This product is part of the RAND Corporation technical report series. Reports may include research findings on a specific topic that is limited in scope; present discussions of the methodology employed in research; provide literature reviews, survey instruments, modeling exercises, guidelines for practitioners and research professionals, and supporting documentation; or deliver preliminary findings. All RAND reports undergo rigorous peer review to ensure that they meet high standards for research quality and objectivity.
Between politics and clinics—the many faces of biomedical policy in Europe

Analysis of drivers and outcomes of Assisted Reproductive Technologies policy

Volume I: Synthesis report

Stijn Hoorens, Annalijn Conklin, Jan Tiessen

Supported by a grant from Schering-Plough
The research described in this report was supported by a grant from Schering-Plough.
Since the birth of the first “test-tube baby” in 1978, several million children have been born through in-vitro fertilisation (IVF). IVF and other assisted reproductive technologies (ART) are now commonly practised and they seem to have been accepted by society in most industrialised countries. But assisted reproduction continues to feature in the media, and it is high on the political agendas in many countries in Europe. Despite European integration and a movement towards evidence-based health policy, ART policy in Europe is highly heterogeneous.

The report is organised into two volumes. Volume 1 presents the findings and analysis of a comparative study on ART policy in three European countries. We aim to shed light on the substantial differences in the way governments have shaped their ART policy by studying these three countries – the United Kingdom, France and Italy – in more detail. We investigated the following key questions:

- To what extent are ART policy and the environment in which it is shaped different in these three countries?
- To what extent may the differences between these policy frameworks be explained by the contexts in which they have been designed?
- What have been the consequences of these differences for the outcomes of ART in different domains?

We conclude that the different contexts in which ART policy systems are designed may lead to variable outcomes in different domains. Some of these outcomes are unintended and even undesirable. Given the different drivers of policy, and their associated outcomes, we identify where common challenges and opportunities for ART policy design lie, and suggest possible ways for policymakers to address them. In doing so, the report aims to contribute to a more evidenced-based discussion and solution-oriented ART policy, which thus far has often been value driven.

The companion Volume 2 is a collection of the three case studies and a comparative analysis of the health outcomes in these countries. The case study reports all follow a similar format based on a common conceptual model, and provide a rich and detailed narrative on ART systems in these countries.

This report will be of interest to policymakers, clinicians, patients and researchers who are concerned with the regulation, policy implementation, funding and clinical practice of ART and its wider context and outcomes.
The study is funded through a research grant from Organon-Schering-Plough.

This document has been peer-reviewed in accordance with RAND’s quality assurance standards (see http://www.rand.org/about/standards/).

RAND Europe is an independent private, not-for-profit, research institution that helps improve policy and decision-making through research and analysis. For more information about RAND Europe or this document, please contact:

Stijn Hoorens
RAND Europe
Westbrook Centre, Milton Road
Cambridge CB4 1YG
United Kingdom
hoorens@rand.org
+44-(0)-1223-353-329

1 For more information about RAND Europe please see our website: http://www.rand.org/randeurope
Contents

Preface ........................................................................................................................ iii
Table of figures ............................................................................................................. ix
Table of tables ........................................................................................................... xi
Glossary of abbreviations and key terms ............................................................... xiii
Executive summary ................................................................................................ xvi
Acknowledgements ..................................................................................................xxiii

CHAPTER 1  Introduction ....................................................................................1
  1.1  Background ....................................................................................................1
  1.2  Need for policy analysis .............................................................................. 1
  1.3  Objectives and research questions .............................................................. 2
  1.4  Structure of this report ................................................................................ 3

CHAPTER 2  Analytical approach ..................................................................... 5
  2.1  Assisted Reproductive Technologies from four perspectives .................... 5
  2.2  Three case studies ........................................................................................ 8
  2.3  Caveats and limitations ............................................................................... 9

CHAPTER 3  Assisted Reproductive Technologies in France: liberté, fraternité et générosité ..........................................................................................11
  3.1  Assisted Reproductive Technology policy in France from four perspectives ...........................................................................................................11
  3.1.1  Regulatory context: comprehensive regulation with moderate restriction ........................................................................................................... 11
  3.1.2  Economic context: free access but to what limit? .................................. 14
  3.1.3  Clinical practice: a strong emphasis on guidance by best clinical practice ........................................................................................................... 15
  3.1.4  Welfare and healthcare tradition: Assisted Reproductive Technology policy fits the Bismarckian model ................................................................. 18
  3.2  Assisted Reproductive Technology outcomes: France shows positive trends in health outcomes over time ................................................................. 20
  3.3  Conclusions .................................................................................................. 23

CHAPTER 4  Italy: from far west to stringent south ............................................25
  4.1  Assisted Reproductive Technology policy in Italy from four perspectives ...... 25
4.1.1 Regulatory context: contested comprehensive and restrictive legislation ................................................................. 25
4.1.2 Economic context: fragmented system with high level of individual payment .......................................................... 28
4.1.3 Clinical practice: value-based ideology trumps international best practice ......................................................... 29
4.1.4 Welfare and healthcare tradition: Assisted Reproductive Technology services fall mostly outside the healthcare system and welfare state ................................................................. 34

4.2 Assisted Reproductive Technology outcomes: unintended consequences of the new law .................................................. 37
4.3 Conclusions ............................................................................................................................................. 40

CHAPTER 5 United Kingdom: postcode lottery in a reputable system ................................. 43
5.1 Assisted Reproductive Technology system from four perspectives ......................... 43
   5.1.1 Regulatory context: a centralised system with regional autonomy ........... 43
   5.1.2 Economic context: funding of Assisted Reproductive Technologies is patchy ....................................................... 46
   5.1.3 Clinical practice: Assisted Reproductive Technology practice is variable, but with minimum good practice standards ................................................................. 48
   5.1.4 Welfare and healthcare tradition: Assisted Reproductive Technologies treatment in the UK is mostly privatised ................................................................. 52

5.2 Assisted Reproductive Technology outcomes: improving health outcomes, but still many twins .................................................. 54
5.3 Conclusions ............................................................................................................................................. 57

CHAPTER 6 Between politics and clinics: a synthesis of differences and their drivers ................................................................. 59
6.1 Assisted Reproductive Technology systems in a comparative perspective ............... 59
   6.1.1 Regulatory context: Assisted Reproductive Technology regulation has many faces despite a common EU directive ................................................................. 59
   6.1.2 Economic context: there are considerable differences, but all have a proportion of individual payment ................................................................. 61
   6.1.3 Clinical practice: variation in Assisted Reproductive Technology outcomes reflects differences in clinical practice ................................................................. 62
   6.1.4 Wider healthcare and welfare tradition: Assisted Reproductive Technology has a distinct status, but its policy system is shaped by a tradition of healthcare and welfare services ................................................................. 64

6.2 Explaining differences between these countries ................................................................. 65

CHAPTER 7 From policy to parent: linking Assisted Reproductive Technology policy systems to their outcomes ................................................. 69
7.1 Assisted Reproductive Technology policy and the extent of provision are closely linked ................................................................. 69
7.2 The unintended consequences of restriction and individual payment ...................... 70
### Contents

7.3 What about long-term externalities of Assisted Reproductive Technology policy? ................................................................. 71

#### CHAPTER 8

**Conclusion and recommendations** ................................................. 73

8.1 In conclusion................................................................. 73

8.2 Addressing the challenges of Assisted Reproductive Technology policy in Europe .................................................... 74

#### REFERENCES

Reference list ............................................................................................................. 79
Table of figures

Figure 2–1 Conceptual diagram for the analysis of Assisted Reproductive Technology policy systems from four perspectives .........................................................5

Figure 3–1 Total transfers of IVF and ICSI per 100,000 reproductive women in France (1997–2004) ...........................................................................................................17

Figure 3–2 Embryo transfers after IVF and ICSI in France (1997–2004) ...........................................18

Figure 3–3 Proportion of singletons, twins and triplets in France (1997–2004) ...............................21

Figure 3–4 Proportion of lost pregnancies after IVF and ICSI is highest in France, compared to Italy and the UK (1997–2004) .................................................................22

Figure 3–5 Proportion of clinical pregnancy per transfer after IVF, ICSI and FER in France (1997–2004) .......................................................................................................23

Figure 4–1 Proportion of women older than 40 in Assisted Reproductive Technology treatment .................................................................................................................31

Figure 4–2 Provision of IVF and ICSI in Italy per 100,000 capita reproductive population (1997–2004) ........................................................................................................32

Figure 4–3 Proportions of 1-, 2-, 3- and 4-embryo transfers in Italy (1997–2004) .........................33

Figure 4–4 Proportion of fetal reductions in all IVF and ICSI cycles in Italy, France and UK (2000–2004) ............................................................................................................34

Figure 4–5 Change in proportion of deliveries to all transfers after Assisted Reproductive Technology treatment in Italy (1997–2002) ......................................................34

Figure 4–6 Triplet and quadruplet deliveries are a significant proportion of higher order deliveries in Italy over time .....................................................................................38

Figure 4–7 The chance of bleeding among all Assisted Reproductive Technology deliveries is highest in Italy between 1999 and 2004 ...........................................................39

Figure 5–1 Assisted Reproductive Technology provision in the UK shows an overall increase over time ............................................................................................................50

Figure 5–2 Proportions of 1-, 2- and 3-embryo transfers in the UK (1991–2006) ..........................50

Figure 5–3 Overall success rate of IVF and ICSI in the UK, by age (1992, 1996, 2000, 2004) .........................................................................................................................51
Table of tables

Table 2-1 Ferrera (1996) typology of welfare states ............................................................... 7
Table 2-2 Selection matrix (EU 15+2 countries) ................................................................. 8
Table 4-1 Regional distribution of IVF and ICSI cycles per million inhabitants ........... 30
Table 4-2 Cycles initiated by age group ............................................................................. 30
Table 4-3 Comparison of clinical practice (IVF and ICSI) in Italy between 2003 and 2005 .......................................................... 34
Table 4-4 Comparison of health outcomes (IVF and ICSI) in Italy between 2003 and 2005 ............................................................................ 38
Table 4-5 Italian cross-border ART from a sample of 53 foreign clinics .................. 40
Table 5-1 Estimated cost of multiple births to the UK NHS ........................................... 47
Table 5-2 Clinics offering Assisted Reproductive Technologies in the UK, by region .... 48
Table 6-1 Summary of key differences between Assisted Reproductive Technology systems from a regulatory perspective .................................................. 61
Table 6-2 Summary of key differences in Assisted Reproductive Technology systems from an economic perspective ....................................................... 62
Table 6-3 Summary of key differences in Assisted Reproductive Technology systems from a clinical practice perspective ...................................................... 64
Table 6-4 Summary of key differences in Assisted Reproductive Technology systems from the perspective of wider healthcare and welfare tradition ......................... 65
### Glossary of abbreviations and key terms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agence</td>
<td>Agence de la biomédecine</td>
</tr>
<tr>
<td>AI</td>
<td>Artificial insemination - the introduction of donor sperm into the vagina, the cervix or womb itself</td>
</tr>
<tr>
<td>ANAES</td>
<td>Agence d’accréditation et d’évaluation</td>
</tr>
<tr>
<td>ART</td>
<td>Assisted Reproductive Technology/ies - the collective term for all artificial techniques used to assist infertile women and men to conceive children including in vitro treatment (e.g. IVF, ICSI, FER, ED, GIFT, ZIFT) or in vivo treatment (e.g. IUI-H, IUI-D)</td>
</tr>
<tr>
<td>CCNE</td>
<td>Comité Consultatif National d’Éthique</td>
</tr>
<tr>
<td>CNAMTS</td>
<td>La Caisse Nationale d’Assurance Maladie des Travailleurs Salariés</td>
</tr>
<tr>
<td>CNT</td>
<td>Central Nazionale Trapianti</td>
</tr>
<tr>
<td>Cryopreservation</td>
<td>Storage of gametes or embryos by freezing at low temperatures</td>
</tr>
<tr>
<td>DHA</td>
<td>District Health Authorities</td>
</tr>
<tr>
<td>DPR</td>
<td>Decreto del Presidente della Repubblica</td>
</tr>
<tr>
<td>DWP</td>
<td>Department for Work and Pensions</td>
</tr>
<tr>
<td>ESHRE</td>
<td>European Society of Human Reproduction and Embryology</td>
</tr>
<tr>
<td>ED</td>
<td>Egg donation- the process by which a woman provides one or several eggs (ova, oocytes) for purposes of assisted reproduction</td>
</tr>
<tr>
<td>ET</td>
<td>Embryo transfer</td>
</tr>
<tr>
<td>FER</td>
<td>Frozen embryo replacement</td>
</tr>
<tr>
<td>Gamete</td>
<td>A mature reproductive cell, either a sperm cell or an egg cell</td>
</tr>
<tr>
<td>GIFT</td>
<td>Gamete intrafallopian transfer - the procedure in which eggs are retrieved from a woman, mixed with sperm and immediately replaced into one of the woman’s fallopian tubes, so fertilisation occurs inside the body (in vivo)</td>
</tr>
<tr>
<td>Gonadotrophins</td>
<td>Hormones that may be used as part of medically induced ovulation</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>HFEA</td>
<td>Human Fertilisation and Embryology Authority</td>
</tr>
<tr>
<td>Hybrid embryos</td>
<td>Generic term for embryos created through mixing genetic material of humans and other species</td>
</tr>
<tr>
<td>ICSI</td>
<td>Intracytoplasmic sperm injection - technique where a single sperm is directly injected into the egg</td>
</tr>
<tr>
<td>Infertility</td>
<td>Diminished or absent fertility; does not imply as irreversible condition as sterility. No conception in one year or more of regular unprotected coitus (Di Renzo et al., 1996)</td>
</tr>
<tr>
<td>IUI</td>
<td>Intrauterine insemination – a procedure in which a doctor places a small amount of concentrated and ‘washed’ sperm directly into the uterus through the vagina and cervix using a catheter.</td>
</tr>
<tr>
<td>IUI-D</td>
<td>Intrauterine insemination with semen from a donor</td>
</tr>
<tr>
<td>IUI-H</td>
<td>Intrauterine insemination with semen from the partner</td>
</tr>
<tr>
<td>IVF</td>
<td>In-vitro fertilisation – a technique whereby human eggs and sperm are mixed together in a laboratory to achieve fertilisation outside the body (in vitro). The embryos produced are transferred into a female patient’s uterus</td>
</tr>
<tr>
<td>LHU</td>
<td>Local health units</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence</td>
</tr>
<tr>
<td>OHSS</td>
<td>Ovarian hyper-stimulation syndrome - a serious complication following medical stimulation of the ovaries (the female reproductive organ producing oocytes from hormone-stimulated germ cells)</td>
</tr>
<tr>
<td>OI</td>
<td>Ovulation induction</td>
</tr>
<tr>
<td>Oocyte</td>
<td>Egg cell before maturation, produced by the woman each month in a follicle in her ovary</td>
</tr>
<tr>
<td>Ovum</td>
<td>A mature egg cell released during ovulation from an ovary.</td>
</tr>
<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
</tr>
<tr>
<td>PGD</td>
<td>Pre-implantation genetic diagnosis - the removal of one or two cells from an embryo to test for specific genetic disorders/characteristics prior to embryo transfer</td>
</tr>
<tr>
<td>PGS</td>
<td>Pre-implantation genetic screening - the removal of one or two cells from an embryo, for testing to ensure the chromosome number is correct (euploidy) and not more or less than usual (aneuploidy)</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetrics and Gynaecologists</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
</tr>
<tr>
<td>SET</td>
<td>Single-embryo transfer - the transfer of a single embryo into the uterus</td>
</tr>
<tr>
<td>SSN</td>
<td>Servizio Sanitario Nazionale</td>
</tr>
<tr>
<td>Sterility</td>
<td>Bearing no progeny (absence of fecundability); incapable of conception (Di Renzo et al., 1996)</td>
</tr>
<tr>
<td>USL</td>
<td>Unità Sanitarie Locali</td>
</tr>
<tr>
<td>ZIFT</td>
<td>Zygote intrafallopian transfer - transfer of embryos to the Fallopian tubes for purposes of achieving a pregnancy. Embryos are transferred at the fertilised egg stage</td>
</tr>
<tr>
<td>Zygote</td>
<td>The fertilised egg cell through the fusion of the male (sperm) and female gamete (ovum), before division begins</td>
</tr>
</tbody>
</table>
Executive summary

There is a striking variation among policy frameworks for Assisted Reproductive Technologies (ART) in Europe. However, public policy does not take place in a vacuum. The structure and effects of regulatory systems are shaped by the wider environment in which they are set. In the case of a policy domain as controversial as that of ART, it is likely that a wide set of cultural values and ethical considerations will have shaped, and will continue to shape, regulatory frameworks across Europe.

This report aims to shed light on the substantial differences in the way governments have shaped their ART policy, based on case studies of three countries: the United Kingdom, France and Italy. The ART policy frameworks in these countries have been studied in detail from four perspectives: regulatory context, economic context, clinical practice, and the wider welfare and healthcare tradition. In this executive summary we address the five research questions that have guided this study.

**Question 1: What are the differences in the ART policy framework, its underlying goals and context between the three countries?**

The case studies uncovered that ART policy frameworks are clearly set within a wider socio-political and economic context, unique to each country. From each of the four perspectives analysed, there are differences in the ART systems between the countries in terms of the rules of access, financing and the extent and nature of regulation. But there are also some similarities. Below, we explore each of these perspectives: regulatory, economic, clinical, and wider healthcare and welfare tradition.

---

**Regulatory context: ART regulation has many faces despite common EU directives**

The case studies have showed clearly that there are differences between the countries in their respective rules and conditions of access to ART services. All three countries have enacted legislation to regulate reproductive technologies; in the three countries they span a spectrum from fully comprehensive and liberal access (France), across more moderate but moving towards liberalising access (UK), to a highly restrictive law (Italy). This legislation refers to the techniques that are allowed, but also to the eligibility criteria for treatment. Since 2004 Italy has moved along this spectrum from an unregulated *laissez-faire* regime to one of the most restricted policy frameworks in Europe. The UK appears to be the most lenient country with respect to techniques available and also to parental relationship status; the government proposed to drop the “need for a father” and same-sex female couples are, in law, equally eligible for ART treatment to heterosexual couples.
Moreover, despite all three European countries being subject to a new European directive protecting the quality and safety of human tissues and cells, including reproductive cells, there are differences between France, Italy and the UK in the implementation of the Europe-wide regulatory context. Italy for example seems to be lagging, particularly in its arrangements regarding the reporting of serious complications.

**Economic context: there are considerable differences, but all have a proportion of individual payment**

In principle, the regulations for financing ART services in each of the three countries studied are similar, although they differ with respect to how costs are shared between the state and individual couples. Financing of ART services in Italy is dominated by a high level of personal payment. In France ART is largely funded through social security via the national health system. The French society seems more willing than those of other two countries to accept the fact that a comprehensive national healthcare system will inevitably be costly and the cost may be expected to increase. However, as in the other countries, there are additional fees for treatment in private clinics. The audit culture in the UK is reflected in a focus on “value for money”, where clinical guidelines aim not only at good clinical practice, but also at cost-effectiveness. Furthermore, autonomous Primary Care Trusts (PCTs) are not legally bound by national guidelines. They have regional autonomy to allocate the healthcare budget on the basis of local health priorities, and hence there is a high proportion of personal payment for ART treatment. Similar regional disparities may also be observed in Italy.

**Clinical practice: ART treatment does not always reflect good clinical practice**

Despite European integration and a movement towards health policy derived from evidence-based best clinical practice, the differences between the countries in clinical practice and consequent clinical and health outcomes are surprisingly large.

A common trend in all countries is the marked increase in the use of intracytoplasmatic sperm injection (ICSI). Although this technique – mainly used when sperm count is low – is similar to IVF, it is more expensive and does not necessarily have higher success rates. Literature suggests that in Europe ICSI treatment is not always in accordance with good clinical practice. Furthermore, despite good practice guidelines, the proportion of multiple-embryo transfers is still relatively high in the UK and Italy. As multiple pregnancies are associated with adverse health outcomes for both mother and child, the clinical community agrees that a shift to more single-embryo transfers (SET) is desirable. Although there is a shift away from transferring three or more embryos, 2-embryo transfers still dominate clinical practice in the UK. The proportion of multiple-embryo transfers in Italy is the largest of all three countries, and has increased since the introduction of the new law. Italian regulation requires that all embryos created must be transferred to the uterus, despite the increased health risks.

**Wider healthcare and welfare tradition: ART has a distinct status, but its policy system is shaped by a tradition of healthcare and welfare services**

We have found that the wider welfare and healthcare tradition also contributes to the distinct characteristics of ART policy frameworks. France’s generous funding of ART treatment for infertile patients reflects the principles of its Bismarckian welfare system,
based on solidarity with disadvantaged individuals. Furthermore, ART services in France are provided within the organisational framework of the healthcare system, and accreditation of infertility clinics is similar to that of other healthcare institutions. However, ART reimbursement stands out as a generous scheme. In Italy’s Southern system, access to welfare benefits and social security payments has traditionally been fragmented and coverage has not been comprehensive. The types of benefits vary by occupation, the length of contribution and region. As with ART, limited access to certain services, therefore, is not unusual in the Italian welfare state. However, because of the absence of an explicit designation of infertility as an illness, ART does not fall within the national health service (Servizio Sanitario Nazionale, SSN) in Italy. The status of infertility within the National Health Service (NHS) in the United Kingdom is also ambiguous. Owing to this status, infertility services are characterised by considerable involvement of the private sector, which is otherwise not common in Britain. Other aspects are more in line with its wider tradition. The reluctance to provide general access to ART services reflects the principle of providing a basic protection rather than generous coverage in UK’s Anglo-Saxon welfare system.

**Question 2: Can these differences be explained by the different contexts in which they have been designed?**

Based on analysis of these three countries, we have identified a number of contextual factors that shape the policy frameworks for ART and their outcomes. As this sample consists of the three case studies only, we do not purport to identify any causal relationships; rather, relationships are exploratory.

The reimbursement of ART and the medical practice have a crucial impact on ART outcomes. In addition to the desire of infertile couples to become pregnant, we see the explanatory factors or drivers of ART policy clustering around the key link between the financing of ART treatment, the medical practice of ART (choice of techniques) and the clinical outcomes. Various factors within a society influence willingness to make ART treatment accessible to a wider population and to reimburse those who use it. The mechanisms and level of reimbursement in turn substantially shape the incentives to use certain medical techniques and adopt certain practices. Effective regulation and implementation of best practice guidelines may, however, limit how far these financial incentives translate into treatment decisions. At the same time, both reimbursement and medical practice are influenced by a multitude of intervening factors in the different contexts.

