

Perspectives and Debates

Medically assisted procreation and fast-moving developments in science and law: ethical and legal issues in heterologous procreation in Italy

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Significance for public health

Continual scientific progress is making new applications available, with significant medical, ethical, legal and social implications, not only for the persons directly concerned. In the area of medically assisted procreation, the use of heterologous techniques is able to overcome problems of sterility or infertility for those requesting access to methods of this kind. On the other hand, legislation is required to regulate the many correlated issues, also with regard to other parties such as ova or sperm donors and the offspring resulting from the use of these techniques: the protection of the health of the offspring; the management of laboratory results obtained during donor selection tests; the protection of confidentiality; the donor-child traceability; the number of donations; and individuals' rights to be fully informed about their biological origins are just some of the questions confirming that the implications of new procreation techniques are not restricted merely to the couples who access them.

In Italy, a law on Medically Assisted Procreation was passed in 2004. In 2014 the Constitutional Court declared section 4 para. 3 of this Law to be unconstitutional in the part where it prohibits couples from accessing heterologous medically assisted procreation techniques if a condition which causes complete, irreversible sterility or infertility has been diagnosed. The fast-moving developments in science and law, and the deep implications that the application of *new* techniques – which involve in the context of procreation a third person – can have in terms of protection of health and not only, makes it appropriate to keep under review this area, taking into account the pronouncements of the European Court of Human Rights and regulations in European countries. In 2004 the Italian Parliament passed a law on medically assisted procreation (MAP).¹ In this regulation the use of heterologous MAP techniques is forbidden (section 4 para. 3 of Law n. 40/2004). Some Commentators have defined this ban as a drastic decision, which clashes with the broader debate which preceded and has also followed the approval of the law.² The debate relating to the maintenance in Italian law of the ban on heterologous procreation specifically introduced by Law No. 40/2004 has had to take into account the pronouncements of the European Court of Human Rights on the case of S.H. and others against Austria,^{3,4} concerning the appeal by two couples of Austrian nationals with infertility problems. The applicants complained that the prohibition by the Austrian artificial procreation act of sperm and egg donation for *in vitro* fertilization – the only medical techniques by which they could successfully conceive children – violated their right to respect for family life under Article 8 of the European Convention of Human Rights and that the difference in treatment compared to couples who wished to use MAP techniques, but did not need to use ova or sperm donation for *in vitro* fertilization, amounted to a discriminatory treatment, in violation of Article 14 of the European Convention of Human Rights.

In its judgment of 1 April 2010 the Court held that there had been a violation of Article 14 in conjunction with article 8 as regards the pro-

hibition of *in vitro* fertilization with the use of donor ova or sperm, which was affecting the two couples, but then the case was referred to the Grand Chamber that underlined that *since the use of IVF treatment gave rise then and continues to give rise today to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is not yet clear common ground amongst the member States, ... the margin of appreciation to be afforded to the respondent State must be a wide one, and even if it finds no breach of Article 8 in the present case, the Court considers that this area, in which the law appears to be continuously evolving and which is subject to a particularly dynamic development in science and law, needs to be kept under review by the Contracting States.*

In these judgments the Court underlines in fact that MAP is regulated in detail in some countries, to a certain extent in others and in further countries not at all. ... Donation of sperm is prohibited in Italy, Lithuania and Turkey, while donation of ova is prohibited in Croatia, Germany, Italy, Lithuania, Norway, Switzerland and Turkey and that in the field of medically assisted procreation legal provision are developing quickly. In Denmark, France and Sweden sperm and ovum donation, which was previously prohibited, is now allowed since the entry into force of new legal provisions in 2006, 2004 and 2006 respectively. In Norway sperm donation for *in vitro* fertilization has been allowed since 2003, but not ovum donation; since 2007 medically assisted procreation is also regulated by law in Finland allowing sperm and ova donation.

In Italy the matter was referred to the Constitutional Court that, in its ruling No. 162/2014, declared section 4 para. 3 of Law No. 40/2004 to be unconstitutional in the part where it prohibits couples from accessing heterologous MAP techniques if a condition which causes complete, irreversible sterility or infertility has been diagnosed.

