

OPINION

Legal harmonization and reproductive tourism in Europe

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Legislation of ethical issues illustrates the uneasy mix of ethics and politics. Although the majority has the political right to express its moral views in the law, a number of important ethical values like autonomy, tolerance and respect for other people's opinions urge the majority to take the minorities' position into account. Ignoring pluralism in society will inevitably lead to reproductive tourism. Although European legislation and harmonization in the domain of medically assisted reproduction is presented as a partial solution to this phenomenon, it is argued that European legislation should be avoided as much as possible. Regulation of these private ethical matters should be left to the national parliaments. A soft or compromise legislation will keep reproductive travelling to a minimum. Reproductive tourism is a safety valve that reduces moral conflict and expresses minimal recognition of the others' moral autonomy.

Key words: ethics/Europe/harmonization/legislation/reproductive tourism

Introduction

On May 1, 2004, 10 new members from Central Europe joined the European Community. This historical occasion was accompanied by songs of praise for the European Union. Alongside attempts to introduce a European Constitution, there is an increased pressure for harmonization in legislation on all domains of life. The field of health care and medicine, including medically assisted reproduction, is not exempt from this endeavour. Everyone who attended any congress in recent years will have noticed the immense variety of rules, regulations and legislation in European countries. Although the call for harmonization has an initial appeal, it may be a siren song leading to more restrictive legislation on reproductive technology. Some defenders of a unified European legislation seem to want to return to a pre-modern world where all citizens share a common world view and a set of rules to define the good life. They say 'harmonization' but they mean 'uniformization'. Because of its denial of ethical, cultural and religious pluralism, this is a dangerous position to hold. Others, on the contrary, believe that Europe can help them to adopt a more liberal law in their own country or are convinced that supranational legislation is the only way to regulate the practice at all. These beliefs in the effects of European legislation result in opposite movements: keeping Europe off and limiting their meddling as much as possible versus accelerating European law making and stimulating intervention. Everyone involved in the field (patients, practitioners and scientists), both as stakeholders and as citizens, should voice their concerns when regulation moves in the wrong direction (Sunde, 2004).

Ethics versus politics

All legislation on ethical issues, including the issues generated by the application of medically assisted reproduction, raises a number of questions regarding the relationship between ethics and law. How should the legislator in a post-modern society, characterized by a multitude of groups holding different moral outlooks, react to moral conflicts? This is a basic problem for all democracies. The most obvious solution to this position is to forsake legislation. However, 'no law' is also a moral position. Neutrality of the state is impossible here. A nation without legislation on bioethical issues supports the liberal position that every citizen should decide according to his or her moral convictions.

There are two general positions regarding the right of the majority to express its views in a binding law. There are those who believe that the law within a pluralistic society should not reflect the substantive moral position of one group. Coercive constraints, like legal prohibitions, lack a common basis in such societies and thus discriminate against the other positions (Engelhardt, 1991). 'Legislation, at least in a democratic society, reflects, and is supposed to reflect, a compromise between the diverse preferences and interests of the members of that society... Hence, a legislative acceptable compromise can be attained only if some considerable degree of moral agreement can be achieved during the course of the political debate' (Wellman, 1994). This would apply both to the national and to the European level.

The second position holds that, from a political point of view, the majority has the right to impose its view of

the good life. In a democratic system, political parties strive to organize society according to their goals, values and principles. Political programs contain ethical and religious convictions. The main cause of friction between ethics and law is that democracy is not based on the principle of consensus but on the principle of majority (Bayertz, 1994). The conflicts between parties are decided by the majority rule in parliament. If the democratic process functions normally, the view of the majority will prevail at the expense of the minority view. Although what is ethical is not decided by the majority, the ethical rules that apply in social life (what is allowed, obliged or forbidden) are, at least partially, decided by the politicians who pass the laws (Kuhse, 1994). Unless one wants to do away with democracy, this is something we will have to learn to live with.