Definition as an illness is a crucial factor influencing ART policy

The most crucial determinant that influences reimbursement for ART in the three countries has been whether infertility is defined as an illness that is analogous to other medical conditions. This determines whether ART treatment is seen as a conventional medical intervention (France) rather than as a means to support the right to have children (UK), or a health privilege of the more affluent couples (Italy). In France this biomedical labelling decision led to a full integration of ART treatment into the healthcare system. In contrast, funding of ART is patchy both in Italy and the UK because of the absence of such a label.
A driving force behind this determinant is the power of the country’s medical profession relative to other stakeholder groups and the subsequent mechanisms to incorporate stakeholder perspectives in decision-making. Drivers behind the willingness to reimburse ART treatment include: fragmentation of healthcare budget allocation, the attention to accountability and value for money in public sector expenditure, and the guiding principles underlying the social security system (needs-based versus universal healthcare).

**Clinical practice of ART is driven by funding, law and clinicians**

We found three main driving factors in ART clinical practice. Firstly, funding arrangements drive the practice of ART. For example, multiple-embryo transfers are more common in environments characterised by a high degree of individual payment. Secondly, our review uncovered substantial differences in the ethical regulation of ART treatment, which influences the selection of treatments available, the application of certain techniques and eligibility criteria. The laws are very much an expression of how different stakeholders were able to shape the public debate about the regulation. Most striking here is Italian regulation, whereby all embryos created must be transferred because of the Roman Catholic dictum that life begins at conception, despite the increased risk of multiple pregnancies and births to the health of both mother and child. Finally, the importance of best practice guidelines in the ART system is that they shape medical practice as such. As these guidelines are usually not legally binding, they can be circumvented under the pressure of other strong incentives, in particular financial ones.

**Question 3: To what extent have these differences led to variable outcomes in different domains?**

The differences between ART policy frameworks have consequences for their outcomes. We have linked the characteristics of certain ART policy systems to the direct and indirect, intended and unintended consequences.

**ART policy and the extent of access to ART are closely linked**

At its most basic level, legislative restriction of treatment has an impact on access to ART services. Prohibiting access to certain technologies or relating the eligibility for treatment to certain conditions or rationing criteria (such as relationship status, gender or age) reduces the number of people who can access ART services. Additionally, the level of funding – and the amount of individual payment – is an important driver of the demand for infertility treatment. The direct outcome of increased ART treatment is that couples with fertility problems have the opportunity to conceive biological offspring. It would be an oversimplification, however, to argue that increasing the provision of ART leads to a positive outcome *per se* as ART cycles may be inappropriate for certain couples, or could have been avoided.

A direct impact of increasing ART provision is the incumbent costs. These costs consist of a number of components. The burden of the direct costs of treatment, depending on the reimbursement regime, is borne by patients and those contributing to the social security system or insurance scheme. The indirect costs include infrastructure costs, equipment costs, opportunity costs of lost employment, and so on. Furthermore, when ART treatment is successful, and especially when it results in multiple pregnancy, the inherent maternal and neonatal healthcare costs are absorbed by the public or private health system.
The unintended consequences of restriction and individual payment

In the case of Italy, we learned that some regulations which are the result of moral considerations and ethical debates may conflict with what the clinical community considers good clinical practice. While protecting the embryo was the original aim of this legislation, multiple embryo transfer tends to threaten the health of both mother and subsequent children.

Furthermore, we concluded that restriction of treatment and limiting financial compensation for ART may have unintended consequences. Firstly, when certain ART services are not available to couples in their native country, they increasingly travel abroad to undergo treatment in a country where it is available. Although cross-border ART may be seen as an opportunity to enjoy moral pluralism, it raises domestic issues of inequality of access to healthcare as the ability to undergo treatment abroad depends upon the financial means of infertile couples. It also raises complex issues of audit, standards, quality clinical practice, legal remedies in cases with adverse outcomes and accountability.

Secondly, the case studies seem to confirm that a high proportion of personal payment is an incentive to couples to prioritise a high pregnancy rate over best clinical practice. In the UK, for instance, the multiple birth rate is surprisingly high for a system with such a tradition of emphasising good clinical practice.

In addition to these indirect outcomes, ART may have longer term externalities, for example demographic impacts, that have so far hardly been considered in policymaking.

**Question 4: How could these outcomes be interpreted, given the context differences?**

Even though their outcomes may not all be equally desirable, it is difficult to challenge the foundations of these different ART policy frameworks. They are grounded in their country-specific contexts and are usually the outcome of a legitimate democratic process. However, the implementation of these principles in clinical regulations may be at odds with good clinical practice, as is the case in Italy. The unintended outcomes of Italy’s ART system need serious consideration and should be addressed.

ART policy, particularly the definition of infertility, is a complicated matter. Not being able to conceive may be a medical condition, but may also be bad luck. Or, infertility may also be due to wider public health issues such as rising age at first pregnancy, sexually transmitted diseases, obesity, smoking, etc. If infertility is defined as an illness, ART will be imbedded in the wider healthcare framework. Sizeable public expenditure on ART in this context is merely an element of the entire healthcare system. If infertility is not explicitly defined as an illness, as is the case in the UK and Italy, principles for provision of care and access to treatment may deviate from those of the national health system. Countries have different approaches to addressing these issues; in Italy and the UK the decisions to address inequality of access to treatment vary regionally.

If citizens’ financial means become an important determinant of their ability to afford infertility treatment, a treatment decision may lead to unnecessary health risks for mother and child. These risks have to be addressed regardless of the societal context – not simply because in Europe the costs of these risks will eventually have to be met by society.
Question 5: Can we make some broad recommendations to address the challenges of ART policy, while taking account of their context-specific requirements?

We have assumed that a policy framework is largely defined by the context in which it is based. Taking account of these context-specific requirements, we have formulated several recommendations that can help in addressing the challenges to ART policy identified:

- Monitor and evaluate the implementation of the EU tissues and cells regulatory framework to ensure its rigour and harmonise protection of human health regarding assisted reproduction.

- Address the negative consequences (health and economic) of multiple-embryo transfers, and consider compensation of the marginal reduction of success rates following a shift to single-embryo transfer (SET) through a number of strategies, including selection of high quality embryos and oocytes, preservation of high quality embryos, and funding of research into human reproduction and embryology. Implementation of these strategies will depend on the acceptability in local context.

- Cost containment through targeted ART funding, for example target good prognosis patients, means-testing of reimbursement schemes, co-payment. This could involve only subsidising the younger infertile patients as age is the best prognosis factor, or bringing age limits down, or choosing only to fund cycles with a certain likelihood of success (e.g. over 10%).

- European co-ordination of cross-border ART. This could take a similar form as the mediation and allocation of organ donation procedures by the international organisation, Eurotransplant. Furthermore, the extent of cross-border ART should be monitored through improved data collection at European level.

- Critically examine ART policy in its wider environment of trends and drivers of infertility (such as the increasing age of motherhood, consumption of alcohol and tobacco, prevalence of obesity, and sexually transmitted diseases and infections), and consider promoting a Europe-wide co-ordinated public health campaign for primary prevention of infertility; for example through detection and treatment of sexually transmitted diseases and infections, prevention of obesity, work-friendly family policies that facilitate earlier motherhood, etc.
We would like to thank a number of people who contributed to this report. First and foremost, we would like to commemorate Alice Farrands, who played an essential role during the inception of this study. Sadly, Alice died in 2007 after having lost a battle against cancer; she was one of the loveliest, liveliest and funniest people around. Alice is one of a number of colleagues whom we wish to thank for their significant contribution to the in-depth case studies that informed this report. We thank Daniel Jones, Lisa Klautzer, Sarah Olmstead, Miriam Shergold and Carlo Drauth. Jenny Knight and Susannah Wight have been responsible for copy-editing the two volumes. In addition, we wish to thank our correspondents at Organon – Dougie Gibb, Véronique Boniface, Tetsuro Namba and Fabio Lepre – who provided feedback on the case study reports. Finally, we wish to acknowledge the peer reviewers of this report, Dr Susan Bewley (Guy’s & St Thomas’ NHS Foundation Trust), Dr Lone Schmidt (University of Copenhagen) and Mark Connolly (Global Market Access Solutions), who provided substantive comments on earlier versions of this report.
CHAPTER 1  Introduction

1.1  Background
In the late 1970s a young British couple, frustrated about their inability to fulfil their wish to have a child, agreed to take part in an experimental medical procedure initiated by British scientists Patrick Steptoe and Robert Edwards. An egg cell was removed from one of the woman’s ovaries and fertilised in a laboratory, and the resulting embryo was implanted in her uterus. On 25 July 1978 Louise Brown, the world’s first “test-tube baby” was born. The event spurred a public and political debate about the ethics of creating human embryos in a laboratory. Many heralded this scientific breakthrough in infertility research, but there were also voices arguing that the scientists should not be “playing God”.

Thirty years onwards, in-vitro fertilisation (IVF) is widely applied and more than 3 million children have been born through this and other Assisted Reproductive Technologies (ART). Nonetheless, assisted reproduction continues to feature frequently on newspapers’ front pages, and it is still high up on the political agenda in much of Europe. While the creation of embryos in vitro seems to have been accepted, debates now concentrate on whether same-sex female couples should have access to treatment, whether embryos can be screened for genetic conditions, and whether surrogacy or donation should be allowed. In addition to these ethical debates, there is increasing discussion in the health policy literature, as well as in decision-making arenas, about the status of reproductive treatment in the wider healthcare system. In particular, attention seems to focus on two questions: ‘Who should be eligible to infertility treatment?’ and ‘Who should bear the costs of those who are – should it be the couple, the government, a private insurance company, or a combination of all three?’

1.2  Need for policy analysis
In line with other medical disciplines, gynaecological and obstetric societies have issued guidelines to promote best clinical practice for ART. Governments have introduced legislation to regulate this treatment too. Policy frameworks for clinical practice across the developed world are roughly comparable, as they refer to the available evidence base of (cost-)effective diagnosis and treatment. Despite this convention and unlike in most medical disciplines, both policy and practice for ART portray a heterogeneous picture across different countries. For example:
• in Germany the government has decided that only married couples can have access to ART, while in the United Kingdom single women are now eligible for treatment;
• in Belgium up to six cycles of ART are reimbursed, but there are limits on the number of embryos transferred, while in Ireland there is no insurance cover for ART;
• donation of egg cells is officially allowed in Belgium, Denmark, Finland, France, Hungary, Slovenia, Spain, Sweden and the United Kingdom, while it is prohibited in Austria, Germany, Italy, Norway, Portugal and Switzerland.

This ongoing level of variation in Europe is surprising, for two important reasons. Firstly, one might expect that the principles of evidence-based medicine would result in a harmonised treatment approach to improve efficiency and efficacy. Secondly, the recently established EU Cells and Tissues Directive (2004) aims at harmonising ART policy in Member States with a view to ensuring minimum standards for human health protection. All EU Member States are expected to comply with this supra-national directive.

However, public policy does not take place in a vacuum. The structure and effects of regulatory systems are shaped by the wider context in which they are set. In particular, a country’s welfare tradition, and specifically its healthcare provision, can be expected to have shaped the setting of regulatory standards and financial policy as well as enforcement strategies. Furthermore, the presence of consensual or adversarial cultural orientations at the policy domain level, or differences in social values, may also account for differences in regulatory approaches. In the case of the ART policy domain, it is likely that a wide set of cultural values will have shaped, and will continue to shape, regulatory frameworks across Europe. Moreover, when compared with other policy domains, this is likely to be more pronounced for ART, given the personal and sometimes controversial nature of reproductive medicine.

But is one policy system better than the others? As each country offers unique framework conditions for dealing with these issues, the practice, results and outcomes of ART will be different in each country. So, a key question is: which framework is most appropriate and leads to optimal outcomes? Unfortunately and unsurprisingly, the answer to is not straightforward: consequences may be direct or indirect, and intended or unintended. Additionally, interpretation of the outcomes does not take place on a level playing field – that is, whilst an increase in perinatal mortality will be considered undesirable across the board, the interpretation of other outcomes may be specific to a country’s wider context and its social values. For example, in Korea – a country with a rapidly ageing population and very low fertility rates – the government has loosened the eligibility criteria for financial support towards IVF treatment (OECD, 2007) as part of a comprehensive master plan to boost the birth rate. Countries like Korea may place relatively more weight on the demographic impact of ART children than countries with relatively high fertility rates.

1.3 Objectives and research questions

This report aims to shed light on the differences in the way governments have shaped their ART policy by studying three countries in more detail: the United Kingdom, France and Italy. We investigate the following:
What the differences in the ART policy framework, its underlying goals and context are between the three countries (Section 6.1).

Whether the differences between these policy frameworks can be explained by the different contexts in which they have been designed (Section 6.2).

To what extent these differences have led to variable outcomes in different domains (Chapter 7).

How these outcomes might be interpreted, given the context differences (Section 8.1).

Whether, given these complicating factors, we can make some broad recommendations for countries to improve ART policy, while taking account of their context-specific requirements (Section 8.2).

1.4 Structure of this report

Chapter 2 explains the approach we have used to address these questions. We have developed an analytic framework to analyse the differences between ART systems and assess their outcomes. Subsequently, this framework was applied to the three case study countries. Chapter 2 also explains the selection of these countries and briefly elaborates on the data collection process. Chapters 3, 4 and 5 summarise the country-specific findings from the case studies by addressing how ART policy has been influenced by factors that are context specific, and what have been the outcomes of the respective systems. Chapter 6 places the characteristics of these systems in a comparative perspective, and tries to assess the extent to which they can be explained by the policy and context variations. In Chapter 7 we assess what the consequences of these variations are for the outcomes; we discuss the direct links between ART policy and practice, as well as more indirect and unanticipated impacts. Finally, in Chapter 8, we draw a number of overall conclusions and suggest some first recommendations towards addressing the challenges of ART policy in Europe whilst taking account of its national context.
CHAPTER 2  Analytical approach

This chapter provides the framework for the policy analysis of ART in Europe. As such, this framework serves three purposes: firstly, it identifies specific country profiles of ART policy by structuring the comparison between three case study countries; secondly, the framework is designed to explain national differences in the institutional set-up of ART policy in these countries; and, finally, the framework is used to assess the performance and outcomes of the systems.

2.1 Assisted Reproductive Technologies from four perspectives

In this report we distinguish four perspectives or contexts from which to consider ART policy: regulatory context, economic context, clinical context, and the wider health care and welfare tradition. Our conceptual framework, illustrated in Figure 2–1 below, links those perspectives to the outcomes of ART policy.

![Figure 2–1 Conceptual diagram for the analysis of Assisted Reproductive Technology policy systems from four perspectives](image)

The framework is structured around what we consider to be the basic causal link leading from a specific ART policy design to a set of outcomes: key regulatory choices influence the ART techniques and practices that are legal in a specific country, and at the same time the economic context determines the funding and reimbursement of those techniques. The
combination of these factors subsequently shapes a specific set of incentives and constraints in the clinical practice of ART, which in turn influences the outcomes of ART policies. The outcomes of the ART systems can be described as direct, indirect and externalities. In this context, we use the term externality to describe the impact of ART on third parties not directly involved in the procedure. Note that this is not an attempt to develop an economic model that describes the factors influencing the market for ART services, but rather to explain the differences and outcomes in the policy system.

As each of those basic causal factors is, however, influenced by a multitude of other factors, the conceptual frameworks adopt a broader approach and consider a wider range of other influencing factors, organised into four contexts.

Those key contexts are the regulatory, economic and clinical context, and the wider welfare and healthcare context. The last named takes a somewhat special role as the regulatory, economic and clinical outcomes are often – however, not always – closely aligned with and embedded in the wider welfare and healthcare system. The four perspectives we consider are presented in more detail below.

**Regulatory context**
The regulatory environment contains the policy framework in which ART policy operates. Typically, the regulatory context is determined by the characteristics of the policy design in a particular country, including:

- designation of a regulatory body (e.g. licensing authority);
- rules of access to ART treatment (e.g. a certain age group);
- restrictions to ART practice (e.g. handling of embryos).

**Economic context**
The economic environment determines the resources available for ART treatment and the affordability of ART treatment for the general public. The economic context of the ART system includes information about, among other aspects:

- reimbursement of ART treatment (e.g. full or partial reimbursement);
- allocation of resources to ART within the healthcare systems (e.g. rationing criteria and waiting lists to access public services, price control mechanisms);
- costs of different ART treatments (e.g. ICSI versus IVF).

**Clinical practice**
Thirdly, the clinical context constitutes the immediate environment in which ART treatment is provided. Elements relevant to the clinical context include:

- capacity of ART treatment (e.g. the number of clinics per million inhabitants, their geographic distribution);
- role of best clinical practice in treatment (e.g. existence of national best practice guides);
- performance of different ART establishments (e.g. geographical performance differential between clinics);
medical outcome of ART in the country (e.g. ART pregnancies that miscarry or end in birth).

**Healthcare and welfare tradition**

Finally, we expect that the contexts directly affecting the ART system are not sufficient to contextualise our research findings. Legislation for and the financing and practice of ART are also influenced by a legacy of healthcare and welfare services that are of a similar nature. This context may help explain how regulatory, economic and clinical context in these countries have become what they are.

To understand this perspective better, we have used the typology of welfare states provided by Maurizio Ferrera (1996). Ferrera argues that welfare states may be grouped according to their positions on four dimensions of welfare statism, namely:

- rules of access (e.g. below a certain maximum income);
- benefit formulae used to determine benefits (e.g. means-testing versus entitlements);
- regulations for financing social protection; (e.g. tax-financed versus income contributions);
- organisational and administrative structures (e.g. public administration, corporatist structures or private).

Based on these dimensions, Ferrera distinguishes four models of welfare statism: the Scandinavian model, the Anglo-Saxon model, the Bismarckian model, and the Southern model. Briefly, the four models of welfare statism are explained in Table 2-1

<table>
<thead>
<tr>
<th>Typology</th>
<th>Country examples</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scandinavian</td>
<td>Norway, Sweden,</td>
<td>These countries are characterised by universal coverage for the risks of life. The right to social protection is attributed on the basis of citizenship.</td>
</tr>
<tr>
<td></td>
<td>Denmark, Finland</td>
<td></td>
</tr>
<tr>
<td>Anglo-Saxon</td>
<td>Ireland, United Kingdom</td>
<td>This family of welfare states is also characterised by a highly inclusive social security coverage, but only in the area of healthcare can one speak of fully universal risk coverage. Also flat-rate benefits and means testing play an important role.</td>
</tr>
<tr>
<td>Bismarckian</td>
<td>Germany, Austria, Belgium, France, Luxembourg, Switzerland, Netherlands</td>
<td>The Bismarckian model is built around the social insurance system, and thus the relationship between social security entitlements, a person’s labour market status and role within the family (breadwinner or not) is still clearly visible. Contributions play an important role in financing the various schemes. Almost everybody has social insurance coverage through their own or derived rights.</td>
</tr>
<tr>
<td>Southern</td>
<td>Italy, Portugal, Spain, Greece</td>
<td>The social protection systems of Southern countries are highly fragmented and, although there is no articulated net of minimum social protection, some benefits levels are very generous (such as old age pensions). Moreover, in these countries healthcare is institutionalized as a right of citizenship. However, in general, there is relatively little state intervention in the welfare sphere. Another important feature is the high level of particularism, with the state directing individual welfare provision with regard to cash benefits and financing.</td>
</tr>
</tbody>
</table>

These types of welfare state are, however, necessarily crude, and different programmes within a single welfare state might follow different design principles, so there is not necessarily consistency in how different strands of the system are organised. In particular, healthcare systems might be organised differently. Therefore, it is also useful to consider
the healthcare system in which the ART system may be more or less embedded. There are two main dimensions along which healthcare systems may be distinguished:

- financing of healthcare services (e.g. direct tax subsidy versus public health insurance model);
- provision of health care services (e.g. the presence of private clinics, public establishments that conduct private services, and private clinics that offer public health care services).

In our analysis, we expect each country to have a unique profile of characteristics along this set of perspectives. These profiles, their differences, the explanation for these differences, and their consequences for the outcomes of the ART systems will help us to address the questions listed in Chapter 1.

### 2.2 Three case studies

For this comparative report we selected three countries that represented a variety of the relevant characteristics of ART regimes and welfare typologies in Europe. We examined the following selection dimensions:

1. The broad welfare-state type to which a country belongs
2. The relative restrictiveness of ART regulation.

These criteria may be combined into a selection matrix (as detailed in Table 2-2) that illustrates the values for each dimension.

<table>
<thead>
<tr>
<th>Type of welfare state-</th>
<th>Anglo-Saxon</th>
<th>Bismarck/continental</th>
<th>Scandinavian</th>
<th>Southern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relatively restrictive regime</td>
<td>Germany, Austria</td>
<td>Norway</td>
<td>Italy</td>
<td></td>
</tr>
<tr>
<td>Moderately restrictive regime</td>
<td>Ireland, France, Belgium, Luxembourg, Switzerland</td>
<td>Sweden, Denmark, Finland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relatively liberal regime</td>
<td>United Kingdom</td>
<td>Netherlands</td>
<td>Portugal, Spain, Greece</td>
<td></td>
</tr>
</tbody>
</table>

We selected France, Italy and the United Kingdom as they are representative of the variety of different welfare-state types (and different healthcare systems), as well as of the varying

---

2 The classification of relatively restrictive, moderately restrictive and relatively liberal is based on a review by Sorenson and Mladovsky (2006).
restrictiveness of the ART regime. Furthermore, ART policy was reasonably high on the political agenda in all three countries and ART has been practised on a relatively large scale. However, these criteria alone did not necessarily exclude other countries from selection. More pragmatic considerations also influenced our choice, such as the availability of data, our network and expertise in these countries, and language skills available.

We have developed a template that structured the data and information collection for the individual country case studies. Volume II of this report (Conklin et al. 2008a) further elaborates on the description of the approach, construction of this template, and the search strategy for data and literature available. To gather the evidence, the research team combined an extensive literature review with the analysis of data sources to achieve a structured comparison of ART policies in the three case study countries. Volume II provides the evidence base from four perspectives of ART systems in these countries. This volume focuses on the main findings from these case studies and their comparison. The following chapters draw out key themes and issues from the three country case studies.

