

# **The impact of legislation and socioeconomics factors in the access to and global practice of assisted reproductive technology (ART)**

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## **Introduction**

Throughout the world, the availability of infertility services is the result of public health policies associated with a variety of socio-economic, political and in many occasions, religious influences. Wide disparities exist in the access, quality, and delivery of infertility services within developed countries, but most of all between developed and developing countries. Relatively few of the world's infertile population have complete equitable access to the full range of infertility treatment at affordable levels. Even in wealthy countries, such as Japan and the United States, access to assisted reproductive technologies (ART) is, or has been marked by high disparity and inequality in the access to treatment, partly due to high costs and legislative decisions.

Access of men and women to health care and specifically to the treatment of infertility requires not only awareness of being infertile and the knowledge there are treatment alternatives; large amounts of funds are also required, irrespective of whether they are provided by national health authorities, by individuals themselves or by a combination of both.

In countries where access to infertility treatment is granted by law, fertility is understood as a right to which all women and men have equal access. Centralized policies are then established in order to have access to these goods. An example of policies regulating who and under what conditions is access granted is reflected in the establishment of an age limit of women where treatment will be provided. Another example is a restriction in the number of embryos to be transferred in assisted reproductive technology (ART).

When access to infertility treatment is not part of a governmental policy, individuals must rely on their personal wealth and or private insurances covering medical care. Under this scenario, what regulates access to diagnosis and treatment is left to a free market policy, leaving out of reach, all those who cannot afford the costs involved. Furthermore, in most countries, companies providing private health insurances do not cover the costs involved in the treatment of infertility.

Coverage of infertility treatments offers some additional difficulties. While nobody would discuss the use of all available tools in order to save the lives of people with cancer, the use of modern reproductive technology is controversial and many legislators wonder whether specific treatments should be available or funded in order to generate a new life. Interestingly, there is much more social acceptance and legislative agreement in saving lives than in generating new ones.

Irrespective as to whether a country is over or under populated, there seems to be less public concern in prolonging the lives of the elder than in generating new young lives.

It is a rule of life that those promoting laws and regulations have already passed by the burden of existing, all they need to worry, is the quality of their aging and death. On the other hand for those who have not yet come to existence there are no chances of influencing policy makers unless the later themselves have experienced infertility or been moved by someone with this condition.

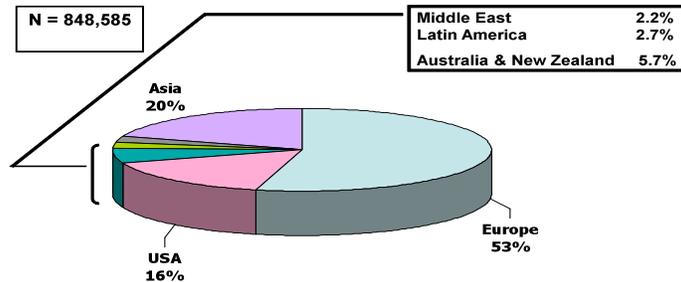
Countries around the world either do not regulate or regulate ART in many different ways. It is the purpose of this chapter, to review how different legislation as well as socio economic, demographic and religious factors influence access to and the way ART is practiced.

Most of the information concerning ART procedures will be related to treatment cycles initiated in 2006.

#### Factors influencing worldwide contribution to ART cycles.

Information on the number of ART procedures performed is now available thanks to worldwide data collected by the International Committee Monitoring Assisted Reproductive Technology (ICMART) <sup>1,2</sup>. While in 2002, forty eight countries reported 584,072 cycles, in the year 2006 fifty one countries reported 848,585 cycles, representing an increment of 60% in 5 years. The major contributor to ART cycles continue to be Europe with 53% followed by Asia with 20% and North America with 16% of initiated cycles reported in 2006. In the decade between 1996 and 2006 the number of initiated cycles increased by 70 %, however, neither the relative contribution nor the % increment in cycles follows an homogeneous pattern since by 2006, Latin America and the Middle east, altogether represented only 4.9% of cycles performed worldwide. (Fig 1). In many ways, the proportion of ART cycles is a reflection of a balance between availability and access to this expensive form of infertility treatment.

