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REPORT

Between politics and clinics—the many faces of biomedical policy in Europe

Analysis of drivers and outcomes of Assisted Reproductive Technologies policy

Volume II: Three country case studies

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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: a regulatory context, an economic context, their 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 to 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 recently 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 (and two Commission Directives related to implementing the quality and safety directive), 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 ART 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 relating the eligibility for 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 – 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, doing so 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 equitable distribution across Europe;
- 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; and,
- 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 STDs/STIs, prevention of obesity, work-friendly family policies that incentivise earlier motherhood for working women, etc.