However, even if the latter position is adopted, a compromise between ethics and politics should be attempted. Although the majority has the political right to impose its views on the minority, a number of important ethical values urge the majority to tread cautiously. Among these values, we count autonomy (the right to organize one's life according to one's own moral principles), tolerance and respect for different moral positions. A state which uses excessive coercive power to promote majority values may end up permanently suppressing minority groups. Imposing a moral opinion on persons who do not share this view increases the risk of conflicts. Consider the new Italian law as an example. Donation of embryos and gametes is banned. Research on, and cryopreservation of, embryos is forbidden. A maximum of three oocytes can be fertilized and every embryo has to be replaced regardless of its quality or the age of the woman. Recently, a woman at high risk for B thalassemia was told by the court that all embryos had to be replaced without preimplantation testing (Turone, 2004). This law results, amongst other things, in an increase in multiple pregnancies in younger women, with all the risks involved for mother and children, and in a reduction in success rate for women older than 35. The main criticism, however, is that the law clearly expresses the beliefs of only one section of society, i.e. Catholics. No attempt was made to take into account other views. It should surprise no one that non-Catholic Italians feel frustrated, ignored, angry and unfairly treated. More than likely, the patients and the practitioners will vote with their feet. Apparently, this process has already started, with hundreds of non-sterile couples at high genetic risk going abroad (Turone, 2004). Ignoring pluralism in law making inevitably results in reproductive tourism. However, although this law should be criticized and the harmful consequences exposed, this does not imply that one should abolish the political system by which it was generated. The law was voted by the majority of the Italian people. Who would have the right (and on what basis) to oblige the Italians to permit preimplantation genetic diagnosis, the Irish to allow termination of pregnancy, or the Belgians to prohibit the creation of research embryos? It is up to the people of these countries to change the law (if they think it is morally unacceptable) by means of the recognized political procedure, i.e. parliamentary democracy.

Reproductive tourism

Reproductive or infertility tourism refers to the movement of citizens to another state or jurisdiction to obtain specific types of medical assistance in reproduction that they cannot receive at home. Diana Blood, who transferred the sperm of her deceased husband from the United Kingdom to Belgium in order to be inseminated, is probably the best known example of this type of medical tourism. Although the media only pick up the more spectacular cases, most instances of 'reproductive tourism' are performed by ordinary groups of patients like older women, donor oocyte recipients or donor sperm recipients. The Belgian register of assisted reproduction for 1999 indicates that 30% of patients receiving *in vitro* fertilization come from abroad. When oocyte donation is considered separately, 60% of all recipients are foreigners (College of Physicians Reproductive Medicine and the Belgian Register for Assisted Procreation, 2001). For preimplantation genetic diagnosis, half of the couples come from Germany and France as a result of legal or practical restrictions in these countries (Vandervorst *et al.*, 2000).

A country like Belgium which has no law on assisted reproduction and an abundance of high quality infertility centres, attracts people from all its neighbouring countries and beyond. From Germany, patients in need of oocyte donation or who want IVF with donor sperm are coming over. French patients cross the border because they want to increase their chances of success by avoiding the obligatory embryo freezing after oocyte donation or because they do not accept the 'personalized anonymity' rule which precludes the use of a known oocyte donor (Baetens *et al.*, 2000). Other fairly substantial groups from France are lesbian couples and single women who request artificial insemination. From the Netherlands, women over 40, donor sperm recipients and couples who want to use surgically obtained sperm with ICSI visit Belgian clinics. Similar flows of patients exist between other European countries. It is well known for instance that Spain attracts oocyte recipients from all over Europe because of the long waiting lists in other countries.

In general, the main causes of reproductive tourism can be summarized as follows: treatment is prohibited in the country of origin because the application is considered ethically unacceptable (use of donor gametes, sex selection for non-medical reasons etc.), because candidate patients possess characteristics that are considered to make them unfit for parenthood (postmenopausal, lesbian etc.) or because the technique is considered medically unsafe (oocyte freezing, cytoplasmic transfer etc.); treatment is not available because of lack of expertise (preimplantation genetic diagnosis); the waiting lists are too long (donor oocytes); or the costs (fees) are too high. Sometimes, a combination of motives exists. For instance, the first stream of patients from Sweden to neighbouring countries for donor sperm after the abolition of donor anonymity was a consequence of scarcity (decrease of candidate donors) in combination with the refusal of recipients to accept identifiable donors (Pennings, 2001). The same applies to the Netherlands at this moment; Belgian clinics near the border notice a steady increase of Dutch patients

the closer they get to the end of the transition period for anonymous sperm donation.