**Figure 1: Regional Contribution of ART cycles to the World Report (2006)**



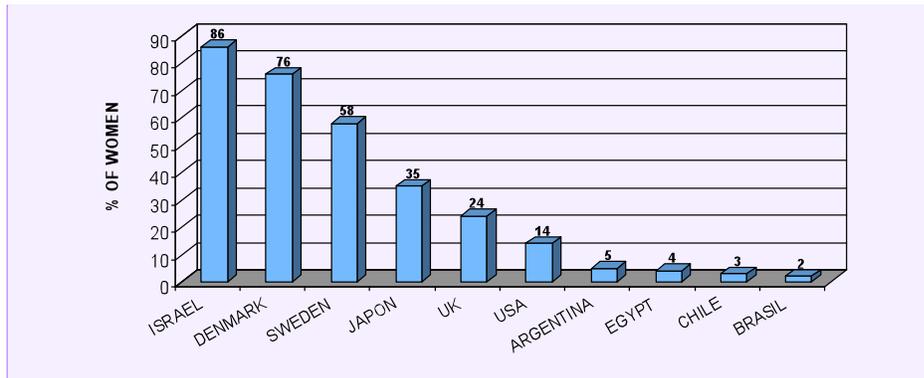
### Inequality in the access to ART

When access is expressed as the number of ART cycles per million women in reproductive age (25 to 40 years), the proportion of treatment cycles fluctuates between 17,000 and 23,000 cycles per million women in reproductive age in Nordic countries such as, Sweden and Denmark and between 5,000 and 7,000 cycles in the UK and Germany. The disproportion is even greater between European countries and other regions of the world. Using the same calculations, access in USA is 3000 cycles per million, 8000 in Japan. With much low access to ART treatments, countries in Latin American such as Argentina, Brazil and Chile, perform between , and 400 and 1000 cycles per million. Similar numbers are found in other developing countries in the world such as Egypt with 800 cycles per million women in reproductive age.

Another way to look at the disparity in access to treatment in different populations is obtained by looking at the relative proportion of treatments performed in a certain population and its theoretical need. This proportion (Fig 2) is calculated by dividing the number of initiated cycles per country, by the number of women age 25 to 40 assuming 10% infertility and 30% of those, requiring ART (3% of all women age 25 to 40). Using this calculation, differences between Sweden and Denmark on the one hand and Latin American countries and Egypt are vast. Interestingly, the mayor source of

difference in access to modern reproductive technology does not only lay on the wealth of the country. It is also a reflection of the distribution of wealth. An example is USA, one of the wealthiest countries, with a disproportionate poor access to ART treatments in its population. Another reality is that of Israel where for a mixture of social and geopolitical reasons, access to ART is facilitated to an extent which provides free access to all those in need.

**Figure 2: Access to ART**



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**Comentario:** JAPAN, BRAZIL

Factors affecting access to ART

Access to ART can be the result of multiple variables. Table 1 describes the relationship between availability of ART and the ways funds allocated to health are distributed among the population. Countries from northern Europe allocate 13 to 15% of their Gross Domestic Product (GDP) to health expenditure, and more than 80% of it is allocated into public as opposed to private health expenditure. On the other hand, USA, with one of the highest GDP per Capita of USD 44,000 also allocates the highest percentage of funds to health (19.1%) but due to a different economic policy, only 46.4% goes to public health expenditure. Countries in Latin American and Egypt are not only much poorer; they also follow trends similar to USA, allocating the majority of their restricted funds into private rather than public health. The consequence of this is that coverage of infertility treatments is reduced in these countries. While in the past, Japan and other Asian countries, allocated a high proportion of their GDP to health and most of it as public health expenditure, its low coverage for ART treatments was the result of a political decision to refrain from funding infertility treatments altogether. However, in 2005 and 2006 Japan and Korea respectively introduced a policy consistent in governmental reimbursement for ART treatments, and although ART remains to be privately funded in Japan, approximately 50 to

60% of costs are reimbursed in women under a certain level of income. This resulted in reimbursement of 65,468 out of 190,690 (34.3%) cycles performed in 2008. This policy is in great part responsible for a rise in ART procedures from 125277 in 2005 to 187715 in 2008

An opposite direction has driven Germany, where severe restrictions in public coverage of ART treatments have been imposed, resulting in a drop in the number of initiated cycles from 80,434 in 2003 to 54,695 in 2006. These two realities are a crude reflection that above cultural and ethnic differences, it is economy what has the largest impact in a couples decision or capacity to use modern reproductive technology in order to procreate.

**Table 1: Number of ART Cycles (2002) According to Public/Private Health Expenditure (2006)**

GDP per capita (dollars)	Country (% General Government Exp)	Public (%)	Private (%)	ART Cycles/ million women in reproductive age (25-40)
34-50,000	Sweden (13,2%)	82,6	17,4	58
	Denmark (14,9%)	84,1	15,9	76
	UK (15,7%)	81,9	18,1	24
	Australia (17,1%)	66,6	33,4	66
	Japan (17,5%)	81,3	18,7	35
44,000	USA (19,1%)	46,4	53,6	14
5-8,000	Brazil (5,1%)	41,7	58,3	2
	Argentina (14,4%)	55,8	44,2	5
	Chile (14,0%)	42,1	57,9	3
1,400	Egypt (6,4%)	44,2	55,8	4

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**Comentario:** CAMBIAR LOS NUMEROS POR MILES DE CICLOS POR MILLON DE MUJERS...POR EJEMPLO SUECIA ES 17,527, DENMARK ES 22,842, ETC

The first conclusion would be that access to ART treatment is strongly influenced by socio economic policies. Countries where infertility treatment is considered a right, to which all individuals are entitled as equals, distribute their wealth through public facilities and have a much higher coverage of treatments. On the contrary, countries where access to infertility treatments is partly regulated by the market, requiring out of pocket funding, have a much lower coverage of fertility treatments, which in turn, decreases the number of treatment cycles.

