may find different, but equally effective, routes to lowering their multiple birth rates. It would therefore be inappropriate, for example, to specify that all patients should receive single embryo transfer (irrespective of their age or prognosis) or to fail to distinguish between blastocyst and cleavage-stage embryo transfer. There is no 'one size fits all' policy that is evidence based."

### **3.8 Commissioning background**

- 3.8.1 The availability of IVF is improving, but surveys of PCT provision have shown variation in access to IVF. A Department of Health survey carried out in March 2009 reported that two PCTs were temporarily not funding IVF, while approximately 30% provide three cycles of IVF, 23% two cycles, 25% one full cycle and 22% one fresh cycle.
- 3.8.2 This was an improvement on a 2007 Department of Health survey, which found that most PCTs funded one cycle, with eight PCTs funding three cycles. A survey carried out by Infertility Network UK in 2006 found that 14 PCTs were not funding IVF. The survey had a response rate of only 50%; if more PCTs had replied, the number reporting that they did not fund IVF might well have been higher.
- 3.8.3 Commissioning fertility services raises issues not encountered in other clinical areas, and these may explain some of the variation between PCTs, and the differences between NICE's recommendations and current service availability. Among these issues are uncertainty as to the place of fertility services among NHS priorities, the emergence of new techniques, the predominance of independent providers, the absence of a national tariff, variation in outcomes and prices between providers, and questions about whether competitive tendering is necessary. This commissioning aid is intended to assist commissioners in handling these issues, without being inappropriately prescriptive.
- 3.8.4 Commissioners need to prioritise investment by making clear policy choices that explicitly describe their criteria for treatment, particularly as NHS expenditure tightens. These choices must balance cost with clinical effectiveness, quality and equity considerations.
- 3.8.5 Commissioners should engage actively with the public and people with infertility in discussing the policy options, the possibilities for stepwise progression towards full implementation of the NICE clinical guideline and the feasible pace of change. They must also meet requirements for public engagement and consultation where necessary, including working with the overview and scrutiny committees of local authorities where significant changes to services are proposed. They should make use of existing engagement mechanisms, alongside collective decision making structures such as priorities committees where they exist.
- 3.8.6 Commissioners should take account of the needs of differing communities and groups with regard to the provision of infertility services, and make appropriate material available to explain local policies. The Department's guidance on the engagement cycle is relevant to this ([www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_098658](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_098658)).

## 4. Why treat infertility?

- 4.1 There are different views as to the degree of priority to be given to infertility services; such debates are a natural part of the process of decision making. However, some have gone so far as to assert that the treatment of infertility should not be available on the NHS at all, but this position is neither rational nor fair. This section explains why.
- 4.2 Firstly, infertility is a bona fide disease, and recognised as such by the World Health Organization. Most of us expect to be able to work; if we cannot because of a medical diagnosis, such as depression or back pain, then we expect NHS treatment so that we can regain normal functioning and take up our role in society. Similarly, the option to become a parent is something most of us expect to have, even if some choose not to take it up. Those who cannot conceive for medical reasons should have access to NHS treatment just as they would for any other clinical problem which restricts their ability to function as we all expect to. Even when investigated and treated as they expect, the experience of infertility can undermine people's mental health and well-being.
- 4.3 Secondly, the NHS provides investigation and some treatments for infertility routinely, indicating an acceptance of the principle that the condition has a legitimate place.
- 4.4 Thirdly, positive recommendations about the provision of IVF have been made by NICE and by government ministers.

## 5. Gauging likely uptake of IVF

- 5.1 The first step in commissioning infertility services is to estimate likely uptake of these services both now and in the future. This is important so that service planning can reflect the services and volumes of activity required. Public health specialists will be of particular value in advising on this process.
- 5.2 Appended to this aid is a spreadsheet (Annex C) to assist in the estimation of likely uptake. When using it, first obtain up-to-date estimates of the numbers of women in the relevant population in the 25–29, 30–34 and 35–39 year age ranges from the Office for National Statistics (ONS) ([www.statistics.gov.uk](http://www.statistics.gov.uk)). These age bands reflect what is routinely published by the ONS; women under the age of 25 may be eligible for IVF, but only rarely. Enter these estimates into the spreadsheets, either for a single PCT or, for specialised commissioners, for those PCTs on whose behalf commissioning is undertaken.
- 5.3 The estimated uptake rates are indicative only. Local uptake will depend on local factors; for example, high rates of teenage births will mean that more local women will be ineligible for treatment of subsequent infertility because they already have a child. Conversely, in affluent areas, more women will defer child-bearing for occupational reasons and be infertile by the time they wish to conceive, increasing the prevalence of infertility.
- 5.4 The models show the effects on activity of three different definitions of childlessness and three different policies on eligibility age ranges – a total of nine different commissioning policies. They are based on assumptions about the incidence of infertility and the proportion of infertile couples who will be suitable for IVF.

