The diversity of regulation and public financing of IVF in Europe and its impact on utilization

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Submitted on May 30, 2012; resubmitted on October 31, 2012; accepted on November 5, 2012

STUDY QUESTION: How do the different forms of regulation and public financing of IVF affect utilization in otherwise similar European welfare state systems?

SUMMARY ANSWER: Countries with more liberal social eligibility regulations had higher levels of IVF utilization, which diminished as the countries’ policies became more restrictive.

WHAT IS KNOWN ALREADY: Europe is a world leader in the development and utilization of IVF, yet surveillance reveals significant differences in uptake among countries which have adopted different approaches to the regulation and and public financing of IVF.

STUDY DESIGN, SIZE, DURATION: A descriptive and comparative analysis of legal restrictions on access to IVF in 13 of the EU15 countries that affirmatively regulate and publicly finance IVF.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Using 2009 data from the European Society of Human Reproduction and Embryology study of regulatory frameworks in Europe and additional legislative research, we examined and described restrictions on access to IVF in terms of general eligibility, public financing and the scope of available services. Multiple correspondence analysis was used to identify patterns of regulation and groups of countries with similar regulatory patterns and to explore the effects on utilization of IVF, using data from the most recent European and international IVF monitoring reports.

MAIN RESULTS AND THE ROLE OF CHANCE: Regulations based on social characteristics of treatment seekers who are not applicable to other medical treatments, including relationship status and sexual orientation, appear to have the greatest impact on utilization. Countries with the most generous public financing schemes tend to restrict access to covered IVF to a greater degree. However, no link could be established between IVF utilization and the manner in which coverage was regulated or the level of public financing.

LIMITATIONS, REASONS FOR CAUTION: Owing to the lack of data regarding the actual level of public versus private financing of IVF it is impossible to draw conclusions regarding equity of access. Moreover, the regulatory and utilization data were not completely temporally matched in what can be a quickly changing regulatory landscape.

WIDER IMPLICATIONS OF THE FINDINGS: Whether motivated by cost, eligibility restrictions or the availability of particular services, cross-border treatment seeking is driven by regulatory policies, underscoring the extra-territorial implications of in-country political decisions regarding access to IVF.

STUDY FUNDING/COMPETING INTEREST(S): There was no funding source for this study. The authors have no conflicts of interest to declare.

Key words: IVF / regulation / public financing / utilization / Europe
Introduction

Europe has been a world leader in the development and utilization of IVF from the first successful birth in the UK in 1978. By 2008, the five largest European countries were responsible for 273,000 cycles of IVF, compared with 148,000 cycles performed in the USA that same year (Ferraretti et al., 2012; Centers for Disease Control and Prevention, 2010). Nonetheless, utilization of IVF varies widely across the European Union (EU), ranging from 2687 cycles per million inhabitants (cpm) in Belgium to 150 cpm in Moldova in 2008, the most recent year for which data are available (Ferraretti et al., 2012). These differences in utilization rates do not appear to be attributable to epidemiological variations among European countries.

Indeed, the need for infertility treatment appears to be similar across countries and regions of the world. The prevalence of impaired fertility is difficult to estimate because self-reported estimates are subject to biases, times to conception are difficult to measure and clinical examination and tests are not always conclusive. The current worldwide prevalence of infertility is estimated at 9% of females in the reproductive age group (defined as women aged 20–44 years) who are in a marital or consensual union and currently not conceiving within one year while not using contraception (Boivin et al., 2007). Infertility may be a result of male or female factors, a combination of factors in either or both partners or an unknown cause.

While IVF is not the only available treatment for infertility, it is often recommended in cases of tubal obstruction and severe male factor infertility, as well as persistent infertility after failure of other treatments, such as fertility drugs, surgery for endometriosis or tubal blockage and IUI. In order to estimate the need for IVF treatment in a population, assumptions must be made about how many infertile people will seek treatment, how many will be candidates for IVF treatment, how many of those are willing to undergo IVF and how many cycles will be necessary for conception. Based on a conservative estimate of the number of IVF cycles needed to meet expected demand, assuming an uptake of 50% with one cycle per couple, health systems would need to provide 1500 IVF cpm each year (ESHRE Capri Workshop Group, 2001). Yet only a third of the EU15 countries met or exceeded that level according to the most recent available data: Belgium (2687), Denmark (2450), Finland (1698), Greece (1826) and Sweden (1751) (Fig. 1).