Access to Art treatment and insurance coverage

Indeed, access to health and insurance coverage are intimately related. Very few countries in the world have national health plans covering full range of

treatment. These are, Australia Belgium, France, Israel, Slovenia, and Sweden. Differences between them reside in the number of ART cycles that are covered by the national health plan and in the regulation imposed to have access to this facility (age limit of the female partner, maximum number of embryos to be transferred, etc.). An interesting observation results from the fact that countries with full coverage also deal with the costs involved in pregnancy, delivery and neonatal care. Today, single embryo transfer is the rule in Sweden and in young women in Belgium. Therefore, the costs they have absorbed by covering ART have been compensated by decreasing the number of multiple births and high costs involved in the care of preterm babies. Some other countries in Europe and Middle East have only partial coverage from public sources like the UK, Denmark, Finland and Tunisia, and today, Japan and Korea. What is more striking is that in Latin America, a region strongly influenced by Catholic tradition which opposes ART, access to infertility treatments is left out of coverage both by public and private insurances. A minor exception is Chile where 11% of treatment cycles are covered by public insurance. In 2011, the province of Buenos Aires; Argentina mandated free coverage of ART treatments to persons having social security which is a public health system.

When ART treatment is covered by out of pocket funding, it results in a source of inequality and disparity in the availability of health resources. The absence of insurance coverage determines that only wealthy couples can access to treatment and as will be seen later in this chapter, this factor is strongly associated with high rates of multiple births.

#### Access to ART and demographic factors.

It is interesting to observe that coverage of infertility treatments in many countries or regions is strongly associated with the mean age of women, the fertility rate (ratio between the number of births and the number of women exposed to the risk of pregnancy) and the population growth rate (the rate at which the number of individuals in a population, increases). Table 2 describes in different countries, the association between access to ART, and the mean age of the female population, fertility rate and population growth rate.

**Table 2: Access to ART (2006) according to: age of female population and fertility rate**

Country/Region	Female median age	Fertility rate	Populations Growth	Access % (25 to 40)
Sweden	42,0	1,66	0,16	58
Denmark	40,7	1,74	0,33	76
UK	40,4	1,66	0,28	24
Japan	44,7	1,4	0,02	35
USA	37,8	2,09	0,91	14
Brazil	29,0	1,91	1,04	2
Argentina	30,7	2,16	0,96	5
Chile	31,4	2,00	0,94	3
Egypt	24,3	2,83	1,75	4

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Countries having the highest access to ART treatments are those with the lowest population growth rate and highest age of women. In contrast, younger populations with higher fertility rate as in most countries in Latin American and Middle East have less coverage or no coverage at all. Again, as discussed before, Japan has in recent years reacted to the high median age of their female population (almost 45 years) and low population growth rate. As referred before, Japan established a partial reimbursement policy, which immediately increased the use of ART, contributing to the renewal of its population through women who otherwise would have stayed childless or with fewer children than desired.

Perhaps the underlying factor responsible for these disparities is that in countries with an older female population and a negative growth rate, the nation as a whole, needs to deal with population renewal. On the contrary, in countries with young female population and high growth rate, it is not the country but the individual who has to deal with his/her reproductive needs. This might perhaps explain why, no Latin American countries consider Infertility as a disease and therefore, infertility treatments do not fall into the public health agenda

The desire to have more children is not a national priority in regions with young female population and high fertility rate. Furthermore, in the absence

of a legislation regulating the practice of ART, access to fertility treatments is not on the agenda of national health policies and companies responsible for health insurance do not cover expenses related to fertility treatments. Furthermore, for many legislators in Latin America, procedures such as in-vitro fertilization (IVF) and embryo transfer are considered morally unacceptable and a luxury that should not be sustained with state funds. An extreme example of this moral dictatorship is Costa Rica where the High Courts decided that IVF was morally unacceptable and illegal, forbidding the practice of ART in the country. The result of this policy is that a small proportion of wealthy citizens could afford travelling abroad while the vast majority of couples requiring ART, remained childless. It was not until mid 2010 that a group of infertile couples won a pledged against the state of Costa Rica at the Inter American Court of Human Rights. As a result, the court obliged Costa Rica to provide ART treatment in that country. Today, the fight is for a reasonably liberal law regulating the practice of Art in that country.

#### Influence of tradition and religion in the practice of ART

It is often difficult to ponder the influence of religion, tradition and other cultural factors in the application of laws regulating reproductive health. The difficulty is not necessarily the result of an imposition of certain religious morality, many times, economic and political forces are strongly bound to religious organizations which at the end, influence legislative processes.

