

Heterologous Fertilization: the Opinion of Italian Physicians and a Brief European Overview

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Abstract: A recent decision of the Italian Constitutional Court has legitimized for the first time heterologous artificial insemination. On April 9th, 2014 the “Consulta” declared unconstitutional the sections of law n. 40 of 19 February 2004 (Judgment n. 162/2014), which prohibited heterologous fertilization: a) section 4 paragraph 3 “It is forbidden the use of techniques of medically assisted procreation of the heterologous type”; b) section 9, paragraphs 1 and 3, which include the prohibition of the disclaimer of paternity and the anonymity of the mother; c) section 12, paragraph 1, which includes penalties for anyone who uses for procreation purposes, gametes from subjects outside the applicant couple. In the present paper the Authors reviewed the recent judgment of the Constitutional Court of April 9th, 2014, trying to evaluate the impact that it could have on Italian society. Secondly, the Authors have administered via internet a questionnaire to a cohort composed of 9000 Gynecologists and other specialists, regarding law n. 40/2004, their opinion of heterologous fertilization, the judgment of the Constitutional Court and the influence of the Catholic Church in Italy. Finally, a brief overview of laws in the field of heterologous fertilization among the European Union States has been provided.

Keywords: Heterologous fertilization, Italian Constitutional Court, questionnaire, medically assisted reproduction, gametes, artificial reproduction.

INTRODUCTION

A recent decision of the Italian Constitutional Court (ICC) [1] has legitimized for the first time heterologous artificial insemination. On April 9th, 2014 the “Consulta” declared unconstitutional the sections of law n. 40 of 19 February 2004 (Judgment n. 162/2014), which prohibited heterologous fertilization: a) section 4 paragraph 3 “It is forbidden the use of techniques of medically assisted procreation of the heterologous type”; b) section 9, paragraphs 1 and 3, which include the prohibition of the disclaimer of paternity and the anonymity of the mother; c) section 12, paragraph 1, which includes penalties for anyone who uses for procreation purposes, gametes from subjects outside the applicant couple [1].

The general structure of Law n. 40/2004 is intended to protect predominantly the unborn, who is qualified as a “person” with rights equivalent to those of adults. For this reason, it establishes a rather strict regulation for medically assisted procreation. The only conditions, which allow the access to these techniques, are: a) adult couples of different

sex, b) married or cohabiting couples, c) potential childbearing age with both partners still living [2-4].

Among the most significant prohibitions provided by the law, it is necessary to underline: a) the prohibition of surrogate maternity; b) the ban of post-mortem fertilization; c) prohibitions of genetic preimplantation diagnosis and production of more than three embryos and their simultaneous implantation [2-4], which was declared unconstitutional by the Consulta with the judgment n. 151 of May 8th, 2009 [5]; d) the prohibition of heterologous fertilization judged unconstitutional by the ordinance under review.

The first aim of this paper is to review the recent judgment of the Constitutional Court of April 9th, 2014, trying to evaluate the impact that it could have on Italian society.

Secondly, the Authors have administered via internet a questionnaire to a cohort composed of 9000 Gynecologists and other specialists, regarding law n. 40/2004, their opinion of heterologous fertilization, the judgment of the Constitutional Court and the influence of the Catholic Church in Italy.

Finally, a brief overview of laws in the field of heterologous fertilization among the European Union States will be provided.

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MATERIALS AND METHODS

An 8 question survey (Table 1) was administered via internet, by a multi-service company operating in health care insurance, to a cohort of 9000 Gynecologists and other specialists. No compensation was given to the participants. The statistical analysis of data was performed by calculating the percentage of answers (yes, no and don't know) and the corresponding 95% confident interval (CI) for each question.

Table 1. Eight question survey. For each question three response options (yes, no and don't know) are available.

N°	Questions
1	Did you know that in Italy since 2004 the Law n. 40 on medically assisted procreation has been in force?
2	Are you in favour of the prohibition of heterologous fertilization according to Law n. 40?
3	Do you support the decision of the Consulta, which declared unconstitutional the prohibition of heterologous fertilization stated in Law n. 40?
4	Should anyone without the means to go abroad be compensated for having to give up medically assisted procreation?
5	Do you think that the Parliament should enact a new law allowing heterologous fertilization?
6	Can the ruling of the Constitutional Court determine a regulatory gap favouring a trade without rules?
7	Do you think that it is possible to introduce in Italy heterologous fertilization taking into account the influence of the Catholic Church?
8	Considering the scarcity of economic resources in the Healthcare, do you feel a partnership between the public and private sectors in the field of medically assisted procreation desirable?