As a health-care good among others in the benefits basket, IVF occupies a unique place subject to a range of characterizations—from discretionary good to fundamental human right—that affect how it is regulated. Beyond the clinical and economic considerations that generally affect access and coverage decisions are complex social, historical and political dimensions that are sometimes cloaked in scientific and ethical rationales. For example, IVF in France is regulated pursuant to its bioethics law, which insists that a couple’s infertility be pathological in nature and medically diagnosed. The law incorporates social eligibility criteria as it describes the “man and woman making up the couple”, thereby excluding single women and homosexual couples regardless of pathology (French Bioethics Law, 2004). In a welfare state, it may be easier for policy-makers to limit access to treatment via laws that are external to the general health system rules rather than to do so within the system of public health coverage.

The clinical context also distinguishes IVF from other treatments. Unlike most maladies, infertility or subfertility is most often diagnosed in the context of a couple, not an individual patient. The medical intervention may involve a patient who herself has no identified pathology, as in the case of infertility linked exclusively to male factors. Age may simultaneously be a clinical factor underlying a patient’s subfertility and also a criterion that excludes treatment. Such restrictions may impede upon medical discretion in determining the appropriate treatment for an individual patient. When resort to donor gametes or embryos is necessary, the interests and protection of additional parties, including donors and the children who may be born as a result, are at issue,

Figure 1  IVF utilization in Europe, most recent data available. cpm, cycles per million; EIM, European IVF-Monitoring Consortium; ICMART, International Committee for Monitoring Assisted Reproductive Technology.
leading to regulations regarding whether donations may be made an-
onymously or not, which may have social, legal and potentially medical
implications.

It is against this complex backdrop that countries have enacted laws
regulating access to, and public coverage of, IVF. In the early days of
IVF, European governments had to play regulatory ‘catch up’, as
uptake of this innovation outpaced the legislative process. More re-
cently, evolving social forces, budgetary constraints exacerbated by
the economic crisis, increased cross-border treatment seeking and
supranational regulation have challenged previously settled paradigms.
Regulatory responses to IVF in Europe have evolved in differing ways, a
phenomenon described by Pennings as ‘legal mosaicism’ (Pennings,
2008).

The aim of this article is 2-fold: first, to describe the regulatory land-
scape in Europe by identifying the various forms of access regulation
and public financing and examining the patterns that emerge; and sec-
ondly, to explore whether a link exists between regulatory patterns
and access to IVF, as measured by the level of utilization.

Methods and Materials

The EU15 countries were selected for comparative analysis because
these countries have well-established health-care systems with exten-
sive experience in providing IVF treatments and monitoring via nation-
al, European and international registers. The comparison was further
limited to those countries that affirmatively regulate and publicly
finance IVF. Thirteen countries were identified as meeting the selec-
tion criteria for this analysis: Austria, Belgium, Denmark, France,
Finland, Germany, Greece, Italy, the Netherlands, Portugal, Spain,
Sweden and the UK. Ireland and Luxembourg were excluded
because neither country has IVF-specific regulations. In addition, IVF
is not covered by Ireland’s national health system and Luxembourg
does not report IVF data via the European IVF-Monitoring Consor-
tium. ‘Regulation’ as used in this article encompasses both legislative
and executive enactments, including authority to impose restrictions
devolved to the regional, local or treatment levels, which were in
force in 2009.

The descriptive analysis of the European regulatory landscape
focused on restrictions on access to IVF treatment, in terms of
general eligibility as well as public financing and the scope of available
services. The selection of specific regulations for comparison was
based on those that were common across countries and that poten-
tially could affect utilization of IVF services. The latter was informed
in part by recent research regarding the reasons patients seek cross-
border reproductive care, which found that it is most often driven
by legal restrictions in the home country (Shenfield et al., 2010).

The eligibility criteria we reviewed included age limits, social criteria
and medical diagnosis requirements. Because fertility declines with
age, soft or strict age limits may be imposed in an attempt to distin-
guish women with pathological infertility from those whose have
reached the natural limits of fecundity. Restrictions regarding the
civil status and/or the sexual orientation of treatment seekers may
be seen as a means of enforcing traditional family norms by limiting
access to heterosexual couples, although broader social trends in
Europe suggest a greater openness to alternative family arrangements.
Some countries require a medical indication as a pre-condition for IVF
treatment, based either on infertility/subfertility or to prevent the
transmission of a serious disease. Such requirements may also
operate as a proxy to exclude the so-called ‘socially infertile’ indivi-
duals who lack a formal medical justification for treatment.

