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## ART in the European Union

Corinna Sorenson

At some point during their reproductive lives, approximately one quarter of all couples experience a period of infertility lasting over one year, leading many to seek council from an infertility specialist.<sup>1</sup> For those who need some form of intervention to assist with conception, there are a range of available treatment options, including lifestyle modification, medication, surgery, and a variety of Assisted Reproduction Technologies (ART), which cover *in vitro* fertilization (IVF), intra cytoplasmic sperm injection (ICSI), frozen embryo replacement (FER), egg donation (ED), preimplantation genetic diagnosis/screening (PGD/PGS) and *in vitro* maturation (IVM), see 'Jargon buster' on page 6. While success rates typically range between only 9% and 28%, ART offers the best chance for conception for many subfertile individuals.<sup>2</sup> To date, ART treatments have enabled the birth of over one million babies worldwide.<sup>3</sup>

Europe is the world leader in ART services, performing over half of all reported treatment cycles worldwide.<sup>4</sup> In 2002, over 324,000 cycles were reported in 25 European countries\*, an increase of 59% from 1997.<sup>5</sup> This marked increase is partly attributable to improved reporting systems, but also to a general expansion of ART procedures, reflecting changing social values and government budgets. According to patient registries of the European Society of Human Reproduction and Embryology (ESHRE), more than half of all treatment cycles in

Europe were carried out in France, Germany, and the United Kingdom.<sup>5</sup> However, in terms of cycles per number of inhabitants, the utilisation of services was highest in the Nordic countries and Slovenia. While significant differences exist across countries in terms of procedures used, IVF and ICSI were the most prevalent. In 2002, approximately 49,000 births occurred as a result of ART across European countries where all clinics reported to national registries, with the proportion of ART infants to all children born ranging from 1.4 (United Kingdom) to 4.2 (Denmark).<sup>5</sup>

While ART treatment presents the best chance for conception for many couples, these procedures and their potential long-term implications are often associated with high costs and safety concerns for both woman and child. As such, these technologies, particularly IVF, have generated important policy questions regarding their cost-effectiveness and safety. Moreover, as the use of reproductive technologies expands due to increased demand and scientific advances, issues surrounding appropriate regulatory mechanisms and equity in access to infertility services have become increasingly relevant for the EU.

### National regulation

The EU represents a complex, highly differentiated regulatory landscape of ART treatment. Across countries, there is considerable diversity in regulatory and funding schemes for

\* Data includes treatment using IVF, ICSI, FER, ED, IVM, and PDG performed between 1 January 2002 and 31 December 2002.

The Observatory is a partnership between the WHO Regional Office for Europe, the Governments of Belgium, Finland, Greece, Norway, Spain, Slovenia and Sweden, the Veneto Region of Italy, the European Investment Bank, the Open Society Institute, the World Bank, CRP-Santé Luxembourg, the London School of Economics and Political Science (LSE) and the London School of Hygiene & Tropical Medicine (LSHTM).

infertility, reflecting their different historical, cultural, social, political, economic, and religious traditions. While some countries place strict prohibitions on certain techniques, such as egg donation and research with embryos, others allow a wide choice of treatments, but require prior regulatory approval of clinical procedures. Some countries leave all decision-making on assisted-reproduction to the discretion of the physician and patient, with minimal governmental oversight. As a result, there are important regulatory and legal differences among nations in the provision of ART services, including divergence on key issues such as the handling of embryos, use of donors and surrogates, embryo research, and PGD treatment.

For example, cryo-preservation is allowed throughout most of the EU, albeit with restrictions. While Belgium, Denmark, France, Hungary, and the Netherlands permit the procedure without limitations, Portugal and Norway restrict the duration of treatment, typically three to five years.<sup>4</sup> Other countries (for example, Italy) allow the procedure for oocytes and sperm, but not embryos. Greece is the only country that has not issued legislation on cryo-preservation. In terms of surrogacy, all countries prohibit its use with the exception of the United Kingdom.<sup>4</sup> However, there are some countries, such as Finland and Greece, where no policy – positive or negative – exists.

