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08 March 2017

The IVF Market in England, France, Germany and Spain - a tale of two systems in 2017

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Europe is the world leader in assisted reproductive technology (ART). In 2012, about 50% (nearly 640,144) ART cycles took place across 34 European countries, with in-vitro fertilisation (IVF) being the most common technique. Since then, demand for fertility treatment has continued to grow, driven by underlying demographic and social trends.

In July 2016, we published a brief on the Pan-European IVF market in England, France, Germany and Spain. Building on that analysis, this note is an update and takes into consideration the latest trends in the IVF market.

French and German General Elections

France and Germany will hold their general elections in spring and autumn 2017, respectively. In France, the question of widening access to IVF services to lesbian couples has been very politically sensitive. Despite passing legislation allowing gay marriage in 2013, demonstrations and political opposition prevented the government to expand access to IVF services. Any possible changes to the existing polices and regulations will depend on the outcome of the presidential elections in April 2017. The conservative front-runners, Francois Fillon and Marine Le Pen, are unlikely to support IVF for same-sex couples while the alternative candidate, Emmanuel Macron, has suggested he is in favour of opening IVF treatment to single and same-sex women. In Germany, access to publicly funded IVF services has been expanded to unmarried couples since January 2016. However, as polls show that the two governing parties, the centre-right CDU and centre-left SPD, have lost support, it is uncertain whether further support for IVF will materialise as the election comes into view.

Forward thinking regulation and innovation in Spain and England

In contrast to France and Germany's conservative approach to regulation, Spain's and England's forward thinking regulation has attracted IVF "tourists" to these two countries from Europe and further afield. In addition, recent legislative changes in some other European countries have made those countries increasingly attractive to IVF tourists, often offering cheaper options with fewer regulations. Spain is an established destination for IVF tourism, supported by relatively low prices for private treatment and high supply of gametes. Moreover, according to the World Bank, Spain still has one of the lowest fertility rates in Europe so the government is likely to favour increased access to IVF. Although clinics in England will find it hard to compete with Spain in terms of price, favourable regulation of innovative techniques, including mitochondrial donation now only available in the UK, have placed the country in an interesting position in Europe.

Rise of individual out of pocket payments

England's socially liberal restrictions on service eligibility, coupled with changing demographics, has created an increase in demand for IVF services that is not met by NHS sponsored service providers, who locally have been restricting access to services. Consequently, more and more patients are opting for financing their own services through the private sector. The situation in Spain is similar. The national health services (SNS) covers IVF costs and almost everyone can access IVF services. However, this results in long waiting lists and with the time sensitivity of ART, this pushes residents to opt for private clinics where payments are made out of pocket. This trend, however, is not echoed in France and Germany where those few who can legally access publicly-funded services usually do so without the same delays and limitations as seen in England and Spain. As a result, France and Germany's IVF markets experience less movement of patients to service that can only be covered by out of pocket payments.

England has proven it has the political will to support innovation and advancements in IVF. Cost constraints and inconsistent priority setting by local CCGs have constrained the public market in favor of the private market.

Spain is a magnet for reproductive tourism due to its liberal access criteria for IVF and progressive policies towards ART. It is also committed to fully reimbursing its citizens' procedures but its public sector is unable to meet these demands. Consequently, Spain's boasts a very vigorous private sector that is projected to grow.

In terms of cycle allowance, **France**'s government is the most generous of the 4 countries, signaling that this is a priority for the French system. Like England and Spain, France offers full reimbursement for citizens. However, it is much more restrictive in terms of who can legally access services.

Germany's IVF market operates within a conservative social environment. It is the most restrictive of all the countries but there is hope for more progressive amendments to the country's access criteria.

Background

Market Structure

People living in England, France, Germany and Spain have access to a mix of accredited public and private IVF providers.

Payers include insurance, government and individuals' out of pocket while providers are both public and private. England, for example, has private clinics and NHS fertility clinics, all of which facilities compete to attract NHS and/or private patients. There is a clearer dichotomy within Spain's system. The SNS covers 100% of costs but only at public clinics and private clinics are paid for out of pocket. France has more than one hundred public and private clinics and all IVF services are covered by the national Statutory Health Insurance (SHI). Germany's two payers are health insurers and local governments who pay a certain percentage after health insurance reimbursement. What and how much health insurance will cost varies from plan to plan.

Spain has the highest number of clinics and England the lowest. However, clinics in England and France tend to be large, while in Germany and Spain there is a mix of small, medium-sized and large providers. Although IVF is overall regulated at the national level in the 4 countries, their organisational models are different and policies that may appear similar are in fact not implemented in the same way, resulting in different outcomes. Overall, centralised systems like France and Germany guarantee more uniformity than the decentralised systems of Spain and England.