- 5.5 The spreadsheets can be used to show the impact on expected activity of different policies on eligible age ranges, on the definition of childlessness and on access for smokers and obese women. The prevalence of these criteria can also be altered to reflect local data.
- 5.6 Smoking and obesity are important public health threats because they cause disabling diseases and premature death. The period before IVF treatment is an excellent time for a woman to lose weight and stop smoking. Smoking and obesity also reduce the effectiveness of IVF, increase the risk of abnormalities during pregnancy and childbirth and, in the case of smoking, damage the health of children born after IVF. Research shows that smokers are 60% more likely to be infertile than non-smokers, so stopping smoking may allow a natural conception to occur. Smoking reduces the chances of IVF producing a live birth by 34% and increases the risk of an IVF pregnancy miscarrying by 30%. Women with a body mass index (BMI) over 27 are 33% less likely to have a live birth after their first cycle of IVF than those with a BMI between 20 and 27. Pregnant women who are obese have higher rates of congenital abnormality, miscarriage, gestational diabetes, hypertension, thrombo-embolism and problems during delivery. Because of the risks of treatment failure and adverse outcomes when obese women undergo IVF, NICE noted that women with a BMI over 30 are less likely to have successful assisted reproductive procedures.
- 5.7 The results of the spreadsheet can be put alongside current activity to indicate the results of policy change. It may not be clear where all activity is taking place, so it is worth enquiring of patients and their local organisations about current directions of flow. This can be combined with price information to gauge the budgetary impact of any proposed change. The local public health team will be useful in interpreting these data. Clomiphene prescribing data may also shed light on the prevalence of fertility problems locally.

## **6. Current service provision – best practice and commissioning issues**

- 6.1 This section describes in outline the investigations and treatments often used in couples with fertility problems. It describes the role of different service components in care provision and introduces a simplified version of the algorithm (Annex B) in the full edition of the NICE clinical guideline. It also summarises the evidence about some new interventions, and new evidence about existing interventions. This does not of course pre-empt the planned review of the NICE clinical guideline, but is intended to assist commissioners in responding to an area of care characterised by rapid technological change.
- 6.2 Although there are aspects of the structure of infertility services which differ from most other services, the services can still be categorised into primary, secondary and tertiary care.
- 6.3 Couples who are having difficulty conceiving will receive lifestyle advice in primary care about how to increase their prospects of a natural conception, and receive an initial diagnosis of infertility, preliminary investigation and a referral to a consultant. Commissioners will wish to pay particular attention to ensuring that appropriate investigations are carried out in primary care so that waiting times of 18 weeks are achieved. They should also ensure that there is close liaison between primary care and specialist fertility units on appropriate investigations and the interpretation of results.

- 6.4 In some areas, there is a secondary care gynaecologist with an interest in infertility able to provide investigation of the problem, and hormonal and surgical treatment. Where this is not available, couples should be referred directly by their general practitioner to a specialist fertility clinic at another hospital, rather than to a local gynaecologist without special expertise. Couples who do not conceive as a result of local treatment will usually then be referred to a tertiary service for consideration of IVF.
- 6.5 The algorithm at Annex B illustrates the main steps in the assessment and treatment of people with fertility problems. It is a simplified version of the algorithm in the clinical guideline published by NICE, and is intended to inform commissioners rather than to guide clinical practice. The clinical guideline should be consulted for a fuller understanding of the recommended process of care.
- 6.6 The NICE clinical guideline makes specific recommendations about who should be offered IUI, including a recommendation against IUI with ovarian stimulation in some circumstances. This is because of the risk of multiple pregnancies. Commissioners should be aware that this risk can be mitigated by using protocols that minimise the number of follicles that develop, using ultrasound to monitor the development of ovarian follicles and adjusting the timing of insemination accordingly or triggering the abandonment of the cycle.
- 6.7 Since the publication of the NICE clinical guideline in 2004, several important developments have occurred in the fertility field. Either new interventions have become available, or new evidence has emerged about better established interventions.
- 6.8 This has given rise to difficult policy choices for commissioners, who have to resolve them at present in the absence of national guidance. This commissioning aid neither constitutes nor pre-empts such guidance. It merely lists developments of which commissioners need to be aware, with a brief summary of what each is and of evidence about effectiveness which other commissioners have found useful. All these developments need to be taken into account in formulating policy and managing procurement.