In addition to these regulations, there is national, binding legislation on human reproductive cell\* donation, which typically encompasses issues of confidentiality, anonymity and non-remuneration.<sup>6</sup> Within such regulations, approximately 25% of EU countries prohibit egg donation, with the remainder either allowing such services or not regulating this area of cell donation. Moreover, most countries place controls on the import and export of human reproductive cells. While countries such

as Austria, Italy, Norway, and Slovenia prohibit all imports and exports of human cells, other countries allow such activities or only exclude the export of embryos and non-fertilized eggs. Many EU Member States also have put forth legislation governing the compensation and consent of cell donors.<sup>6</sup>

The EU's Tissues and Cells Directive (2004) was created to harmonize ART regulations. It aims to ensure the quality and safety of human tissues and cells used in relevant therapies, and provides for a coherent approach to the import and export of reproductive cells.<sup>6</sup> While this Directive does not affect IVF and other ART procedures (for example, ICSI) directly, it is relevant to PGD, reproductive cell donation, and embryo cryo-preservation. Although many countries already meet the requirements of the Directive, the primary objective is toward improved consistency and safety of clinical standards across Member States, in addition to enhanced data collection and monitoring.

### Funding and access

The majority of EU Member States have deemed infertility a medical condition and their national policies fund all or some portion of infertility treatment. However, there is significant variation between countries regarding the extent of public funding for ART treatments, from full to no coverage. In addition to public funding, third-party reimbursement by private insurance companies for infertility services is increasingly prevalent in Europe. Such entities typically provide partial or complete coverage for ART treatment.<sup>4</sup> Alternatively, some individuals decide to fully or partially self-fund infertility services, in some cases simply as a means to gain more expedient access to care and circumvent long waiting lists.

In all countries where there is coverage by a national health plan or a private insurance entity, there are restrictions on access to ART treatments, including the

type of ART treatment used, age of eligibility, number of allowable treatment cycles or embryo transfers, marital status, previous children, and place of treatment provision (i.e., public or private clinic) (See Case Study on *Funding and Reimbursement*). As a result of this variation, it is becoming increasingly common for individuals to travel to other countries to obtain a more expansive array of ART treatments and/or more affordable services (termed 'reproductive tourism'). (See Case Study on *Reproductive Tourism*).

### Cost-effectiveness and safety

With increased demand and utilization across Europe, important policy considerations have been raised about the cost-effectiveness of ART treatment, the economic and health implications of age and multiple births, and inequities in access to fertility services.<sup>2</sup>

Several studies have assessed the costs of a successful pregnancy resulting from IVF treatment. The available estimates vary widely, ranging from £4,202 to £90,112 (€6,139 to €131,651), depending on the number of cycles, use of combination regimens (for example, IVF with gonadotrophin or ICSI treatment), and inclusion of the cost of complications, obstetrics, and neonatal costs.<sup>7,8,9</sup> Beyond direct costs, there are indirect costs associated with ART treatment, such as time lost from work and child care expenses, which may contribute to the financial burden experienced by individuals undergoing infertility treatment.<sup>\*2</sup>

A number of factors affect the success, costs, and safety of ART interventions, particularly the age of a woman. Due to declining fertility and greater risk of miscarriage with increased age, the costs of IVF per successful pregnancy are more than three to five times higher for women aged 40 years and older, compared to those 30 years and younger.<sup>10</sup> Moreover, the use of ART treatment significantly increases the risk for multiple pregnan-

\* Human reproductive cells include eggs and sperm.

\*\* Cost effectiveness for ART is not measured across the lifespan of the child and therefore cannot take into account its contribution to society as an economically-productive individual.

cies. It has been estimated that following ICSI/IVF, approximately 24% of pregnancies are multiple births, which can result from treatment when more than one embryo is transferred to maximize the likelihood of conception.<sup>11</sup> In 2002, the majority of all transfers in Europe involved more than one embryo, with 76.4% of transfers requiring more than two embryos.<sup>5</sup> However, there is now a clear trend towards transfers with fewer embryos; for instance, compared to 2000 and 2001, the number of three embryo transfers decreased in 2002, from 33.3% and 30.8% to 26.9%, respectively.<sup>5</sup>