Our review also examined the regulation of public coverage based
upon eligibility criteria and level of coverage as a measure of financial
access to IVF. In terms of eligibility, both medical diagnosis require-
ments and age limits may be more narrowly defined for publicly-
financed IVF, with the ostensible justification of limiting expenditure
of public health-care resources to those with demonstrated medical
need and statistically better chances for success. In addition, we
looked at the percentage of treatment costs officially covered by
public health insurance or other public financing for eligible individuals,
as well as the maximum number of treatment cycles covered, which
can affect drop-out rates and the likelihood of success.

Finally, we surveyed the range of reproductive technologies and ser-
vices, from the availability of PGD to the legality of surrogacy arrange-
ments. We decided to limit this part of the analysis to the regulation of
donor gametes (sperm and oocytes) and donor embryos because
donor restrictions can limit access and constitute a significant motivat-
ing factor for those seeking cross-border IVF (Shenfield et al., 2010).
Beyond the issue of the availability of donor gametes and embryos
is the question of donor anonymity, which can affect donor recruit-
ment (and thus the supply of donor gametes) as well as recipients’
willingsness to use them.

In order to explore the patterns of regulation across countries and
to determine whether there was an impact on utilization of IVF, we
undertook empirical legal research, which employs quantitative
methods to investigate the effects of laws, regulations and policies
on a particular outcome. We used multiple correspondence analysis
(MCA), a statistical tool that allows a joint observation of a number
of categorical variables—in this case, the different forms of IVF regu-
lation in a number of countries—in order to identify systematic asso-
ciations among them. MCA is a geometric approach that projects
the data of an n-dimensional space onto a succession of two-dimensional
planes. The row (countries) and column (regulations) points are pro-
jected in the space created by two axes, which represent part of the
total inertia (Micheloud, 1997). The two-dimensional display is appro-
riate for purposes of interpretation if the cumulative percentage of
variance explained by the first two axes of inertia is sufficiently large
(Härde and Simar, 2012). The multidimensional graphical map
allows a global view of the trends within the data. The strength of as-
sociation between the modalities of variables is defined by their spatial
closeness and their positions within the quadrants: the closer the
modalities are to each other, the stronger the association among
countries sharing these features, and the greater the distance of a
modality from the mean centroid (intersection of the axes), the
greater its significance in the interpretation of results. In addition, it
is possible to project supplementary variables onto the map to
provide, in effect, a ‘visual regression’. Utilization, the outcome inves-
tigated here as a supplementary variable, is one of the most common
proxies for measuring access to health-care services.

In order to perform the MCA, the regulations were first categor-
ized. Given the small number of countries in our analysis (13), it
was necessary to limit the number of categorical variables to as few
as possible. Moreover, variables that were highly correlated or that
represented services with low utilization were eliminated. The statis-
tical analysis was carried out in two steps. First, each of the variables
for the eligibility regulations (age limit, medical/social indications, civil status and sexual orientation) and one of the treatment variables (donor anonymity) were categorized as follows: age limit (soft, strict, none); only medical indications (yes, no); only couples eligible (yes, no); only heterosexuals eligible (yes, no); donor anonymity (yes, no, not applicable). Each of the selected categories, as well as the overall regulatory profiles for each country, were combined into an indicator matrix and then mapped. Four levels of utilization (<750, 750–1000, 1000–1500, >1500 cpm), ranging from less than half to in excess of the anticipated demand of 1500 cpm, were projected onto the map as supplementary variables.

Secondly, the IVF public financing variables (coverage level, maximum cycles covered, age limit and medical/social indications) were categorized, using the same categories for age limit and medical/social indications as for the eligibility analysis. Binary modalities were defined for the level of coverage (full, partial) and number of cycles (1–3, >4). These categories, along with the overall country profiles, were then mapped, again supplemented with the four levels of utilization. The MCA was carried out using SAS software version 9.1 for Windows (SAS Institute, Inc., Cary, NC, USA).