## **6.9 Techniques ancillary to IVF**

- **Use of donor gametes**

Some people cannot produce gametes, so IVF using donated gametes is the only means by which they can conceive. The source of eggs or sperm can be donation by a relative, friend or altruistic stranger, or egg and sperm sharing, an arrangement in which people receive self-funded treatment at a discounted price in exchange for releasing some of their gametes for use by others. While full implementation of the NICE clinical guideline would reduce the availability of shared gametes (particularly eggs), commissioners may need to consider their policy on funding of egg sharing, balancing the shortage of donated eggs with the indirect NHS subsidy of IVF for the woman who provided the eggs, who may not be eligible for NHS IVF under the terms of the local commissioning policy.

Donated eggs and sperm are in short supply in the UK, because of the nature of the procedure required to provide them (unless the donor is undergoing IVF herself), and also the fact that the law allows people conceived using donor gametes access to the identity of the donor when they become adults. Further information on the recruitment of sperm and egg donors can be obtained from the National Gamete Donation Trust ([www.ngdt.co.uk](http://www.ngdt.co.uk)).

Gametes sourced from outside the UK may not be subject to the stringent safety and quality assurance processes required by the HFEA. Commissioners are responsible for the quality of services they commission, so they should be very cautious about funding the use of such gametes, whether the gametes are imported or the treatment occurs overseas. The HFEA can provide more information.

The use of donated eggs results in higher success rates with IVF than the use of a woman's own eggs, and was recommended in the NICE clinical guideline. However, the cost of IVF with donated eggs and sperm varies substantially between clinics.

- **Surgical sperm retrieval**

Surgical sperm retrieval is the name given to a set of techniques for collecting sperm from within the male reproductive organs. It is used in cases of male subfertility where there is testicular sperm production but an absence of sperm in the semen (azoospermia). Surgical sperm extraction leads to satisfactory rates of successful sperm retrieval and acceptable pregnancy rates.

- **In-vitro maturation**

In-vitro maturation is a new and experimental technique in which eggs are harvested from the ovary earlier in their development than with conventional IVF. They complete their maturation in an incubator and are then processed as in conventional IVF. The earlier harvesting means that the woman needs fewer drugs to promote ovulation than in conventional IVF. This may be particularly desirable in women at higher risk of ovarian hyperstimulation syndrome, a dangerous side effect of ovarian stimulant drugs.

In-vitro maturation was not covered by the NICE clinical guideline. The effectiveness of the technique is as yet unproven, and commissioners should await more convincing evidence before commissioning it.

- **Blastocyst transfer**

Embryos from IVF are usually transferred to the woman's uterus at the cleavage stage, when they are two or three days old. Recently, researchers have explored the effects of keeping them in the incubator for another three days, until they become blastocysts. This means that only high-quality embryos are transferred – those most likely to implant, survive and lead to a successful pregnancy. Blastocyst transfer complements elective single embryo transfer, by enabling live birth rates to be maintained with fewer embryos transferred and a lower risk of multiple births, but is technically demanding and may increase costs because of the longer incubation period required.

Commissioners should make themselves aware of whether providers are able to carry out blastocyst transfer and consider whether they do so clinically-effectively and cost-effectively.

- **Gamete intra-fallopian transfer (GIFT)**

GIFT is a procedure in which eggs are retrieved from a woman, mixed with sperm and immediately replaced in one of the woman's fallopian tubes so that they are fertilised inside the body.

The NICE clinical guideline recommended avoiding the use of GIFT because the evidence of its effectiveness was insufficient. It can also lead to multiple births. Few British clinics now offer it.

- **Gamete and embryo storage to preserve fertility**

Some medical treatments, for example those for cancer, render people permanently infertile. Gamete and embryo storage is intended to preserve reproductive potential in these circumstances. Gametes can be frozen for subsequent use in IVF, while embryos fertilised in-vitro can be frozen for later transfer.

The evidence shows that frozen sperm is as likely to produce a live birth as fresh sperm, but frozen oocytes produce a live birth in less than 2% of cycles. Frozen embryos are somewhat less viable than fresh ones.