Despite these general trends, multiple pregnancy still remains an issue for many countries, with significant health and economic implications. Multiple pregnancies generate higher costs than single births, as a result of increased antenatal, obstetrical, and neonatal treatment, long-term disability services, and increased demands on family resources.<sup>2,9</sup> It has been reported that average hospital charges for twin deliveries were four times higher than for a singleton, with charges increasing exponentially for triplet and quadruplet deliveries.<sup>2</sup> Moreover, women with higher order pregnancies frequently require hospitalization, Caesarean delivery, and many give birth to premature, low-weight babies or suffer miscarriage.<sup>2</sup> Short- and long-term complications for the child include increased risk for perinatal mortality, mental retardation, learning disabilities, and behavioural problems.<sup>3</sup> Moreover, multiple births also affect families by introducing financial hardship\* and a higher incidence of maternal depression and marital problems.<sup>11</sup>

The health and economic implications of multiple births has increased regulatory and policy attention on the number of embryo transfers used during ART treatment, with increased movement toward single embryo transfer (SET). To date, there is inconclusive scientific data to suggest that the transfer of more than two embryos significantly enhances the

likelihood of pregnancy. Preliminary data emerging from Finland, Sweden, and the UK have demonstrated that single embryo transfer can be introduced on a national level without a decline in the ongoing pregnancy rate, but with a marked reduction in the proportion of multiple pregnancies.<sup>11</sup> This can be facilitated by targeting good prognosis patients (i.e., young women without previous failed IVF attempts) and effective embryo freezing (cryopreservation) programmes.<sup>11</sup>

Consequently, most countries have either passed national legislation or disseminated guidelines addressing the number of transferred embryos.<sup>2</sup> In general, northern Europe has been at the forefront of employing SET as a strategy for reducing multiple pregnancies. For example, Belgium only provides funding if SET is used in the first treatment cycle, while Sweden stipulates that only one embryo should be replaced, apart from exceptional circumstances.<sup>11</sup> Such legislation has proven successful in reducing multiple pregnancies; for instance, Belgium has experienced a near avoidance of triplet births, while the prevalence of twins has declined to approximately 7%.<sup>11</sup> Some countries also have undertaken a more comprehensive approach in promulgating guidelines on ART treatment. Most notably, the UK National Institute for Health and Clinical Excellence (NICE) recently issued new guidelines on fertility treatment (See Case Study on *NICE Guidelines*).

### Policy directions

Over the last 25 years, the use of ART treatment in the EU has increased significantly, with demand expected to rise as a result of increased incidence of infertility and associated scientific and technological advances. In addition, coupled with the dual concerns of infertility and population aging the increased uptake of IVF and other ART treatments has also been suggested as part of a population policy mix strategy. Consequently, the use of

ART treatment and its appropriate and equitable regulatory and funding mechanisms have become increasingly relevant for the EU, raising new and complex policy questions. In particular, there are several issues that deserve further consideration.

First, while there have been economic evaluations of ART treatment to date, more robust and systematic economic evaluations on IVF, in addition to some of the newer technologies, are needed in order to develop guidelines on public provision and reimbursement. When possible, indirect costs, including potential productivity loss and costs arising from ART complications (for example, multiple births), should be measured and included in analyses to more accurately assess the wider societal costs resulting from infertility treatment. At the national level, issues of cost-effectiveness need to be balanced against socio-cultural factors and budgetary constraints.

Second, regarding regulation, it appears that even in countries where some of the cost of ART treatment is covered by public schemes, a significant proportion of treatment is provided through private entities, presumably due to long waiting times and eligibility and reimbursement restrictions. Consequently, there is a need for increased investigation of relevant oversight activities to ensure the quality, safety, and equity of private sector treatment provision. Given that many of the factors (for example, eligibility) leading individuals to seek private care contribute to reproductive tourism for infertility treatment, it will also become increasingly important to develop effective monitoring of such services for both reporting purposes and to protect patients from low-quality and inappropriate treatment.

Third, due to the complexity of many issues related to ART treatment, there is a need to examine and debate the ethical and moral dimensions of ART, and how these issues relate to policy decisions regarding treatment access and financing.

\* Beyond the additional costs of caring for multiple children, there is also no routine financial or social support made available to parents of newborn twins or even triplets.