Data regarding access and coverage regulations came from a study by the European Society of Human Reproduction and Embryology of regulatory frameworks for medically assisted reproduction as of 2009 among the EU27 (ESHRE, 2010) and were supplemented with additional legal research. IVF utilization data are from the European IVF-monitoring reports for 2007 (de Mouzon et al., 2012) and 2008 (Ferraretti et al., 2012) and from the International Committee for Monitoring Assisted Reproductive Technology (ICMART) world report for 2003 (Nygren et al., 2011).

Results

The 13 EU countries studied reflect the diversity of regulatory approaches to eligibility and public financing of IVF, as well as to donor issues. Moreover, certain criteria underscore the fact that IVF is often subject to greater restrictions than other health-care goods.

### Eligibility for IVF

Patterns emerged with respect to certain eligibility criteria, in particular the personal characteristics of those entitled to treatment, reflecting a clear division between countries with more restrictive versus more liberal regulations (Table I). In seven of the 13 countries, a medical indication must form the basis for a demand for IVF, regardless of whether the treatment is publicly covered. Austria, Germany and Italy are particularly restrictive, limiting treatment to diagnosed infertility, while France, the Netherlands, Portugal and Sweden also permit the use of IVF to avoid the transmission of serious diseases, such as human immunodeficiency virus or genetic disorders. Of countries that insist on a medical indication, all but two countries (the Netherlands and Sweden) also require treatment seekers to be heterosexual couples. This latter restriction based on sexual orientation and relationship status is unique to fertility treatments among health-care goods.

Six countries have taken a more liberal approach to access to IVF. These countries (Belgium, Denmark, Finland, Greece, Spain and the UK) do not require a medical diagnosis of infertility for access to IVF treatment, nor do they exclude single women and lesbians. The Netherlands and Sweden fall between the two extremes, with both requiring a medical indication while allowing access to treatment for lesbians who are otherwise unable to conceive. Sweden excludes single people from access to treatment, while providing treatment to lesbian couples.

Regulatory patterns were less clear with respect to upper age limits. Of the six countries with no set age limit, three were among the countries with more liberal access (Finland, Spain and the UK), while the other three had more restrictive policies (Austria, Germany and Portugal). The remaining seven countries imposed either strict (fixed age) or soft (child-bearing age) limits for women to access IVF independent of coverage. Sweden’s soft limit also applies to men, requiring that they be sufficiently young to parent an infant through childhood. In countries with soft or no age limits, discretion to determine access based on age generally rests with the clinic or doctor, who may rely upon other clinical indicia, such as the patient’s ovarian reserve.

<table>
<thead>
<tr>
<th>Country</th>
<th>Age limit (years)</th>
<th>Only medical indications</th>
<th>Only couples</th>
<th>Only heterosexuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>None</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Belgium</td>
<td>Strict &lt;45</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Denmark</td>
<td>Strict &lt;45</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Finland</td>
<td>None</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>France</td>
<td>Soft (child-bearing age)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>None</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Greece</td>
<td>Strict &lt;50</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Italy</td>
<td>Soft (child-bearing age)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Strict &lt;45</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Portugal</td>
<td>None</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>None</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sweden</td>
<td>Soft (child-bearing age)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>UK</td>
<td>None</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Some countries have imposed fixed limits that would appear to be linked to the age of natural reproduction (<45 years for Belgium, Denmark and the Netherlands; <50 years for Greece), thereby avoiding controversy regarding post-menopausal motherhood.

**Public financing of IVF**

Regulations governing access to publicly financed IVF coverage are generally more restrictive than the general eligibility criteria as a means of limiting the covered population—and thus the budgetary outlays—based upon health system priorities (Table II). Indeed, all but two countries (Denmark and Finland) condition coverage upon the existence of a medical indication.

In contrast to the general eligibility regulations, four of the six countries with no age limit for access to IVF established age limits only for publicly financed treatment, while two with age limits reduced it for covered treatment. Overall, more than half of the countries (seven) set strict age limits for coverage, including two (Austria and Germany) that impose age limits for both women (40 years) and men (50 years). In the other countries with strict upper age limits for women, the range is from <40 years as in the UK to <50 years in Greece, with an average of <42. In countries with no fixed age limit, age criteria may vary by region, the size of the waiting list or be set by the center.