Commissioners should therefore consider commissioning sperm and embryo storage for people about to undergo treatment likely to render them permanently infertile, but also take into account the substantially different outcomes in determining the appropriateness of commissioning oocyte storage. The NICE clinical guideline noted the “very limited” success of oocyte freezing. Although it went on to recommend offering it to suitable women about to undergo medical treatment likely to render them infertile, the reasons for this recommendation are not stated. It was graded at the lowest level available to the guideline’s authors.

Commissioners should also consider the circumstances under which the gametes and embryos will be stored, and used or transferred, and ensure that these are adequately specified in their policies. Patients whose gametes or embryos are to be frozen should be warned that their subsequent use may be subject to different policies than those prevailing when they are frozen.

## **6.10 Disease prevention techniques**

- **Sperm washing**

Semen can contain viruses including hepatitis B virus and human immunodeficiency virus (HIV), the virus that can lead to AIDS. Therefore, if only the male partner is infected with a virus, unprotected intercourse risks infecting the woman and any resulting child. Such virally serodiscordant partners can conceive more safely using IUI or IVF. Nevertheless, there remains a risk that virus in the sperm will be transmitted to the woman and/or the child. In the case of HIV at least, semen can be processed to reduce as much as possible the amount of HIV which it contains, by separating the sperm from the seminal fluid and non-sperm cellular components of semen. This is because it is believed by the technique’s proponents that sperm itself is HIV-free; the risk arises from other components of semen. The resulting “purified” sperm is then tested for the presence of HIV before use in IUI or IVF.

Sperm washing is not a treatment for infertility, so falls outside the scope of this commissioning aid. Evaluations of the technique have reported no transmission of HIV to mother or child, but the quality of the studies is generally poor, with inadequate follow-up to detect transmission. Commissioners should be aware that there is insufficient evidence to be sure that sperm washing prevents HIV transmission and should ensure that any services are closely linked with infectious disease treatment to ensure that IUI and IVF take place when viral load is maximally suppressed.

- **Pre-implantation genetic diagnosis**

This technique involves sampling the DNA of an embryo conceived by IVF to diagnose congenital disease before transfer and so ensure that, where possible, only unaffected embryos are transferred. IVF is used to provide an early opportunity to test for the disease, rather than because natural conception is difficult; couples using pre-implantation genetic diagnosis are

usually fertile. The technique is a means of preventing the birth of an affected child, not a treatment for infertility, and therefore falls outside the scope of this document.

Commissioners should consider the place of pre-implantation genetic diagnosis when specifying the scope of their genetics service.

It is important to consider the question of equity between patients seeking pre-implantation genetic diagnosis and patients with infertility when reaching decisions on the amount of NHS-funded treatment (for example cycles of IVF or IUI) that will be funded.

### 6.11 The handling of existing frozen embryos from previous self-funded cycles

This is one of the more difficult policy questions, to which a variety of responses are possible. Commissioners will need to identify an approach to this issue themselves. The advantages and disadvantages of three possible approaches are summarised below.

Option	Advantages	Disadvantages
Provide NHS funding for transfer of embryos from self-funded cycles, and then fund an NHS full cycle if there is no live birth.	Follows NICE guidance by using existing embryos before commencing another cycle of ovarian stimulation.  May avoid risks and costs associated with further ovarian stimulation.	If frozen embryo transfer does not result in a live birth, an NHS-funded cycle will be provided. So couples with embryos from self-funded cycles will inequitably receive more NHS-funded treatment than those without, and will be more likely to end up with a successful pregnancy.  There may be technical reasons why the transfer of embryos from self-funded cycles needs to take place in a unit with whom commissioners do not have a contract, with possible cost implications.
Fund the transfer of embryos from self-funded cycles as the frozen embryo component of the couple's NHS full cycle. If the NHS-funded frozen embryo transfer(s) does not result in a live birth, only a fresh cycle would then be funded by the NHS.	Follows NICE guidance by using existing embryos before commencing another cycle of ovarian stimulation.  May avoid risks and costs associated with further ovarian stimulation.  Maintains equity of funding with others who do not have embryos from self-funded cycles.  Less expensive than first option.	There may be technical reasons why the transfer of embryos from self-funded cycles needs to take place in a unit with whom commissioners do not have a contract, with possible cost implications.  Inapplicable to commissioners that only fund fresh cycles.
Do not fund transfer of embryos from self-funded cycles.	Maintains most clearly the distinction between self-funded and NHS treatment, with embryos from self-funded cycles considered as component of the previous, self-funded episode of care.  Maintains equity of funding with others who do not have embryos from self-funded cycles.	Does not follow NICE guidance on clinical management. There may be ethical concerns about bringing further embryos into existence when suitable ones already exist.  Exposes proportion of women who would achieve pregnancy from frozen embryo transfer to unnecessary treatment.