Access to publically funded (tax or insurance) services

Centralised healthcare systems guarantee a more homogenous access to IVF services than decentralised systems. In France and Germany, the entire eligible population has access to the same number of IVF cycles regardless of where they live. In Spain, access variation between regions has decreased due to more coordination between regions and trends towards re-centralisation of healthcare. However, until 2013, some regions limited access to IVF services to married couples only. England presents the highest access variation. NICE recommendations on the number of IVF cycles to be funded by the NHS are not binding on local commissioners (Clinical Commissioning Groups, CCGs) who are free to decide how many cycles they can/will actually fund as well as set the age limit for women. As a result, access depends on the place of residency and only a minority of CCGs finance the recommended 3 cycles of IVF.

In Spain, there are almost no restrictions on who can access publicly funded IVF services. In England, recommended criteria set by NICE relate to age and health of individuals seeking services. In both countries, single women and lesbian couples are eligible to access publicly funded services. In addition, criteria only apply to public services and individuals who are not eligible have the option to use private services.

Access to IVF services is more strictly regulated in France and Germany. The French legislation strictly limits access to IVF to couples with medically-diagnosed infertility, for both publicly funded and private patients. Legislation is not as explicit in Germany, but in practice few clinics offer treatment to lesbian couples and single women because male donors have little protection from paternity and the legal risk is too high. In addition, in both countries age restrictions apply. As a result of tougher restrictions,

Germany and France nationals make up a larger number of the fertility tourists found in Spanish clinics.

All countries put a limit on the number of IVF attempts financed by the public healthcare system. In this regard, France is the most generous country, with the SHI system covering 4 IVF attempts, performed in a public or an accredited private clinic for eligible individuals.

In Germany, legislation states that 3 cycles can be publicly funded, however, Germany's SHI only covers 50% of the costs in private and public clinics. It is possible for individuals to pay privately and use supplementary PHI, but PHI will only cover the cost of treatment if the insured person is also the one responsible for infertility.

In Spain and England, it is recommended that women can get up to 3 publicly funded full IVF cycles. In England, the NHS covers 100% of the costs in public and some private clinics but the precise number of IVF cycles funded is decided locally. Finally, Spain's SNS also covers all the costs but only for treatments delivered by public clinics.

Pricing

The price paid by public healthcare systems varies quite widely across and within the 4 countries. This is closely linked to the way healthcare is organised and the level of decision making. In France's highly centralised healthcare system, the SHI sets a national tariff for IVF services that applies uniformly to the whole country. Similarly, costs in Germany tend to be approximately the same across the country. In Spain and England, prices are set at regional and local level, respectively, and as a result there is some variation. In England, in particular, prices are negotiated between CCGs and can double between two providers. Recently, there have been calls for capping the amount IVF providers can charge the NHS but no action have been taken at this stage. Furthermore, the UK Parliament is increasingly concerned of differences in accessibility of IVF in different areas and recently have debated whether funding should come at the national level rather than through CCGs.

Wider regulatory and ethical concerns

Innovation

Innovation policy and regulation covers testing techniques, gamete donations and more recently genetic manipulation, which due to ethical concerns is strictly regulated everywhere. However, some countries have taken a more liberal approach than others. England, in particular, has emerged as leading on reproductive innovations. In 2015, the UK became the first country in the world to legalise mitochondrial donations (better known as the "3-parent babies" regulation), allowing for the replacement of a woman's dysfunctional mitochondria with the healthy mitochondria of a third-party female donor. In 2016, the Human Fertilisation and Embryology Agency (HFEA) approved a new more natural IVF technique and gave a licence to a research institute to carry out genetic manipulations on leftover human embryos from IVF clinics in order to better understand reasons behind miscarriage.

Researchers in France are responding to the increasing awareness of male infertility, an area of IVF that is experiencing growth. A French start-up has successfully reproduced in vitro spermatogenesis through the use of a testicular biopsy and cell therapy. More tests are being carried out before it is certain that it is free of defects and are functioning gametes. Nonetheless, the development is certainly

a step towards addressing male infertility. This process will be more appealing to couples as it allows for the assisted reproductive industry to move away from the use of sperm from anonymous donors.

Gamete and Embryo Donation

The use of a third party gamete in IVF is necessary when one of the partners' gametes are dysfunctional or for lesbian couples. Spain leads in this area with high supplies of gametes, in particular oocytes, and of embryos. Regulation guarantees donors' anonymity and oocyte donors also receive the highest financial compensation in Europe. In France, sperm, oocyte and embryo donation is also anonymous but supplies are much lower – donors are only compensated for travel expenses, while donations in England are not anonymous. Finally, although sperm donation is legal in Germany, oocyte and embryo donations are not.

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Kayleigh Hartigan Managing Director, UK and European Healthcare Advisory Office: +44 (0)20 3744 1774 x302 khartigan@marwoodgroup.com FOLLOW US ON SOCIAL MEDIA LinkedIn

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