Christian tradition: Although religion and public laws have been separated for centuries in countries in Western Europe and the Americas, Christianity and most of all, the Roman Catholic Church is by far the most outspoken religious body when it comes to moral behavior concerning sex and reproduction. Catholic tradition has a strong influence in Latin America, less in USA, and even though most European countries have more rational, evidence based approach to ethics in reproductive health issues, the Catholic tradition can still exert strong influence. A recent example was Italy's law regulating the practice of ART.

The fundamental basis for the Catholic opposition to any form of ART, starts in the late sixties, when Pope Paul VI established in his Encyclical Humane Vitae that the uniting and procreative meanings of the conjugal act should not be voluntarily dissociated. Consequently, both contraception and assisted reproduction are considered immoral as they voluntarily dissociate these two meanings; one by allowing sexual intercourse devoid of its procreative meaning, the other, by allowing procreation not mediated by sexual intercourse. Later, in 1987, the Vatican published a document

“Donum Vitae”, which contained an “Instruction on respect for human life”, issued by the Congregation for the doctrine of faith and signed by Cardinal Joseph Ratzinger, today, Pope Benedictus XVI. This document stated that a person, as we understand it, exists from conception onwards and therefore, condemned all forms of assisted reproduction, irrespective of its intention, the source of gametes and marital status. This principle carried such power that later, the vast majority of countries in the Americas, signed the “American convention on human rights, pact of Costa Rica” which states that “laws should protect the lives of those to be born -in general- from conception onwards”. Based on this principle, the Supreme Court of Costa Rica stopped Art in that country. In the rest of Latin America ART is performed but no laws are available, in spite of the fact that most countries have law projects sitting in their parliaments. In the majority of cases, this is mainly because no agreements are reached between legislators as to whether pre implantation embryos are entitled to rights of their own. Needless to say that any form of embryo manipulation, genetic diagnosis, or research, is performed in few countries without the possibility of discarding abnormal embryos.

The influence of Catholicism concerning ART is less evident in USA, where more value is placed in the right to autonomy, both from the perspective of couples and providers. It must be said however that the opposition of US government to therapeutic cloning, and embryonic stem cell research, which lasted until the new president was elected, was mainly the result of lobbying by the Catholic church under the argument that a pre implantation embryo is entitled with the same rights of an existing person.

For various reasons, the council of bishops in Europe has been more liberal in the application of directives arising from the Vatican. An example is the Catholic University of Leuven, Belgium, where ART, including embryo cryopreservation is offered openly. A reverse example however, is the recent law passed in Italy, which forbids fertilization of more than 3 oocytes, embryo cryopreservation, use of donor gametes, genetic diagnosis, etc. The reason behind this restrictive law is the result of pressure from the Catholic Church on the bases of human rights attributable to embryos from conception onwards.

In a different attitude towards reproduction, all protestant denominations (Baptist, Methodist, Lutheran, Mormon, Presbyterian, Episcopalian and others, are very liberal concerning infertility treatments and the promotion of reproductive science. ART is accepted as long as gametes belong to spouses and embryos are not intended to be destroyed.

Islamic tradition: Differently to religious laws regulating the Western world, Sharia law, which constitutes the bases for Islamic religion °also, regulates political, public and private lives. Its teachings and directions are open for interpretation as science and technology discovers new routs and they serve humankind and society <sup>4</sup>.

Concerning reproduction, almost all scholars agree that it is legitimate for infertile couples to pursue any form of therapy as long as both male and female gametes belong to the couple and pregnancy takes place in the woman’s uterus <sup>5</sup>. Consistent with this concept of genetic heritage, Islam does not approve adoption. Thus, it is the duty of physicians to help infertile couples achieve conception with the freedom to use technology as long as this takes place inside the married couple <sup>6</sup>. The embryo is entitled to due respect and genetic diagnosis can be practiced as long as it does not harm the embryo <sup>5</sup>. Although law allows for PGD in Islamic countries, couples can not practice their autonomy to decide upon the fate of their embryos. In Islam, embryos can not be discarded.

Jewish tradition: The application of the Jewish tradition is circumscribed to the teachings found in the Torah, subsequently followed by a compilation of traditions and interpretations, such as the Talmud and other ancient religious documents. Israeli laws are secular and rule public affairs while private matters are the domain of Judaic law, enforced by special rabbinical courts. When it comes to procreation, both secular and religious laws are pragmatic and favor the stability and strength of the family and in agreement with the first commandment “Be fruitful and multiply”, laws allow almost any form of assisted reproduction. Although marriage and/or a stable relationship are required to have access to ART, single mothers can also receive fertility treatments. Different religious branches of Judaism have marked differences in the interpretation of the law; nonetheless, at the end, the decision to use modern reproductive technology is dealt with freedom by infertile couples and provided by the government. Israeli law allows gamete donation (with strict regulations on the source of male gamete), any form of ART, pre implantation genetic diagnosis, even for sex selection, oocyte donation, etc. Israel holds the highest number of IVF clinics per capita and the National Health Insurance Fund provides IVF treatment for up to two live birth for childless couples and for single mothers.