The financial motive for cross-border treatment deserves special attention because the classic argument against reproductive tourism is inequality of access. Only 'well-heeled people from well-regulated countries go to less well regulated ones to buy services' (Rose and Rose, 2003). The argument is based on the principle of equality: it is discriminatory and unjust when only the rich can afford treatment. Firstly, this is a strange argument when it is advanced by those who installed the restrictive legislation in the first place. If the prohibitive laws were abolished, neither poor nor rich people would need to go abroad. Secondly, this is not an argument against those who have the financial means unless envy is recognized as a basis for moral judgment. The first question is whether people should decide about their way of reproducing.

Moreover, the cost of infertility treatment may vary considerably from one European country to another. Contrary to the allegations, reproductive tourism may actually reduce social injustice and unfairness by allowing poorer patients from rich countries to obtain the treatment they cannot afford in their home country. Reproductive travelling motivated by costs will probably increase in the future. A brief search on the Internet reveals several clinics from Central Europe, Russia and India that actively recruit foreign patients by emphasizing a cost reduction of 50% and more. This type of tourism can be largely prevented if public health insurance would cover a substantial part of the costs. A worrying aspect of this move towards poorer countries is the recruitment of oocyte donors. Informed consent regulations may be less strict in these countries. Firstly, payment of large amounts (according to the donor's standards) may have a deleterious effect on informed consent of the donors. In addition, the general commercial atmosphere surrounding the recruitment of donors and the provision of infertility treatment is not conducive to elaborate attention to ethical standards. A recent survey in the United States showed that in the first telephone contacts, the risks and inconveniences of egg donation were downplayed in order to attract a higher number of donors (Gurmankin, 2001). Clinics in countries without (reliable) control may be even less scrupulous.

Solutions

Reproductive tourism is usually presented as a problem. Scholars and politicians rack their brains to find solutions to prevent or diminish this phenomenon. A remarkable finding is that commentators ignore the major cause of reproductive tourism (i.e. restrictive legislation) when they consider solutions. Most of the time, they accept this as given and start from there. The most obvious solution, i.e. not to issue strict prohibitions, is rarely considered seriously. Nevertheless, the possibility of law evasion by travelling has already been used by the Swiss Federal Council as an argument to reject a referendum initiative that wanted to prohibit most forms of *in vitro* fertilization and the use of donor gametes (Conseil Fédéral Suisse 2000). The only consequence of such a law would be the flight of infertile couples to neighbouring

countries. Other countries react in a coercive or repressive manner. Several examples are known of European countries attempting to force their citizens to abide by the law. One way to do this is by punishing citizens who violate the law abroad. Around 1990, German border guards forced gynaecological examinations upon women coming back from the Netherlands in search of evidence of extraterritorial abortions. Prosecutors also brought criminal charges against women who obtained abortions in other countries. The European Parliament eventually condemned these practices in 1991 (Kreimer, 1992). Other countries tried to prevent people from crossing the border to obtain treatment elsewhere. Ireland wanted to ban Irish women from leaving the country to obtain an abortion in Great Britain. In 1992, a 14 year old rape victim was restrained from leaving Ireland for 9 months but this injunction was later overturned (Lawson, 1994). Although the ban on abortions was maintained, two amendments to the Irish constitution stated that the freedom to travel between states could not be limited and that the freedom to obtain services lawfully available in another state could not be restricted. These changes were partially based on articles 59 and 60 of the European Community treaty which guarantee free movement of services, including medical services and thus infertility treatment.