In terms of financial access to IVF, policies regarding the level of coverage and the number of cycles covered vary significantly. Four countries offer full coverage to eligible couples or individuals: Belgium, France, Netherlands and Sweden. ‘Full coverage’ in this context is defined as 100% coverage of at least one cycle of IVF on a national basis. In Sweden, full coverage is only available in public clinics.

Countries offering ‘partial coverage’ include those that impose additional fees and/or cost-sharing beyond what is generally applicable to other maladies, as well as those countries with regional differences in access to or level of coverage of IVF. For example, in the UK access to IVF is determined by primary care trusts, which has resulted in a ‘postcode lottery’ for services, with differing conditions for access to publicly financed treatment and no IVF offered in some areas. Variations in coverage can be seen in other countries as well, depending upon waiting lists (Finland), the particular social security organization providing coverage (Greece) or region (Italy and Spain). In countries providing partial public coverage, cost sharing for drugs is seen in Denmark, Finland and Portugal. Austria has a special fund outside of the health-care system that covers 70% of IVF costs, while Germany requires 50% cost sharing for IVF.

Another aspect of IVF coverage is the number of treatment cycles covered, which can in turn affect the cumulative birth rate following treatment as well as the drop-out rate for financial reasons. European countries have taken differing approaches to this issue. Some do not specify a maximum number of cycles, leaving the coverage decision to regional or local authorities (Finland, Italy, Sweden, UK), social security funds (Greece) or individual doctors (Portugal). However, most countries have established coverage limits of three or four cycles. In France, for example, a treatment cycle constitutes a fresh stimulated cycle, and any subsequent transfers using frozen embryos do not count against the four covered cycles. Moreover, if treatment results in a live birth, the ‘counter’ is reset to 0, so that another four cycles may be covered. Belgium has the most generous plan, covering up to six cycles provided the treatments are in compliance with its single-embryo transfer policy to reduce multiple births.

**Regulation of donor IVF**

All of the countries studied except for Austria and Italy allow donor gametes to be used in IVF, although Germany limits donor IVF to semen only (Table III). Austria’s restriction on the use of donor gametes in IVF was challenged under the Convention for the Protection of Human Rights and Fundamental Freedoms on the grounds that it was discriminatory for Austria to allow donor semen for IUI while completely prohibiting the use of donor semen or oocytes in IVF. The European Court of Human Rights found that there was no violation of the Human Rights Convention based in part on its contention

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**Table II** Legal regulation of IVF coverage in Europe (2009).

<table>
<thead>
<tr>
<th>Country</th>
<th>Coverage level</th>
<th>Maximum cycles covered</th>
<th>Age limit (years)</th>
<th>Only medical indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Partial</td>
<td>4</td>
<td>Strict female &lt;40, Male &lt;50</td>
<td>Yes</td>
</tr>
<tr>
<td>Belgium</td>
<td>Full</td>
<td>6</td>
<td>Strict &lt;40</td>
<td>Yes</td>
</tr>
<tr>
<td>Denmark</td>
<td>Partial</td>
<td>3</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>Finland</td>
<td>Partial</td>
<td>Varies</td>
<td>Strict &lt;43</td>
<td>Yes</td>
</tr>
<tr>
<td>France</td>
<td>Full</td>
<td>4</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>Partial</td>
<td>3</td>
<td>Strict &lt;50</td>
<td>Yes</td>
</tr>
<tr>
<td>Greece</td>
<td>Partial</td>
<td>Varies</td>
<td>Soft (child-bearing age)</td>
<td>Yes</td>
</tr>
<tr>
<td>Italy</td>
<td>Partial</td>
<td>Varies</td>
<td>Strict &lt;45</td>
<td>Yes</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Full</td>
<td>3</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Portugal</td>
<td>Partial</td>
<td>Varies</td>
<td>Soft</td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>Partial</td>
<td>3</td>
<td>Soft (child-bearing age)</td>
<td>Yes</td>
</tr>
<tr>
<td>Sweden</td>
<td>Full</td>
<td>Varies</td>
<td>Strict &lt;40</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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that ‘there is no sufficiently established European consensus as to whether ova donation for IVF should be allowed’ (European Court of Human Rights, 2011).