The coexistence of Jewish religion and law represents a remarkable example of equilibrium and tolerance between the strength found in tradition and the need to use science and technology to bear children and strengthen the family.

The purpose of reviewing religious morality is that specially in the developing world, religion can have a strong influence in political decisions. In countries dominated by Catholic tradition, which today are concentrated mainly in Latin America, much of the discussion is not centered in the rights of infertile women and men. On the contrary, most of the discussion is centered on the moral rights of an embryo. As a consequence of the above, ART is accepted because it is there, but no country has been able to reach a consensus on minimal standards to regulate the practice of ART. This lack of pragmatism in confronting biomedical and social realities is at least in part responsible for the low access to treatment generating inequality, lack of autonomy and therefore absence of diagnostic and therapeutic procedures, such as preimplantation genetic diagnosis (PGD) and other forms of preventing the inheritance of genetic diseases. In countries where the influence of religion in public policies has been restricted, it is the right of persons what prevails in as much as it does not affect society as a whole. In general, the more separation there is as to how and who is entitled to impose religious and public laws, the more respect there is for the needs of women, men and for the children to be born.

#### How Legislation and culture influence the practice of ART

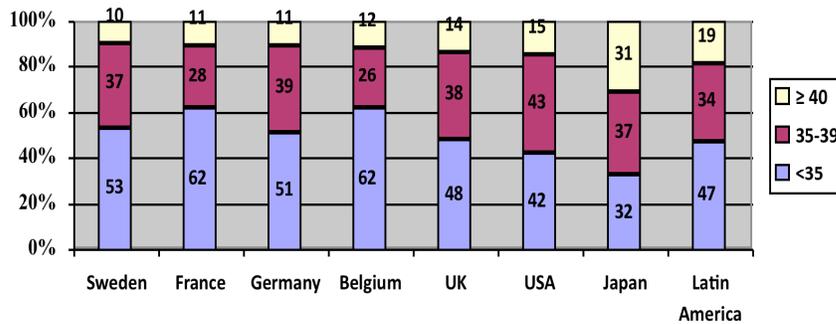
##### - Age of female population receiving ART treatments

The age of the female partner has a great impact in the outcome of any fertility treatment and therefore in the mean number of embryos transferred. Therefore, when comparing Art policies and outcomes between countries or between different years, it is important to adjust the results by age. In 2006, the proportion of women  $\geq 40$  ranged from 31% in Japan to 19% in Latin America and only 11% in Sweden (Fig.3). While in Latin America the high proportion of older women probably results from economic variables, in Japan there is a mix of economic, cultural and demographic reasons. Contrarily, in Nordic countries in Europe women request infertility treatment much earlier in their life because access is easier. This impacts success rates as well as the way ART is practiced. It is indeed easier to implement programs such as mild controlled ovarian stimulation (COS) protocols and elective single embryo transfers (eSET) in younger and therefore more fertile populations.

But the easiness for access to treatment is not all. Both Sweden and Japan share similar policies towards embryo transfers; in fact, both countries have

reached 70% of SET, in spite of major differences in population structure, reimbursement policies and law.

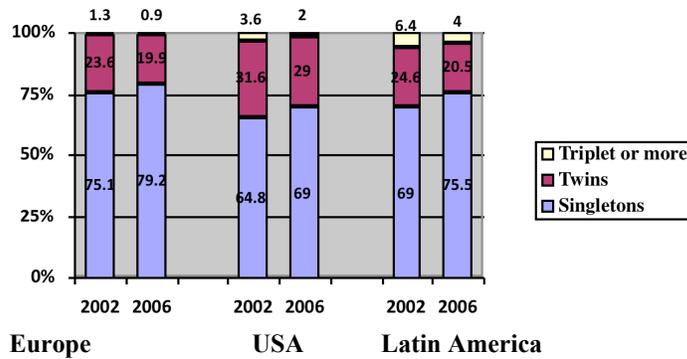
**Figure 3: Age distribution of patients undergoing ART**



- Number of embryos transferred and multiple births.

The issue of multiple births is one of the most serious complications generated by ART. The risks related to multiple birth, do not only involve maternal and perinatal complications, it also generate financial and social problems, the majority of which, have to be dealt with by the family alone. The rate of multiple births varies in different countries and regions. For 2006 the proportion of twin and triplets and more in Europe was 20.8%, compared with 24.5% in Latin America and 31% in USA. In the past 5 years, every region has moved in a similar direction, towards reducing the number of embryos transferred, (Fig 4).