Commissioners will be aware that this area of interaction between NHS and self-funded treatment is affected by the Richards Report on improving access to medicines for NHS patients ([www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh\\_089927](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_089927)), and questions of co-payments will need to be handled accordingly.

If a patient receives IVF in the private sector, this does not take away her right to seek NHS IVF subsequently. However, in their policies on funding fertility treatment, commissioners will wish to take into account the likely effectiveness of further cycles if a patient has already had several unsuccessful ones in the private sector.

## 7. Development of commissioning

7.1 This section sets out key commissioning principles for infertility services. In developing their policies, commissioners should have regard to World Class Commissioning ([www.dh.gov.uk/en/managingyourorganisation/commissioning/worldclasscommissioning/index.htm](http://www.dh.gov.uk/en/managingyourorganisation/commissioning/worldclasscommissioning/index.htm)), and in particular the eleven competencies for commissioning, all of which are relevant to this field:

- locally lead the NHS;
- work with community partners;
- engage with the public and patients;
- collaborate with clinicians;
- manage knowledge and assess needs;
- prioritise investment;
- stimulate the market;
- promote improvement and innovation;
- secure procurement skills;
- manage the local health system; and
- make sound financial investments.

7.2 Commissioners should ensure that they take account of all relevant factors in reaching their judgements. Those judgements will vary between commissioners. This variation is inevitable given the devolved nature of NHS decision making; however, their judgements should all be based on inclusive, balanced and transparent decision making processes. Commissioners should pay attention to public expectations, setting infertility services alongside other calls for funding.

7.3 Among the factors that commissioners should consider are:

- what government ministers have said that they expect to be provided;
- what the NICE clinical guideline recommends;
- what the evidence shows is clinically and cost-effective; and
- the needs of their local population, and the relative priority of infertility services for their population.



- 7.4 In approaching these decisions, commissioners must comply with the Ministerial Directions on decisions about drugs and other treatment ([www.dh.gov.uk/en/publicationsandstatistics/publications/publicationslegislation/dh\\_096067](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationslegislation/dh_096067)). They should take account of the Department of Health's *Defining Guiding Principles for Processes Supporting Local Decision Making about Medicines* ([www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh\\_093413](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_093413)) and the National Prescribing Centre's handbook of good practice, *Supporting Rational Local Decision-Making about Medicines (and Treatments)* ([www.npc.co.uk/policy/local/constitution\\_handbook.htm](http://www.npc.co.uk/policy/local/constitution_handbook.htm)). Although primarily intended to improve the consistency and quality of local decision making about prescription drugs, these documents are relevant to the management of other kinds of medical innovation, including fertility services.
- 7.5 Commissioners should develop a service specification which describes the service to be commissioned and the outcomes expected. This should reflect the infertility care pathway described in section 6, and include the commissioner's decisions about the specific policy issues discussed there. It should not be limited to technological elements of care, but should also include counselling and psychological support for couples.
- 7.6 Initial versions of the service specification may contain options rather than a single recommended course of action, to stimulate local engagement and decision making. The final version should explicitly state the commissioner's definitive position.
- 7.7 Commissioners who have previously had lower levels of expenditure on fertility services may have concerns about the affordability of moving from lower levels of provision to higher levels. This process may be taken in a single step or approached as a series of incremental ones, with the cost of each step gauged in advance and the pace of progress set with an understanding of what rate of budgetary expansion is locally affordable.
- 7.8 Incremental steps which commissioners may wish to consider include:
- moving from one fresh to one full cycle;
  - moving from one to two, and then to three, full cycles; and
  - widening the access criteria so that more people can benefit (see [www.infertilitynetworkuk.com/](http://www.infertilitynetworkuk.com/)).
- 7.9 In proposing these steps, commissioners will need to manage stakeholders' expectations and media engagement, taking a strategic approach to communication. The Department of Health has commissioned research which includes a decision choice experiment to inform these decisions; the results are expected later in 2009. This will inform commissioners about the relative importance of the different areas of investment to those with infertility.

7.10 Great care is needed to ensure that the specification is thorough and specific with regard to the details of the service to be commissioned. It needs to describe:

- access criteria for treatment;
- the exact care pathway to be implemented;
- the interface between local gynaecology services and specialist services (at what point will hand-over occur?);
- who can refer patients for treatment;
- clinical and cost effectiveness, including the choice of drugs;
- where levels of treatment will be provided;
- what the minimum dataset for contract monitoring will contain;
- the reporting mechanisms to be followed; and
- the performance indicators to be used.