The judgement of the Constitutional Court is firstly based on the verification whether or not a reasonable balance has been ensured between protection of reproductive needs and protection of the newly born child: according the Judges, the absoluteness of the prohibition under examination is not justified by the requirements to protect the newly born child, already guaranteed under current legislation.⁵⁻⁸

Section 8 of Law No. 40/2004 establishes that children born following the application of medically assisted reproduction techniques have the status of children born outside of marriage or children recognized by the couple; Section 231 of the Civil Code takes account of the new concept of paternity and provides that the husband shall be the father of any child conceived or born during the marriage; Section 9 of Law No. 40/2004 specifically establishes that birth as a result of heterologous assisted procreation will not result in the establishment of legal relation of parentage between the donor and the newly born child and that any action seeking to deny paternity will be inadmissible.

The Court first states that the prohibition under examination does not reflect a practice which has been consolidated over time, since it was introduced into Italian law in 2004, and nor is it the consequence of obligations arising from international conventions.

The Court therefore underlines that the decision of the couples

intended to benefit from Law No. 40/2004 to become parents and form a family constitutes an expression of the fundamental, general right to self-determination, enshrined in articles 2, 3 and 31 of the Constitution,⁹ since it concerns the sphere of private and family life, and that therefore restrictions on this right can only be reasonably, appropriately justified if the use of the right would jeopardize other interests of equal importance.

With regard to article 32 of the Constitution,⁹ the Court finds that the impossibility of forming a family with children together with the chosen partner, with the aid of heterologous MAP, may have even significant adverse effects on the couple's health.

Moreover, the prohibition is obviously irrational, since the absolute denial of the right to form a family with children, with its effects on the right to health, is enforced at the expense of couples suffering from the most serious reproductive problems, a factor which conflicts with the *ratio legis*.

The *therapeutic model* is indeed the foundation of the regulation of MAP: the access to the techniques is directed to the protection of health; *sterility and infertility should be addressed as a human health issue, and reflection on access to MAP should be framed in terms of access to treatment and health care*.¹⁰

Then the Court underlines another irrational aspect of the law in question, in the light of the growth of *reproductive tourism*, in that it leads to an unjustified difference in the treatment of the couples suffering the most serious reproductive problems, arising from the financial resources available to them.

Some underline that couples who travel abroad to undergo MAP face a considerable psychological stress and risks of *unnecessary treatments imposed on patients (such as PGD in the absence of a significant risk of genetic disease) to obtain substantial economic gain*; prohibition of heterologous MAP has also the indirect effect of discriminating couples on the basis of fortune, the lower the price of treatment the higher the risks of insufficient guarantees.¹⁰

Italian law already regulates some aspects related to the use of heterologous MAP.

Specifically, the Law n. 40/2004 at above mentioned Section 9 prohibits the husband or partner whose tacit consent can be demonstrated to deny paternity and specifies that an egg or sperm donor does not acquire any legal parental relationship with the child and cannot establish any right over or hold any obligations in relation to him or her.

The Legislator, while prohibiting heterologous assisted procreation, mindful of the fact that these techniques are lawful in many European countries, had subjected it to appropriate regulations as Italian citizens were able to travel abroad to take advantage of it.

In more general terms, a number of important markers for the regulation of heterologous MAP can be found in the legislation governing human tissue and cell donation, that lays down general principles, applicable notwithstanding the differences between the situations (concerning for example the accreditation of facilities, the requirement that donation must be voluntary and unpaid, the procedures for consent, the anonymity of the donor and the requirement of protection from a healthcare point of view).¹¹

Important guidelines are also available in Annex III of Commission Directive 2006/17/EC, which however has not yet been incorporated into Italian law: this directive provides minimal regulations for the selection of reproductive cell donors, in relation to health and medical history, evaluation of risk factors and the infective disease and genetic tests to be performed.¹²

The Conference of the Regions and Autonomous Provinces passed a document containing operational and clinical guidelines for the application of heterologous procreation techniques.¹³

One fundamental factor deriving from the Italian legal system is that ova and sperm donation must be a voluntary, altruistic, unpaid act. The regional guidelines obviously apply the ethical principles of respect for

autonomy, freedom and solidarity and aim to ensure that no possible economic pressures are brought to bear: the sale of reproductive cells and any form of remuneration of donors not only reduces the ethical value of donation and tends to introduce inappropriate commercial factors into the relationship between the donor and egg or sperm Banks or between the donor and the recipients, but also encourages speculative intents in both donors and reproductive cell Banks – which may lead to fraudulent practices intended to minimize the contraindications to a donation and/or to maximize the return.¹⁴

Prohibiting the remuneration of ovum and sperm donation is an important measure to combat any potential risk of exploitation of women particularly from economically disadvantaged backgrounds; a profit would also incite people to withhold information, which may be relevant for the safety of the donation.