Such considerations include whether assisted conception is a medical need and/or an absolute right, and if treatment should be offered to non-heterosexual couples and single women.

Fourth, there is a need for improved data collection, monitoring, and reporting of ART services and patient outcomes within the EU, particularly with regard to the new Member States and services provided within the private sector. Currently, data generated from the national registries is incomplete, derived through different methods, and based on varying definitions of ART treatment. Improved monitoring will help to ensure the safety, quality, and effective use of ART. Moreover, information pertaining to the quality of public and private ART treatment facilities (typically clinics) should be publicly-available to facilitate informed decision-making among patients and to improve the treatment standards and accountability of clinics.

Fifth, there is a need for additional research regarding infertility and ART treatment, including:

- Monitoring the implementation of the EU Tissue and Cell Directive and the impact on data collection activities and clinical standards across Member States.
- Given the rapidly evolving base of reproductive technologies, it is important to monitor the impact of such advances on various outcome measures – costs, safety, efficacy (in terms of live births), cost-effectiveness, and equitable access. Moreover, newer treatments should be evaluated against existing ART procedures in order to ensure that practice guidelines are relevant and appropriately address all available and viable treatment options for infertility.
- While there is a recent trend toward fewer embryo transfers, multiple births remain a cost and safety concern. As such, there should be international movement toward more extensive use of SET in ART. Research is needed to identify potential barriers to the effective implementation of such policies. Moreover, further inves-

tigation is needed to determine other mechanisms (for example, guidelines, guidelines with sanctions, specific regulations) to decrease multiple births.

- Given the use of reproductive tourism for infertility treatment, there is a need to better understand the extent to which these services are being used and the underlying reasons driving individuals/couples to seek treatment in other Member States. Additionally, it will be important to monitor the impact of relevant policy and regulatory developments on the prevalence of reproductive tourism.

With the recent proliferation in the provision of ART treatment, there is increased scope for EU involvement in terms of addressing some of the resulting cost-effectiveness, equity of access, regulatory, and ethical implications. To effectively address these multifaceted issues, a European consensus forum(s) should be organized, bringing together a comprehensive spectrum of stakeholders such as clinicians, HTA experts, policy-makers, payers, and patients. Given the complexity of issues surrounding assisted-reproduction and the consistently evolving technology base, such meetings should be convened on an on-going basis. Understanding these issues is a fundamental prerequisite to deciding the broader questions of whether IVF and related treatments should be extended to address the declining fertility rates in Europe.

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# IVF and reproductive tourism

Philipa Mladovsky

The diversity in IVF prices, regulations and practices across Europe has created scope for people with the resources and desire to privately fund infertility treatment outside their own country. For example, in 1999, 30% of IVF recipients and 60% of donor egg recipients in Belgium came from abroad, with the high numbers of overseas patients attracted in part by the relatively low cost of Belgian IVF services.<sup>1</sup> More recently, central and eastern European countries also have become popular destinations for reproductive tourism due to low costs and ease of access to infertility services.

Reinforcing the movement of patients is the increasing availability of low-cost international travel. Some clinics facilitate access by offering treatment packages including visas, hotels and interpreters.

In addition to cost, at least five other features that promote reproductive tourism have been identified.<sup>1</sup>

*Prohibition of certain procedures for ethical reasons:* The Netherlands and England have recently prohibited sperm and egg donor anonymity to ensure the right to know the identity of genetic parents by offspring. In the 1980s in Sweden this policy led to IVF patients travelling to Denmark. Another example concerns pre-implantation genetic diagnosis (PGD), which can be used to reveal an embryo's gender. This use of PGD is not permitted in the UK; however, if parents-to-be wish to choose their offspring's gender, one clinic provides sex selection by offering treatment in Spain.<sup>2</sup>

*A procedure is unavailable due to safety concerns:* Some individuals may be willing to risk undergoing potentially unsafe treatments in countries with weaker regulation if they believe they can increase the chance of producing offspring.<sup>1</sup> Regulation has also created incentives for providers to establish clinics in countries where laws are relatively permissive,<sup>3</sup>

causing concerns about quality, safety requirements and standards.