Related to the issue of donor gametes is the question of the donation of frozen embryos remaining after IVF treatments have ended. Couples may opt to use donor embryos, owing to infertility factors affecting both parties, as a last resort because of unexplained failure of IVF using their own gametes, or to avoid long waits for donor oocytes. Of the 11 countries that permit the use of donor gametes, three forbid embryo donation (Denmark, Sweden and Germany). The reasoning in Denmark and Sweden is similar, based on the idea that the child should have a genetic link with at least one of his parents. Although France prohibits ‘double donation’ of gametes, it nonetheless permits embryo donation subject to judicial oversight. Germany’s prohibition of donor oocytes effectively precludes the use of donor embryos.

An additional factor that may affect the decision-making of both donors and recipients is whether the donation is anonymous or not. The 11 countries that allow gamete donation are split on this matter, with 6 insisting on anonymous donations (Belgium, Denmark, France, Greece, Portugal and Spain), and the other 5 requiring or permitting non-anonymous donations (Finland, Germany, the Netherlands, Sweden and the UK). Interestingly, this dichotomy is not consistent with the countries’ overall liberal or restrictive regulatory policies regarding IVF.

### Table III

<table>
<thead>
<tr>
<th>Country</th>
<th>Donor gametes (semen, oocytes)</th>
<th>Donor embryos</th>
<th>Donor anonymity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Finland</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>France</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>Yes (semen only)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Greece</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Italy</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Portugal</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sweden</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>UK</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Regulatory patterns and impact on utilization

The first mapping of the MCA combined the IVF eligibility criteria with the donor anonymity regulations. The regulation of access to donor gametes was not included in this analysis because this information was captured by the regulation of donor anonymity. The donor embryo variable was excluded because it represents a very small portion of overall IVF utilization (e.g. <0.5% of total IVF cycles in the UK) (HFEA, 2010, 2011). The first two axes of inertia combined (Fig. 2a and b) explained nearly two-thirds (66%) of the weighted variance, providing a sound basis for analysis, particularly the first axis, which accounted for 49% of the variance (Fig. 2a).

The map of the first axis revealed that the restrictive and liberal modalities of the eligibility criteria were in direct opposition as we saw in the descriptive analysis, and two distinct groups of patterns of regulations and countries emerged. The countries with more restrictive policies limiting IVF eligibility to couples with medical indications (Austria, France, Germany, Italy, Portugal and Sweden) were grouped on the right side of the map. Within this grouping degrees of restriction are apparent, ranging from Sweden with its policy of extending eligibility to lesbian couples on the left side of the group to Italy at the far right side of the map because of its outright prohibition of donation. The countries with more liberal policies all extended IVF eligibility to single women and lesbians (Belgium, Denmark, Finland, Greece, the Netherlands, Spain and the UK) and were grouped on the left side of the map. The Netherlands was a bit closer to the center of the map as a result of requiring a medical indication for treatment. We can note the association of strict age limits with otherwise liberal regulatory regimes and soft age limits with the more restrictive policies.

The second axis of inertia (Fig. 2b) explained a smaller proportion of the variance (17%) and was essentially tied to the donor anonymity and age limit modalities. Age limits and the availability of anonymous donations were grouped in opposition to no age limits and prohibition of anonymous donations. The countries, however, were not clearly grouped but rather dispersed from Finland, Germany and the UK associated with no age limit and non-anonymous donation to France, Belgium, Denmark and Greece at the other extreme.

Examining the relationship between eligibility regulations and utilization, we found a clear negative relation between the degree of restriction of IVF eligibility and the level of IVF utilization, with utilization diminishing as the criteria became more restrictive and vice versa (axis 1). However, no link was evident between age limits and donor anonymity (axis 2 criteria) and utilization.

Regarding access to coverage and level of public financing of IVF, the second MCA mapping (Fig. 3a and b) also explained two-thirds of the variance (67%), but the picture was less clear in defining groups of countries with similar patterns of regulation. On axis 1 (Fig. 3a), the countries were spread across a continuum from more restrictive access to coverage (coverage restricted to women with medical indications who fall within strict age limits) that appear to be associated with more generous policies regarding the extent of coverage (covering a greater number of cycles covered and offering full coverage) to more flexible regulations in terms of age limit and medical criteria for access, which were closer to less generous policies offering only partial coverage and covering a smaller number of cycles. On axis 2 (Fig. 3b), the regulations were much closer to each other, except for the soft age limit and the countries applying this criterion (Sweden, Italy and Spain).