Finding donors altruistically motivated, reimbursed only for their effort may be not easy: *advertising in order to recruit donors is best performed by an independent, non-profit making body whose duty it is to promote donation... based on the principle of solidarity and excluding financial incentives*.¹⁵

The Ministry of Health itself considered it necessary to encourage *egg sharing*, meaning the unpaid, voluntary donation of surplus ova by women who undergo MAP treatments, by including an optional declaration of willingness to donate in this way in the informed consent form.

A fundamental phase requiring regulation is egg and sperm donor selection: the regional guidelines establish selection criteria such as age (18-40 years for males and 20-35 for females), full possession of faculties, good health and absence of known genetic abnormalities within the family, and recommend the tests and analyses to be performed to assist in appropriate medical and genetic assessment, intended to guarantee the right to health of the parents and child. During assessment of the donor, consideration must also be given to potential financial or emotional reasons which may be influencing the wish to donate and to the donor's understanding of the significance of the act of donation.

Another important factor is *donor phenotype screening*: although patients are not allowed to choose specific donor phenotypes in order to prevent eugenic selection, on the other hand, in view of the fact that for the couple heterologous fertilization is a procedure which enables them to achieve parenthood by obtaining a pregnancy, the centre must reasonably ensure that the donor's main phenotypical characteristics match those of the recipient couple.

A European Society of Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law document explores the ethical issues involved in the debate about the scope of genetic screening of gamete donors, mainly consisting of a medical history of the donor and his/her family and additional tests for some specific disorders.¹⁶ Broadening the scope of donor screening, may have the counterproductive effect of limiting donor availability, *either by excluding candidates with relatively small risks or by scaring potential donors who fear the consequences that genetic testing may have for themselves*; recipients may also be harmed when *wrongly led to believe that given expanding screening protocols, they can be assured of healthy children: in human reproduction, genetic risks can never be completely ruled out*. In addition, *for the donor and his or her close relatives, genetic screening may reveal risks knowledge of which may be beneficial (if the finding allows for prevention, treatment or other meaningful course of action), but that may also turn out to be psychologically harmful, especially if findings reveal a serious genetic risk that is not medically actionable*.

Particular importance is given to the consent of the donor, who must be fully informed about all the aspects related to the donation, the discomfort and risks related to ovarian stimulation and egg retrieval, the possible implications that testing procedures may have both for him or herself and for any close relatives, the management of the results of the tests performed – positive test result should be confirmed before the

donor is informed, and if they are confirmed the person should be offered suitable medical advice and clinical work up – and the fact that he/ she does not acquire any legal parental relationship with the child.

Information and thus consent are also required with regard to the possible even future implications of the donation: the possibility that the reproductive cells may be used for research purposes once they are no longer usable for MAP procedures, and the possibility that the donor may be contacted, in accordance with strict procedures to protect his/ her confidentiality, in order to request data if the child suffers health problems.

The regulations surrounding the question of donor anonymity and the protection of confidentiality require a delicate balancing act, in view of the child's need to access data about his or her biological origins.

The National Bioethics Committee has underlined that,¹⁷ on the one hand, the principle of secrecy – that concerns the conception modalities – refers to autonomous choices, while on the other *the problem therefore arises of the legitimacy or not of parental behaviour that prefers to maintain secrecy, preventing offspring from asking themselves about their own existence in a complete way, with possible negative repercussions on family relations, particularly on the primary relationship of trust between children and parents.*

Many important reasons are put forward in support of the choice to remain silent, but in *the balancing of the various interests and points of view... the Committee does not consider that secrecy... is an advisable option for guarantee the stability of the family and the right to the respect for their private life of each of its members, nor for safeguarding the offspring's peace of mind*; furthermore, secrecy is difficult to maintain over time and could be harmful to the child also because of genetic tests that are *increasingly widespread and accessible for obtaining information about genetic origins with the possibility of identifying the risks of illness and actual illnesses, and influence reproductive choices on the basis of the knowledge of the biological parent's clinical data.*

Once secrecy has been lifted, the question therefore arises of the possibility of obtaining more complete information – connected to health or also extended to include personal data – with regard to biological origins. Some of the Committee members support the option of *partial anonymity* allowing the offspring to access only those data that, according to the circumstances, may be necessary for their mental and physical health; other members recognize the offspring's right to full information concerning the reproductive cell donor, indispensable for the reconstruction of the offspring's personal identity.