The frequencies of answers obtained from the Gynecologists and the other specialists were compared by using the chi-squared test. The STATA software 11.0 version was used.

RESULTS

Of the 9,000 surveys administered, 7,380 were completed and submitted (response rate: 82%). The group of participants was composed of 45% by gynecologists, and 55% by other specialists. The age of the participants was in 89% \geq 40 years, while in the remaining 11% under 40.

All results are fully reported in (Fig. 1). The differences obtained from the two groups (Gynecologists and other specialists) were not statistically significant at the 5% level.

DISCUSSION

The analysis of the results of the survey show how law n. 40/2004 on medically assisted procreation in broadly known

among doctors (question 1), in fact more than 96% of them affirms to know the law (95% CI: 95.9-96.8) and the 66.1% (95% CI: 65-67.2) is not in favor of the prohibition of heterologous fertilization stated by Law n. 40 (question 2) and therefore almost the same percentage: 64.1% (95% CI: 63-65.2) supports the decision of the Consulta of declaring unconstitutional this prohibition (question 3). The ICC [1] in fact upheld the complaint of illegality from the following three Tribunals: a) Order of the Court of Milan of 8 April 2013, regarding a couple suffering from absolute infertility because of the complete azoospermia of the male partner; b) Order of the Court of Florence of 29 March 2014, regarding a couple where the male was affected by an absolute infertility due to "azoospermia with absence of spermatogenic cells"; c) Order of the Court of Catania of 13 April 2013 about a couple, in which the woman was affected by infertility due to a premature menopause. In all three cases, the couples have provided the following reasons to support the illegality of the prohibition of heterologous fertilization:

- a) Evident violation of the constitutional principles contained in section 2 (right to identity and self-determination), section 3 (right to equality) and section 117 paragraph 1 of the Italian Constitution (adaptation of internal legislation to the restrictions arising from international obligations);
- b) Violation of section 8 of the European Convention on Human Rights (ECHR) [6], which protects the right to respect private and family life by prohibiting (paragraph 2) the interference of the public authority except in cases where other rights or interests of equal or greater priority are recognized, and section 14, which prohibits discrimination with regard to the use of the rights and freedoms recognized in this Convention, taking into account the arguments reported in the case S.H. and others v. Austria (April 10, 2010) [7, 8], in which despite the Grand Chamber of the European Court of Human Rights rejected the appeal, it invited the national legislator to use as guiding principles for its own jurisdiction, the advancement of medical science and the consent of society.

The answers to question 5 of the survey reveal that the three-quarters of participants (65.6% - 95% CI 64.5-66.7) think that the Italian Parliament should enact a new law allowing heterologous fertilization and more than 50% of the doctors who completed the questionnaire (55.4% - 95% CI 54.3-56.6) believe that the immediate impact of the judgment of the Constitutional Court can determine a regulatory gap favouring a trade without rules (question 6).

A legislative change in this field is well linked to medical science, which by its nature constantly evolving; in particular, the increasing of knowledge involves the identification of new methodologies, which are able to offer achievement of objectives previously unthinkable and therefore the law should conform to this evolutionary process. The Constitutional Court also abolished the prohibition of heterologous fertilization considering it harmful in "many constitutional requirements" and in particular "does not respect the balance to ensure a minimum level of legislative protection" [1]. As stated in judgment n. 151/2009 [5], embryo protection is not