*Eligibility criteria such as age, marital status or sexuality:* Some women are excluded from receiving services or coverage at public expense in their own country. For example, France prohibits IVF treatment for post-menopausal women and while there is no legal upper age limit for IVF treatment in the UK, most clinics are unlikely to treat women in their sixties; but such women can travel to eastern Europe or the US where this service is more readily available.<sup>1</sup>

*Long waiting lists:* This is often due to a shortage of donated gametes or embryos, inducing women to seek treatment where queues are shorter, particularly given that female fertility shows a strong negative correlation with increasing age.<sup>1</sup>

*Unavailability of a specific service:* This simply may be due to lack of expertise or equipment, causing people to travel abroad to seek out high-tech facilities.<sup>1</sup>

Should European Union governments be concerned about the practice of reproductive tourism and aim to minimise it by harmonizing regulations across countries? From a societal perspective, one libertarian view accepts variation between countries and the ensuing practice of reproductive tourism as a way of promoting tolerance and respect of the minority by granting individuals autonomy in a 'private matter'.<sup>4</sup> In contrast, a more restrictive view argues that a lack of EU-wide policy will eventually result in a convergence of national policies that accept the most permissive IVF practices.<sup>5</sup> This is probably a narrow perspective, since cost is a significant issue in most countries. Others argue that it is inequitable for wealthier Europeans to travel to purchase IVF services that others cannot afford.<sup>2,6</sup> Finally, another viewpoint is that societies that oppose

certain practices in assisted reproduction should not have to pay their social and economic costs<sup>2</sup> (for example, the costs of multiple pregnancy if a woman undergoes multiple embryo transfer overseas but gives birth in her home country).

From an individual perspective, reproductive tourism may be ill-advised as it may be a false economy once travel and accommodation costs are included. In addition, utilizing services provided in a foreign language may result in poor access to information and counselling, considered crucial for those undergoing IVF.

It is difficult to predict how the trend in reproductive tourism will develop in Europe. Some Europe-wide consensus is emerging on issues such as the number of embryos transferred in IVF treatment (see *Overview*), perhaps signalling an increase in collaboration among countries. Harmonization of regulatory developments may be difficult though, as there is currently little consensus of values relating to ART across Europe.

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## Jargon Buster

### **FER frozen embryo replacement**

Also known as embryo cryopreservation. The process of freezing fertilized eggs or embryos in a special protective culture medium and liquid nitrogen for use at a later date.

### **GIFT gamete intra-fallopian transfer**

A procedure in which eggs are mixed with sperm and the mixture injected into the fallopian tube, where fertilization takes place, as in natural reproduction.

### **ICSI intra cytoplasmic sperm injection**

An *in vitro* fertilization procedure in which a single sperm is injected directly into an egg. It is distinguished from conventional IVF where many sperm are placed with an egg in a dish and compete to be the first to enter the egg cell, after which the egg cell blocks the entry of any other sperm.

### **IUI intrauterine insemination**

Also known as artificial insemination. The process of preparing and delivering sperm so that a highly concentrated amount of active motile sperm (ie. sperm that swim in a progressively straight line) is placed directly through the cervix into the uterus.

### **IVF *in vitro* fertilization**

Generally, any technique in which egg cells are fertilized outside the woman's body.

### **IVM *in vitro* maturation**

A new method whose safety record has not yet been established, involving the collection of immature eggs and maturing them outside the body instead of using drugs to stimulate women to produce many mature eggs.

### **PGD/PGS preimplantation genetic diagnosis/screening.**

The testing of IVF embryos before implantation by removing one or more cells for analysis. It may also refer to the testing of eggs before fertilization.

### **Oocyte cryopreservation**

Procedure involving the freezing of unfertilized eggs for use at a later date.

### **Ovulation induction**

Involves the use of medication to stimulate development of one or more mature follicles (where eggs develop) in the ovaries.

# IVF/ART funding and reimbursement

Corinna Sorenson

The majority of EU Member States have introduced provisions within their national policies to fund all or some portion of infertility treatment, but with significant variation regarding the extent of reimbursement for ART treatments. Table 1 shows a broad continuum of funding for such therapies, with some countries, such as Spain and France, providing full coverage. Conversely, some countries, including Finland and Ireland, extend minimal to no reimbursement.