Attention to these details is of particular importance, whether procuring services from the independent sector, a foundation trust or any other provider, as the arrangements may be legally binding and longer lasting than previous NHS service agreements. Commissioners of fertility services who use an insufficiently detailed and precise service specification may have to pay for a less satisfactory service.

7.11 The 18-week maximum waiting time applies to fertility services. More details on commissioning to achieve this are available online ([www.18weeks.nhs.uk/Content.aspx?path=/achieve-and-sustain/Specialty-focussed-areas/Gynaecology/Fertility/](http://www.18weeks.nhs.uk/Content.aspx?path=/achieve-and-sustain/Specialty-focussed-areas/Gynaecology/Fertility/)).

7.12 There is, at present, no national tariff for fertility services, though work is under way to establish one. In the meantime, commissioners will need to decide what outcome will trigger payment. They may wish, for example, to pay for cycles regardless of outcome, or only for confirmed pregnancies, or even only for pregnancies which result in a live birth, rather than for cycles regardless of outcome. In pursuing this approach, they will need to be mindful of the risks of creating perverse incentives for providers to transfer two embryos inappropriately, despite the importance of pursuing elective single embryo transfer, or conversely to deny treatment to women with a less favourable prognosis who nevertheless fulfil the commissioner's eligibility criteria. These risks can be mitigated by a service specification which minimises the opportunity for unwanted provider behaviour. For example, the specification could require adherence to a multiple births minimisation strategy and penalise the provider for failure to achieve the HFEA's target number of multiple births.

7.13 Commissioners should also note that the CQUIN (Commissioning for Quality and Innovation) Payment Framework applies to providers using the NHS national standard contracts, requiring that 0.5% of the provider's NHS contract income in 2009/10 should be available in addition to contract payments if locally agreed quality improvement and innovation goals are achieved. The agreed CQUIN scheme for a general acute provider whose contract includes fertility services may therefore include a goal related to fertility services if this is thought appropriate by both commissioner and provider. Guidance on using the CQUIN Payment Framework can be found at: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_091443](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091443). Locally

agreed CQUIN goals related to fertility services should encourage quality improvement and innovation rather than rewarding compliance with mandatory national requirements.