2.3 **Caveats and limitations**

It is important to emphasise that this study has a number of limitations. The synthesis of differences in policy systems, their drivers and outcomes have been based on a very limited sample of three country case studies. We have chosen these case study countries on the back of a simple set of selection criteria, which do not necessarily capture the variety of ART policy systems in these countries. The conclusions and recommendations therefore have to be interpreted in light of these limitations.
CHAPTER 3

Assisted Reproductive Technologies in France: liberté, fraternité et générosité

A tradition of public welfare provision, state laïcism, a Roman Catholic population, and lavish medical system are only some characteristics that spring to mind when characterising France and its provision of public and healthcare services. The aim of this chapter is to describe the relative importance of these and other factors in relation to the provision of ART in France.

3.1 Assisted Reproductive Technology policy in France from four perspectives

Infertility is classified as an illness in France. Therefore, ART treatment is considered to be a standard medical intervention, and it is fully covered through the collectively funded health insurance system. The underlying principle of this system is that these medical interventions should be accessible to all, regardless of personal financial means. However, access is tied to a number of conditions. This section reviews the characteristics of the ART system in France from a regulatory, economic and clinical perspective.

3.1.1 Regulatory context: comprehensive regulation with moderate restriction

In France ART is regulated by the law on bioethics (Loi No.2004-800, 2004). The law takes a comprehensive approach to the ethical dimension of biomedicine, addressing issues including, but not limited to, organ donation and stem cell research as well as ART. Initially drawn up in 1994, the law regulating ART underwent an extensively debated substantial revision in 2004. Further revisions are scheduled to take place at five-year intervals, and discussion of the 2009 version is currently underway.

ART is strictly regulated by the biomedical agency

ART treatment is administered in co-operation between two groups of professionals who operate in separate establishments: on the one hand, doctors based at clinical centres and, on the other hand, biologists in laboratories working in biological centres. In order to be able to practise, both types of centres, as well as the professionals working in them, require authorisation. The recently established Agence de la biomédecine (Agence) authorises all clinical and biological activities in ART. More specifically, the Agence directly oversees the authorisation of professionals, whereas centres are approved by the regional agencies for hospitals on the basis of site visits and a review of local results. At present there are 107 clinical centres and 214 biological laboratory centres authorised to practise ART. Just over
40 per cent of authorised clinical centres are private (Agence, 2008b). The Agence is charged with conducting site inspections to ensure that the authorised practice of ART is guided by good practice rules (MES, 1999).

An important force driving the current ART regulation has been the role of the medical profession. Firstly, the medical profession enjoyed a special position of authority in the design process because its self-regulation had already delivered a legislative blueprint for the handling of ART. Secondly, as France has no single body representing the medical community, various associations and hierarchical levels were given their own voice in the consultation (Hassenteufel, 1997). This not only enhanced the presence of the medical profession as a whole, but also gave disproportionate influence to smaller groups such as ART specialists (Engeli, 2004).

**EU directives have been implemented in national legislation**

At European level, there are three legal directives concerning human tissues and cells which have relevance to the field of assisted reproduction: the standards on quality and safety directive (Directive 2004/23/EC); the technical requirements directive (Directive 2006/17/EC); and the directive on traceability and notification of serious adverse reactions and events (Directive 2006/86/EC). Member States were expected to implement these directives in national biomedical policy by 2007. In France, all three directives have been transposed into national law and the Agence is responsible for human reproductive tissues and cells (European Commission DG SANCO, 2008).

It is interesting to note that the transposition of the directives did not occur without difficulties. The Agence notes that some requirements cannot be applied to the field of ART services or are not relevant (ibid.). In particular, the Agence considers the definition of processes for which clinics have to be accredited a key difficulty. In comparison, the UK has included more activities than France in the accreditation of reproductive tissues and cells preparation processes (European Commission DG SANCO, 2007).

**Donation is legal but restricted**

Although donation of both sperm and eggs is legal in France, its moderately restrictive regime is expressed by the various conditions regulating this: egg and sperm donation is strictly anonymous, donation for money is legally prohibited, women of 42 and older are excluded from access to donation, there is a requirement to have had at least one child, and the consent of the donor’s partner is needed (Agence, 2007b). Finally, surrogate motherhood is illegal, and so is the use of gametes from a deceased partner (Agence, 2008c). There are reports of French patients circumventing these national rules by seeking treatment abroad, with high profile cases of surrogate motherhood and post-menopausal conception stimulating the political and public debate on the boundaries and sanctioning of ART practice in France. Infertile couples are believed to favour, in particular, neighbouring Belgium and, increasingly, Eastern Europe as good destinations for cross-border ART on account of their more liberal rules on ART techniques such as pre-implantation diagnostics and surrogate motherhood (Mladovsky, 2006). These travelling

---

3 As of 31 December 2007.
infertile couples may face severe complications regarding the legal status of the child, which has implications for citizenship.

**Full coverage reflects the definition of infertility as an illness**

Infertility is regarded as an illness in France. Those suffering from infertility – “suffering” is an appropriate term to use as the recognition of possible associated pathological disorders has been important for the classification as an illness – are entitled to the solidarity of the general public, which is the governing principle of the country’s *sécurité sociale*. However, this medical label does not reflect the broader international concept of reproductive health as defined by the United Nations (United Nations, 1995). Nonetheless, we raise the policy interpretation of infertility, because of the implications for financing of ART services in France and the other case study countries.

Before the bioethics law of 1994 was passed, treatment of sterility was already fully reimbursed. By the same logic of medical indication, however, individuals seeking treatment for other reasons – for instance the desire of a same-sex female couple to conceive a child – do not qualify for any support for, or indeed any access to, ART treatment (Engeli, 2004, p. 147; Mehl, 1999). As McGregor and Dreifuss-Netter (2007) highlight, this sets the French approach in stark contrast to the notions of reproductive rights or procreative liberty used in debates about access to ART in the United States.

The prevailing idea that ART exists to cure infertility within stable heterosexual couples (rather than to provide a path to parenthood for all) explains why the current legal framework is at the same time relatively exclusive and comparatively generous. Current discussions of the next revision of the bioethics law have put the issue of same-sex female couples’ rights to parenthood via ART back on the political agenda. While equality may turn out to be a potent driver for liberalisation, ART has not been a prominent feature of the debate around the support for families in France.

**ART legislation may be traced back to existing legal frameworks**

The current bioethics law is the result of the political processes described above, but its roots reach far beyond the parliamentary process. It is the direct heir of previous frameworks, filtered by restriction. As Engeli (2004) points out, “current regulation on ART does not contradict previous rules, but considerably enlarges their restrictive scope”. The first policy design of 1988 was substantially informed by existing self-regulation. In all subsequent iterations and revisions, this self-regulation’s basic premise – that IUI and IVF should be allowed – was never challenged (*ibid*).

Furthermore, the ART legislative framework evolved in the immediate context of existing regulation in related fields, and was informed by fundamental concepts developed in the context of other, previously debated issues. Importantly, legislation on abortion already had to deal with the question of how to consider the embryo, whose endowment with current legal status would have conflicted with the lawfulness of terminations (Law No. 75–17, 1979; Law 82–1172, 1982).

Other aspects of the current framework may similarly be traced back to already accepted norms and legal practicalities. The ban on surrogacy, for example, refers directly to the non-negotiable concept of human dignity, which was confirmed as a constitutional value by the *Conseil constitutionnel* in 1994. Surrogacy is viewed as a form of exploitation because
the surrogate mother functions as an instrument to produce another couple’s child; the practice therefore infringes on the surrogate’s human dignity (McGregor and Dreifuss-Netter, 2007).

**An evolving political and socio-economic context**

ART regulation is inseparable from an evolving political and socio-economic context; it is also influenced by what is possible and allowed in other countries. As the debate of the next revision of the law on bioethics begins, there are two key areas of ethical dilemma that are likely to be at the centre of political attention in France.

Firstly, there may be a shift towards ART for same-sex female couples. In its 2006 expert opinion on the anonymity of gamete donors, the national committee for ethics consultation (*Comité Consultatif National d’Éthique*, CCNE), observed that any such reform would signify a fundamental shift from the current idea in the political context of ART as medical therapy to ART as an instrument to realise an individual right to a child, warning that this may unduly prioritise individual interest over collective interest (CCNE, 2006).

Secondly, parental anonymity of gamete (egg or sperm) donors has recently been at the centre of public and political debate. However well established, the practice of parental anonymity poses an ethical problem in that it denies the child personal knowledge of their biological descent and native ancestry. In the United Kingdom anonymity was recently lifted in acknowledgement of this consideration of the child’s right to information, but with the result that the number of donors dwindled. In trying to reconcile this dilemma, the CCNE recommended that donors should remain anonymous, but that the child should be informed about the mode of conception. That being said, the committee has also called for a genuine public debate to explore the deep ethical and political questions of identity and parenthood at stake (CCNE, 2006).

**3.1.2 Economic context: free access but to what limit?**

France’s ART system is fundamentally characterised by universal access to ART provision as a medical intervention, regardless of the patients’ financial means. Therefore the costs of ART treatment are fully reimbursed by the publicly funded social security system if treatment is provided in a public clinic or hospital. This reflects the fact that infertility is regarded as an illness in France. Services in private facilities are covered up to the public amount and patients are expected to pay the difference. Although the additional fee is not reimbursed, many patients can apply for subsidy by a privately funded supplementary insurance fund (*mutuelle*). Doctors are required to inform patients about all such additional costs before any treatment starts.

*Generous funding of ART treatment, but increasing inequality*

There are no restrictions on the number of cycles. However, the recommendation is to limit IVF/ICSI with embryo transfer to four cycles if no pregnancy is achieved (Sorenson, 2006b). At present, the public health insurance system funds up to six attempts at intrauterine insemination (IUI), provided that the woman patient is less than 42 years of age (Agence, 2007b).
The economic forces at play in the ART services in France show two trends that are likely to increase in force in the near to mid-term future. Firstly, French ART centres will continue to compete with foreign clinics for those wealthier patients who can afford to forego the full reimbursement of costs associated with ART treatment in France. Current competition between ART centres in France and foreign clinics is driven by two underlying factors: a demand-driven need to achieve shorter waiting times, and a demand-driven need to undergo forms of ART treatment that are otherwise illegal in France. As in other EU countries, in France cross-border ART is an important factor that contributes to tangible inequalities in ART access in favour of the wealthy. This inequality occurs despite the fact that, at the national level, an egalitarian system of access and costs is in operation for those that qualify for treatment in France (Tain, 2003).

Is there a need to ration this generous but expensive system?
The second major economic force involved in ART services provided in France concerns the growing need to contain costs and ensure system sustainability. As in most industrialised countries, France’s national system is under severe financial strain as its traditionally lavish healthcare system is expected to cater for an increasing burden of medical need from an ageing population, along with rising costs for medical interventions. Within the specific field of ART services, pressure on financial (and human) resources has been rising in France in recent years. While the exact effect is unknown and not quantified here, it will probably mean that any future liberalisation of access to ART services in France may be curtailed for macro-economic reasons as well as reasons of principle (see Section 3.1.1.).

### 3.1.3 Clinical practice: a strong emphasis on guidance by best clinical practice

The legal practice of ART in France is strictly guided by good practice rules formulated in 1999 and encoded in national law (MES, 1999). Notably, promoting the quality of care provided and the evaluation of medical practice became visible issues only in the mid-1990s (Sandier et al., 2004). These issues were addressed in practical terms by: 1) establishing and disseminating a system of practice guidelines; and 2) increasing the emphasis on continuing medical education. Furthermore, as it is considered a medical intervention, ART is operating within a well-provisioned and highly respected medical system. However, there are some areas where implementation of regulation deviates by region or by clinic.

It is estimated that one is seven women of reproductive age (15–49 years) in France will seek consultation on problems of infertility and it is estimated that each year 60,000 couples will consult a gynaecologist for reasons of reproductive difficulty (Cohen et al., 2000). Figures published in the annual reports of the Agence indicate that ART accounted for 20,757 live births, representing 2.4 per cent of all births in France in 2006 (Agence, 2008a). Among the ART live births, 6 per cent were realised after gamete donation (sperm and oocyte) (ibid.). Notably, the number of oocyte donations increased by nearly 30 per cent between 2004 and 2005 (Agence, 2007a).

**Regional variation between clinics**

French couples in need of medical assistance for infertility have, in theory, the choice of seeking treatment in either a public or semi-public hospital, or a private clinic. However,
in practice, couples’ choices are limited by the geographical distribution of clinical centres. For example, the densely populated Ile de France (Paris) has twenty-four licensed clinical centres, whereas only one centre exists in Limousin, one of the least populated areas in France.

Waiting times for ART treatment also vary between centres, and may be considerably longer than the recommended interval of two to six months. Due to a severe shortage of oocyte donors, couples requiring donor eggs are advised not to expect treatment in less than two years. Some centres have been known to fast-track couples when they bring an egg donor with them to the clinic, if not donating directly to the couple recruiting (CHU-ClermontFerrand 2008). This practice has been viewed with suspicion due to its discriminative potential, but has not actually been banned in France (Desmarescaux, 2003).

French law limits access to IVF to couples of “normal” reproductive age, defined as being up to, but not including, forty-two years. However, there is uncertainty over how this provision should be interpreted in clinical practice, especially with regard to the question of where the line should be drawn regarding men in couples with a significant age difference, given that a couple’s fecundity is less dependent on male age than on female age. Clinics take individually different approaches to resolving this question, with some adding the ages of both partners and rejecting couples reaching a combined age of over 100. Furthermore, as the law does not regulate the number of embryos to be implanted, individual clinics are also left to make this decision on a case-by-case basis (Desmarescaux, 2003).

**IVF provision has remained relatively stable, while ICSI is on the rise**

The total number of IVF clinics in France has marginally increased from 92 to 100 over the last decade. The total number of embryo transfers after ART has increased somewhat faster than the rise in clinics: from 32,684 in 1997 to 43,821 in 2004. Compensating for the relative size of the reproductive population, Figure 3–1 shows that the absolute increase in embryo transfers is primarily attributed to a marked rise in embryo transfer after intracytoplasmic sperm injection (ICSI), a similar technique to IVF, but where a sperm cell is injected directly into the egg cell.

The marked increase in the proportion of ICSI cycles seems primarily due to an increased use in couples classified as having mixed causes of infertility, unexplained infertility and advanced age together with a relative decline in tubal factor infertility (Nyboe Andersen et al., 2008). However, some argue that this trend is not necessarily driven by medical need; Jain and Gupta (2007) concluded that in the United States reimbursement of IVF services is associated with greater use of ICSI for infertility that is not attributed to male-factor conditions. A similar phenomenon may be applicable to France, despite the notion that several studies have shown that clinical outcomes are not improved by ICSI for infertility that is not attributed to male-factor conditions (e.g. Moreno et al., 1998; Bukulmez et al., 2000; Bhattacharya et al., 2001).
A shift away from multiple-embryo transfers

Over the last decade, there has been a consistent decline of higher embryo transfers in France: 3-embryo transfers have decreased from 42.3 per cent of all transfers after IVF and ICSI in 1997 to 18.7 per cent in 2004, and 4-embryo transfers dropped from 11 per cent towards 3–5 per cent in the same period. At the same time, there has been a parallel rise in 2-embryo transfers – from 32.1 per cent to 59.1 per cent. These trends, shown in Figure 3–2, indicate an important change in the process of providing ART treatment to infertile couples. It is rooted in the dominant paradigm of good clinical practice, as the number of embryo transfers can impact on the risk of higher order pregnancies, with all the associated maternal and child harms. Furthermore, it is inspired by experiences in countries such as Belgium and Sweden, which successfully shifted away from multiple-embryo transfers (Giorgetti et al., 2006). There is an ongoing debate in France about whether a single-embryo transfer (SET) policy should be systematic or targeted to selected couples (e.g. Cohen, 2007; Merviel et al., 2007; Hamamah et al., 2007). The predominant belief is that individual clinicians and clinics should maintain the freedom to select the most appropriate treatment. This may explain why the proportion of single-embryo transfers is still relatively small.
3.1.4 Welfare and healthcare tradition: Assisted Reproductive Technology policy fits the Bismarckian model

The French welfare state is rooted in the Bismarckian or continental welfare-state tradition, characterised by a strong link between employment and social protection. The basic benefit programmes such as the pensions, disability benefits and the unemployment benefits are based on a social insurance system to which employers and employees contribute. Eligibility for payments is based on membership of the schemes and the amount of contributions paid. This system is, however, supplemented by a means-tested social net for those who are not in work and do not have access to the employment-related schemes.4

France is the fourth highest-ranking country in terms of national health expenditures (Minogiannis, 2003), and is ranked no. 1 in the world in terms of health outcomes and population health by the WHO (2000). France’s healthcare system corresponds to a welfare system rooted in a social insurance system. Healthcare is organised around type of employment and originally restricted access to those in work and their dependants. With reforms in 2000, however, the French system got a decidedly more universalistic touch. The introduction of the Universal Health Coverage Act extended healthcare coverage to those outside the occupational schemes and basically enabled universal access to the healthcare system on terms of residence. At the same time, the role of health insurance contributions in financing the system had been reduced in favour of general social contributions which require tax transfers rather than social insurance contributions (Sandier et al., 2004).

4 For details of the welfare programmes, see e.g. the MISSOC tables published by the European Commission (2007).
France provides universal access to ART treatment

The classification of treating infertility as an illness places ART policy well into the healthcare system. Access to ART policy follows the same rules as access to the healthcare services in general. Coverage is *de facto* universal and all residents in France have the right to access ART-related services, with the restriction of medically justified age limits and following best practice established by the profession. Classifying ART as a disease has, however, other consequences in terms of access as it does not establish a way of parenthood for all, but limits the treatment to stable heterosexual couples. Same-sex female couples do not qualify for support in ART treatment under this paradigm.

Universal access to ART is in contrast to the set-up of the wider welfare and social security system, which is characterised by a strong link between work position (and/or family state) and social entitlements. Residents and citizens who have not contributed to the scheme in turn are only eligible for a means-tested, minimum (European Commission, 2007; SSA, 2006). More modern layers of the welfare system, such as family allowances, are similar to ART support and cover the whole population, irrespective of previously paid contributions and means tests. Nonetheless, given the integration of ART policy into the healthcare system, France has a wider access to ART services than would have been expected from the broader welfare-state context in which it operates.

**ART reimbursements stand out as a generous scheme compared to other health services and the welfare state as a whole**

French national health insurances only partially reimburse healthcare expenditure. For most services a co-payment by the patient is required, which is either a direct payment or one covered by voluntary additional health insurance. In 2002 social health insurance constituted 73.3 per cent of total health expenditure, with the remainder consisting of voluntary health insurance (13.2%), individual payments (9.8%) and national taxes (3.7%). Infertility treatment and ART provision is, however, exempted from co-payment and reimbursement seems even more generous than for other services.

The French system so far has been relatively unsuccessful in containing costs, and overall spending ceilings have been repeatedly exceeded (Sandier *et al.*, 2004). This may be due to the fragmented system of healthcare provision, with a multitude of public, private non-profit, and private for-profit actors as well as multiple funding and reimbursement streams.

Every hospital in France has its own unique budget, and because of private clinics France has a dual system of hospital finance. Local representatives of the ministry of health screen the needs, the staff and clinical plans. Every month the local sickness funds then send to the hospitals lump sums proportional to their shares of the patient numbers. ART provision in public hospitals is part of this process and is budgeted on an annual basis. In contrast, private clinics are regulated for safety but have much more discretion in their operational costs and budgeting. That is, they do not submit cost reports and prospective budgets to government regulators, but rather negotiate their rates with the general offices of the French national health insurance scheme (CNAMTS, *La Caisse Nationale d'Assurance Maladie des Travailleurs Salariés*).
ART is provided within the organisational framework of the healthcare system

Overall, the organisation and management of insurance schemes for social protection and healthcare provision in France are driven by unions and employer organisations. These joint bodies are typical of welfare systems based on the social insurance principle and a Bismarckian welfare tradition. However, the organisational structure and management of France’s healthcare system was profoundly affected by the Juppé reform of 1996, which introduced parliamentary control over the healthcare system and its resources as well as reinforcing the role of regions by instituting new institutions created at the regional level (Sandier et al., 2004).

In line with other healthcare services, the provision of ART services may take place in private or public hospitals. The costs, however, are reimbursed only up to the level of the public hospitals; private top-up is allowed. The geographical distribution of facilities for ART treatments also mirrors those of general health services provision. For example, disparities in the distribution of doctors have existed for a long time without any justification in terms of different health needs.

Finally, ART services follow a similar system of accreditation to the general healthcare system. The 1996 Ordinances in France obligate all healthcare institutions to be accredited in order to continue to provide treatment. This accreditation procedure, carried out by the Agence d’accréditation et d’évaluation (ANAES), is an external evaluation of the quality and safety of the healthcare provided within an institution, based on the implementation of a certain number of procedures and the compilation of quality indicators. A distinct feature of the ART system is that the national Agence accredits and regularly inspects the organisation and management of ART clinics and laboratories to ensure quality and safety standards are met, but overall the provision of ART services takes place in, and is interwoven with, a system very similar to the general healthcare system.

3.2 Assisted Reproductive Technology outcomes: France shows positive trends in health outcomes over time

A relatively stable proportion of multiple births from ART in France

The marked decrease in the proportion of multiple-embryo transfers over the last decade, as observed in Section 3.1.3, has caused a minimal decline in the proportion of multiple deliveries in France (see Figure 3–3). By 2004, still 21.9% of births were twins. Since approximately half of all twins and ninety per cent of triplets can be expected to be born prematurely and suffer low birth weight (HFEA, 2007c), we can crudely assume that approximately 19 per cent of ART babies in France suffer from these poor conditions. The recent annual report of the Agence laments the fact that, despite adopting a policy of more prudent embryo transfer in all the centres (around 2 embryos per transfer on average), the percentage of multiple pregnancies remains above 20 per cent (Agence, 2008a).
Success rates are relatively low and vary considerably between clinics

Of the patients who have sought infertility treatment, 80 per cent have become pregnant from IVF and gamete intrafallopian tube transfer (GIFT) within four attempts. However, 20 to 25 per cent of these pregnancies are not delivered (Cohen et al., 2000), which compares unfavourably with both Italy and the UK (see Figure 3–4 below). The figures for France have not changed much in 2006, when the percentage of reported miscarriages and medically interrupted pregnancy per pregnancy ranges from 16.4 per cent to 25.2 per cent, depending on the technique and source of gamete used (Agence, 2008a).