Legal approaches to regulation regarding anonymity and disclosure vary considerably inside Europe: a number of European countries have prohibited anonymous donation; in other countries the anonymity is protected by law;^{18,19} and regulations gradually change over the years, in the light of changing social and professional attitudes.

In the UK, in the past disclosure to donor-conceived children about their origin had been seen as unnecessary and potentially harmful; now this advice has reversed. In 2005 anonymous gamete donation was abolished: donor-conceived people born as a result of donations made after April 2005 will therefore be able, at the age of 18, to obtain identifying information about their donor (while those conceived before that date will not be able to obtain identifying information unless their donors choose to make themselves identifiable); in 2009 the age for accessing non-identifying information about the donor was reduced from 18 to 16.¹⁸

Several reasons may move donor-conceived people to obtain information about their donor: *reasons include finding out what kind of person the donor was and their motivation for donating; identifying features or characteristics in common; and accessing medical information. Such information may help some donor-conceived people integrate their donor into their existing life story.*¹⁸

Some commentators consider what are the potential consequences of heterologous MAP in terms of public health and in particular the impact of parental anonymity and underline that *a significant propor-*

*tion of the population with no anamnestic familiar data implies serious difficulty also for ordinary clinical care.*²⁰

In most cases information about medical history of the donor *would be of little medical relevance for the donor-conceived person because of the screening and assessment that potential donors undergo before being accepted as donors, and because of the low predictive value of much family history information, the situation may, however, occasionally arise when factors in the donor's own medical history or family history are insufficient to exclude the donor from donating, but may be of future relevance to the health care of the donor-conceived person.*¹⁸

Otherwise, the prohibition on donor gamete anonymity in conjunction with a prohibition on compensation may play a role in the creation or enhancement of gamete shortage, and then impede the ability of infertile people who desire to conceive from achieving conception, with individual and social ramifications.²¹

The prohibition on anonymity may also result in fertility tourism: recipients of gamete donors may be forced to go abroad for fertility treatment, mostly by long wait lists resulting from shortage in their countries.^{22,23}

Some commentators suggest a procedure to *balance between the conflicting rights of donors, parents, and offspring*:²⁴ on the one hand *extensive non-identifying information about the donor can be provided to recipients and their offsprings*; on the other hand, a *double track* policy could be installed, to give donor the choice to remain anonymous or to become identifiable, and recipients the choice for an anonymous or identifiable donor. The Italian Constitutional Court, after citing the principle of donor anonymity in the regulations concerning the donation of human tissues and cells,²⁵ refers to the regulation concerning adoption²⁶ and to a recent ruling²⁷ by the Constitutional Court on the rule prohibiting access to information regarding the mother who stated at the child's birth she did not want to be named: the irreversibility of the secret is in contrast with Italian Constitution, the provision is unconstitutional in so far as it does not provide, through a mechanism established by law, to ensure confidentiality, the possibility for the judge to question the biological mother at adoptee's request, for the purpose of any withdrawal of such a declaration.

In this case, the knowledge of data regarding the biological mother would enable the adoptee to obtain a family history, essential for prophylaxis interventions or diagnostic tests, since he already devoid of news about the health history of the paternal branch of the family tree.

The complexity of the matter seems to suggest the opportunity for the establishment of *ad hoc* rules, to guarantee the various and important interests involved. Another key point is the number of donations: according to the Ministry of Health,²⁸ the most reasonable criterion for regulating this matter, to prevent the birth of too many children to the same donor, would be to count offspring or families, and link the collection of reproductive cells from every single donor, their distribution to the recipient couples and the children born to the donor concerned.

The aforementioned guidelines state that the reproductive cells of any one donor cannot result in more than ten births, a limit which may be waived only in those cases in which a couple who have already had a child by means of MAP wishes to use the procedure again, with the reproductive cells of the same donor. Another fundamental factor is donor-child traceability: a complete traceability is essential for counting the maximum number of children born from the cells of a single donor, and, of course, for health needs, in compliance with data protection legislation with regard to anonymity. A National Register of donors of reproductive cells for purposes of MAP of heterologous type is established at the National Institute of Health, National Transplant Centre (Law No. 190/2014). All persons admitted to the donation are recorded by attributing to each donor of a code; to this end, health facilities must communicate personal data to the Register, with information systems likely to ensure the anonymity of the donors themselves. The dynamism of the matter under consideration therefore, even in light of the recent ruling by the Constitutional Court and of the deep implica-

tions that the application of *new* techniques – which involve in the context of procreation a third person – can have in terms of protection of health and not only, makes it appropriate to update current regulations in this field.

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