It is one thing to introduce rules regarding procreation and family building in one's society, it is quite another to take every possible measure to force individual citizens to abide by these rules. Such pushed enforcement leads to a frontal clash and may jeopardize social peace. A different attitude towards national legislation is needed. This will not come easily. Commentators frequently express disapproval and even resentment when talking about reproductive tourism. Hervey for instance asks 'whether it is equitable that some people can in effect "buy their way out" of ethical or moral choices given legislative force in their own Member State' (Hervey, 1998). Reproductive tourists are seen as disloyal, as 'circumventing national laws' (Henn, 1999), as 'evading their domestic constraints' (Brazier, 1999), as 'health-care shopping... where the law may be more lax' (Millns, 2002). This attitude may be based on a number of convictions: a belief in moral truth, a desire to ensure that others observe our standards, the belief that ethical rules apply to everyone everywhere etc. This position results in an attempt to make laws that coerce people to abide by the ethical rules. However, the purpose of national regulation should not be to prevent those who disagree to perform certain acts or to make use of certain interventions or services. Prohibitive laws can only determine which services are available on the territory. As such, the law expresses the moral values of the majority within a community; nothing more, nothing less. Tolerance towards movement by minority members to other countries shows a healthy degree of relativism. The fact that reasonable people in one's home state and a majority in another country accept an act or treatment as perfectly legitimate and ethically acceptable should raise a spark of doubt about the unique correctness of one's own position. Allowing people to look abroad demonstrates the absolute minimum of respect for their moral autonomy.

Harmonization: a wolf in sheep's clothing?

The call for harmonization is frequently triggered by a particular case of reproductive tourism (Pennings, 2002). In reaction to the birth of twins to a 59 year old British woman, the health secretary of the United Kingdom stated that 'we'll renew our efforts to have discussions with other countries as to the examples we set and they can establish ethical controls over some dramatic achievements of modern medicine' (Morgan, 1998). In a similar vein, Allan Rock, the Minister of Health of Canada, argued that 'a collective international effort is also necessary to prevent unethical practitioners from "country shopping" for opportunities to pursue unethical practices such as human cloning and "reproductive tourism"' (Rock, 2001). The attempts at reproductive cloning undoubtedly gave a major boost to the feeling that international legislation was urgently needed to prevent totally unacceptable practices.

Harmonization has a nice, positive connotation of people growing towards one another peacefully. However, the proponents of legislative harmonization seem to consider harmonization as a one-way movement: the others should adopt the same laws we have and they should forbid the same acts we forbid. It is obvious that when two parties start with this position in mind, they will not reach harmony. The direction of the 'harmonization', towards more limitations or towards more freedom, is crucial. If the European Convention on Human Rights and Biomedicine is any indication of the future evolution, harmonization moves towards more restrictive legislation. It is much easier to move from permission to prohibition when controversial issues are considered than vice versa. Most opponents of reproductive travelling start from the premise that the tougher and more restrictive legislation is also morally superior. One seldom hears a liberal country urge others to demonstrate equal flexibility. Apparently, people are more convinced of the moral correctness of their prohibitions than of the correctness of their permissions. On the other side we can find those people who argue that international legislation should be aligned in a liberal direction. No member state should penalize or forbid a treatment that is allowed and practised in another member state. This would imply a down regulation to the level of the most permissive country. Legislation would then express the lowest common denominator (Nielsen, 1996). For some authors, this constitutes the real danger of reproductive travelling. McGleenan predicted after studying the Blood case that the jurisprudence of the European Court of Justice on article 59 of the European Community treaty would generate a structural downward pressure so that any regulation would gravitate towards the most permissive laws (McGleenan, 1999). To prevent this, a community wide policy on assisted reproductive technology should impose a minimum standard. However, liberal harmonization has a strong argument in its favour, namely recognition of, and respect for, the autonomy and rationality of other people. Not forcing them to adopt our position shows a minimal degree of respect. Even if we do not see their position as equal to ours (why else do we prefer ours?), we should not consider them as moral idiots or as immoral barbarians.