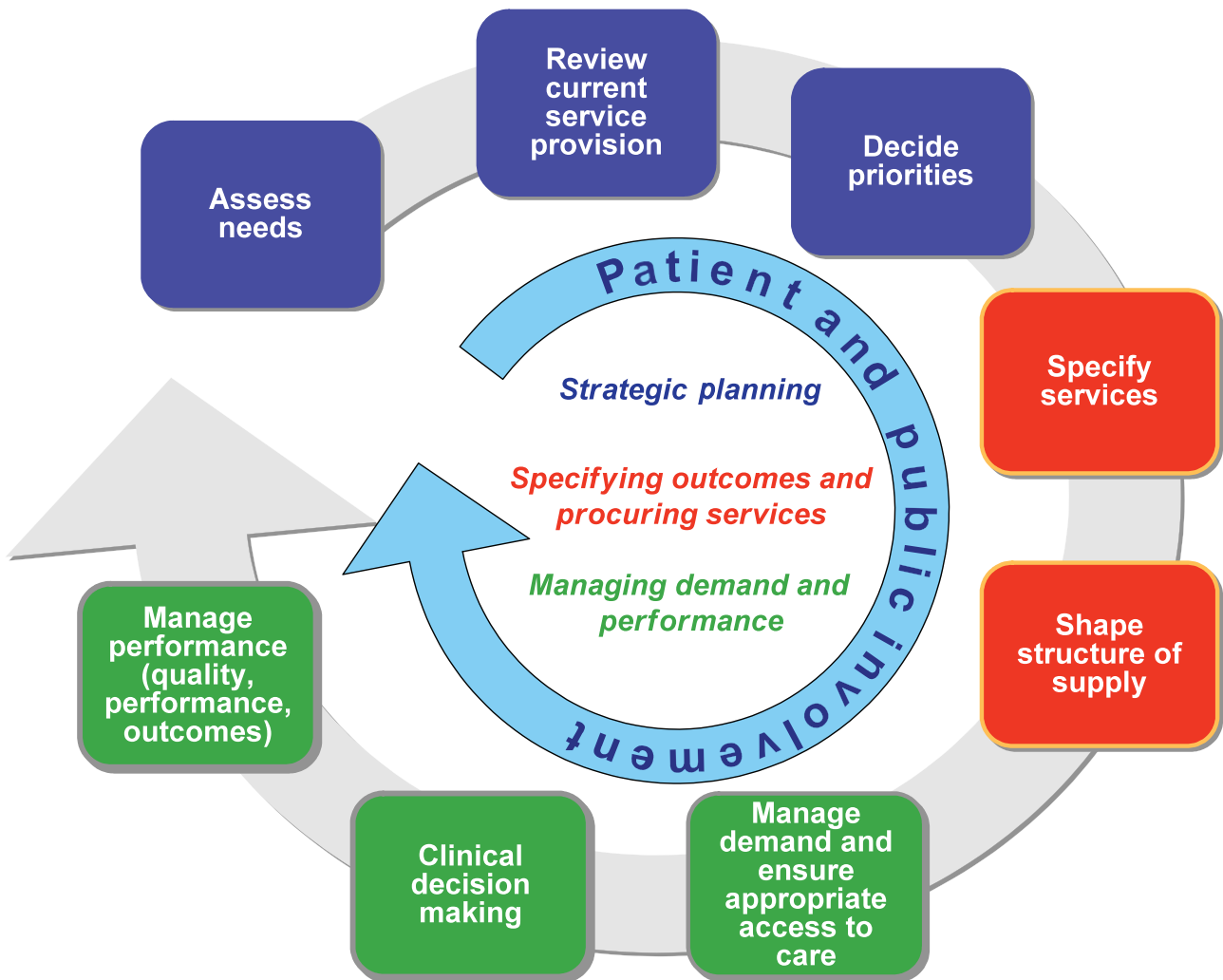
- 7.14 The East of England Specialised Commissioning Group has produced a useful service specification for fertility services ([www.escg.nhs.uk/default.asp?id=83](http://www.escg.nhs.uk/default.asp?id=83)). Another useful document is available from the Cheshire and Merseyside Local Specialist Services and Collective Commissioning Group or from [Gwen.Skinner@dh.gsi.gov.uk](mailto:Gwen.Skinner@dh.gsi.gov.uk).

## 8. Procurement

- 8.1 Fertility services have been identified as suitable for full contestability via an open competitive tendering process. The current lack of a national tariff, the large market share of independent providers and the variability of prices and provider performance underline the importance of considering all potential providers before committing.
- 8.2 In approaching the procurement process, commissioners will need to follow the Department's guidance, *The PCT Procurement Guide for Health Services* ([www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh\\_084778](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_084778)). Although the document's title implies that it only applies to PCTs, it is also intended to guide specialist commissioners.
- 8.3 The guide stipulates the principles that should be followed:
- Transparency – including the use of sufficient and appropriate advertising of tenders, transparency in making decisions not to tender, and the declaration and separation of conflicts of interest.
  - Proportionality – making procurement processes proportionate to the value, complexity and risk of the services contracted, and critically not excluding potential providers through overly bureaucratic or burdensome procedures.
  - Non-discrimination – ensuring consistency of procurement rules, transparency on timescale and criteria for shortlist and award.
  - Equality of treatment – ensuring that all providers and sectors have equal opportunity to compete where appropriate; that financial and due diligence checks apply equally and are proportionate; and that pricing and payment regimes are transparent and fair.
- 8.4 Another useful document is the Department's *Framework for Managing Choice, Cooperation and Competition* ([www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh\\_084779](http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_084779)).
- 8.5 Commissioners may find it helpful to use a local procurement hub or specialised commissioning group in transacting the process of procurement. They should use the NHS national contract, amended with quality outcomes and key fertility performance indicators. The HFEA will be a valuable source of data on providers' performance, including clinical outcomes and inspection reports. Performance data need particular care in interpretation, as live birth rates can be confounded by differences in rates of multiple embryo transfers and in women's ages.
- 8.6 Commissioners should compare the willingness and capability of potential providers to comply fully with their service specification.