Overall, no relationship was found between the generosity of coverage and the degree of utilization. Moreover, no link could be found between the eligibility and coverage mappings, underscoring the fact that there is no clear relationship between the policy approach of a country with regard to the restrictiveness of its IVF eligibility criteria and its generosity in terms of public financing.
Figure 2 (a) MCA of regulation of access to IVF: variance explained by axis 1. The strength of association between the modalities of variables is defined by their spatial closeness and their positions within the quadrants: the closer the modalities are to each other, the stronger the association among countries sharing these features, and the greater the distance of a modality from the intersection of the axes, the greater its significance in the interpretation of results. Note: the size of the circles reflects the relative weight of the regulatory modalities in defining axis 1. (b) MCA of regulation of access to IVF: variance explained by axis 2. The strength of association between the modalities of variables is defined by their spatial closeness and their positions within the quadrants: the closer the modalities are to each other, the stronger the association among countries sharing these features, and the greater the distance of a modality from the intersection of the axes, the greater its significance in the interpretation of results. Note: the size of the circles reflects the relative weight of the regulatory modalities in defining axis 2.
Figure 3 (a) MCA of regulation of coverage of IVF: variance explained by axis 1. The strength of association between the modalities of variables is defined by their spatial closeness and their positions within the quadrants: the closer the modalities are to each other, the stronger the association among countries sharing these features, and the greater the distance of a modality from the intersection of the axes, the greater its significance in the interpretation of results. Note: the size of the circles reflects the relative weight of the regulatory modalities in defining axis 1. (b) MCA of regulation of coverage of IVF: variance explained by axis 2. The strength of association between the modalities of variables is defined by their spatial closeness and their positions within the quadrants: the closer the modalities are to each other, the stronger the association among countries sharing these features, and the greater the distance of a modality from the intersection of the axes, the greater its significance in the interpretation of results. Note: the size of the circles reflects the relative weight of the regulatory modalities in defining axis 2.
Discussion

While there is a clear positive relationship between the rate of utilization and the breadth of general eligibility for IVF, no link was found between restrictions to publicly financed IVF and utilization. Nonetheless, our analysis underscored that the more generous the coverage in terms of number of cycles and share of cost publicly financed, the greater the restrictions with respect to who may be covered. Budgetary constraints likely play a role in this phenomenon.

Two groups of countries with similar patterns of regulation of access to IVF were distinguished: one with more liberal regulations extending eligibility to single woman and lesbians and the other with more restrictive policies limiting access to couples (generally heterosexual) with medical indications; there was no clear grouping of countries with regard to the regulations of public coverage and no relationship between the general access patterns and the coverage pattern.

Other studies have explored the impact of various aspects of IVF regulation, particularly in terms of health economics (Collins, 2002; Chambers et al., 2009) or significant regulatory changes within a single country (Griesinger et al., 2007; Levi Setti et al., 2008). However, to our knowledge, this is the first to examine the impact of a broad spectrum of regulations, including those establishing social eligibility criteria, on IVF utilization across Europe. Our findings are consistent with a recent study examining the reasons patients seek cross-border reproductive care, which found that most do so to avoid legal restrictions related to patient characteristics, such as age, sexual orientation and civil status, and to obtain specific services such as anonymous gamete donation (Shenfield et al., 2010).

Our study has a few limitations. We faced the common challenge encountered in international comparisons: matching data across countries and across time. This is all the more difficult in this rapidly changing regulatory landscape. We chose to include the regulations in effect in 2009, while the latest utilization data is primarily from 2008. The temporal mismatch is exacerbated in the cases of Greece and Spain, for which the most recent utilization data are from 2003 owing to the low number of clinics reporting in later surveys.

In terms of method, we selected MCA, a descriptive approach, to compare the countries’ regulatory policies to their utilization rates. Normally an explanatory method, such as linear regression, would be used to measure the impact of these variables on the utilization rate. However, given the nature of the data, in particular the low number of countries, such a method could not be used. One option we considered was qualitative comparative analysis, which attempts to maximize the number of comparisons that can be made across cases in order to examine how configurations of conditions are linked to a certain outcome. We decided not to use this method because it is generally limited to dichotomous variables (Mills et al., 2006). Moreover, we believe that MCA is the best method for enriching the understanding of tabular data because of its graphical representation.