**Figure 4: Regional Variability in Multiple Birth IVF & ICSI (2002-2006)**

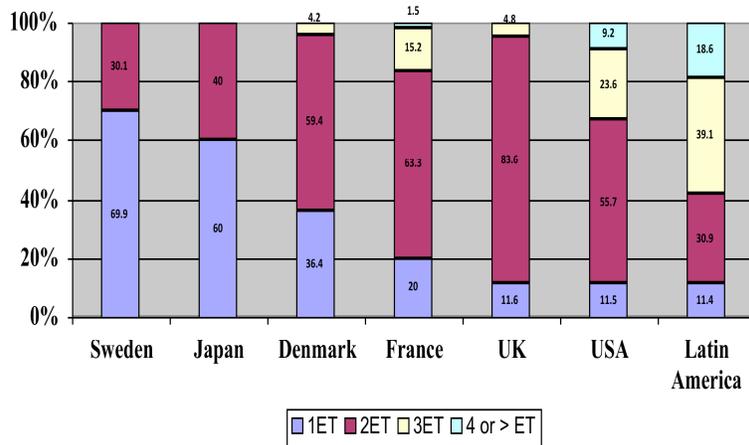


Perhaps, the most remarkable difference is in the number of triplets and more, which increase from 0.9% in Europe to 2% in USA and 4% in Latin America. The differences in high order multiple births in Latin America and USA is in part the result of embryo reduction in the latter.

Reports by the Latin American Registry of ART, show that between 1990 and 2009, a total of 92,791 babies were born, 42,290 had cohabitated with at least one other fetus with a direct impact in perinatal mortality; which increased 2.8 times in twin births and 6.4 times with the birth of triplets and 18.7 times with the birth of quadruplets <sup>7</sup>.

There is no doubt that the number of embryos transferred has a direct effect on the chances of becoming pregnant, and is the one single factor which by itself increases the risk of multiple gestation and birth. Indeed, this risk also increases as the age of woman decreases. In 2006, 57.7% of transfer cycles in Latin America included 3 or 4 embryos; compared with 32.8% in USA, 16.7 in France, 4.8 in the UK and none in Sweden and Japan (Figure 5).

**Figure 5: % Transfer cycles according to the embryo transfer**



Many factors can be responsible for these regional differences, but the pressure for success placed by the couple and their family plays an important role. This pressure increases due to economic constraints. Thus, if for economic reasons, the couple can afford only one treatment cycle, the risk/benefit evaluation of multiple births as opposed to no birth is pondered differently than if couples have 6 cycles for free. Table 3 compares the number of embryos transferred and the proportion of high order multiple births in different countries during 2006. Data is presented according to whether the source of funding was public or out of pocket.

There is no doubt that the most efficient way to decrease the number of multiple births is by reducing the number of embryos transferred and this is easier to do when the high costs are totally or partially covered by public or private sources other than her/his own pocket.

**Table 3: Source of funding influences the number of transferred embryos and high order multiple births (2006)**

Source of Funding	Country	Mean N° Embryos Transf.	High order Multiple births (%)
Public or Private with Partial/Total reimbursement	Denmark	1,7	0,1
	Sweden	1,3	0*
	UK	1,9	0,3
	France	2,1	0,5
Out of pocket	Brazil	3	4
Out of pocket	Chile	2,5	1,8
Out of pocket + Private Insurance	USA	2,6	1,8
Out of pocket	Japan	1,4*	0
Out of pocket	Australia	1,6	0,4*
Out of pocket	Egypt	2,8	2*

\* Data corresponds to cycles performed in 2005 and 2006

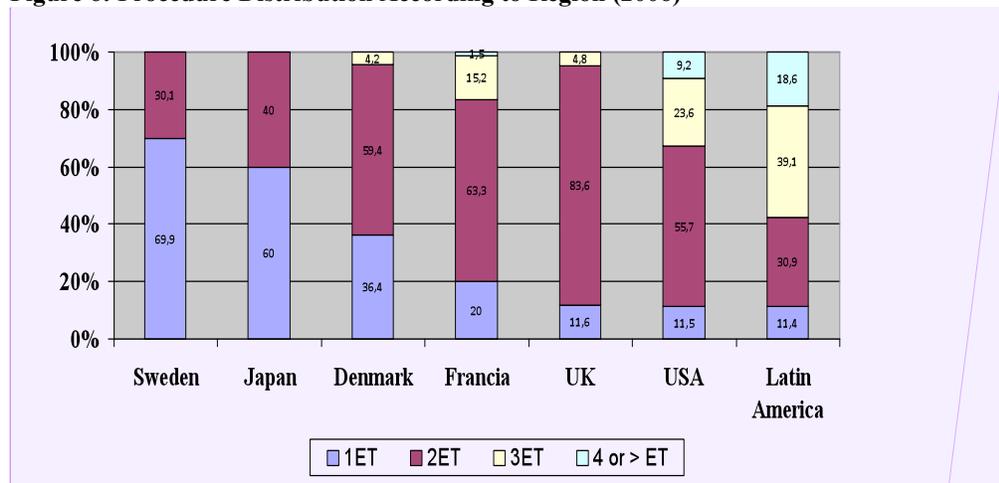
- The experience with eSET in the Nordic countries and Japan