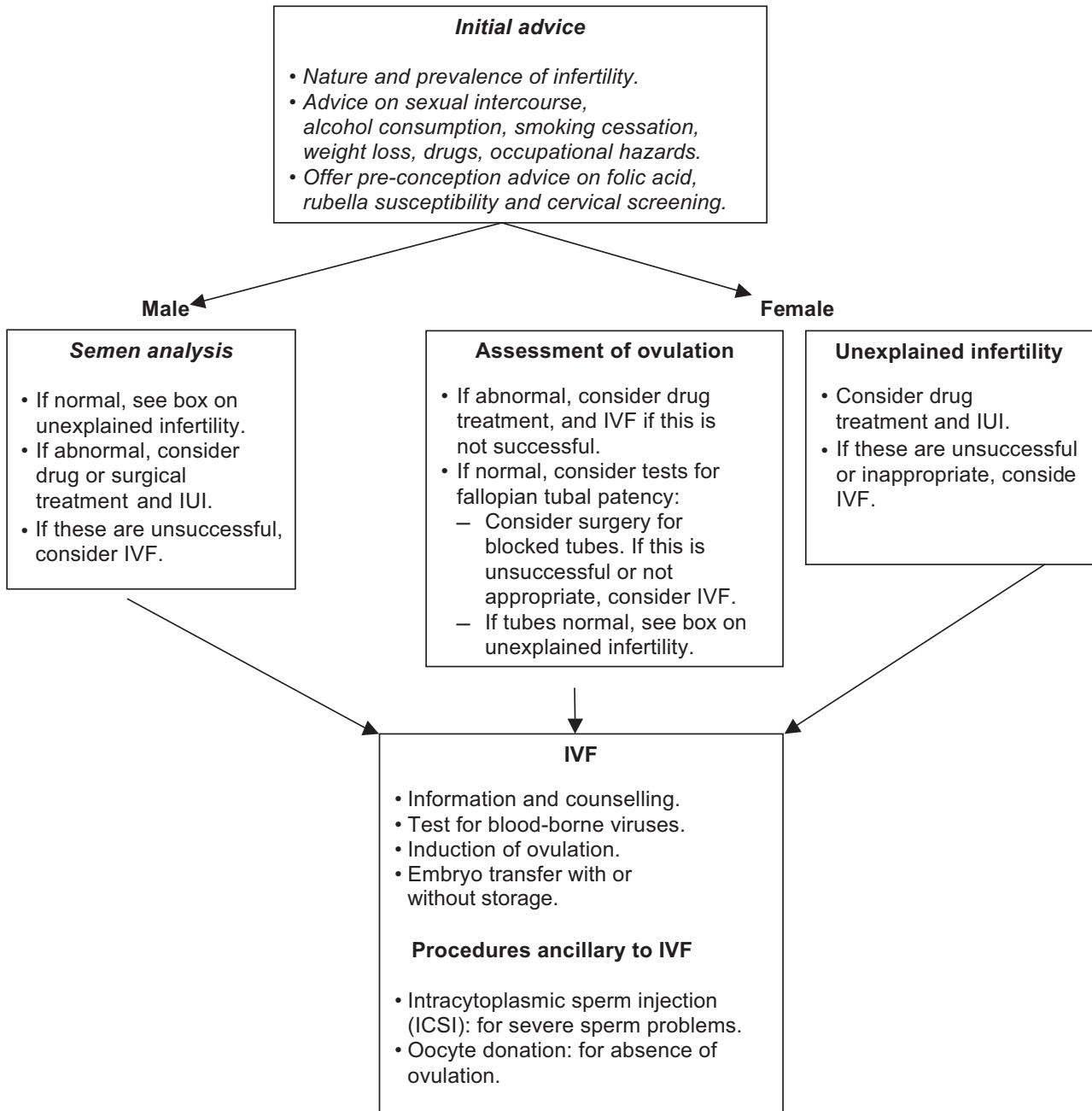
- 8.7 Some providers have a conflict of interest, both referring patients for IVF and then providing it in the independent sector. Particularly in these cases, the fulfilment of eligibility and access criteria needs to be recorded, with a signed affirmation from the referring clinician that they are met in full.
- 8.8 For example, a commissioner may find that all the local secondary care consultants who would be referring patients for IVF have a financial interest in providers that would be bidding for the IVF contract. The commissioner could then specify the format and wording of the referral proforma, requiring the referring consultant to sign a statement that the patient meets all the criteria in the local policy. The IVF provider would only be allowed to accept the referral if it were complete and signed.
- 8.9 However, issues may still arise if referring consultants can direct patients towards providers in which they have an interest, at the expense of those in which they do not. One way of responding to this might be through designated centres, nominated by commissioners to undertake an assessment and give assurance of probity of process.
- 8.10 We hope that commissioners will find this aid useful in developing their policies on fertility services.

## Annex A: World Class Commissioning cycle



## Annex B: Algorithm of assessment and treatment of people with fertility problems

Steps shown in italics should be taken in primary care.







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