There are a number of potential causes for the comparatively low success rates in France. Firstly, the system may be relatively inefficient due to the lack of competition – compared to, for example, the United Kingdom. Secondly, the relatively long waiting lists in France may result in higher spontaneous pregnancy rates among women seeking assistance. As a result, the population of couples who eventually receive treatment in France may have on average more cases of complete infertility (i.e. sterility), which would result in poorer success rates. Thirdly, it may possibly be explained by the demographic characteristics of those seeking ART treatment. As funding for infertility treatment is accessible for everyone, income level is not a barrier to treatment. Therefore the social profile of French ART patients is more representative of the total population than in countries where patients (partly) pay out of their resources, representing a sub-group of the population with higher socio-economic status and having better health outcomes generally (Tain, 2003).

Since the prevalence of, for example, smoking and obesity (factors associated with lower success rates) tend to be higher among lower-income groups (Power et al., 2005; Power et al., 2005; Power et al., 2005; Power et al., 2005), Both smoking and excess weight unfavourably affect the live birth rate after IVF. The negative association of smoking with the live birth rate in IVF treatment is comparable with an increase in female age of >10 years from the age 20 up to 30 years (Lintsen et al., 2005). For an overview of smoking and fertility, see a report by...
Sundquist and Johansson, 1998), success rates in France may be affected by their patient population.

![Graph](image)

**Figure 3–4 Proportion of lost pregnancies after IVF and ICSI is highest in France, compared to Italy and the UK (1997–2004)**

In a recent analysis of ART results in France, Pouly and Larue (2007) argue that the outcomes in a number of clinics are alarmingly poor. As the authors discuss, these outcomes cannot be explained by either the recruitment of patients or clinical practice. For example, despite the quite homogeneous recruitment between clinical ART centres in France, the success rate differs between the ten best and the ten worst centres by a factor of 2.5. More specifically, the authors found that fewer than 14 per cent of ART pregnancies are reached by 25 per cent of French ART centres, fewer than 12 per cent by 10 per cent of centres, and fewer than 10 per cent by two or three centres. The authors comment that the variations in pregnancy rates between centres are not due to differences in the mean female age or the average number of embryos transferred.

Despite Pouly and Larue’s criticism, it is worth considering that the average chance of becoming pregnant after IVF, ICSI and frozen embryo replacement (FER) in France has been relatively constant from 1997 to 2004, as shown in Figure 3–5 below. Similarly, France also demonstrates a relatively constant rate of percentage of deliveries per transfer after IVF, ICSI or FER (except for 2001).

---

The Practice Committee of the American Society for Reproductive Medicine (2004). And, for a systematic review on overweight and obesity and ART outcome, see Maheshwari et al. (2007).

6 The denominator, total FER, was chosen due to incomplete European Society of Human Reproduction and Embryology (ESHRE) data on the percentage of pregnancies per cycle, which may be more appropriate given that success rate is equal to the proportion of live births to total cycles.
France’s ART system sits within the strong healthcare vigilance system

Despite the relatively high proportion of lost pregnancies, France performs relatively well on other indicators of maternal and perinatal care, one of which is the extent of ovarian hyper-stimulation syndrome (OHSS) complications. It is important to note that, although France had a small increase from 1997 to 2004, the country has consistently had less than 0.5 per cent of OHSS relative to all transfers after IVF, ICSI and FER.

The relatively low occurrence of this negative health outcome after ART preparation might be explained by the fact that financing of ART in France is covered by the universal healthcare system, thereby relieving the financial pressure on individual couples to maximise their potential for harvesting a high number of eggs (despite the increased risk of OHSS and its complications).

The incidence of other ART-related complications is also relatively low. A notable exception is the reported number of infections after ART treatment. France had 88 per cent of the total reported infections in Europe in 2002 and 83 per cent in 2004. We suggest caution in interpreting these figures for France. The high number of reported incidents may be due to its robust national reporting and learning system specifically for healthcare-acquired infections (Conklin et al., 2008b). In fact, we found that only in France is there an explicit reference to an ART-specific vigilance system (AMP-vigilance), or procedure for adverse events and reactions (Agence, 2007a, 2008a).

3.3 Conclusions

The set-up of the French healthcare system is unique within its welfare tradition. Most welfare services are usually accessible only to those participating in the economy –
employed and self-employed people and their close relatives – while healthcare services are universally accessible for all, based on residency. Nonetheless, the key characteristics of French public support of ART treatments – full coverage of costs through the social security system within the limits of specific criteria – reflect the fact that infertility is regarded as an illness, and that France runs a welfare state within which the ill are entitled to receive help. In line with the social security system, couples in need of treatment are entitled to the solidarity of the general public. The idea that ART exists to address infertility in stable heterosexual couples, rather than to provide a path to parenthood for all, explains why its legal framework is both relatively exclusive and generous – even more generous than the reimbursement of most healthcare services.

Similarly, the ART system is also founded on the general principles of the healthcare system regarding the strong emphasis on good clinical practice. The Agence oversees accreditation and regularly inspects the organisation and management of ART clinics and laboratories. Despite relatively low success rates, regional disparities and still a substantial proportion of multiple births, France’s ART health outcomes generally compare favourably with the other case study countries. It is likely that the relatively low incidence of complications may be attributed at least partially to France’s good clinical practice in ART services. In contrast to the UK, for example, clinical best practice guidelines are separated from recommendations regarding cost-effectiveness and subsequent funding. Given this combination of generous benefits and strict reliance on good clinical practice, there seem to be few negative unintended consequences, except that the proportion of multiple births is still relatively high compared to countries such as Sweden and Belgium. There is nonetheless little public dissent about the regulatory and funding framework.

The most important drawback of the French ART system may be the sheer costs of reimbursing three cycles of those diagnosed with infertility. With the looming retirement of the baby boomers, and the associated healthcare costs, there may be a future need to ration public healthcare expenditure. However, there are few indications that funding of ART is at stake, given the public acceptance that universal healthcare is costly and the strong government support for families. In addition, the current institutional set-up seems not to encourage cost containment in the system.
Until recently, Italy was considered the “far west” of ART, because of the lack of comprehensive regulation. With the introduction of the 2004 legislation, the tables have turned. The media have reported on large numbers of patients going abroad for fertility treatment, and the international clinical community is concerned about deterioration in clinical practice following this law. The aim of this chapter is to discuss the importance of these and other factors in relation to the ART system and its performance in Italy.

4.1 Assisted Reproductive Technology policy in Italy from four perspectives

Infertility or sterility is not recognised as an illness in the Italian health system. Hence, ART services and treatment are not considered regular medical intervention and therefore are not covered by the country’s mixed-financing healthcare system. The underlying principle of Italy’s ART system is one of individual privilege, rather than being rights based. That is to say, access to ART services is highly particular to private sector access tied to regional availability and personal financial means. Furthermore, private access, whether in a public clinic or a private facility, is also tied to a number of restrictive conditions and eligibility criteria determined by Italy’s contested comprehensive legislation. This section reviews the distinct characteristics of the ART system in Italy from four perspectives: regulatory, economic, clinical, and welfare and healthcare.

4.1.1 Regulatory context: contested comprehensive and restrictive legislation

ART in Italy is regulated by the first comprehensive law regulating ART, enacted in 2004 (Legge 19 febbraio 2004, n.40, hereafter referred to as Law 40/2004). Due to Italy’s specific cultural footprint of the strong influence of the Roman Catholic Church and a fragmented political system, the political debate has been overshadowed by a focus on preserving the classical concept of the family and protection of the unborn. International best practice for ensuring maternal and neonatal health and assisting the most severe forms of infertility seem to have been considered as of lesser importance.

A drastic move from unregulated to restrictive policy

Prior to the Law 40/2004 on ART, Italy was described as the “far west” of assisted reproductive technologies (Hanafin, 2007). The topic has been at the forefront of the political debate since the first practice of artificial insemination in 1958, and the issue re-emerged when the first IVF baby was born in Italy in 1983. Given the regulatory vacuum, Italian doctors enjoyed a high level of autonomy in practising ART. Only a few specific
activities were regulated by ministerial regulations, while doctors had freedom in respect to medical and ethical decisions in non-regulated areas.

The promulgation of Law 40/2004 marks the end point of a long and troubled journey that has seen many bills come and go. Various proposals to establish regulation of ART have ranged from very restrictive to rather liberal, yet all of them have failed. A proposal put forward in 1985, for example, showed that the debate on ART was not driven by the clinical and technical issues but rather by ethical concerns. Protecting the classical concept of the family prevailed over considerations about the health impact on a woman and her baby (Valanzuolo, 2004).

**Box 1 Treatments prohibited under Law 40/2004**

- Freezing or destruction of human embryos
- Use of donated sperm
- Use of donated eggs
- Pre-implantation genetic testing of embryos
- Scientific research on embryos
- Fertilisation of more than three oocytes within one ART cycle
- Not transferring all embryos created into the woman’s womb
- Post-mortem insemination

Under the current law – the highly disputed Law 40/2004 – the Italian system prohibits certain types of assisted reproductive services. For example, cryopreservation of human embryos, the use of donated oocytes or sperm, and pre-implantation genetic diagnosis and pre-implantation genetic screening (PGS and PGD) of embryos are all prohibited under Italian law (See Box 1). In contrast, France permits the procedure of cryopreservation without any limitations (Sorenson, 2006a). Furthermore, a maximum of three oocytes may be fertilised within one ART cycle, and all embryos created must be transferred into the woman’s womb. This means in practice that if the fertilisation of all three oocytes were successful, then all three embryos created would have to be transferred into the woman, increasing the risk of multiple births and a negative impact on the health of mother and child. Italy’s conservative eligibility criteria for ART provision are summarised in Box 2.

Although not recognised as an illness, and hence not covered by the healthcare system, infertility can be certified by any doctor who is allowed to practise medicine in Italy. The definition of infertility (used interchangeably with the term sterility) is “at least one year of unprotected sexual intercourse without conception (Annex, Law 40/2004, Art. 7).”

---

7 This means in practice that if the fertilisation of all three oocytes was successful all three embryos have to be transferred.
Box 2 Eligibility criteria for ART services in Italy

- Cohabitant, heterosexual couple (marriage is not required)
- Both partners of the age of 18 years or older and within the fertile age group (attested by doctors)
- Certification of being infertile by the doctor

The 2004 policy change has fuelled criticism

Perhaps not surprisingly, the adoption of this first comprehensive law in Italy has triggered severe public criticism. Secularists campaigned against the law’s restrictive regulation of ART, considering the decision of whether to undergo ART a matter of individual freedom. Moreover, the law was criticised against the background of a potential “brain drain” caused by the limitations of research in this area compared to other European countries. Furthermore, some argued that the ban on fertilisation of more than three oocytes would cut success rates, translating to unneeded further treatments, expenses and risks for women (Turone, 2004). Another major concern among critics relates to the requirement to transfer all embryos, regardless of their quality. This is associated with an increased rate of multiple pregnancies and hence poorer health outcomes for both mother and any surviving babies (Ragni et al., 2005). Data published by the health ministries appear to support some of these concerns (see Section 4.1.3 and Section 4.2). Publication of these data should be considered in a political context, as they were released by the left-of-centre minister Livia Turco – who succeeded the conservative Francesco Storace, who was responsible for the 2004 law. Some legal experts have also questioned the law, saying it conflicts with Italy’s Constitution, which explicitly protects the health of its citizens, including the health of the mother with multiple pregnancies. But criticism has also occurred at international level (e.g. Robertson, 2004).

The current Italian regulation foresees the re-evaluation and potential amendment every three years of the guidelines for ART in the light of new technical and scientific developments. In addition to a request from the ministry to review the legislation, various stakeholder groups – such as associations, civil society groups, patient groups and medical professionals – have called for amendments. These other requests for change go somewhat further than the ministry’s position, with examples given in Box 3 below.

Box 3 Examples of amendments requested by critics of the current law (Robertson, 2004)

- Allow fertilisation of more than three eggs
- Allow cryopreservation of eggs
- Allow embryo biopsy (e.g. PGS and PGD)
- Legalise cryopreservation of excessive embryos after fertilisation to avoid unnecessary multiple-embryo transfer
- Heterologous treatments
- Declare sterility and infertility as being an illness

Given the fact that the Italian legal system foresees only the possibility of referenda to abrogate a law, opponents immediately launched the initiative of a referendum in 2005.
With only one out of four Italians voting in the referendum (25.9%), the required quota of more than 50 per cent was not met. Some surveys indicated that support for the amendments ranged between 78 per cent (in favour of embryo donation) and 90 per cent (all other points) (Turone, 2005). The failure of the referendum was seen as a result of the abstention from the vote which was promoted by opponents (in particular the Roman Catholic Church), the biased media coverage, and the complexity of the issue, which made it hard to explain to the general public (Turone, 2005).

New ART practice guidelines in Italy were announced in April 2008. Following the ministry of health’s recently completed assessment, these new guidelines allow couples with sexually transmissible illnesses to use ART, and require every clinic practising ART to have adequate psychological support for the treated couples (Annex, Law 40/2004, Art. 7). A fundamental revision of the law, however, seems unlikely in the near future, especially considering the experience of the complicated debate preceding the adoption of the current comprehensive law on ART. Issues such as ART for same-sex female couples that are on the horizon in other countries, as in the case of France and United Kingdom, seem far too controversial to be adopted any time soon in a country that is so heavily influenced by the strong presence of the Roman Catholic Church in matters of reproduction and the family.

**The implementation of EU directives is lagging behind in Italy**

Of the three EU Directives relevant to assisted reproduction, Italy has only transposed the setting standards of quality and safety directive into its national law. The other two directives are expected to be implemented and enforced by the end of 2008 (European Commission DG SANCO, 2008). The responsible authority gave the “many competing priorities for legislators” in Italy as the reason for delay (*ibid.*).

The Centro Nazionale Trapianti (CNT), designated to implement the European Tissues and Cells regulatory framework did not conduct any regular inspections in 2007 in assisted reproduction centres. The reason for this is that reproductive tissues and cells are explicitly excluded from the CNT’s remit. For the same reason, there is no system in place for the reporting of serious adverse events and reactions in the reproductive field (*ibid.*). Therefore, it is unclear yet how the European quality and safety standards will be guaranteed in the reproductive field (*ibid.*).

### 4.1.2 Economic context: fragmented system with high level of individual payment

Italy’s ART system is characterised by individual couples making payments according to means because ART provision is not covered by the country’s publicly funded national health service (*SSN, Servizio Sanitario Nazionale*). In some regions, however, reimbursement schemes have developed but this regionally based financing further exacerbates any existing disparities in the country’s fragmented system. Yet, despite reimbursement for couples in such regions, many continue to pay out of their own pockets or even to leave the country in order to bypass the long waiting times.

---

8 As of 30 May 2008.
Out-of-pocket payment and regional disparity
Because infertility is not considered an illness, the Italian healthcare system does not, in principle, reimburse ART services. The costs of ART that are carried by individual couples are estimated as around €1,500 in public clinics and between €2,000 and €4,500 in private clinics (Amato, 2007).

Since there is no law at the national level to oblige the financial coverage of ART services, Italian regions have a certain degree of autonomy regarding funding decisions. As a consequence, already in 2005 – a year after the introduction of Law 40/2004 – several regions had introduced specific provisions foreseeing some form of financial coverage of ART. In Lombardy, ART treatment was completely covered if provided by a public healthcare facility, and no limitation of cycles has been introduced yet (Porciani, 2005).

This has resulted in a very fragmented picture for the economic context of ART in Italy. In addition to regional schemes for financial compensation of ART, there are some professional associations like the association of teachers (Ordine degli Insegnanti) that provide healthcare coverage for ART treatments at private institutions to their members.

4.1.3 Clinical practice: value-based ideology trumps international best practice
The central regulation and the guidelines at federal level based on this law provide the general framework for provision of ART in Italy. The DPR (Decreto del Presidente della Repubblica, 1997) establishes the basic requirements for all public and private institutions that provide healthcare services, while there are regional regulations which further specify the concrete requirements for institutions providing ART in their territory.

Unlike in France, minimal requirements for the specific clinical practice of ART in Italy are established by an inter-regional agreement (Gruppo Tecnico Interregionale, 2001). Of the 330 clinics authorised to perform ART treatment, roughly 40 per cent practise the so-called first level treatments (stimulation of egg production and insemination), while the other 60 per cent practise second and third level treatments (IVF, GIFT, ICSI, FER, etc) (Ministero, 2007).

In brief, Italy is different from France to the degree that Italy’s law does not prescribe the minimum requirements for the clinical practice of ART, whereas best practice in France is encoded in law at the federal level. This difference is important in the wider context of the country’s healthcare system: since it is not considered a medical intervention, ART in Italy operates outside the country’s healthcare system and therefore the government has less control over the quality of care provided and less ability to enforce patient safety practices. The health impact of this disconnection (between ART services and Italy’s healthcare system) is explored below.

Regional variation in clinic density and waiting times
In addition to regional disparities in reimbursement, there are also differences in the density of clinics providing ART second level services. There are between 0.4 and 3.5 ART clinics in Italy per 100,000 reproductive women (Ministero, 2007), with a predominance of clinics in the north-west (see Figure 4–1).
Table 4-1 Regional distribution of IVF and ICSI cycles per million inhabitants

<table>
<thead>
<tr>
<th>Region</th>
<th>Treatment cycles / 1 million population</th>
<th>Clinics (private and public) performing second and third level treatment (ICSI, IVF, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North-east</td>
<td>717</td>
<td>42</td>
</tr>
<tr>
<td>North-west</td>
<td>683</td>
<td>43</td>
</tr>
<tr>
<td>Centre</td>
<td>562</td>
<td>46</td>
</tr>
<tr>
<td>South and islands</td>
<td>407</td>
<td>67</td>
</tr>
</tbody>
</table>

SOURCE: Ministero (2007: p. 40 and p. 45, graph 2.1.5)

NOTE: Based on data from 174 centres and clinics performing second and third level treatments

There is no fixed scheme for waiting times in Italy, which suggests that in practice there could be as many different waiting times as there are clinics in the country. One estimate from the region of Reggio Emilia indicates that couples have to wait around twelve months for their first visit/interview. If the couple is subsequently registered in the waiting list, the pair has to wait again for between five and seven months for the actual treatment (Municipio Regione Emilia-Romagna, 2007). To bypass waiting times in public clinics in regions with reimbursement schemes, couples often resort to financing their ART treatment at private clinics in Italy individually or travelling abroad to undergo ART.

**Italy provides ART treatment to more older women than elsewhere**

Although Italy prohibits ART to infertile individuals under the age of 18, there is no upper limit. Thus, unlike in France, women older than forty-two years of age can and do receive ART in Italy. Although the women older than 45 comprise only a fraction of the total ART patients (see Table 4-2), Italy has consistently had a higher proportion of older women treated with IVF or ICSI from 1998 to 2004 and this proportion is increasing, compared with France and UK (see Figure 4–1).

Table 4-2 Cycles initiated by age group

<table>
<thead>
<tr>
<th>Age group</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 29</td>
<td>3,304</td>
<td>10.1</td>
</tr>
<tr>
<td>30–34</td>
<td>9,590</td>
<td>29.3</td>
</tr>
<tr>
<td>35–39</td>
<td>13,100</td>
<td>40.0</td>
</tr>
<tr>
<td>40–44</td>
<td>6,265</td>
<td>19.1</td>
</tr>
<tr>
<td>&gt;= 45</td>
<td>510</td>
<td>1.6</td>
</tr>
<tr>
<td>Total</td>
<td>32,769</td>
<td>100.0</td>
</tr>
</tbody>
</table>

SOURCE: Ministero (2007). Note: 475 initiated cycles, 4 institutions, are missing
ART provision has increased substantially over the last decade. The number of embryo transfers after ART in Italy increased nearly threefold, from 6,296 in 1997 to 18,521 in 2004. In particular, there has been a drastic considerable rise in per capita embryo transfers after ICSI in Italy (see Error! Reference source not found.). ICSI provision in Italy is also high when compared to France and the UK. This may be a consequence of the restriction to fertilizing a maximum of three oocytes. Moreover, the dominance of ICSI is particularly strong in private clinics: 82.1 per cent of all cycles in private centres use ICSI, compared to 72.8 per cent of cycles in public clinics (Ministero, 2007).

**Figure 4–1 Proportion of women older than 40 in Assisted Reproductive Technology treatment**

**Figure 4–2 Provision of IVF and ICSI in Italy per 100,000 capita reproductive population (1997-2004)**

A moderate reduction in transfers of three or more embryos

A positive trend observed in Italy is the one away from high numbers of embryo transfers. Between 1997 and 2004 the percentage of 4-embryo transfers after IVF and ICSI conducted among all embryo transfers after IVF and ICSI reduced from 19.5 per cent to 0.9 per cent (see Figure 4–3). The 2007 data published by the ministry of health report that 4-embryo transfers after IVF and ICSI dropped to zero (Ministero, 2007) – an expected result after it was made illegal to extract more than three eggs.

Figure 4–3 Proportions of 1-, 2-, 3- and 4-embryo transfers in Italy (1997–2004)

A similar trend may also be observed for 3-embryo transfers – from 42.3 per cent in 1997 to 37.7 per cent in 2002. But after 2002 this proportion increased again to 48.5 per cent in 2004. The ministry of health reports that 3-embryo cycles after IVF and ICSI have increased to, respectively, 49.5 per cent and 50.4 per cent in 2005 (Ministero, 2007). Although some 4-embryo transfers have been replaced with 3-embryo transfers, there is a real, albeit moderate, reduction in the aggregate proportion of transfers of three or more embryos until 2004.

Clinical practice in Italy eliminates the use of fetal reductions to limit multiple pregnancies

There is another aspect of Italian clinical practice that may contribute to an increased number of multiple pregnancies: the number of reported fetal reductions has decreased and there is an absence of data reported to ESHRE after 2002 (see Figure 4–4). It seems clear that the value-based ART policy in Italy trumps the clinical importance of limiting multiple pregnancies. With growing international best practice to limit embryo transfer and reduce higher order pregnancies, it is perhaps not surprising that the percentage of fetal reductions in France and in the UK has been higher than in Italy. The observation that clinical practice in Italy has moved away from (reporting) fetal reductions to limit
multiple pregnancies is consistent with the fact that the technique of fetal reduction is normatively at odds with Italy’s value-based regulation aimed at preserving the rights of the embryo.

