

## Demographic crisis in Europe

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Fertility treatment is more than a medical need. It is the sole recourse for some couples to build a family, while contributing to society's population growth. Infertility is a disease affecting roughly one in six couples worldwide. Its effects can be devastating – producing feelings of isolation, anger and desperation. Treatments for infertility are increasingly successful, with live birth rates of 25–30% being recorded from one cycle of IVF in couples of normal reproducing age.

Receiving a diagnosis of low fertility (or infertility) represents a significant life crisis for a couple and WHO estimates that some 60–80 million couples worldwide will require medical help in order to conceive. Infertility affects men and women equally (40% each), with both parties affected in a further 20% of couples. Low fertility is therefore both a male and a female health issue.

A number of countries face an unwanted situation of falling birth rates. Europe has 22 of the 25 lowest-birth rate countries, thus the best estimates predict a lost of 41 million people by 2050 despite the current immigration rates. Fertility treatments can help to tackle this problem by enabling the sizeable part of those populations that would like to – but cannot – have children, to raise a family. Some countries invest resources to encourage people to raise a family but will not make state funding available for proven fertility treatments.

On November 2004, a report commissioned by the Employment and Social Affairs Directorate General of the European Commission (Grant et al), evaluates the causes, consequences and policy options relating to low fertility rates across Europe, and calls for broader and more effective baby-friendly policies. Whilst noting the limited research-based information available to inform this debate it drew the following conclusions:

- National policies, such as social policy reform and/or economic incentives, can slow fertility declines and its consequences under the right circumstances;
- No single type of policy intervention will necessarily slow fertility declines;
- Population policies take effect slowly, and therefore may be politically less attractive;

After that study, the European Commission prepared a Green paper titled “Confronting demographic change: a new solidarity between the generations” (COM

(2005) 94 final) that originated a wide debate within the European Parliament, which materialized into an interesting Report.

Age is a contributory factor, given that fertility substantially declines in women over 35 years old, with a chance lower than 52% of conceiving in one year. This is of importance in developed countries, where societal issues, such as the development of a successful career by both partners, often delays the decision to start a family. As a result, the average age of mothers having a first baby is increasing, as is the proportion of babies born from a mother older than 35 which has more than double since 1990 (currently at 25% in some European countries).

Modern fertility treatments are highly successful and have developed from 50 years of intense medical research. This has explored the physiology of reproduction, examined the causes of low fertility, designed effective interventions and defined the most cost-effective treatment pathway. Assisted reproductive techniques (ART) have greatly improved and, in the last 20 years, hundreds of thousands of babies have been delivered after IVF or ICSI procedures. In Germany, for example, 40,000 babies are born annually as a result of fertility treatments. This represents more than 5% of the total live births (1.6% due to ART) making a substantial contribution in a country where the birth rate is declining by 1.7% each year. More than 70,000 children are born annually in Europe as a result of assisted reproduction (ART).

Changes in reimbursement policies covering fertility treatment have significant impact on countries' demography. In Belgium, a Real Decree in 2003 increased the coverage of fertility treatments in 50%, enough to cover 100% of 6 cycles per patient. As a result of this policy change, one year later, treatment increased 49% and live births due to IVF increase 23% (multiple birth declined from 26% to 8%), representing an additional 1% of the total live births in Belgium.

Health economic studies indicate that increased spending on ART might be a very cost-effective measure to increase the total fertility rate of a population.

The pivotal event in the fertility treatment is to obtain an appropriate and controlled ovarian hyper stimulation (COH). Several protocols have been developed to increase effectiveness of the therapy. Follicle Stimulation Hormone (FSH) is currently the most common treatment used for ovulation induction. Originally extracted from the urine of menopausal women, biotechnological innovation has produced recombinant preparations of follicle stimulation hormone (r-FSH) which are characterized by a higher level of purity, reduced batch-to-batch variability and no risk of infection.

In conclusion, low fertility is a medical condition for which an effective and safe biotech treatment is currently available. Various baby-friendly policies have been implemented in an essay-and-error fashion, lacking so far of evidence supporting its effectiveness in increasing population growth. From a population point of view, fertility treatments should be considered a baby-friendly policy, the only one with a known cost-effectiveness, and able to make a measurable and major contribution to overall population growth.

The problems originated by the dramatic decrease of the population in Europe and other regions has forced the governments to re-think many of the policies implemented

until now in an irresponsible manner. With population numbers plummeting, Europe may be arguably committing slow demographic suicide. Around the beginning of the 20th century about 15% of the world population lived in EU-25, a century later it is 7%. The extremely low fertility levels observed in some countries are the culmination of the process of social change that started with the demographic transition a few hundred years ago. There is growing concern about a decline in the total fertility rate worldwide, but nowhere is the concern greater than in OECD countries.