These two different cultural and ethnic realities have dealt with the burden of multiple births using a similar strategy, which is prioritizing SET. In the case of countries like Sweden, infertile couples receive a substantial reimbursement (approximately 60% of costs) and 70% of transfers are SET while the rest are Dual embryo transfers (DET). The results of this policy is that more than 90% of babies born are singletons, and less than 7% twins. There is no high order multiple births in Sweden and Finland; this policy was implemented in the early 2000. It took approximately 5 years for Japan to start ART treatments in similar directions but in the absence of or with little reimbursement. The main motives to implement the SET policy were its benefit in the prevention of multiple births without severely affecting success rates. Thus, in 2008 60 to 70% of ART treatments performed in Japan are SET, Differently to the Nordic experience, in Japan, where there are no laws regulating this treatment, it was the Japanese professional society which decided to implement this therapeutic strategy, and it has been followed by the majority of today's 500 institutions providing ART treatments.

- Mode of fertilization - ICSI vs. IVF

Since its introduction, the use of intracytoplasmic sperm injection (ICSI) has increased yearly. Today, in certain regions of the world, ICSI is used in more than 70% of ART cycles. Worldwide, the proportion of ICSI over IVF increased from 24% in 1995 to 56.2% in 2003. However, this proportion has regional variations which, similarly to what happens with the number of embryos transferred, is influenced by different legislations, specially by socio economic variables such as who is responsible for the costs of treatment. In countries where ART is subsidized by public funds, the proportion of ICSI is relatively low: 53.2% in Australia, 56.3% in Europe. In regions where ART is paid directly by consumers, the proportion of ICSI rises to over 75% in Latin America and 94.8% in the Middle East<sup>3</sup> (figure 6). Irrespective as to whether it is right or wrong, there is a tendency to avoid unexpected failed fertilization or low fertilization rate with regular IVF; and centres tend to use more ICSI to “ensure” fertilization.

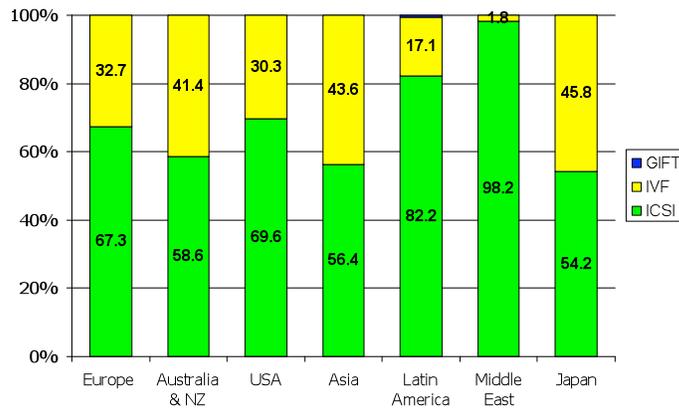
**Figure 6: Procedure Distribution According to Region (2006)**



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Figure 4: Procedure distribution  
According to Region (2006)



Examples of the effect of laws on the outcome of ART treatments.

Perhaps the best examples of the impact of legislation in the outcomes of ART can be found with the implementation of the new laws in Belgium and twice now in Italy.

The Belgium example: In July 2003, the Belgium health authorities introduced legislation to improve financial access to ART treatments and to reduce multiple births. The main decision included that laboratory costs would be refunded for six cycles in a lifetime for women under the age of 43. This benefit is conditioned by the number of embryos that can be transferred, which varies from 1 to 3 depending on the age of women and the cycle number. Furthermore, it obliges each centre to report all its data to a centralized registry who can evaluate trends. This policy not only eliminates inequality in access, it also decreases the risks of multiple births. In this way, the reduced neonatal costs should be enough to cover the costs of treatment. This is perhaps one of the best examples on how a legislative body examines the available data and implements a solution that brings equality and benefit to all members of society. Belgium is a multi religious community cohabiting with a proportion of non-religious community. The important fact is that this policy does not enter in the philosophical discussion of when does personhood begin. On the contrary, it looks at the economic, social and

biologic evidence with pragmatism and implements a legislation that can deal with them in the best possible way, allowing individuals to decide by themselves. The consequences of this legislation are still in evaluation, but so far, at least two conclusions can be extracted. First, the policy does not jeopardize the chances of a couple to have a baby. It can take more cycles to achieve the goal, but the cumulative birth rate is not affected. Second, there is a marked reduction in the rate of multiple births. A good review of this data can be found in a publication by L. van Landuyt <sup>8</sup>.