![Figure 4–4 Proportion of fetal reductions in all IVF and ICSI cycles in Italy, France and UK (2000–2004)](image)

**Figure 4–4 Proportion of fetal reductions in all IVF and ICSI cycles in Italy, France and UK (2000–2004)**

The success of ART in Italy may be diminishing in recent years
Prior to the 2004 law, the chance of becoming pregnant after IVF and ICSI had remained relatively constant between 1997 and 2004 (fluctuating around 25%), and increased slightly after FER treatment in that time period (from 16.4% to 18.5%). Clinicians were allowed to fertilise more oocytes in order to select the most viable zygotes. However, the delivery rate in Italy after IVF, ICSI and FER shows a sharp decline in the same time period (see Figure 4–5) – a trend that appears to continue in 2005 after the new law enters into force. According to the first official data on the effects of the restrictive law – which have been made public by the Italian health minister in 2007 – pregnancy rates per eggs extracted decreased from 24.8 per cent in 2003 to 21.2 per cent in 2005 (Ministero, 2007) (see Table 4-3). Data from the Italian registry also show a decrease in the delivery rate occurred after the new law from 22 per cent in 2003 to 18 per cent in 2005 (Bartolucci, 2008; Ministero, 2007). This appears to support the major political concern that the legislative requirement of the 2004 law to limit fertilisation of up to three egg cells would reduce success rates in Italy (Ragni et al., 2005).
Figure 4–5 Change in proportion of deliveries to all transfers after Assisted Reproductive Technology treatment in Italy (1997-2002)

Table 4-3 Comparison of clinical practice (IVF and ICSI) in Italy between 2003 and 2005

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics participating</td>
<td>120</td>
<td>169</td>
</tr>
<tr>
<td>Pregnancies</td>
<td>4807</td>
<td>6235</td>
</tr>
<tr>
<td>Average pregnancies per clinic</td>
<td>40.1</td>
<td>36.9</td>
</tr>
<tr>
<td>Pregnancies per eggs extracted</td>
<td>24.8%</td>
<td>21.2%</td>
</tr>
<tr>
<td>1-embryo transfers</td>
<td>13.7%</td>
<td>18.7%</td>
</tr>
<tr>
<td>2-embryo transfers</td>
<td>34.4%</td>
<td>30.9%</td>
</tr>
<tr>
<td>3-embryo transfers</td>
<td>30.9%</td>
<td>50.4%</td>
</tr>
<tr>
<td>Cycles</td>
<td>22,517</td>
<td>33,244</td>
</tr>
<tr>
<td>Pick-up</td>
<td>19,962</td>
<td>29,380</td>
</tr>
<tr>
<td>Transfers (fresh and cryopreserved)</td>
<td>17,829</td>
<td>25,402</td>
</tr>
<tr>
<td>Total of pregnancies</td>
<td>4,914</td>
<td>6,235</td>
</tr>
<tr>
<td>Pregnancies/transfers</td>
<td>27.6%</td>
<td>24.5%</td>
</tr>
<tr>
<td>Delivery rate</td>
<td>22%</td>
<td>18%</td>
</tr>
</tbody>
</table>

SOURCE: Ministero (2007), p. 100

4.1.4 Welfare and healthcare tradition: Assisted Reproductive Technology services fall mostly outside the healthcare system and welfare state

Italy’s Southern welfare system is similar to France’s continental or Bismarckian welfare state: it relies on corporatist arrangements that set up social insurance funds, and benefits are largely dependent on participation in the labour market. However, the overall scope of the programmes and benefits differs, as well as the importance of the family and the administration and implementation structures. In very general terms, social insurance and welfare provisions are patchy: in some areas, such as pensions, very generous benefits are paid; while some areas are non-existent, such as a minimum social support, (Ferrera, 1995). Until 1978 Italy’s healthcare system was also based on a social insurance scheme
built upon occupational group, but was then reformed into a universalistic, yet decentralised national health service (SSN).

**No universal access to ART in Italy’s SSN**

With its establishment in law in December 1978, the Italian SSN spelled out a wide range of personal health services to be provided by local public health units (Unità Sanitarie Locali, USL). The underlying principle is that healthcare is to be provided to all citizens (universal coverage) free of charge at the point of service. This coverage has been extended to 3.5 million Italians (Brown, 1984). Partly driven by the public sentiment that healthcare in Italy was too expensive and delivered too little, the organisational framework of the SSN has, however, been changed, however, by the gradual introduction of an elaborate system of user co-payments (Ferrera, 1995). The sentiment seems unfounded as Italy ranks third in the world with respect to the efficiency of its healthcare system, according to the WHO (Evans *et al.*, 2001). Nonetheless, currently around a third of healthcare expenditure in Italy is contributed either out-of-pocket or as payments for voluntary private health insurance. Access to healthcare for recognised illness nevertheless is a constitutional right for every citizen.

The universal access to healthcare is not reflected in the provision of ART services. Infertility is not defined as an illness within the framework of the SSN, and thus access to ART services does not fall under the provision of the constitutional right for healthcare. ART treatment usually has to be paid for by patients. In addition, access is limited to cohabiting heterosexual couples, reflecting conventional family values. However, somewhat surprisingly, couples do not have to be married to be eligible for ART. Due to the regional character of the Italian health service, access to ART policy is not uniform across the country.

Traditionally, access to welfare benefits and social security payments has been very fragmented, and coverage has not been comprehensive (Ferrera and Gualmini, 2000). The types of benefits vary by occupation, length of contribution and region. Limited access to certain services, therefore, as in the case of ART, is not unusual in the Italian welfare state.

**Reimbursement: a tradition of fragmented coverage**

Italy’s general welfare system is characterised by a mix of partly very generous welfare schemes and partly areas without coverage or only very low coverage. The Italian welfare state cannot be easily classified as generous or parsimonious and it is difficult to see how this context influences the reimbursement of ART services.

In contrast, the Italian SSN provides universal access to health services and covers some costs of medical care and treatment. Patients have to contribute to the cost of treatment and the cost of drugs, however. If private facilities adhere to a convention with the SSN, healthcare services may also be covered by public funding; otherwise, they need to be paid for by the individual patient. In order to bypass waiting lists, patients often resort to private payment for healthcare services. As a result of an increase in co-payments in the public system throughout the 1980s and early 1990s – in terms of the amount and the

---

9 Public expenditure accounts for only 68% of the total healthcare spending, one of the lowest percentages in Europe (HiT Summary Italy 2001).
types and levels of care (Ferrera, 1995), as well as of the growing utilisation of private service providers involving individual payments – privately financed healthcare expenditure is significant in Italy.\textsuperscript{10}

The general principle of ART provision is that it has to be paid for by the individuals receiving it or by private insurance. Some regions, however, partially reimburse ART treatment as long as it takes place in public clinics or through contracted specialists. Although Italy’s regulations for financing its healthcare system are in principle nationwide, there are regional disparities. The combination of private and public financing of ART treatment reflects the existing fragmentation of the welfare system as well as the structure of the regionalised SSN.

\textit{Organisation and management: a split between private and public providers}
The organisation of the Italian welfare system as well as the healthcare system is characterised by a large degree of fragmentation. Italy’s healthcare system is organised at three levels: central, regional, and local, all under the supervision of the ministry of health. The regions have considerable influence in the provision of healthcare services. The local health units (LHUs) are responsible for providing healthcare at the local level, and they do this either themselves or through contract arrangements with public and private providers. Italy has a mix of public and private healthcare providers, and patients may choose between them as long as the providers have a contract with the LHUs. Still, the lion’s share of hospital care (61\%) is delivered by public structures. The remaining 39\% consists of contracted-out services, mainly provided by (private) non-profit institutions. ART services follow a similar pattern of provision, with a split between public and private providers – also resulting in regional differences.

Quality of care in authorised ART services as well as in other healthcare services (such as organ donation and transplantation) in Italy is governed by a national accreditation procedure of the competent authority, the Centro Nazionale Trapianti (CNT), the Centro Nazionale Sangue, and the Regioni (Regional Health Authorities) (European Commission, 2007). All clinics providing ART services in Italy must be accredited to operate under the public convention (contract) with the Italian national health service. The national registry by the national institute of health holds a list of all authorised institutions that can apply techniques of medically assisted reproduction (European Commission DG SANCO, 2006). But, while the public convention and authoritative decisions envisaged by the Degan Circolar cover all public institutions providing ART services, ART regulation does not address the private sector – in which there are private structures performing ART cycles without convention (Ministero, 2007). For the non-regulated areas of ART practice in Italy, there is self-regulation by a variety of stakeholder groups, including the orders of doctors and dentists.

\textsuperscript{10} In 1999 private financing accounted for 33\% of total healthcare expenditure. according to Donatini \textit{et al.} (2001)
4.2 Assisted Reproductive Technology outcomes: unintended consequences of the new law

While outcomes of ART have always been relatively poor compared to other countries, the introduction of Law 40/2004 seems to have several additional adverse consequences. These will be discussed in this section.

Health outcomes have worsened since the 2004 policy change

Italy’s new law requires all created embryos to be transferred, irrespective of their quality. Quality of eggs for fertilising is clearly an important issue given that previously there was no transfer in 22.5 per cent of initiated ART treatments, due to lack of embryonic development (Ministero, 2007). The consequence of the 2004 legal obligation is that multiple embryos may be transferred to women for whom a single embryo would have been appropriate. The increase in multiple-embryo transfers since 2004 (see Section 4.1.3) was therefore expected to have adverse consequences for both maternal and neonatal health. For women higher order pregnancies are associated with a higher incidence of hospitalisation; caesarean delivery; premature, low-weight babies and miscarriage. For the future child, short- and long-term complications include increased risk of perinatal mortality, learning disabilities and behavioural problems (ESHRE, 2003). As a consequence, multiple pregnancies and births have been shown to generate higher costs than singletons; this is due to antenatal, obstetrical and neonatal treatment, and to long-term disability services (Katz et al., 2002; Goldfarb et al., 1996).

The ministry’s data indeed show an increase in the number of multiple births from 22.7 per cent to 24.3 per cent. Although there is no definitive evidence of causality, it is not unlikely that this is a direct consequence of the implementation of the 2004 law (Robertson, 2004). Additionally, the data report that “negative outcomes” from ART services in Italy have increased since the new law came into force into 2004 – rising from 23.4 per cent in 2003 to 26.4 per cent in 2005 (Ministero, 2007). However, we are not aware of how this category is defined. Moreover, these figures could be an underestimate of the true incidence of adverse outcomes; Boggio (2005) argues that it is very likely that some of the provisions will be circumvented in daily practice by physicians who have issues of conscience.

Table 4-4 presents the health outcome data from the latest ministry report (2007) demonstrating the short-term impact of the 2004 policy change. It is worth noting that not all clinics have provided data for the ministry’s report, and that due to Italian privacy law there are insufficient follow-up data available publicly, according to Dr Giulia Scaravelli, who is head of the registry at the Instituto Superiore di Sanita (Sinclair, 2007).11

---

11 For example, on the number of cycles women had undergone before getting pregnant or stopping their attempts.
Table 4-4 Comparison of health outcomes (IVF and ICSI) in Italy between 2003 and 2005

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycles</td>
<td>22,517</td>
<td>33,244</td>
</tr>
<tr>
<td>Delivery rates</td>
<td>22%</td>
<td>18%</td>
</tr>
<tr>
<td>Proportion of miscarriages</td>
<td>18.4%</td>
<td>22.5%</td>
</tr>
<tr>
<td>Proportion of multiple births</td>
<td>22.7%</td>
<td>24.3%</td>
</tr>
<tr>
<td>Proportion of ‘negative outcomes’</td>
<td>23.4%</td>
<td>26.4%</td>
</tr>
</tbody>
</table>

SOURCE: Ministero (2007)

Some health outcomes after ART have always compared unfavourably with other countries

Since multiple-embryo transfers remain very common in Italy, the proportion of triplet deliveries continues to be a significant proportion of ART births. The proportion of twin deliveries fluctuates by a few percentage points from year to year, ranging from a high of 24.1 per cent (2002) to 19.3 per cent (2003) (see Figure 4–6). Although the proportion of multiple births in Italy is consistently higher than in France, it is not much out of line with that of the UK.

![Figure 4–6 Triplet and quadruplet deliveries are a significant proportion of higher order deliveries in Italy over time](attachment://Figure4.6.png)


As an indirect indicator of poor health outcomes, we can crudely assume that 21% of all ART babies born in Italy will suffer from prematurity and low birth weight (among other prematurity-associated health conditions), given that this is the reality for 50% of twins and 90% of triplets who are born (HFEA, 2007c). When comparing health outcomes after ART with those in other countries, the incidence of bleeding to total ART deliveries stands out in Italy. However, reported data from ESHRE suggest caution as data were generated through different methods using different definitions in different countries. Among our countries of interest, Italy has the highest percentage of bleedings in the three countries, with a sharp rise after 2002 to above 3 per cent (see Figure 4–7).
The percentage of OHSS complications after ART in Italy has been decreasing in recent years, to 0.82 per cent in 2004 from a high of 1.64 per cent in 2000. Although it might be expected that there would be a financial incentive in Italy for couples to maximise the number of oocytes retrieved for fertilisation since many pay individually for their ART treatment; Italian regulation limits the number of oocytes to be fertilised. Thus there may be a disincentive to overstimulating a woman’s ovaries to retrieve a greater number of eggs, which would decrease the risk of OHSS and its complications.

Cross-border ART tripled since the 2004 policy change

The introduction of the new law on reproduction in 2004 has made it more difficult for couples who have infertility problems to receive ART treatment in Italy. A survey by the Osservatorio sul Turismo Procreativo (2007) showed that the number of couples crossing the border to undergo ART significantly increased since the law came into force. The survey comparing the reproductive travel of Italians before (2003–2004) and after the enactment of the Italian law (2004–2005) found that the number had nearly tripled (see Table 4-5).
Among the Italian infertile couples who obtained ART in foreign countries, 32 per cent went to Switzerland – given the vicinity and the common language, predictably mostly to the Ticino Canton. The survey also showed a certain trend towards Eastern European countries and Greece, which may be driven by their lower prices for treatments (data not shown). An update of this survey of the period 2005-2006 showed that the increases in cross-border ART continued. The 27 foreign clinics contacted for the latest survey reported that a total of 4,173 Italian couples had undergone ART at their institutions in 2005–2006 (Osservatorio sul Turismo Procreativo, 2008).

### Conclusions

Italy has a turbulent history of ART policy and practice. Until 2004, it was considered the “far west” of reproductive medicine. There was little regulation and it was clear that legislation should be improved to control clinical practice. The decision-making process for a new regulatory design of ART policy took several decades; proposals ranging from very restrictive to very liberal. The resulting Law 40/2004 seems to be unconnected to international best clinical practice. Rather, the restrictive nature of this new policy has been the result of an ethical debate that is highly dependent on its context. In the decision-making process, party politics and the influence of the Roman Catholic Church on matters of public concern played a dominant role. It is difficult to argue against this; although the law fails to define the concept of an embryo, protection of individual life is considered to commence with conception, and therefore human intervention in this process is highly contentious in Italy. Restriction of certain techniques, such as screening embryos for genetic conditions prior to implantation in the uterus or surrogacy, may be explained by Italy’s conservative and religious context.

In contrast to its fragmented system of social protection linked to labour participation, access to healthcare in Italy is by right of citizenship. However, this does not apply to ART treatment; the high proportion of individual payment is a direct consequence of the fact that infertility is not defined as an illness. Despite this, Italy’s welfare system allows for considerable regional variation. Several regions have introduced their own reimbursement schemes for ART treatment.
This chapter shows that the characteristics of Italy’s current ART system can be explained through analysis of different perspectives. In this context, protection of unborn life has prevailed over protection of maternal and perinatal health. The introduction of Law 40/2004 clearly had a number of unintended consequences that should be addressed. As the body of evidence available is as yet scanty, it is difficult to establish unambiguous causal links. Although the health outcomes in Italy have always been relatively poor compared to the UK and France, the new law correlates with a striking deterioration in maternal and perinatal health. A second unintended effect of the new law is that infertile couples are increasingly travelling abroad to undergo treatment that is prohibited in Italy. Upon their return the maternal, perinatal and neonatal healthcare costs will have to be borne by the Italian healthcare system.
CHAPTER 5  United Kingdom: postcode lottery in a reputable system

The United Kingdom has the longest history of ART provision of any country in the world, with a tradition in the pioneering of controversial biomedical research and techniques. But the provision of ART varies significantly across the UK, a situation often referred to as a “postcode lottery” (i.e. geographical variations in public funding of treatment). This chapter’s case study will explore the regulatory, cultural and economic landscape of ART use in the UK, and discuss its characteristics and performance in a comparative context.

5.1 Assisted Reproductive Technology system from four perspectives

Since the birth in 1978 of Louise Brown, the world’s first “test-tube baby”, the UK has remained at the forefront of developments and research into reproductive technologies. Despite its reputation and its tradition of universal healthcare, reproductive health professionals and patients complain about the relatively poor funding of infertility treatment.

5.1.1 Regulatory context: a centralised system with regional autonomy

The UK was the first country to introduce a statutory body with a mandate to shape and regulate reproductive treatment (Doyle, 1999). The Human Fertilisation and Embryology Authority (HFEA) is an independent licensing authority that regulates the clinics and laboratories which are legally authorised to perform certain ART practices. The HFEA, established in 1991, is made up of medical professionals and lay people (including academics, doctors and nurses, social workers and religious leaders, together with people who have experienced infertility) who have responsibility for the regulation of ART. Updates to the code of practice are issued three to four times every year. Revisions stemming from these reviews are based on advances in technology and their relationship to the evolving ethical landscape. In addition, the HFEA directly inspects and licenses ART clinics through site visits. In its practical guidelines, the HFEA offers only standards for clinical practice. Individual clinics – in co-operation with Primary Care Trusts (PCTs) if they are National Health Service (NHS) funded – make decisions about which clinical services they choose to offer, and about access to those services.

The legislative framework was based on the conclusions of the ethics committees of various professional organisations, such as the Royal College of Obstetricians and Gynaecologists...
(RCOG) and the British Medical Association, which produced guidance documents on the use of ART for their members. Many of these professional ethics committees came to similar conclusions to those of the Warnock Committee (Warnock et al., 1984).

While, according to a consultation paper (DHSS, 1986), most of the British medical community preferred self-regulation of ART, they recognised that this was unlikely to happen in the tight regulatory context and nature of the contemporary political climate. Likewise, many anti-ART interest groups recognised that they were not going to win the push for state control. Both sides decided to agree to the licensing authority route of regulation, so that they are involved in the progression of regulation.

EU directives have been transposed into national law
All three EU directives related to assisted reproduction have been transposed into national law in the UK. Similar to Italy, the designated authority, the Human Tissues Authority (HTA), is responsible for all human tissues and cells, other than reproductive cells. Instead, it is the HFEA that is responsible for reproductive cells. The difficulties observed in France around the definition of activities to be accredited do not seem to apply to the UK. It has listed a wider range of activities that are subject to accreditation than France (European Commission DG SANCO, 2007; 2008).

Furthermore, already in 2007, the existing regulatory framework for human tissues and cells already provided for a control system to ensure that all gametes and embryos coming into the UK had been handled to the same standards (ibid.). Among the three country cases, the UK is the only to report figures on gamete imports and exports (European Commission DG SANCO, 2006).

Finally, the UK has an established electronic system for the reporting of serious adverse events (European Commission DG SANCO, 2008). Similar to France, the UK has clearly defined criteria for reporting, using the definitions of each term given in the Directive 2004/23/EC as well as providing additional term specifications. However in contrast to France, the UK has explicitly reported data on these events and analysis thereof.

Britain is least restrictive regarding technologies allowed
With few exceptions, British law is the least restrictive of the three countries studied as it allows most ART practices. Commercial surrogacy is forbidden, though not-for-profit surrogacy agencies do exist. The HFEA allows PGD and PGS for testing of a relatively long list of specified genetic conditions. Finally, the Human Fertilisation and Embryology Bill 2007–2008 will permit certain types of research into human–animal hybrid embryos, under strict licensing criteria requiring scientists to demonstrate that their planned research projects are both “necessary and desirable”. The HFEA has explicitly acknowledged that public opinion on this type of research is very divided, so any future widening of these ART-related policies is likely to be contentious (HFEA, 2007d).

There is considerable regional autonomy in the NHS
Within the NHS, there is a certain degree of regional autonomy given to the PCTs, so that there is no country-wide standard for who can receive ART procedures. The National Institute for Clinical Excellence (NICE) advocates offering ART treatment in England and Wales to women aged between 23 and 39 with an identified cause of infertility, or who
have not conceived after three years of regular unprotected sex, although it actually defines infertility as “failing to get pregnant after two years of regular unprotected sex” (HFEA, 2008b). It does not define infertility as an illness. NICE also recommends that it is appropriate to fund IVF treatment when the chances of success are more than 10 per cent (ibid.). Nonetheless, PCTs in Britain may operate different criteria of eligibility for fertility treatment. The result of regional variation in eligibility criteria among PCTs is a difference in access, commonly referred to as a sort of “postcode lottery” (most pronounced in England); that is, geographical variation in public funding of treatment, one PCT offering coverage of the treatment while the neighbouring one may not (BBC Health, 2008). Each PCT decides on the scope of its ART funding and the eligibility criteria for treatment.

Almost a quarter of UK PCTs did not fund ART treatments at all in 1998. For instance, the Cambridgeshire PCT had not previously provided ART services, which its board had declared “a low priority for resources” (Birenbaum-Carmeli, 2004), although in a recent shift in policy the East of England NHS (encompassing Cambridgeshire PCT) agreed to implement the 2004 NICE guidelines. Most local PCTs claim that the main reason for non-provision of ART is its expense and the lack of necessity. For PCTs looking at budget shortfalls, it is probably much easier to justify cutting ART programmes than it is, for instance, to eliminate funding for cancer programmes. These observations therefore reveal either a lag in the implementation of NICE guidelines, or a gap between central government’s rhetoric, national guidelines and local accountability.

Despite geographically related differences in who is eligible for public funding for ART in England, there are some requirements common to all PCTs. These include the following two criteria: 1) the proven ability to provide a caring environment for the child and 2), most importantly, an absence of child-related convictions or offences related to domestic violence. Furthermore, the HFEA recommends that fertility clinics encourage potential patients to undergo counselling in order to determine: 1) likely future ability to look after or provide for a child’s need; 2) the couple’s commitment to having and bringing up a child; 3) their economic status and ability to provide for the child; 4) the mental and physical health of the parents; and 5) the need of the potential child to know about their origin (IVF-Infertility, 2008).