Harmonization limited to general principles and/or safety considerations

Two suggestions have been made to avoid the problems with harmonization while still introducing a minimal common legislation. The first solution is to limit European legislation to broad ethical principles. Knoppers and Lebris identified a number of common normative values that transcend cultural and jurisdictional differences, i.e. the inherent dignity of the human person, the security of human genetic material, the quality of services and the inviolability and inalienability of the human person (Knoppers and Lebris, 1991). The same values are expressed in the Charter of Fundamental Rights of the European Union relating to technological innovation (European Union, 2000). At this very general level, everyone agrees. However, the consensus is fake. As soon as the general principle or value is applied in concrete cases, it becomes clear that the agreement was based on the mistaken belief that the parties were talking about the same thing (Sass, 2001). Respect for human dignity is for some the right to decide when one's life is no longer worth living, while others believe that human dignity is best protected by not allowing people to decide when they wish to die. What advantage is there of having a legally binding document that includes only general principles?

Another proposal is to avoid substantive moral issues in legislation and to concentrate on safety conditions and quality issues. Patients all over Europe (or the world for that matter) have the right to be protected against incompetence, negligence and recklessness on the part of the practitioners. Quality standards regarding donor screening, cryopreservation, success rates, complication rates etc. should be guaranteed. The legal framework should mainly focus on licensing and controlling centres of assisted reproduction with the aim of ensuring homogeneous and adequate standards (Ferrando, 1996). At the very least, reliable information should be available on these issues. For countries with little or no control on what happens in fertility clinics, it may be especially difficult to verify the information. There is anecdotal evidence that standards are not always respected in countries where infertility clinics are ill-regulated and ill-controlled (Templeton, 2003). However, perhaps the most important point to prevent unsuspecting patients from being lured into low-cost clinics is education about general rules to evaluate certain information, like the need to take into account the multiple pregnancy rate when comparing the success rate of clinics. The awareness of the risks for mother and children of multiple pregnancies may also counterbalance the possibly increased request of couples who look for treatment abroad to replace more than one embryo. However, the preference to replace several embryos exist in all patients who know that they can only have one or a very limited number of cycles. Treatment abroad is in this respect probably not worse than expensive treatment at home.

Although safety and quality standards are important and patients should be informed about the performance of the clinics, regulation on safety should be carefully screened to prevent trespassing on ethics. There are two reasons for

caution. Firstly, safety is primarily a moral and not a technical issue. It concerns the balance between benefit and harm and it is expressed in principles like 'responsible parenthood', 'good clinical practice' and 'the best interests of the child'. A moral standard is needed to evaluate the medico-technical data (Pennings, 1999). The choice of a standard is decisive for the acceptability of treatment options: some people accept almost no risk while others take a more lenient position. This is illustrated in the discussion on the prohibition of ICSI with surgically obtained sperm in The Netherlands or in the debate on the use of cryopreserved oocytes in the United Kingdom. The second reason for caution is that technical documents may serve as Trojan horses for ethical positions. The European directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells demonstrates this point (European Parliament and European Council, 2004). This directive is explicitly presented as a way to guarantee the safety and quality of human cells and tissues used for transplantation and therapeutic purposes, to safeguard public health and to avoid transmission of infectious diseases. Remarkably, article 12 states that 'member states shall endeavour to ensure voluntary and unpaid donation of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation'. Payment has very little to do with safety and quality; it is at most indirectly linked to safety of the tissues (as it is recognized in the explanatory note). Remuneration is a moral principle that should be discussed openly and should not be forced sneakily upon the member states. The European Group on Ethics also pointed out in its opinion on stem cells that, although the European Union has no legislative competence to regulate research, some directives allude to the issue of embryo research and use. For instance, the directive 98/79/EC on *in vitro* diagnostic medical devices provides that 'the removal, collection and use of tissues, cells and substances of human origin shall be governed by the principles laid down in the Convention' (European Group on Ethics, 2000). In this way, member states which have not ratified the Convention, are indirectly forced to follow its principles.