The Italian example: In March 2004 a new Italian law imposed a number of limitations to the medical profession and to infertile couples. In fact, no more than three oocytes could be inseminated because no more than three embryos could be generated. Furthermore, all embryos needed to be transferred since embryo cryopreservation, PGD or any form of embryo manipulation was not allowed. In a different dimension, only married couples or heterosexual couples living a stable relationship, had access to ART treatment. No treatment is available for gay couples or single women. This law establishes the right of an embryo over the rights of her and/or his progenitor. This is especially confusing in a country where the termination of a clinical pregnancy is legal. Furthermore, by restricting ART to only married and cohabiting, heterosexual couples, it specifically discriminates against infertile women since if they were fertile, they could become pregnant without requiring a stable heterosexual relationship. This discrimination is only restricted to those infertile women requiring ART; since infertile women are not required to have an heterosexual stable partner to have access to ovarian stimulation or pelvic surgery nor any other form of infertility treatment. The ethical and clinical implications of this law have been discussed by Benagiano and Gianaroli <sup>9</sup>.

Fortunately, after extensive lobbying and the use of scientific evidences, the right of women and men prevailed and in May 2009 the Italian Constitutional Court declared that the statement “the prevision of the creation of a number of embryos in any case not exceeding three and the mandatory transfer of all the embryos created for a maximum of three” was “unconstitutional”. Today, the law says “ART techniques must not create a number of embryos exceeding the one strictly necessary”; entrusting the decision of the right number of embryos to be created to the doctor, according to the different patient’s conditions. With the Italian national Registry created in 2005, it will now be possible to evaluate the effect on multiple births and success rates of the restrictive law passed in 2004 and at the same time, evaluate its reversal in 2009 <sup>(10)</sup>.

These examples represent two different ways of legislating in areas related with sex and reproduction.

In the Italian experience in 2004, the main intention of legislators was to defend a moral principle “The respect of a person from conception (fertilization) onwards”; irrespective of the effects this might cause in actual persons, (men and women) in the family and in society.

In the Belgian experience the main intention of legislators was to defend the right of actual persons to receive medical treatments. It was also an objective to protect the quality of life of those to be born by facilitating the birth of singletons.

There is a world tendency to procure safety over (or balanced with) efficacy, particularly in countries where access to ART is guaranteed or at least facilitated by public resources. In the search for safety, a single embryo transfer (SET) policy has been established in Sweden, Finland and Belgium. There is more than one strategy to reach this goal, and these three countries have arrived to a SET policy by different roads.

In Sweden, currently in the lead of the SET transition, 70% of all embryo transfers are now SET, with the eradication of triplets, and a reduction of twinning from over 25% before, to now only 5%. This transition is a result of a combination of several factors. A professional decision, soon supported by the national patient organization, and later followed by governmental regulation. The process took 4 years, from 2002 to 2005.

The main factor behind this move was a cooperative effort between the professional societies of gynecologists and pediatricians and governmental authorities, where the medical risks for IVF children were thoroughly investigated. A national IVF register of all women giving birth after IVF was formed and, using the personal identification number given to each Swedish citizen, cross links were made to five different population based health registers already in operation. Very convincing evidence emerged, showing that the much higher risk profile of IVF children was caused not by the IVF technique per se, but to an elevated multiple delivery rates. A large randomized clinical study followed by national data demonstrated that pregnancy rates did not drop, after a substantial increase in the proportion of SET. This, finally made the case for SET as the norm. A very important driver for the transitions was the back-up by the lay press.

In the midst of this process the law was changed to say that SET must be the norm. The change of law merely confirmed what was already happening, and was therefore welcomed in the country. Discussion on economy was never involved.

In Finland the transition to SET as the norm, was the result of professional decision only, with no governmental interference, and again economy was not an issue.

In Belgium, on the other hand, economical arguments on high national costs for post-natal health care of prematurely born multiple-birth IVF children convinced the government to change reimbursement policies to strongly favor SET.

There is thus not one single road to procure an equilibrium between safety and efficacy; in this case through the single embryo transfer policy: in Sweden national data on safety and efficacy, followed by governmental regulations on the practice of IVF did it, in Finland the same process but with no governmental intervention, and in Belgium a change of governmental re-imburement policies. But the effect is the same: a much reduced risk for the children.

The most recent example of a national change towards a balance between safety and efficacy has been established in Japan. In contrast with the Nordic countries, reimbursement in Japan covers less than 40% of ART cycles, 30% of women are  $\geq 40$  compared to 11% in Sweden and Finland and the vast majority of women receive mild forms of COS which include Clomiphene Citrate and alternative injections of HMG or rFSH. Similarly to what took place in Sweden, in Japan there are no laws regulating the practice of ART. The Japanese Society of Obstetrics Gynecology took the decision and the vast majority of institutions followed its recommendation.

It is interesting to note that countries where the influence of religious morality is well balanced by strong and independent lay organizations, laws tend to follow realistic and sensible evaluation of reality and public decisions are adopted after incorporating the lay public and society as equals in the discussion of public policies. On the contrary, countries with strong religious influence, tend to moralize in such a way that the value of embryos become the dominating issue overlooking the rights of actual persons, in this case, infertile couples in the pursue of effective and safe treatment of infertility.

The examples of the Nordic countries and Japan in contrast with countries in Latin America are true reflection of this reality.

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