This last point indicates the 2004 change in ART regulations that previously guaranteed anonymity of gamete donors. Under the new UK guidelines for ART services, donors are required to consent to their name being released to the child upon reaching their eighteenth birthday if they request it. In comparison, the French debate on donor anonymity remains in favour of the donor and not the right of the child to the donor’s private information (see Section 3.1.1).

Do children need a father and should scientists be allowed to create human–animal hybrids?
The British media seem to have disproportionate interest in controversial issues related to assisted reproduction and embryology. IVF often makes the front-page headlines.

---

12 Some PCTs consulted the public about their healthcare budget with explicit reference to the provision of ART. There are few indications that the community has other priorities. For example, see Gloucestershire NHS (2006)
Nonetheless, the UK is at the forefront of political decision-making relating to many of the most controversial issues concerning ART that are still being hotly debated in other countries. In particular, the UK recently made two big policy decisions: allowing single women and lesbians to have ART – an existing practice that was recently endorsed by MPs in a parliamentary vote (Watt, 2008) – and the licensing of certain types of human-animal hybrid embryo research under certain conditions.

In December 2006 the HFEA released a White Paper updating their position on a number of controversial rules that were part of their original 1990 charter (Department of Health, 2006). The White Paper did not propose to allow the creation of human–animal hybrid embryos, but subsequent consultation with a joint parliamentary committee produced recommendations that the HFEA be allowed to judge which scientists could create hybrids and what type of hybrids may be created (Department of Health, 2007). The resulting bill, approved by MPs through parliamentary vote in May 2008, will permit the creation of only certain types of human–animal hybrid embryo, under licence, where scientists can prove their proposed research project to be both necessary and desirable, satisfying both scientific and ethical criteria.

The other and most controversial change to be announced was to remove the “need for a father” when assessing the welfare of the potential child, which, if finally passed, will remove obstacles of equal access to ART through the NHS for lesbian couples and single women, a move lauded by human rights activists and many in the gay and lesbian community as an end to unnecessary moralising on the part of the UK government. At the same time, social conservatives opposed the change, claiming the removal would transmit the wider societal message that fathers can be dispensed with in family matters.

5.1.2 Economic context: funding of Assisted Reproductive Technologies is patchy

The economic context of Britain’s ART system reveals a heterogeneous picture.

*Significant difference in funding between trusts*

Although the NICE guidelines recommend that the NHS in England and Wales should pay for up to three cycles of treatment for women in infertile couples under specified conditions, in practice this is still not the case. According to the findings of a 2006 study (Ledger et al.), at that point only 25 per cent of IVF treatments were paid for by NHS. In February 2004 the government announced that it would request that PCTs provide for all women of appropriate clinical need – as defined by the NICE guidelines – at least one cycle of ART treatment paid for by the NHS from 1 April 2005. In March 2005 a survey conducted by a UK patient network found significant differences between PCTs in both eligibility criteria and access to NHS funding (Infertility Network, 2005). Similarly, Maheshwari et al. (2008) report that there was wide variation in reported upper-age limits for access to both publicly funded IVF. The age limits ranged between 35 and 50 years, and for self-funded IVF, from 42 to 50 years. Older data from 1998 on NHS funding suggest that the UK is a country with "one of the poorest access to fertility treatment". That year the NHS funded an average of 10.8 IVF cycles per 100,000 persons, or 633 cycles per million. This average deviates by region, ranging from 0.3 to 21.5 women undergoing ART per 100,000, depending on the PCT (College of Health, 1997). While recent, more exactly comparative, data could not be found, figures for the number of NHS
clinics and the number of PCTs providing ART services do suggest an increase in NHS provision since 2004, the year that NICE announced its eligibility recommendations.

Costs per treatment cycle in the UK vary greatly by treatment. For example, IVF costs around €4,194 per cycle, ICSI between €6,770 and €11,510 per cycle, GIFT around €7,689 per cycle, and zygote intrafallopian transfer (ZIFT) between €10,150 and €13,540 per cycle. A somewhat dated cost-effectiveness study found that an ongoing IVF pregnancy costs on average roughly €12,580–15,380 (Sykes et al., 2001). Much progress has been made since the beginning of IVF treatment, and the cost-effectiveness of technologies will continue to improve, with the prospect of potential cost reductions for ART treatment.

**ART has indirect cost consequences for the NHS**

In the future, the cost of IVF may decrease as a result of the improvements in its success rates. Additionally, the decision of the HFEA to discourage multiple births for safety and health reasons may have economic consequences in the future if the new policy leads to an increased number of cycles. In the long term, however, this may lead to positive consequences for the healthcare costs as a result of improved neonatal and maternal outcomes.

Ledger et al. (2006) estimated the annual costs of multiple births to the NHS (Table 5-1). These costs included both routine care costs and the costs of stays in hospital neonatal units, but did not include the cost due to other co-morbidities associated with the very low birth weight that are a direct result of multiple births. Neither does the study include the cost of maternal health complications associated with ART, of which OHSS is the most common in the UK (Nyboe Andersen et al., 2008).

<table>
<thead>
<tr>
<th></th>
<th>Singleton</th>
<th>Twin</th>
<th>Triplet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estimated maternal cost (€)</strong></td>
<td>4,366</td>
<td>8,469</td>
<td>16,125</td>
</tr>
<tr>
<td><strong>Estimated neonatal cost (€ per family)</strong></td>
<td>267</td>
<td>4,283</td>
<td>29,106</td>
</tr>
<tr>
<td><strong>Total cost per family (€)</strong></td>
<td>4,632</td>
<td>12,753</td>
<td>45,231</td>
</tr>
<tr>
<td><strong>Number of IVF births in UK</strong></td>
<td>4,621</td>
<td>1,579</td>
<td>109</td>
</tr>
<tr>
<td><strong>Costs of IVF births to the NHS (€)</strong></td>
<td>21,402,503</td>
<td>20,136</td>
<td>4,930,167</td>
</tr>
</tbody>
</table>

SOURCE: Ledger et al. (2006)

**A dilemma for gamete donation**

In the light of a recognised shortage of donated gametes in the UK, the Glasgow Royal Infirmary was required in 1999 to import sperm from Denmark. Notably, male gamete donors receive compensation only for “reasonable expenses”, such as loss of time at work and transportation costs. However, there has been discussion about increasing the financial incentives for donation to thousands of pounds – a decision that anti-ART groups oppose, equating it with “buying a life. In the context of competing pressures, recruitment expenses for broadening the male gamete donor pool may become an added burden on the NHS.

---

13 Twin and triplet figures are number of sets, rather than individual babies

14 The number of egg and sperm donors has been dropping fairly steadily in recent years, from 325 sperm donors and 1,242 egg donors in 2000 to 259 sperm donors and 956 egg donors in 2005 (Murray and Golombok, 2000).
Similarly, egg donors have historically not been compensated, other than for travel expenses. There is some discussion of changing this to provide women with more compensation for what is, after all, a much more involved and invasive donation procedure than semen donation (BBC Health, 2004). In some cases in the UK, clinics have offered women free or discounted IVF treatment if they also donate some extra oocytes.

5.1.3 Clinical practice: Assisted Reproductive Technology practice is variable, but with minimum good practice standards

National regulation of ART in the UK means that it can be practised legally only under the accreditation of and regular audit by the country’s independent competent authority, the HFEA, which licenses clinics and laboratories to perform certain ART practices. Moreover, the quality of care provided throughout ART treatment is guided by good clinical practice guidelines, produced by the RCOG and commissioned by the HFEA. Though these guidelines do not constitute legislation in themselves, the HFEA does have the power to revoke clinics’ licences for non-compliance. The provision of ART services in the UK operates within a wider vigilance system for ensuring the quality and safety of human tissues and cells, including oocytes and sperm: the European Commission Legal Directive on Tissues and Cells (European Commission, 2004). In turn, the HFEA is responsible for ensuring compliance with the directive.

ART services may not always be provided in the UK within the established NHS, particularly in those regions where trusts do not offer financial coverage of ART and infertile couples are forced to seek private care. The HFEA reported sixty public NHS clinics and forty-nine private clinics offering IVF services, as of September 2008 (see Table 5-2). However, there is no clear separation in the oversight of care quality between public and private institutions as there is some overlap between public and private clinics that may accept either type of payment (some NHS clinics accept private payment, and vice versa). Licensed ART clinics in the UK are concentrated in the south-east (13) and in London (24).

Table 5-2 Clinics offering Assisted Reproductive Technologies in the UK, by region

<table>
<thead>
<tr>
<th>Region</th>
<th>Public</th>
<th>Public, but can pay for unfunded treatment</th>
<th>Private</th>
<th>Private, but also accepts NHS patients</th>
<th>Total</th>
<th>Total public</th>
<th>Total private</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>East of England</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>London</td>
<td>2</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>24</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>North-east</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>North-west</td>
<td>1</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>10</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Scotland</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>South-east</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>8</td>
<td>13</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>South-west</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Wales</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>West Midlands</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Yorkshire and the Humber</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

UK Total         | 109    | 60                                         | 49       | 49                                    |       |              |               |

SOURCE: HFEA, 2008a.
ART provision in the UK varies widely at the local level

Added to the unequal geographical distribution of funded IVF cycles have been waiting times for infertile couples in the UK, which are greater than a year in over half of the PCTs (Birenbaum-Cameli, 2004). Because of restrictions or lack of access to some types of ART, some UK couples desiring IVF may travel outside the country to receive lower-cost treatment or treatment that is not allowed in the UK. There is, however, currently no reliable data on the extent of cross-border ART to clinics abroad.

Moreover, the variation among clinics at local level also has implications for disparities in the quality of care provided to British infertile couples. Notably, in 2006, there was a stir in the media after an HFEA review raised the concern of poor adherence among clinics to the HFEA national guidelines, stating that one in five clinics (20%) fails to meet the basic standards expected by the independent licensing authority.15 However, more recently the HFEA (2007b) reported a high level of compliance and of patient satisfaction, as well as few adverse events.

Access to ART per capita in UK is amongst the lowest in Europe

Over the 1997 to 2004 period, the number of IVF clinics in the UK remained relatively constant over time (ranging between 72 and 80).16 Moreover, while the total number of embryo transfers after IVF and ICSI in the UK has increased from 23,553 in 1997 to 26,092 in 2004, this increase is relatively small compared to the steeper rise in these figures for both France and Italy. Provision per capita in the UK is among the lowest in Europe. Of those countries surveyed by ESHRE in 2004 that reported to a national registry, only Latvia (0), Austria (2) and Macedonia (1) had fewer cycles than the UK (at 3 per thousand women of reproductive age) (Nyboe Andersen et al., 2008).

While overall provision of ART in the UK has remained relatively constant, the number of ICSI transfers per capita has steadily increased over the last decade. The trends for IVF and ICSI seem to be mirroring one another, suggesting a substitution effect (see Figure 5–2).

Transfers of three embryos are being phased out

For the time period of ESHRE-reported data on changes in the proportion of higher order embryo transfers (1997–2004), the UK shows a large decline in 3-embryo transfers (from 48.8% to 5.5%), with a concomitant rise in 2- transfers (from 42.1% to 85.1%). This pattern is also seen in France, but the change is less dramatic. Transfers of more than three are not practised in the UK since they are banned by HFEA. At the same time, the proportion of 1-embryo transfers in the UK is very low, and has seen a marginal increase over the last few years (see Figure 5–3).

---

15 See, for example, Hope (2007).
16 Notably, this number has risen recently to 109 clinics in total, as shown in Table 5-2.
As multiple births are known to be associated with various adverse health outcomes, both the HFEA and NICE have advocated that no more than two embryos be transferred per cycle in order to cut down on multiple births (Ledger et al., 2006). Although this limit is not yet legally binding, the recommendation reinforces a trend of good clinical practice towards improving maternal and child health after ART treatment in the UK.
Success rates are gradually increasing

The pregnancy rate after ART in the UK has increased by approximately 3 per cent between 1997 and 2004, and the proportion of transfers that result in delivery has also improved, by approximately 5 per cent, in the same period.

As Figure 5–3 illustrates, success rates decrease considerably after the female age of 35. However, it is women between 35 and 40 that form the dominant age group among infertility patients seeking treatment in recent years. Despite the increasing proportion of older women undergoing ART, aggregate success rates have increased. Therefore, age-specific success rates have increased considerably, particularly for women between 30 and 35 (see Figure 5–4). Bearing in mind that these are aggregated figures, it would be useful to disaggregate the data by more variables than age, such as smoking or drinking behaviour, in order to understand better how these improvements in clinical practice come about.

![Figure 5–3 Overall success rate of IVF and ICSI in the UK, by age (1992, 1996, 2000, 2004)](image-url)

SOURCE: HFEA (2007a)
5.1.4 Welfare and healthcare tradition: Assisted Reproductive Technologies treatment in the UK is mostly privatised

The welfare state in the UK is commonly classified as liberal, or in Ferrera’s typology as belonging to the Anglo-Saxon type. This type is characterised by a strong reliance on individual risk prevention and only basic social protection. The UK system, which is financed through taxes and national insurance contributions, is characterised by relatively low flat-rate payments and means-tested benefits as a basic social protection net. In contrast to Bismarckian systems, benefits are not systematically linked to the contributions paid in and do not aim to maintain the social and economic status of a recipient, but provide only a basic protection; at the same time the whole population is eligible to top-up payments in cases of hardship.

In contrast to the welfare system, the healthcare system of the UK is truly universal and provides access to healthcare free of charge to the whole population. Following the nationalising of healthcare by the 1945 Labour government, the entire population in the UK is covered by the NHS, with all contributing taxes in some fashion. All persons have the same benefits and rules. Hospitals have since come under state control and institutional and physician services have been financed from the general budget of the national government. Some healthcare, such as physiotherapy, has remained private.

There is restricted access to ART services

The UK’s NHS differs from national health insurance in other countries where members of different regimes vary in payroll tax rates and benefits, and where some classes may remain completely uncovered. The main principle of access is residence; every legal resident in the UK is eligible for treatment by the NHS. Unlike in France, uniformity in the operation of the NHS structure and in the delivery of NHS services throughout the UK has always been sought. This is done through the framework of law enacted by Parliament and regulations formulated by the Department of Health, by monitoring
providers’ reports about their expenditures and performance, and by nationwide contracts between the Department of Health and NHS executives on the one hand and the labour unions and professional associations on the other side, both representing providers and employees (Glaser, 1994). Although primary care and general practitioners’ services are fully public, there is a small private market for healthcare services in the UK, which is largely limited to specialty care.

Although part of the treatments offered by the NHS and recognised as a cost-efficient treatment by NICE, there is no country-wide standard for who may receive ART procedures. Each PCT decides autonomously on the eligibility criteria for infertile couples seeking ART treatment in its catchment area. The unclear status of infertility as an illness leads to an ambiguous situation of access to fertility treatment. Reluctance to provide general access to ART services may be a reflection of the health and welfare-state tradition of the UK. Both are designed to secure against the basic risks of life rather than to provide generous welfare protection to citizens. Under the tight budgets of the PCTs to the need for prioritisation of treatment of harmful diseases seems understandable. The selection of specific prioritised treatments over ART, however, remains subject to discussion.

Thus, while the rules of access to ART are implemented in a way that is quite different from the functioning of the welfare and healthcare system, restricting the access to ART appears to be in line with the wider tradition of providing a basic protection rather than generous coverage.

Reimbursement of ART treatment has a low priority in a welfare and healthcare system that focuses on basic needs

In a comparative perspective, the British welfare state is less generous than its continental counterparts in relying more on flat-rate payments and tying its payments to needs rather than to previous income or contributions to the national insurance scheme (Hill, 2003). Similarly, despite universal access, health expenditure as a share of GDP is relatively low and the UK has a relatively tight system of cost control in place. This may be the result of the basic budgeting procedure, which assigns each local PCT a fixed budget on a top-down basis, founded on a formula taking into account the population and specific local needs, and incentivising the management of the PCTs to break even within this budget. PCTs have to prioritise certain elements of service delivery over others and in such a situation non-essential treatments may not be provided by a PCT under financial strain (HiT UK, 1999).

Given the ambiguous status of infertility as an illness, it is not surprising that ART services are not funded and provided in a nationally consistent way. Given the primary focus of the welfare state as well as the health service, of providing a net of basic protection against the risks of life rather than to provide generous services, the funding of ART treatment is very much in line with the overall macro context of the welfare state and the healthcare system.

The UK provides a large share of ART treatment outside the NHS

In the UK the state is the main provider of both welfare and healthcare. The Department for Work and Pensions (DWP) and the Department of Health are directly responsible for organising as well as overseeing the main schemes of the welfare state as well as the healthcare system. This is quite different from the continental welfare states, where joint
bodies of employers and employees with autonomy play a much larger role or even dominate the provision of services.

In the past an NHS hospital was an integral division of the District Health Authority (DHA)\(^{17}\) whereby the DHA administered a global budget to each hospital and dictated the plans for service provision. Since reforms by the Thatcher government, NHS hospitals have become autonomous trusts, empowering them to develop their own services, set their own employment rules and attract patient referrals from outside their district. Although it might be expected that Thatcher’s innovative market-driven reforms would cause a cost explosion, this has not occurred in the NHS because the DHAs collectively cannot pay out more than Parliament’s annual appropriations (HiT UK, 1999). A hospital trust’s budget to cover its operating costs originates mainly from patient revenue, provided by several DHAs. Because the UK government cannot risk large cost overruns or bankruptcies and because public money and patients’ needs are involved, the regional and district tiers of the NHS monitor and regulate the trusts’ economic operations (HiT UK, 1999). Despite these market-driven reforms, the UK (24) ranks considerably lower than France (4) and Italy (3) with respect to healthcare system efficiency (Evans et al., 2001).

The provision of ART services is not dominated by public sector provision, but relies more heavily on the private sector than other branches of the healthcare system. The large majority of ART cycles in the UK take place in private clinics, although there is some overlap between private and public clinics as some NHS clinics accept private payment, and vice versa.

In terms of regulation, the system of ensuring the quality of treatment, a separate accreditation system with the HFEA as watchdog, was set up to control the ART treatment provided. The oversight through the HFEA allows societal interests to be brought into the system. Therefore, in terms of ensuring the quality of treatment and regulating the use of ART, the UK relies on institutional arrangements that differ from the standard procedures, both in the NHS as well as in the welfare sphere. Furthermore, the far larger involvement of the private sector in the provision of services is very distinct from the NHS.

5.2 Assisted Reproductive Technology outcomes: improving health outcomes, but still many twins

The HFEA is responsible for the accreditation of clinics and ensuring good clinical practice, with the aim of protecting patient and child. Health outcomes generally compare favourably with those of other countries. However, as implementation of guidelines is lagging and funding of infertility treatment has relatively low priority in many PCTs, many couples have to finance their treatment themselves. Access to reproductive treatment is therefore in many cases limited to those who have the ability to pay. Despite Britain’s dominant paradigm of evidence-based medicine and best clinical practice, individual

\(^{17}\) DHAs were administrative units of the NHS in England and Wales from 1982 to 1996. The districts were a second tier below the health regions – the two layers of administration had been introduced in 1974. However, in 1996 the DHAs were abolished when new single-tier Health Authorities replaced both districts and regions.
payment and other inequalities have several undesirable consequences, which will be discussed below.

**Triplets after ART are becoming rare in the UK**

The proportion of deliveries after ICSI and IVF that are multiple births in the UK fluctuates between 25 per cent and 30 per cent. This is relatively high compared to most Western European countries (but is rather average among the whole region). In 2004, 25.5 per cent of births after IVF and ICSI were from multiple pregnancies, compared to 21.3 per cent in France and 22.4 per cent in Italy. On the positive side, there is an overall trend of reducing the proportion of triplet deliveries from 3.7 per cent to 0.3 per cent between the years 1994 to 2004. Twin deliveries in the UK have fluctuated around 24–25 per cent between 1991 and 2004, but there seems to be a marginal downward trend in recent years. In parallel, we see a modest increase of 5 per cent in the proportion of all ART births that are singleton in the UK (see Figure 5–5).

![Figure 5–5 Proportions of singletons, twins and triplets after IVF and ICSI in the UK (1992–2004)](image)

**SOURCE:** HFEA (2007a)

**Figure 5–5 Proportions of singletons, twins and triplets after IVF and ICSI in the UK (1992–2004)**

The proportion of multiple deliveries after IVF and ICSI is a useful proxy for adverse health outcomes, as they are associated with higher incidence of maternal and perinatal complications. In particular, given that 50 per cent of twins will be born prematurely and suffer associated low birth weight, as will 90 per cent of triplets (HFEA, 2007c), we can expect that 20% of all ART babies in the UK will suffer these conditions.

The phasing out of 3-embryo transfers in the UK shows improvement over time in the health outcomes associated with ART. Although the proportion of multiple-embryo transfers is still relatively high, the NICE recommendation to transfer no more than two embryos is paying off at least somewhat with respect to triplets and their associated health risks.
Adverse events after IVF and ICSI are rare in the UK, except for OHSS

Among the many care quality and patient safety indicators, the UK appears to show better health outcomes with regard to infections and bleedings. Only one infection after IVF and ICSI was reported in the UK in 2004, compared with 299 in France that year. And very few reports of bleeding between 2000 and 2004 were made, compared with double-digit figures in both Italy and France over this period. The proportion of pregnancies after IVF and ICSI that are lost over time in the UK is also much lower than in France and Italy (Nyboe Andersen et al., 2008).

Annual cases of still births and neonatal deaths after IVF and ICSI have ranged between 65 and 104. Per 1,000 births, these events show a marginal downward trend in recent years (see Figure 5–6). In the wider healthcare context, it is important to note that the UK, like France, has a national reporting and learning system for adverse events and reactions to improve patient safety. However, the vigilance system in the UK includes a variety of adverse events, where as the French system reports only on healthcare-acquired infections, predominantly in the country’s hospitals (Conklin et al., 2008b).