While there is no fixed minimum number of variables or modalities in MCA, the limited number of countries in our analysis could lead to misinterpretation. In order to reduce this possibility, we limited the number of categorical variables to the extent possible and systematically verified that there were no fewer than two modalities per variable. In defining categorical modalities, certain nuances may have been lost or not captured. For example, the discretization of continuous variables, such as utilization and the number of covered cycles, entails some loss of information. The same is true with respect to the use of broad categories, such as full versus partial coverage. We tested various configurations of the categorical variables to ensure that the diversity of regulatory patterns across the countries studied remained apparent in the analyses while avoiding outliers that could dominate the interpretation of the axes. Nonetheless, the balance between parsimony and interpretability requires subjective choices.

Similarly, the definition of a variable can lead to counterintuitive results. Indeed, while the association of strict age limits with more liberal regulatory regimes may seem anomalous, in fact, the strict age limits for general eligibility in the countries we examined were relatively high (45–50 years), corresponding to the natural limits of conception (Melby et al., 2005). Moreover, such active regulation may actually support higher utilization by sending clear signals to patients and healthcare providers regarding the contours of permissible treatment.

We focused on utilization defined as cpm population as the outcome measure to assess the impact of regulations. We also examined the cpm women of reproductive age (15–45 years) to determine whether age differences across the countries studied would affect the analysis. They did not. Nonetheless, utilization data alone do not permit us to draw conclusions regarding access to IVF. Indeed, it is debatable whether utilization is a good proxy for actual access to treatment, given that those with equal need and equal access to treatment may not make equal use of the opportunity because of individual preferences (Oliver and Mossialos, 2004). Certainly with respect to IVF, factors beyond access, including religion and cultural norms, may come into play. Finally, the utilization data do not distinguish cycles for cross-border treatment as opposed to in-country care.

While our study found that regulations related to public financing, including eligibility for coverage and level of financing, were not linked with utilization levels at the population level, it is important to underscore that we did not explore the effect of no public coverage on utilization, as all of the countries studied provided at least partial public coverage of IVF. Caution must be applied in drawing conclusions regarding the effect of public financing, particularly with respect to equity of access. Affordability has significant implications for equity, as only those individuals with the resources either to pay out of pocket and/or travel to a foreign jurisdiction will have access to treatment. This concern is illustrated by the significant drop-off in utilization that occurred in economically weak regions of Germany after IVF coverage was reduced to 50% in 2004 (Griesinger et al., 2007). Better data are needed on how much, and at what cost, treatment is privately financed versus publicly covered because the extent of IVF in the private sector implicates inequalities in access based on the ability to pay (Mladovsky and Sorensen, 2009). In the UK, for example, nearly 60% of IVF treatments are privately financed (HFEA, 2011). Cost, rather than restrictions based on social criteria, have been found to be a major motivation for British cross-border treatment seekers (Culley et al., 2011).

Whether driven by cost or legal restrictions, regulatory policies lie at the heart of cross-border reproductive care. The actual level of cross-border IVF in Europe is unknown, although estimates suggest a minimum of 18 000–22 500 cross-border IVF cycles annually (Shenfield et al., 2010). In March 2011, the European Parliament adopted a directive regarding patients’ rights in cross-border health care, delineating the circumstances under which a health system must finance treatment in another Member State (Directive, 2011). While coverage of treatments that are not included among the home country benefits is...
not required, the manner in which treatment is provided may differ (e.g. number of embryos transferred, criteria for donors, etc.) and may have public health implications for the home country. ICMART, which collects worldwide data on IVF, has called for prospective monitoring of cross-border reproductive treatment, including the reasons for seeking cross-border care (Nygren et al., 2010). At a minimum, collecting data on patients’ countries of origin would provide a much clearer picture of this phenomenon and would give policy-makers an important data point regarding the extent to which their own citizens are seeking care elsewhere and therefore the degree to which there may be inequity of access to IVF in a given country.

Acknowledgement

We thank Françoise Shenfield for her helpful comments on this manuscript.

Authors’ roles

K.B.B. contributed to data collection and analysis; led manuscript preparation. B.C. involved in substantial contribution to data analysis; contributed to manuscript preparation. K.C. contributed to study design and analysis; made substantial contribution to interpretation of data and manuscript preparation. K.B.B., B.C. and K.C. contributed to final approval of the manuscript.

Funding

No external funding was either sought or obtained for this study.

Conflict of interest

None declared.

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