In conjunction to the level of public financing, most countries restrict access to treatment by placing eligibility criteria on reimbursement, such as age and marital status, or limit the conditions of treatment. Such constraints typically involve the service provider (for example, public or private clinic) and allowable treatment cycles or embryo transfers. The latter constraint increasingly is being implemented by insurance schemes, as existing evidence connects the number of cycles or transfers with not only increased costs, but also significant health and safety concerns (see *Overview*). Moreover, EU countries differ in terms of coverage of treatment-related drugs.

Due to access and reimbursement restrictions, many couples decide to fully or partially self-fund infertility treatments.<sup>1</sup> Others may seek private treatment even if public funding is available to gain faster access; in Sweden, for example, it can take up to two to three years to obtain treatment.<sup>2</sup> In fact, as infertility rates continue to rise, a market for private insurance has emerged, especially in Germany, Portugal, and Turkey. Typically, private insurance provides partial or complete coverage for ART services,<sup>3</sup> and this trend is likely to continue as demand for infertility treatment continues to grow. Alternatively, couples may seek services in other countries or in unlicensed clinics

with potentially questionable safety and quality standards. Despite these options, the costs of ART make services unattainable for many and, consequently, only a small proportion of infertile woman actually undergo treatment.

The availability and funding of ART treatment across Europe reflects various national health and economic factors, including fertility rates, infant mortality rates, GDP, and the proportion of health spending from government sources.<sup>2</sup> Moreover, as with most issues related to the complex landscape of assisted reproduction, access considerations are tightly bound with cultural and social mores, human rights, equity, and ethics.

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Table 1: Funding and reimbursement status of ART in EU-15

Country	Reimbursement of ART Treatments	Specific Eligibility Criteria
Austria	Since 2000, 70% of treatment, care, and drug costs for IVF/ICSI have been reimbursed by the <i>in vitro</i> fertilization fund. Reimbursement is provided for care obtained in facilities contracted by the fund and for couples with existing SHI coverage. Four cycles are reimbursed. If a pregnancy is achieved, reimbursement for 4 cycles starts again.	Couples must be married or living in a stable relationship for not less than 3 years. Women younger than 40; men younger than 50. No other medical condition(s) can be present other than infertility.
Belgium	Reimbursement for 6 cycles of ART, but limits on the number of embryos transferred.	Women younger than 42.
Denmark	Three cycles reimbursed, but only in public clinics/hospitals. Related drugs are 0–85% reimbursed, depending on total costs.	Information not available
Finland	Patients pay 25–40% of infertility treatment costs; the national Social Insurance Institution covers the remainder.	Information not available
France	Treatment reimbursed up to 100%, if provided in a public clinic/hospital. Services in private facilities are covered up to the public amount and patients pay the difference. No restrictions on the number of cycles. However, it is recommended to limit IVF/ICSI with embryo transfer to 4 cycles, if no pregnancy is achieved.	Couples must be married or living together for >2 years. Women younger than 43. Single women are not eligible.
Germany	Approximately 70% of 4 IVF or IVF/ICSI cycles or 2 GIFT are reimbursed. Additional treatment requires permission of the sickness fund. OI and IUI cycles reimbursed up to 6 (with gonadotropin) or 8 (without gonadotropin) attempts. Donor insemination is not covered.	Couples must be married or in a de facto relationship. Male must not have undergone sterilization. Women younger than 40. Only the costs of treatment using the gametes of the couple are reimbursed.
Greece	Treatment costs are reimbursed if performed in a public hospital/clinic. Otherwise, patients may be reimbursed a set amount per ART cycle, for up to 3 cycles.	Information not available
Ireland	No insurance coverage. However, couples can apply for a tax refund on treatment costs.	Information not available
Italy	Procedures partially reimbursed only in public hospitals or clinics operating within the national health service.	Information not available
Netherlands	A maximum of 3 IVF treatment cycles reimbursed under Social Health Insurance. No limit on OI/IUI and associated drugs are 100% covered. GIFT and ICSI treatment not reimbursed. Most private insurance companies also pay for up to 3 IVF treatment cycles.	Information not available
Norway	Treatment reimbursed only if provided in a public clinic/hospital. Medication is not typically covered.	Information not available
Portugal	ART procedures 100% reimbursed, only if provided in a public clinic/hospital.	Information not available
Spain	ART procedures 100% reimbursed, only if provided in a public clinic/hospital.	Couples must be married or in a de facto relationship.
Sweden	Between 1–3 cycles reimbursed, depending on the county council.	Information not available
UK	The National Institute for Clinical Excellence (NICE) recommends provision of up to 3 funded cycles of IVF. However, each Health Authority/Primary Care Trust determines eligibility and coverage. Level of provision and funding varies significantly across the country.	The NICE recommendations apply to women under 40 in couples who have been unable to conceive for 3 years or have an identifiable cause of infertility.