![Figure 5–6 Still births and neonatal deaths per 1,000 births in the UK (1991–2004)](source: HFEA (2007a))

Although there are few complications in Britain after IVF and ICSI, there is a relatively high incidence of OHSS. This serious complication is the consequence of an overdose of gonadotrophins, drugs for medically induced ovulation, which may cause enlargement of the ovaries, fluid retention and weight gain. Not only does OHSS occur at least twice as frequently as in France or Italy, but the incidence of the condition has also increased in recent years (see Figure 5–7). This trend could be the consequence of pressure to produce as many viable oocytes as possible, due to financial constraints. If couples have to pay themselves they have an incentive to produce as many oocytes as possible. Additionally, the anecdotal evidence that some clinics offer free (or discounted) IVF in return for oocyte donation may contribute to this trend.
5.3 Conclusions

The UK has a moderate system of regulation involving an overseeing body, the HFEA, which issues licences to fertility clinics and provides recommendations in the form of a code of good practice. The body has the power to take into consideration a clinic’s adherence to the prescribed standards when reissuing licences, which it has the power to revoke. Over the last few decades, licensing authorities have been a regulation instrument commonly used in the UK to introduce governance and audit in liberalised sectors. As in sectors such as telecoms, water utilities and food, the HFEA – popularly known as the ‘fertility watchdog’ – conducts performance measurement and benchmarking of infertility clinics to improve transparency of the sector and regulate clinical practice. This model is very similar to other watchdog models, and it has gained international praise for the way it deals with ethical issues and promotes the welfare of the child.

Although infertility is not explicitly defined as an illness, NICE has issued guidelines to fund up to three cycles of ART for infertile couples under certain conditions. Implementation of this guideline is, however, lagging. Given the financial discretion that PCTs have to allocate their budgets, reimbursement of infertility treatment within the NHS varies considerably by region. This creates disparity of access and is often perceived as unfair to patients. However, the practice is not unique to infertility; many treatments – including certain cancer treatments – compete for funding, and allocation priorities are different in different trusts. In contrast to a country like France, there is a very high public awareness of health costs, resulting in constant pressure to ration healthcare expenditure.

As a consequence of the lagging implementation and the relatively low health priority of infertility treatment in many trusts, many couples have to finance their treatment
themselves; only 25 per cent of all cycles are paid for by the NHS. Access to reproductive treatment is therefore in many cases limited to those who have the ability to pay.

Italy’s case study has shown that a high proportion of payment by individuals leads couples to prioritise a higher success rate over best clinical practice. Although most health outcomes compare positively with other countries, the proportion of multiple-embryo transfers, and thus of multiple births after ART, is still relatively high. Furthermore, because of attempts to optimise the number of oocytes produced for IVF, the proportion of women who suffer from OHSS is relatively high. In recent years the HFEA as well as the clinical community have expressed concerns about these health risks and urged a shift towards single-embryo transfers. While the multiple birth rate has improved marginally in recent years, it will be difficult to persuade couples who have limited time and funding to have only one embryo transferred, especially if it is the only attempt they can afford.
The three case studies have uncovered a large number of differences between the ART systems in three European countries, France, Italy and the UK. An obvious difference is seen in the health outcomes. There is wide variation between these countries at aggregate level, but there is also wide variation within each country in a number of health domains. The case studies uncovered that a public health perspective of ART is clearly set within a wider socio-political and economic context, unique to each country. From each of the four perspectives analysed, there are differences in the ART systems of the countries in terms of the rules of access and the extent and nature of regulation. Where there appears to be more overlap between the three countries is in the financing of ART services, and this occurs despite differences in the economic context of each country’s wider healthcare system. Below we explore each of these perspectives: regulatory, economic, clinical, and wider healthcare and welfare tradition. It is important to note that these contexts should not be seen in isolation – because, for example, economic forces may influence the course of clinical decision-making and its consequent outcomes.

6.1 Assisted Reproductive Technology systems in a comparative perspective

From the regulatory perspective, it is clear that there are differences between the countries in their respective rules and conditions of access to ART services. Moreover, despite all three countries being subject to a new European directive protecting the quality and safety of human tissues and cells (including oocytes and sperm for ART), there are differences between France, Italy and the UK in implementation within this Europe-wide regulatory context. In the economic context, the regulations for financing ART in all the countries share many features, but they deviate in the extent to which public reimbursement and individual or co-payment financing are implemented. Finally, despite European integration and a movement towards health policy derived from evidence-based best clinical practice, the differences between the countries in clinical practice and in the consequent clinical and health outcomes are surprisingly large.

6.1.1 Regulatory context: Assisted Reproductive Technology regulation has many faces despite a common EU directive

Despite the fact that all three countries adopted similar definitions of infertility per se, only France has explicitly defined infertility as an illness – thereby making ART accessible to all
in principle. It is this very definition that is crucial for the country’s ART policy. Neither Italy nor the UK has such an explicit definition of infertility as an illness. Infertility does not have a conventional status within the healthcare system in these countries, and this is partially reflected in the prioritisation of funding ART.

There are also differences between the three countries in the nature of their regulations for access. All three countries have enacted legislation to regulate reproductive technologies: the three countries span a spectrum from fully comprehensive and liberal access (France), through more moderate but moving towards liberalising access (UK), to a highly restrictive law (Italy). The different types of regulation for these three distinct ART systems can be more specifically compared in terms of the regulation of reproductive cell donation. For example, both France and the UK have explicitly included confidentiality, anonymity and non-remuneration in their law. However, these two countries differ in the details of their regulations for donation: 1) reproductive cell donors are not compensated in France, while in the UK they are reimbursed for direct costs or receive discounted IVF treatment; and 2) anonymity in the UK has been removed from new donors registering with a licensed clinic from 1 April 2005. In contrast, Italy has prohibited by law reproductive cell donation.

The differences between the three ART systems occur not only in the countries’ rules for ART access, but also in the eligibility for financing. These vary according to age, marital/relationship status, sexual orientation and other factors. Here again, there is a difference between ART systems in Europe. Where France has a clearly defined set of eligibility criteria, the UK has a high level of local autonomy and therefore has variable conditions for granting ART funding Italy’s restrictive set of criteria indicate ambiguity about the role of medical certification of infertility as an illness and eligibility for ART over the country; in some regions the cost is reimbursed. The UK appears to be the most lenient country with respect to parental relationship status; the “need for a father” is being dropped and same-sex female couples are eligible for treatment.

EU Member States are subject to and expected to comply with a higher level regulatory context: namely, the recently enacted Legal Directive for the Quality and Safety of Tissues and Cells (European Commission, 2004). The purpose of this European legislation is to harmonise ART regulations in Member States – including France, Italy and the UK – with a view to ensuring minimum standards for human health protection. All Member States were expected to have completed their formal transposition of the directive into national law by the end of 2007. Italy seems to be lagging in the implementation of this directive. Both France and the UK have already had some of the directive’s elements included in national law or established a regulatory framework with provisions that mirror the directive. It is unclear for Italy how the accreditation for establishments that deal with reproductive tissue under the directive is implemented. In France, all reproductive tissue establishments had been fully accredited in February 2006, while this process had been completed in December 2007 in the UK.

Finally, an important area of difference in the ART systems concerns the reporting of serious complications. As mentioned above, France and the UK have established national-level reporting systems for ART activities that result in serious adverse events or reactions. While these two countries include in their reporting the definitions of each term given in the EU directive as well as providing additional term specifications, Italy has not
specifically defined either the term “serious event” or the term “serious reaction” (European Commission DG SANCO, 2007). The main difference is the fact that, unlike in France, the UK’s HFEA publicly reports on its figures and undertakes analysis of the reports from licensed establishments (Conklin et al., 2008b).

### Table 6-1 Summary of key differences between Assisted Reproductive Technology systems from a regulatory perspective

<table>
<thead>
<tr>
<th>Domain</th>
<th>France</th>
<th>Italy</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Legal framework at national level</strong></td>
<td>Law on bioethics</td>
<td>Law 40/2004</td>
<td>Human Fertilisation and Embryology Act 1990 (c.37)</td>
</tr>
<tr>
<td>Confidentiality, anonymity and non-remuneration of donation (a safeguard to prevent organ trade or trafficking)</td>
<td>Highly restrictive</td>
<td>Donation is banned, except between homologous couples</td>
<td>Moderate, with liberalisation of access</td>
</tr>
<tr>
<td><strong>European Tissues and Cells Legal Directive (2004)</strong></td>
<td>Elements already transposed in national law</td>
<td>Lagging in national transposition</td>
<td>Confidentiality, anonymity (before 1 April 2005) and non-remuneration of donation (except for direct costs), a safeguard to prevent organ trade or trafficking</td>
</tr>
<tr>
<td>Fully accredited all reproductive tissue establishments in February 2006</td>
<td>No accreditation for establishments dealing with reproductive tissue (although gamete donation is prohibited)</td>
<td>Elements already transposed in national law</td>
<td>In process of accrediting the remaining 100 establishments by February 2006</td>
</tr>
<tr>
<td>Inspection and accreditation of licensed authorities under different authorities</td>
<td>Terms for adverse events and reactions remain undefined</td>
<td>Same authority (HFEA) inspects and accredits licensed establishments dealing with reproductive cells</td>
<td>National reporting system for serious adverse events, with analysis</td>
</tr>
<tr>
<td>National reporting system for serious adverse events</td>
<td></td>
<td></td>
<td>Infertility is not an illness</td>
</tr>
<tr>
<td><strong>Biomedical paradigm</strong></td>
<td>Infertility is an illness</td>
<td>Infertility is not an illness</td>
<td>ART is outside NHS</td>
</tr>
<tr>
<td>ART sits within healthcare system</td>
<td>ART status within the national health service is ambiguous</td>
<td>Doctor-certified infertility, both partners of ≥18 yrs</td>
<td>Variation by local autonomy, except in Wales (centrally established criteria) “postcode lottery most pronounced in England</td>
</tr>
<tr>
<td><strong>Eligibility criteria</strong></td>
<td>Heterosexual couples</td>
<td>Heterosexual couples, but marriage not required</td>
<td>Stable relationship (min. 2 years)</td>
</tr>
<tr>
<td>Must be of “normal reproductive age” (&lt;42 years)</td>
<td></td>
<td>No existing children</td>
<td>Same-sex female couples eligible</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ability to provide caring environment and no child-related convictions or offences related to domestic violence</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Commercial reproductive cell donation</td>
<td></td>
</tr>
<tr>
<td><strong>Techniques allowed</strong></td>
<td>ICSI, IUI, IVF, IVF/ET (embryo transfer), FER, OI (ovulation induction), GIFT</td>
<td>ICSI, IUI, IVF, OI, GIFT, FER</td>
<td>Commercial reproductive cell donation</td>
</tr>
<tr>
<td>Cryopreservation</td>
<td>Cryopreservation for sperm and oocytes only</td>
<td>Cryopreservation (Non-commercial) surrogacy</td>
<td></td>
</tr>
<tr>
<td>Egg donation</td>
<td></td>
<td>Egg donation</td>
<td></td>
</tr>
<tr>
<td>Imports and exports of reproductive cell donation</td>
<td></td>
<td>Imports and exports of reproductive cell donation</td>
<td></td>
</tr>
<tr>
<td>Fetal reduction for multiple pregnancy</td>
<td></td>
<td>Fetal reduction for multiple pregnancy</td>
<td></td>
</tr>
<tr>
<td><strong>Techniques prohibited:</strong></td>
<td>Surrogacy</td>
<td>Surrogacy</td>
<td>Surrogacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive cell donation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Imports and exports of reproductive cell donation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sperm banks prohibited in public hospitals</td>
<td></td>
</tr>
</tbody>
</table>

### 6.1.2 Economic context: there are considerable differences, but all have a proportion of individual payment

In principle the regulations for financing ART services in each of the three countries studied are similar, although they deviate with respect to how costs are shared between the
state and individuals. As described above, the financing of ART services in Italy is dominated by a high level of individual payment. France has fees for ART treatment in private clinics which are not reimbursed by the public healthcare system but individual payments for ART services are consistent with the cost-sharing and large private insurance industry for other healthcare services in France. In the UK there is a high proportion of private payment as autonomous PCTs are not legally obliged to follow national guidelines for the funding of ART. Similar regional disparities may also be observed in Italy. 

Despite some similarities regarding the existence of co-financing, the ART systems in each of the three countries differ from each other in their overall economic contexts. We identified considerable differences in the proportion of private sector involvement. Despite the notion that only a fraction of healthcare services are provided in private clinics, they dominate ART services in the UK. Furthermore, it is important to note here that the UK has a distinct value-for-money focus in the regulations for financing healthcare services. The UK’s NICE is mandated to produce good clinical practice guidelines that also aim to save the NHS money – mainly through the systematic review of cost-effectiveness and other economic evaluations of health interventions. In contrast, in France there is much less of a value-for-money ethos. French society seems more willing to accept the fact that a comprehensive national healthcare system will inevitably be costly and the cost may be expected to increase. This is in direct contrast to the public sentiment observed in Italy, where the public healthcare expenditure is traditionally believed to be “relatively inefficient” (see, e.g., Brown, 1984). These sentiments, however, do not reflect findings from studies of healthcare system efficiency, in which France and Italy rank considerably higher than the UK (e.g. Evans et al., 2001).

Table 6-2 Summary of key differences in Assisted Reproductive Technology systems from an economic perspective

<table>
<thead>
<tr>
<th>Domain</th>
<th>France</th>
<th>Italy</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle source of financing</td>
<td>Social health insurance</td>
<td>No tax-funded financing of ART treatment, only public financing for improving clinical infrastructure</td>
<td>Level of funding varies across PCT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dominated by private sector, high level of individual cost</td>
<td>In general:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- private out-of pocket payment 75%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- tax-funded public budget 25%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>60 public clinics (some of which allow private patients)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>49 private clinics (some of which allow NHS-funded cycles)</td>
</tr>
<tr>
<td>Public vs private provision</td>
<td>105 public or semi-public clinics (2 outside mainland France)</td>
<td>330 clinics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>47 private clinics (2 outside mainland France)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reimbursement</td>
<td>Country-wide treatment reimbursement from the national healthcare budget up to 100%, if provided in public clinic/hospital. No limitations on number of cycles, but recommendation to limit IVF/ICSI to 4 cycles Services in private facilities covered up to public amount, then patients pay any additional fees not reimbursed by healthcare system</td>
<td>Regionally based public reimbursement schemes, varying between 43% (south) and 75% (north) Procedures partially reimbursed only in public hospitals or clinics operating within national health service</td>
<td>Locally based public funding through NHS Guideline to fund up to 3 cycles, minimum of 1 cycle Funding decisions vary regionally</td>
</tr>
</tbody>
</table>

6.1.3 Clinical practice: variation in Assisted Reproductive Technology outcomes reflects differences in clinical practice

There appear to be considerable differences in clinical practice between the three countries. For example, the UK shows a marked decrease in 3-embryo transfers in recent years,
whereas Italy’s initial decline if followed by an upward turn after 2002. Despite urging from the sector’s licensing authority, 2-embryo transfer still dominates clinical practice in the UK, and to a lesser extent in France. Whilst the proportion of multiple-embryo transfers in Italy is the largest of all three countries, the proportion of 1-embryo transfers after IVF and ICSI is increasing steadily in Italy.

In addition, there are minor differences between the countries in the success rates of ART. The rate of pregnancies per transfer after IVF and ICSI fluctuates around 25 per cent. When it comes to actual percentage of deliveries per transfer, there are greater differences between the three countries, with Italy being the only country with significant declines in recent years.

These changes and differences in clinical practice in each of the countries are also reflected in their clinical outcomes. France is the one country that consistently shows a lower and decreasing trend in multiple births in recent years. Although the UK used to have the highest proportion of multiple births among the three countries, this value has been reduced to similar levels to those in France and Italy. Following the introduction of the Law 40/2004, there has been a marked increase in multiple births in Italy.

Finally, the three countries also deviate with respect to the relative number of fetal reductions reported, documented pregnancies lost, and adverse events and reactions (infections, bleeding and OHSS). An important observation is that clinical outcomes for both mother and child have generally improved over the last decade in the three countries. However, in recent years the incidence of negative outcomes seems to have increased in Italy.
### Table 6-3 Summary of key differences in Assisted Reproductive Technology systems from a clinical practice perspective

<table>
<thead>
<tr>
<th>Domain</th>
<th>France</th>
<th>Italy</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best practice guidelines</td>
<td>Legal proscription of best practices</td>
<td>No clinical guidelines</td>
<td>Recommended best practice</td>
</tr>
<tr>
<td></td>
<td>Evidence-based guidance</td>
<td>Value-laden guidance</td>
<td>Evidence-based guidance</td>
</tr>
<tr>
<td>Access to ART</td>
<td>Per capita provision of ICSI is on the rise, but IVF is stable</td>
<td>Per capita provision of ICSI shows marked increase, also slightly for IVF</td>
<td>Per capita provision of ICSI is rising while IVF is declining and then levelling</td>
</tr>
<tr>
<td></td>
<td>Egg donation is in high demand, but also great shortage</td>
<td>Egg (or sperm) donation are prohibited – unless in homologous couples</td>
<td>Egg donation is in high demand but also in great shortage</td>
</tr>
<tr>
<td>Single-embryo transfer vs multiple-embryo transfer</td>
<td>2-embryo transfer dominates Many centres have applied a single-embryo transfer policy</td>
<td>High proportion of multiple-embryo transfer – 3-embryo transfer on the rise since 2002, but 4-embryo transfer has decreased dramatically over time</td>
<td>Marked increase in 3-embryo transfer 2-embryo transfer dominates Single-embryo transfer recommended No 4-embryo transfers</td>
</tr>
<tr>
<td></td>
<td>Gradual decrease over time in 4-embryo transfer</td>
<td>Marked increase in multiple births since new law</td>
<td>Comparatively high proportion of multiple births</td>
</tr>
<tr>
<td>Singletons, twins, triplets, etc</td>
<td>Consistently low and still decreasing trend of multiple births</td>
<td>Marked increase in multiple births since new law</td>
<td>Marked increase in multiple births since new law</td>
</tr>
<tr>
<td>Multi-fetal reductions</td>
<td>Slightly declining, fluctuating around 1% of all pregnancies after IVF, ICSI and FER</td>
<td>Dramatic decline between 2001 and 2002 No longer reported after 2002</td>
<td>Highest among the three countries, fluctuating around 1.2% of all pregnancies after IVF, ICSI and FER</td>
</tr>
<tr>
<td></td>
<td>Incidence of negative outcomes are increasing since 2004</td>
<td>High reporting of bleeding Reports of maternal death</td>
<td>Health outcomes are generally improving High reporting of OHSS complications</td>
</tr>
<tr>
<td></td>
<td>Nearly 25% of documented pregnancies after IVF and ICSI are lost</td>
<td>Around 20% of documented pregnancies after IVF and ICSI are lost</td>
<td>Fewer than 10% of documented pregnancies after IVF and ICSI are lost</td>
</tr>
</tbody>
</table>

6.1.4 **Wider healthcare and welfare tradition: Assisted Reproductive Technology has a distinct status, but its policy system is shaped by a tradition of healthcare and welfare services**

We found that the drivers of ART policy and their outcomes depend largely on the environment in which they take place. Therefore, the differences between countries can partially be explained by drivers in the regulatory, economic and clinical contexts of ART systems. Furthermore, we have found that the wider welfare and healthcare systems and traditions in which the ART system is set also contribute to the distinct characteristics of country-specific ART systems.

In all three countries we found that ART policy is shaped by the wider healthcare and welfare tradition. France’s generous funding of ART treatment for infertile patients reflects the principles of its Bismarckian welfare system, based on solidarity with disadvantaged individuals. Furthermore, ART services in France are provided within the organisational framework of the healthcare system and accreditation of infertility clinics is similar to that of other healthcare institutions. In Italy’s Southern system, access to welfare benefits and social security payments has traditionally been fragmented and coverage has not been comprehensive. The types of benefits vary by occupation, length of contribution and region. As happens with ART, limited access to certain services therefore is not unusual in the Italian welfare state. Finally, the welfare and healthcare tradition in the UK is also reflected in its ART policy system. Reluctance to provide greater access to ART services UK-wide is in line with the UK’s Anglo-Saxon welfare tradition of providing only a basic protection rather than generous coverage. Other diseases are facing similar “postcode lotteries” as PCTs have autonomy to allocate their budget.
ART policy, however, has a distinct status within the wider healthcare and welfare tradition, particularly in France. Unlike the contribution-based welfare system, access to ART is universal irrespective of previously paid contributions and means tests. ART reimbursement stands out as a generous scheme, even compared to other health and welfare services in France. By contrast, given the absence of an explicit designation of infertility as an illness, ART does not fall unambiguously within the national health services in Italy and the UK. Furthermore, a key aspect in which the ART system in the UK deviates from its wider healthcare tradition is in accreditation and ensuring quality of treatment; a separate accreditation system, with the HFEA as watchdog, has been set up to control ART treatment. Another difference from standard procedures within the NHS is the embedding of societal stakeholder perspectives in the ART system. Furthermore, due to their ambiguous status, infertility services are characterised by considerable involvement of the private sector, which is distinct from other medical services in the NHS.

Table 6-4 Summary of key differences in Assisted Reproductive Technology systems from the perspective of wider healthcare and welfare tradition

<table>
<thead>
<tr>
<th>Domain</th>
<th>France</th>
<th>Italy</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Bismarck/continental</td>
<td>Southern</td>
<td>Anglo-Saxon</td>
</tr>
<tr>
<td>Rules of access</td>
<td>Social insurance system, with</td>
<td>Fragmented system of income</td>
<td>Highly inclusive social security</td>
</tr>
<tr>
<td></td>
<td>strong link between work position and social</td>
<td>guarantees linked to work position</td>
<td>coverage</td>
</tr>
<tr>
<td></td>
<td>entitlements</td>
<td>Healthcare is institutionalised right of</td>
<td>Only healthcare coverage is fully universal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>citizenship</td>
<td></td>
</tr>
<tr>
<td>Benefit formulae</td>
<td>Healthcare is universal</td>
<td>Generous benefits (e.g. retirement</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>pension) without articulated net of</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>minimum social protection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financing through contributions</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>and fiscal revenues</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tax-financed national health service</td>
<td></td>
</tr>
<tr>
<td>Financing regulation</td>
<td>Financing through contributions,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>reasonably substantial social assistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple health insurance funds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>financed through contributions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>to cover medical costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisational–managerial</td>
<td>Insurance schemes mainly governed by unions</td>
<td>In general, little state intervention</td>
<td>Highly integrated organisational</td>
</tr>
<tr>
<td>arrangements</td>
<td>and employer organisations</td>
<td>in the welfare sphere; high level of</td>
<td>framework entirely managed by public</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(regional) particularism with regard to</td>
<td>administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cash benefits and financing,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>expressed in high levels of</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>clientelism</td>
<td></td>
</tr>
<tr>
<td>Service provision</td>
<td>Healthcare services are delivered by a</td>
<td>National health service relies</td>
<td>NHS relies heavily on public provision</td>
</tr>
<tr>
<td></td>
<td>multitude of private, private not-for-profit</td>
<td>heavily on public provision</td>
<td></td>
</tr>
<tr>
<td></td>
<td>and public providers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.2 Explaining differences between these countries

In an era in which health services are adopting evidence-based medicine to improve outcomes, the controversial nature of IVF and its regulatory framework often disrupts the application of this paradigm to ART practice. Many procedures remain controversial, and the design of policy frameworks is often the result of intense ethical debate and a need to curb vested interests and perverse incentives. In this section we discuss the factors that explain the key differences between the systems in France, Italy and the UK. While they are based on three countries, they may help understand ART policy in countries beyond this limited sample. We shall draw up a tentative model of how contextual factors shape the outcomes of ART policy. As this model is informed by the three case studies only, it is
best understood as being explorative. We do not purport to identify any causal relationships that would warrant further research beyond the scope of this project.