European Convention on Human Rights and Biomedicine

The European Convention on Human Rights and Biomedicine (in short, the Convention) is an attempt to create uniformity of legislation on medicine across the European countries. The Convention has been widely criticized for its methodological and ethical deficiencies and political bias (Mori and Neri, 2001; Sass, 2001). Moreover, the usefulness of a minimal European legislation that expresses consensus is unclear. If there is agreement on the prohibition of a certain treatment or on the acceptability of a technique, the individual member states can incorporate this point in their national legislation. Take sex selection for non-medical reasons. In the Belgian law on research on embryos *in vitro* of 28 May 2003, an article stipulates that this application is prohibited.

Article 14 of the Convention does not add anything on this point. However, the Convention contains a series of articles which are not all acceptable for Belgium. If Belgium would want to ratify the Convention now, it would have to make reservations for articles 13 and 18 of the Convention since no prohibition on germline therapy is included in the Belgian law, and because the creation of embryos for research is allowed (Pennings, 2003). Instead of arguing that the member states should adopt the Convention and make reservations about specific articles and provisions, it would be much more logical not to ratify, and to introduce the points one accepts into one's national legislation. This would also permit countries to change their minds. The present evolution is necessarily one-directional; national states can grant a wider measure of protection (read 'be more restrictive') than the Convention but, after ratification, never be more permissive. If the competence of the member states regarding ethical issues is taken seriously, national law should take precedence over the Convention whenever it is voted. The majority of the new countries (but not the old ones), in an urge to show their Europe-mindedness, have already signed and ratified the Convention. It would be very unfair if they would not be able to review their law, for instance on embryo research, away from the Convention. Moreover, the Italian law clearly illustrates that the Convention is no protection against very prohibitive initiatives in particular countries, as some claim.

Political apathy

People do not identify with Europe. A major problem for all European elections is to motivate people to vote. Every step that increases the distance between the citizens and the level of political decision making risks to increase political apathy. By lifting ethical issues to the European level, the citizens will feel that their right and competence to decide about deeply felt moral issues, that touch upon very private aspects of a person's life, are taken away from them. Glover warned 15 years ago: 'People are unlikely to change their outlook on issues so fundamental because of some decision about harmonization made in Brussels or Strasbourg. An insensitive attempt to tidy up differences might, if it succeeded at all, obtain uniformity at a great cost in resentment' (Glover, 1989, p. 15).

There is no unified European culture and no core of substantive common values. However, this diversity is to be valued, not regretted. The wish to obtain homogeneity not only denies the richness of cultural, political and ethical differences, it also impedes progress towards a better regulation. The presence of other ethical codes and legislations in Europe renders it impossible to present a law as self-evident; the law or regulation must be shown to be better than the alternatives. When Sweden broke unanimity regarding sperm donor anonymity in 1985, the other countries were forced to justify their law on this issue. This confrontation stimulates progress and public debate. Each country can learn something from the others, but with the big difference that possible alterations in national legislation are based on persuasion and not on coercion. Moreover, each country constitutes

a 'natural experiment' on a limited scale from which the others may collect useful information for their own legislation. Due to the open attitude of some countries, it is now known that children growing up in lesbian families are doing well (Baetens and Brewaeys, 2001). Such empirical data could not have been gathered if all countries had adopted the same view on family formation. The same applies to numerous other aspects of assisted reproduction. The Council of Europe and other European institutions can play a beneficial role in stimulating discussion among national legislators and in disseminating information about alternative legal solutions.

Conclusions

In a democracy, the majority has the political right to express its moral position in legislation and regulation. However, tolerance, respect for the ethical position of others and recognition of their autonomy as rational persons should prompt the majority to look for ways to take into account the views of the minority. Legislation should be mitigated by including moral concerns of others and by inserting particular considerations. Such legislation will not completely accommodate the minority, but it will reduce reproductive travelling while still allowing the majority to make a public statement about their convictions. Blocking every way for minority members to obtain the treatment they desire would be dangerous, as it could increase feelings of frustration, suppression and indignation. Reproductive tourism should be seen as a safety valve that avoids moral conflict, and as such, contributes to a peaceful coexistence of different ethical and religious views in Europe.

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