Sources: O'Donnell C et al, 2005<sup>1</sup>; WHO, 2002<sup>2</sup>; IFFS, 2004<sup>3</sup>; BMFG, 2004<sup>4</sup>; White C, 2004<sup>5</sup>; BRZ, 2002<sup>6</sup>.

Key: IVF=*in vitro* fertilization; ICSI=intra cytoplasmic sperm injection; GIFT=gamete intra-fallopian transfer; OI=ovulation induction; IUI=intrauterine insemination.



World Health Organization  
Regional Office for Europe



Government of Belgium



Government of Finland



Government of Greece



Government of Norway



Government of Spain



Government of Sweden



European Investment Bank



Veneto Region of Italy



Open Society Institute



World Bank



CRP-Santé Luxembourg



London School of Economics and Political Science



London School of Hygiene & Tropical Medicine

# NICE guidelines for infertility treatment

Corinna Sorenson and Philipa Mladovsky

A National Institute for Clinical Excellence (NICE) guideline was issued in February 2004<sup>1</sup> to outline appropriate treatment regimens for various infertility problems and to increase access to National Health Service-funded treatment by addressing the historic 'postcode lottery' (i.e., geographic variation in public funding of treatment) for ART services.

The guideline is based on an extensive review of clinical and economic evidence and expert consultation, and includes recommendations on nine different ART treatments. For IVF it recommends that: couples in which the woman is aged 23–39 and who have an identified cause for their fertility problems, or who have experienced infertility for at least three years, should be offered up to three stimulated cycles of IVF treatment without charge; and that no more than two embryos should be transferred during any one cycle of IVF treatment. These recommendations were based on evidence that after 33 years of age, treatment costs rise significantly with increasing age; the clinical effectiveness of more than three cycles is not conclusively proven; and that there may be significant resource savings from limiting embryo transfer after IVF. While the guideline received support for improving equity of access to NHS-funded assisted conception treatment, it also raised new issues relating to cost and implementation.

**Cost:** The guideline estimated the cost of one cycle of IVF to be £2,771 and if the guidance were fully implemented, the demand for infertility treatment would increase by 80%, at a projected additional cost to the NHS of £85m (\$159m, €126m). However, implementation of the guideline is discretionary, with no extra central funding for enforcement or development of services. Consequently, the Health Secretary stated that Primary Care Trusts (PCTs) could offer one funded IVF cycle from April 2005, with a longer-term aim of three cycles per eligible patient. As a result, there are concerns that PCTs already offering more

than one cycle of IVF might decrease services. Moreover, as one cycle of IVF has a notably low success rate (approximately 25%), funding only one cycle may not be a cost-effective investment, since many couples will not be able to pay out-of-pocket for additional treatment.

**Implementation:** There has been no central guidance from the Department of Health to the PCTs on implementation of the guideline or how to prioritise treatment for patients with varying eligibility criteria. By March 2005, a survey of all PCTs showed that only 22% of trusts were meeting the one cycle objective, with a further 58% confirming that they had taken the necessary steps for implementation. Moreover, IVF waiting lists have varied widely across the country; less than a third of the PCTs surveyed reported waiting times of one year or less while nearly 10% indicated waiting times of over two years.<sup>2</sup> It is estimated that in 2006, only 25% of IVF treatment in the UK would be funded by the NHS, with the remainder financed via private sources.<sup>3</sup> This figure does not represent much improvement over the estimated private to public funding ratio (80% and 20%, respectively) for IVF treatment prior to the NICE guideline.

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