The reimbursement of ART and medical practice have a crucial impact on ART outcomes. We see the explanatory factors or drivers of ART policy clustering around the key link between the financing of ART treatment, the medical practice of ART (choice of techniques) and the clinical outcomes. Various factors within a society influence willingness to make ART treatment accessible to a wider population and to reimburse it. Furthermore, there seems to be an association between the proportion of provision within private clinics and the subjectivity to financial incentives. The mechanisms and level of reimbursement in turn substantially shape the incentives to use certain medical techniques. If, for example, only a small number of cycles are reimbursed, this may work as an incentive to transfer more embryos than would be advisable under best clinical practice. Effective regulation and implementation of best practice guidelines may, however, limit how far these financial incentives translate into treatment decisions. At the same time, both reimbursement and medical practice are influenced by a multitude of intervening factors emanating from the different contexts.

Definition as an illness is a crucial factor influencing ART policy. The most crucial determinant that influences the reimbursement of ART in the three countries has been whether infertility is defined as an illness. This determines whether ART treatment is seen as a conventional medical intervention (France), rather than a means to support the right to have children (UK) or a health privilege of affluent couples (Italy). In France the biomedical labelling decision led to a full integration of ART treatment into the healthcare system. Public funding of ART is patchy both in Italy and the UK because of an absence of such a label.

A key driving force behind this determinant is the power of the country’s medical profession relative to other stakeholder groups. France has not only a rich tradition of supporting the family, but also a powerful medical profession that labels infertility an illness so that infertile couples receive financial support to treat the condition. In the UK the medical profession has much less power in determining the funding of healthcare. In Italy, on the other hand, funding decisions appear to be the outcome of a complex series of party-political negotiations, which in turn are subject to societal pressures. In ART policy the Vatican plays a more pivotal role than the medical community.

In our analysis, the decision to define infertility as an illness had much greater influence than the differences in the healthcare set-up, with both universal healthcare systems – UK and Italy – not consistently offering funding for ART treatment. However, Italy does reimburse ART treatment in some regions, and the UK has more generous provision in some PCTs than others. This points to the importance of the governance of healthcare systems. The degree of decentralisation affects the degree of autonomy at the local level in deciding on treatment provision and funding.

Cost awareness differs by country and type of healthcare system. This may contribute further to willingness to reimburse or fund ART treatment. The British system in particular is characterised by tight control over healthcare budgets that are centrally controlled, rather than having a fragmented system of health insurances for different
There are three key drivers for the medical practice of ART that we identified in this study: 1) funding and reimbursement; 2) regulation of techniques and practice; and 3) importance of the good clinical practice paradigm. The notion that funding and reimbursement arrangements are driving the practice of ART has been a premise of this study. For instance, we found that multiple-embryo transfers are more common in environments characterised by a high degree of individual payment.

Secondly, the boundaries of acceptable practice are defined by biomedical legislation in all three countries. Given the difficult ethical implications of ART treatment, these tend to be motivated by moral considerations and reflect the values of a society rather than being the expression of best medical practice. It is however difficult to define what is ‘best medical practice’ is, particularly when there are so many ethical issues in a policy area. Our review uncovered substantial differences in the ethical regulation of ART treatment, which influences the selection of treatments, the application of certain techniques, and eligibility criteria. Most striking here is Italian regulation, whereby all embryos created must be transferred, based on the Roman Catholic dictum that life begins at conception, despite the increased risk of multiple pregnancies and births to the health of both mother and child.

These laws are very much an expression of how different stakeholders were able to shape the public debate about ART regulation. Typically, conflicts arise between morally conservative stakeholders, like the Roman Catholic Church, the medical profession (driven by knowledge about what is medically feasible), and “progressive” stakeholders, patient groups for example, who see ART as the right of an individual. Our analysis also points towards the role of these stakeholders in governance structures as part of the regulation process. In France the process was dominated by the medical profession, while the UK created a mechanism to include a wide range of stakeholders in the management of ART regulation. Finally, the Italian case is dominated by the mobilising capabilities of the Roman Catholic Church, which halted attempts to loosen the strict regulatory framework.

The third key factor shaping the medical practice is the importance of best practice guidelines in the ART system. These guidelines are usually not legally binding and thus can be circumvented under the pressure of other strong incentives – in particular financial ones. The integration of ART treatment into the conventional healthcare provision apparently has strengthened the role of best practice in France compared with the UK, for which low compliance with guidelines has been reported. In Italy, where ART largely falls outside the remit of the national health service, clinical guidelines are of even less importance. Furthermore, integration of best practice guidelines into rationing decisions, thus considering cost-effectiveness in addition to best clinical practice – as in the case of NICE in the UK – may have an impact on the generosity of treatment.
An illustration of the key contextual factors, rather than merely medical factors, influencing ART policy, practice and outcomes is provided in Figure 6–1.
Chapters 3, 4 and 5 have explained how the differences in ART policy have inherent consequences for the clinical practice of reproductive treatment, and their outcomes. In this section we shall link the characteristics of certain ART policy frameworks to the direct and indirect, intended and unintended consequences.

7.1 Assisted Reproductive Technology policy and the extent of provision are closely linked

At its most basic level, legislative restriction of treatment has an impact on access to ART services. Prohibiting access to certain technologies or regulating eligibility of treatment to certain conditions (such as relationship status, gender or age) reduces the number of people who can access ART services. Additionally, the level of funding is an important driver of access and provision of care. Although there has been little research into the price elasticity of ART treatment, it is fair to assume that the demand for ART will increase when the proportion of individual payment reduces. Indeed, the relative provision of IVF and ICSI in the three countries reflects the generosity of funding: France has most transfers per capita, followed by the UK and Italy. An additional example of this impact may be found in Germany, which restricted access to ART to married couples and reduced reimbursement, leading to a 50 per cent drop in provision (DIR, 2007). Of course, there may be other policy levers influencing 1) the demand for ART treatment, such as policies addressing maternity employment protection and delayed childbearing; and 2) the supply of ART, such as training of clinicians affecting treatment capacity.

The direct benefits of ART treatment are simple to explain but hard to quantify. A proportion of the couples with fertility problems have the opportunity to conceive offspring. The effectiveness of medical treatment is usually measured in the number of years of healthy life that the patient is willing to give up for successful treatment (quality-adjusted life-years or QALYs). In the case of infertility treatment, it is not only that the quality of the patient’s and partner’s lives improves with successful treatment, but another life is created as well. Although it is difficult to measure the extent of these outcomes, it may be safe to assume that these benefits of treatment increase with an increasing number of children that would otherwise not have been born, as long as the QALYs are not
negative. It would be an oversimplification, however, to argue that increasing the provision of ART leads to a positive outcome \textit{per se} as ART cycles may be inappropriate for certain couples, or could have been avoided. Furthermore, there may be negative consequences, for example mental depression, for the large population of patients who do not achieve successfully offspring. But when treatment fails, quality of life could even improve compared to the uncertain and frustrating period prior to treatment.

The main downside of increasing ART provision is the incumbent costs (both short term and long term). It has been beyond the scope of this study to assess the total costs of ART per country, but we do know that they consist of a number of components. In France, for example, full reimbursement of up to four cycles of ART treatment has considerable cost consequences for public health expenditure. The burden of these direct costs is shared by those contributing to the social security system. The indirect costs include infrastructure costs, equipment costs, opportunity costs of lost employment, and so on. Furthermore, when ART treatment is successful, the inherent maternal and neonatal healthcare costs are absorbed by the Sécurité Sociale, the Servizio Sanitario Nazionale and the National Health Service.

7.2 The unintended consequences of restriction and individual payment

In the case of Italy, we learned that some regulations that are the result of moral considerations and ethical debates may conflict with what the clinical community considers good clinical practice. In particular, banning preservation of embryos and the subsequent need to transfer all fertilised embryos back to the uterus is thought to be associated with unnecessary and potentially severe health risks. The first data published after the introduction of Law 40/2004 echo these concerns. While protecting the embryo is the original aim of this legislation, in doing so it tends to threaten the health of both mother and child.

The case studies also showed that restriction of treatment and limiting financial provision for ART may have unintended consequences. Firstly, when certain ART services are not available to couples in their native country, they increasingly travel abroad to undergo treatment in a country where it is available (but where the quality of care may be different or unknown). In Italy cross-border ART has nearly tripled since the enactment of Law 40/2004. When such treatment is successful, the maternal, perinatal and neonatal, and healthcare costs will have to be borne by the Italian healthcare system. We are not aware of any estimates of the impact of these indirect policy consequences as it is difficult to track these pregnancies and their health outcomes systematically. Also, although cross-border ART may be seen as an opportunity to enjoy moral pluralism (Pennings, 2004), it raises domestic issues of inequality of access to healthcare. The constitutional right to healthcare and to equal protection is undermined if access to certain infertility treatments depends upon the financial means of infertile couples (Boggio, 2005).

When there is no full provision for infertility treatment through public or private health insurance, couples need to pay (a proportion of) the expenses from their own resources. As these costs may amount to several thousands of Euros affordability is a serious issue, particularly for lower-income households. In order to maximise the probability of take-up
and pregnancy, many couples decide to have multiple embryos transferred into the uterus. The case studies seem to confirm that a high proportion of individual payment is associated with couples who tend to prefer a higher pregnancy rate over best clinical practice. In the UK, for instance, the multiple birth rate is surprisingly high for a system with such a tradition of emphasising good clinical practice.

It is often assumed that a shift from multiple- towards more single-embryo transfers implies a reduction in the success rate of ART. Rather, in recent years there is growing empirical evidence from Finland, Sweden and the UK demonstrating the fact 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 (Braude, 2006). Legislation in Belgium, for example, has succeeded in achieving near avoidance of triplet births, while the twinning rate has declined to approximately 7 per cent. In these cases the reduction in the probability of take-up of at least one embryo has been compensated for by selection of high quality oocytes and embryos, targeting good prognosis patients (i.e. healthy, relatively young women) and programmes of effective (cryo)preservation of embryos.

### 7.3 What about long-term externalities of Assisted Reproductive Technology policy?

Although this report has not studied possible long-term externalities of ART in detail, empirical research suggests that these may exist. Recent studies argue that the future net tax revenue to the government of ART children will outweigh the costs of treatment and subsequent healthcare (Connolly et al., 2008). Furthermore, as ART has a small but noticeable impact on birth rates (Hoorens et al., 2007), public funding of ART could be seen as a way to invest in families in countries with very low fertility rates and a looming burden of an ageing population. However, in countries where fertility rates are not as alarmingly low, this demographic impact may be regarded as a negative externality, increasing a country’s carbon footprint (see, e.g., Dasgupta, 2000).
Figure 7–1 Indicative overview of the outcomes of Assisted Reproductive Technology policy systems
This report has delineated ART policy, its determinants and wider context in three countries, and has highlighted and explained the differences between them. In this section we revisit three important determinants that have a crucial impact on the performance and the outcomes of the system. Subsequently, we suggest some broad policy recommendations. Given the findings of this study, we do not suggest a harmonised European ART policy as policy environments are shaped by cultural and ethical norms, healthcare and welfare-state traditions, and so on. Instead we provide a set of suggestions for countries to address the challenges of ART policy, while taking account of the context in which they are designed.

8.1 In conclusion

Although all EU Member States are subject to a common legislative framework – the EU Directive for Cells and Tissues – the differences between the three case study counties are substantial. We found that the ethical considerations underlying the legislative framework have definitive consequences for the outcomes of the system. Since such a framework may be the preferred outcome of a democratic process, it is impossible to challenge its foundations. However, the implementation of these principles in clinical regulations may be at odds with good clinical practice, as is the case in Italy. The unintended outcomes of Italy’s ART system need serious consideration and should be addressed.

Secondly, the decision to define infertility as an illness or not has critical consequences for the design of the ART policy framework. The inability to conceive can be a symptom of a variety of medical conditions. But it may also be merely bad luck as on average 80 per cent of couples become pregnant after one year regular unprotected intercourse. The causes of infertility often remain unexplained and there are some severe cases which ART cannot address. Therefore, the definition of infertility is a difficult issue, and not a purely medical one. If, as is the case in France, the underlying paradigm is that ART exists to help address infertility within stable heterosexual couples, infertility treatment becomes an integrated part of the social security system. Sizeable public expenditure on ART in this context is merely a part of the healthcare system. If infertility is not explicitly defined as an illness, as is the case in the UK and Italy, principles for provision of care and access to treatment may deviate from those of the national health system. Countries have different approaches to addressing these issues; in Italy and UK the decisions to address inequality of access to treatment vary regionally.
If citizens’ financial means become an important determinant of their ability to afford infertility treatment, maximising the probability of success is likely to be prioritised over avoiding certain health risks. Even in countries with a solid evidence-based medicine tradition, private treatment decision may lead to unnecessary health risks for mother and child. The downstream costs of that will have to be met by society.

8.2 Addressing the challenges of Assisted Reproductive Technology policy in Europe

The conclusions above show that there are fundamental decisions which determine the broad principles upon which an ART policy framework is designed. In this study we have assumed that a policy framework is largely defined by the context in which it is based. Therefore we aim to formulate a small number of broad recommendations that can help in addressing the identified challenges to ART policy, while taking account of the national context in which they are designed.

Monitor and evaluate the EU Directive for Cells and Tissues

The enforcement of the EU Directive for Cells and Tissues (European Commission, 2004) is lagging, particularly in Italy. The directive provides a common ground for ART policy in Europe and aims to harmonise regulations in Member States. In policy areas which do not fall within its remit, the EU shall take action in accordance with the principle of subsidiarity. The directive allows Member States leeway to base national ART regulation on country-specific principles, while subjecting its implementation to a set of common good practice rules to ensure and improve quality and safety (such as clinic accreditation and reporting complications). We recommend the prioritisation of the enforcement of these provisions in countries that are lagging to ensure its rigour and equitable distribution across Europe.

Address the negative consequences of multiple-embryo transfers

In order to address the unintended negative health outcomes of ART that result from maximising the probability of take-up and pregnancy, we recommend following the current good practice guidelines regarding embryo transfers. Governments can incentivise couples to avoid multiple-embryo transfer by offering funding for single-embryo transfer under certain conditions up to a maximum number of cycles. Payment can be organised through public or private health insurance, depending on the healthcare system. Licensing authorities may also target incentives at the clinic rather than the couple. Single embryo transfers can be encouraged by accrediting only those clinics which maintain the proportion of multiple transfers under a certain limit. Depending on legislation, the governing body may try to compensate for the marginal reduction of success rates following a shift to single-embryo transfer through a number of strategies. Enhanced cryopreservation techniques, for example, and identification of high quality embryos and oocytes could offer cost-savings to health services by reducing need for fresh cycles or additional cycles, respectively. Furthermore, further research into human reproduction and embryology to study the effectiveness of ART could lead to improvements in success rates. Funding such research may be cost-effective in the long run. Implementation of these strategies, however, will depend on the acceptability in local context.
**Conclusion and recommendations**

*Cost containment through targeted ART funding*

The considerable costs of ART are often used as an argument against public funding of infertility treatment. In the case of the UK, these decisions are made by PCTs, based on local public health priorities. Increasing funding by offering funding for several (or a package of) single-embryo transfer treatments, as suggested above, will inevitably lead to an extra burden on the national health service and social security system. These costs will be somewhat relieved by cost reduction in maternal and neonatal healthcare due to improved health outcomes. Nonetheless, there are a number of strategies that decision-makers can consider to avoid excessive budget strains:

- Focus on funding patients up to a certain age as age is the best prognosis factor. After the age of 35 success rates for ART drop considerably. Linking eligibility criteria based on age (female or combined age) with funding may also discourage couples from postponing childbearing.

- Target good prognosis patients: possible criteria for eligibility could include body mass index, smoking prevalence and alcohol consumption. This strategy may not only improve the overall success rate of ART treatment, but also have positive spin-off effects for other health indicators.

- Means-testing of reimbursement schemes. In order to focus public resources on those couples for whom affordability of treatment is a serious issue, benefits can be means-tested according to household income.

- Instead of meeting 100 per cent of the treatment costs, funding schemes could require individual co-payment of a proportion of the costs. Balancing the level of co-payment is important to trade off the willingness to pay and affordability. If the amount is too high couples may be deterred from treatment (and, e.g., travel abroad); if the amount is too low couples may wish to undergo treatment that is not strictly necessary.

Another consequence of increased funding for ART is that the existing clinics have difficulties absorbing the demand for treatment, often leading to sizeable waiting lists for public clinics. Countries should develop a strategy to address this issue. In some cases this could involve sending couples to clinics in different regions or countries with more capacity to deliver timely care.

*European co-ordination regarding cross-border ART*

Unless legislation and funding of ART are streamlined across the EU, which is unlikely given the conclusions of this study, couples will continue to travel abroad to places where certain treatment is allowed, less regulated or less expensive. We must emphasise that having the option to travel abroad for treatment is not a negative outcome *per se*; it is an opportunity to benefit from moral pluralism. However, it could lead to issues of inequality of access to healthcare, which essentially is not different from some other controversial medical interventions. The outcome of successful ART treatment, however, is fundamentally different from other interventions because it results in one or more babies. The maternal and neonatal health consequences of the assisted pregnancy are usually absorbed by the couple’s country of origin. The consequences of uncoordinated cross-border ART – as opposed to co-ordinated reproductive travel, suggested above – are system disparities that are unintended and undesired system disparities. However, little is known
about the extent of cross-border ART in Europe and its impact on both countries. International co-ordination between host and origin countries is needed to understand this phenomenon better, subsequently address it and possibly find synergistic opportunities where appropriate. Coordination could take a similar form as the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxemburg, the Netherlands and Slovenia by the international organisation, Eurotransplant. Furthermore, the extent of cross-border ART should be monitored through improved data collection.

Consider ART policy in its wider environment of trends and drivers of infertility
This study has focused on policy frameworks for assisted reproductive treatment—technologies to overcome difficulties with conceiving. Drivers of infertility and policy systems for prevention of these conditions have been outside the scope of this research. It is, however, important to consider ART in its wider environment of drivers and trends, and policymakers should be aware of these.

The mean age of motherhood, and female mean age at first childbirth, have increased over the last decades. Simultaneously, national registry data show that the mean age of women undergoing ART treatment has risen as well. Although success rates are relatively poor for women over 35, the representation of this age group among women reporting to infertility clinics is continuing to grow. At the moment ART cannot compensate for the natural loss of fecundity with age.

There are a number of other risk factors affecting the ability to conceive, including consumption of alcohol, use of tobacco and, most notably, sexually transmitted diseases and infections such as chlamydia, syphilis and gonorrhoea. Finally, the increasing prevalence of obesity in Europe is thought to affect the prevalence of infertility as well.

When designing ART policy, it is therefore important to co-ordinate this related policy issue with other public health policy issues with a view to promoting the prevention of infertility. Governments should improve awareness among both men and women of the determinants of infertility, and age in particular.
Agence de la biomédicine, *Rapport Annuel: Bilan des activités de l’Agence de la biomédicine 2006*, Saint-Denis La Plaine, Cedex, France: Agence de la biomédicine; Autumn 2007a


Conseil constitutionnel, décision no. 94-343-344 DC 27 July 1994


Decreto del Presidente della Repubblica, ‘Approvazione dell’atto di indirizzo e coordinamento alle regioni e alle province autonome di Trento e di Bolzano, in


Gruppo Tecnico Interregionale, ‘Requisiti Strutturali, strumentali e di personale per l’autorizzazione delle strutture che erogano prestazioni di procercazione medicalmente assistita’, Riunione, 12 July 2001


Hope, J., ‘Named and shamed, the failing fertility clinics’, *Daily Mail*, 11 January 2007

Human Fertilisation and Embryology Authority (HFEA), ‘A long term analysis of the HFEA Register data 1991–2006’, HFEA Long term data, version 1, revision 2, saved 11 July 2007a. [an updated version of the full report was made available from 18 June 2008]


Human Fertilisation and Embryology Authority (HFEA), ‘Clinics at a glance’, home page, circa 2008a. As of 29 September 2008: http://guide.hfea.gov.uk/guide/pdf/AtAGlance.pdf [figures found at this URL are continuously updated and hence may not reflect data cited in this report]


Law No. 75–17 of 18 January 1975, concerning the Voluntary Termination of Pregnancy, as amended by Law 79–1204 of 31 December 1979, Journal officiel de la République française, No. 1, 1 January 1980, p. 3

Law No. 82–1172 of 31 December 1982, concerning the extension of social security coverage to 70 per cent of the costs of care and hospitalisation associated with lawful non-therapeutic termination of pregnancy, Journal officiel de la République française, Edition des Lois et Decrets, No. 1, 1 January 1983, p. 15


Linee guida contenenti le indicazioni della procedure e delle tecniche di procreazione medicalmente assistita Art. 7 – Legge n. 40/2004 (Annex to the Law 40/2004 based on Article 7 of the law)


Ministère de l’emploi et de la solidarité (MES), Arrêté du 12 janvier 1999 relatif aux règles de bonnes pratiques cliniques et biologiques en assistance médicale à la procréation, NOR: MESP9920284A

Ministère du budget, des comptes publics et de la fonction publique (MBCF), Projet de loi de financement de la sécurité sociale pour 2008, République Française, NOR : BCFX0766311L/B1


The Practice Committee of the American Society for Reproductive Medicine, ‘Smoking and infertility’, *Fertility and Sterility*, Vol. 82 (Suppl. 1), 2004, pp. 62-67