Economics and evolutionary sciences have explored the interactions between mortality and fertility. In the European Union life expectancy has risen considerably while the number of children per woman dropped significantly, since the 1960s. Over the last thirty years, fertility rates in the region of current EU25 have dropped and sustained well below the replacement level of 2.1 children per woman. The total fertility rate (TFR) was 1.50 in 2004. European populations have already entered a period of negative population momentum and are expected to fall after 2025. Between 2004 and 2050, the largest declines are expected to be observed in the new member States. Policy makers must identify infertility as a priority within family, social-demographic and health policies, and become pro-active in developing appropriate policies.

The capacity to reproduce is related to many different factors, some of them being inherent to biological differences, but a significant proportion of infertility is related to "life style factors". Low and late fertility lead to some demographic, socio-economic and health constraints. The growing necessity of reconciling work and child care has been the focus of much social science and policy research and debate during the 1990s.

Equality between sexes is a necessary requirement but not a sufficient one. Effective fiscal policies protecting families would bring flexibility to work requirements and could lower pressure on unemployment. The concept of subsidies should be reduced to the minimum to prevent the creation of dependent societies. As far as possible, help should originate from tax deductions to the parents' income. Similarly, the concept of the personal contribution of each worker to their own pension should be recovered. Each person should be able during their active working life to contribute the necessary amount to guarantee a dignified pension without relying on contributions from the next generation. Only in exceptional cases of real need, should this be a responsibility of society in general, and even then it should not be imposed as a burden on the next generation. It is not fair or reasonable for society to place a mortgage over future generations. We should not be living this technological era on the basis of outdated policies. The current society should define a real policy towards children, with a perspective of social investment in the future of society. It is necessary to build policies consisting of a combination of infrastructure policy, time-frame policy and fiscal transfer-policy, without forgetting to reform the current social security system in order to mitigate its unintended effects on family formation and fertility and improve its financial solvency.

Econometric and macroeconomic model analyses have demonstrated the negative impact of the demographic decline over the next 50-years, particularly, reduced per

capita growth. In the context of changes in current demographic forecasts, this fertility impact of enhancing IVF services is not insignificant. There is mounting pressure on Governments to enhance their baby-friendly policies as a measure to reverse future reductions in fertility. Decisions about who will access health care resources can be complex and difficult. Governments have argued that the costs of providing reimbursement for infertility treatment are too high but it can be argued that the financial costs are less significant than the real costs of infertility. For countries with very low fertility rates, it is time for comprehensive action. A comprehensive approach to very low fertility would simultaneously address the financial impact of having children, child care and early childhood education and workplace arrangements.

France is a very peculiar situation concerning fertility. French family policy is generally considered as one of the most explicit and intensive ones in Europe. Child birth is considered as a human capital. However, monetary benefits are not sufficient; it is necessary appropriate conditions for the realization of life plans and to reconcile family and work.

At the end of the day what it is at stake is the model of society and the values that support it. The defence and protection of individual rights and equality are not incompatible with family support. The impact of what it is considered politically correct, the imposition of alternative models, in all ambits, including the family one, and the attempts to impose minority or special patterns as a general model are having devastating effects on the future of society.

Technological advances during the past decade have dramatically increased the success rates of ART. Unlike the leaps that technology has taken, the law and public policy have been slower to advance. The legal regulation of the techniques that help to overcome infertility problems are based on the fundamental rights of the persons. The freedom to procreate, as a premise to the right to form a family, is the realisation of the free development of human personality. We need to consider the meaning of human procreation in all its aspects and entailments. The law must address transcendent ethical concerns. However, there must not be confusion between the ethical and legal dimensions. The main problem which the legislator face is finding the right balance between the protection of human dignity, the health of the human beings, human freedom, the intrinsic value of new technologies, the promotion of justice and equality, privacy and the relief of the suffering of those afflicted with infertility.

For Europe and other countries the decline in population might be dramatic. It is time for action. Pharmaceutical Policy and Law wish to thank very vividly all authors that have made this monograph possible. The European Commissioner of Social Affairs, Mr. Spidla, has highlighted the importance and political implications of demographic problems and low birth rates in the Foreword to this volume. Authors of very diverse backgrounds and experiences such as demographic experts, sociologists, economists, lawyers and physicians and other Social Scientists have shared with us their scientific authority with the purpose of presenting a precise and multidisciplinary panorama giving visibility to this complex problem that political parties, parliaments,

governments, international institutions and social agents must respond to in order to secure a better future for the next generation. To all of them we give our most sincere thanks.