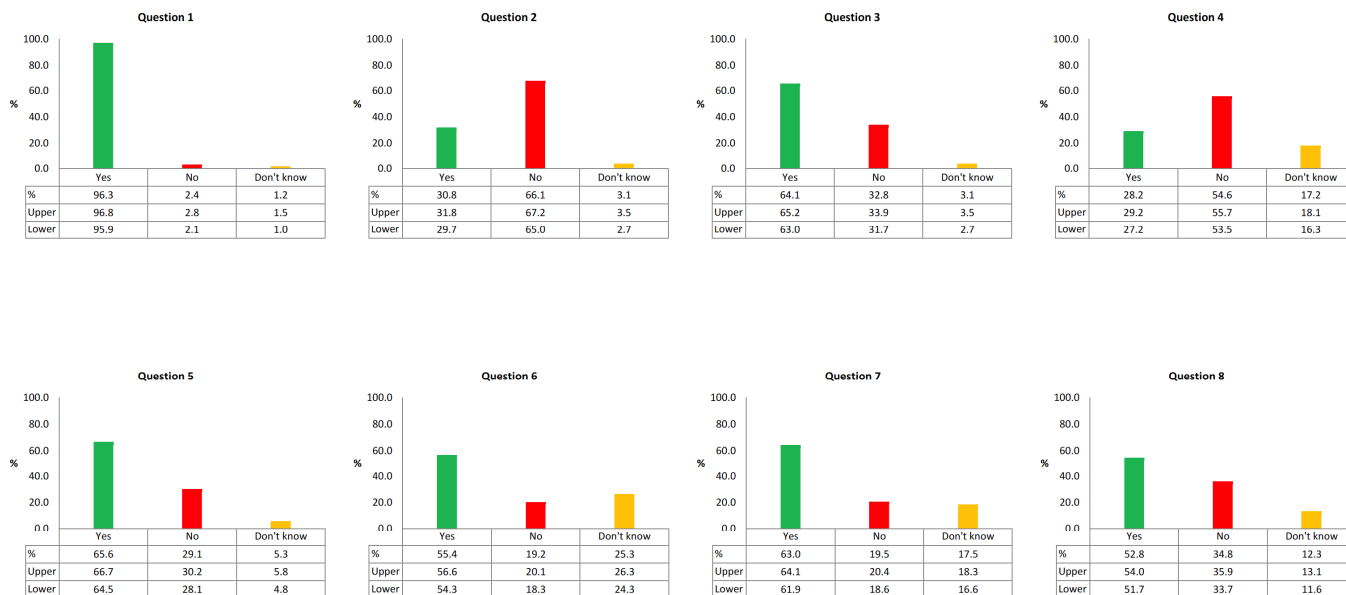


Fig. (1). Graphical representation of the percentages of answers with 95% CI for each of the 8-question survey.

absolute but limited to the necessity of finding the right way to protect the needs of procreation. For the Italian judge the prohibition of heterologous fertilization infringes on the right of self-determination of any couple unjustly hindered in its freedom to raise a family. In particular, the decision to use medically assisted procreation does not enter into conflict and neither does it affect other constitutional values. The same institution of adoption introduces the idea of a family, which differs to the “traditional” one, where the genetic origin is replaced by social parenthood. On this point, the Constitutional Court states that the freedom and the will of the act which allows parenthood thereby starting a family can neither be limited nor can it be an absolute prohibition. Such a ban would be detrimental to the right to the physical and mental health of the couple, whose protection must be equally guaranteed. In the field of therapeutic practice “the ratio should be the doctor’s autonomy and responsibility, who with the consent of the patient, makes the necessary professional choices”. And the unborn child and its protection? For the Court its protection is contained in law n. 40, which is still in force and guarantees the status of a child born in a marriage or recognized as the child of a couple who has expressed a willingness to resort to these techniques. The social father will not be able to disown the child and neither will a legal relationship between the donor of gametes and the newborn ever exist. As for the institution of adoption, the anonymity of the genetic parents must still be guaranteed in order to ensure the cohesion of the family formed by medically assisted procreation. The issue of anonymity or the right to know the genetic parents may generate numerous concerns of ethical, legislative and even medical nature. During the last 15 years in numerous countries where heterologous fertilization is permitted, there has been a significant shift from anonymous to open-identity gamete donation. Presently, in several European and extra-European states (Sweden, Norway, Netherlands, the United Kingdom, New Zealand, Australia etc.) allow children conceived by donor insemination after reaching maturity to have access to infor-

mation regarding their donor. Therefore, it has gone from a perspective in which the anonymity of donors was out of the question, to another one in which it is claimed that children born of heterologous fertilization have a fundamental right to know the identity of their progenitor [9].

The prohibition to have access to this information can be considered a violation of Sections 7 and 8 of The United Nations Convention on the Rights of the Child (1989) in which the rights to respectively “know and be cared for by his or her parents” and “preserve his or her identity” are set out [10]. In addition, in this case there was a reference to Section 8 (Right to respect private and family life) of ECHR as a reason for obtaining information about the gamete donor [11-12].

Moreover, the knowledge for a human being born of heterologous fertilization of his genetic origins is always more useful for a proper evaluation of health and possible pathological conditions. Therefore, the awareness of a genetic background is considered necessary for a better understanding and decision-making related to risk factors for health [13].

Finally, the second last question of the survey (question 7), taking into account the significant influence that the Catholic Church exerts in Italy in numerous ethically sensitive issues, asked the doctors if heterologous fertilization can be introduced in Italy despite this influence and the 63% of them (95% CI 61.9-64.1) said yes. It is noteworthy that the Pope himself has spoken immediately after the pronouncement of the judgment reaffirming that “Human life is sacred and inviolable”.

If the Italian scenario in the field of medically assisted reproduction (MAR), including heterologous fertilization, appears more than complicated, what about the other European Union Members?

European legislation in the field of Medically Assisted Reproduction is rather different in each Country of the Union

and not all European countries have specific legislation. These laws derive from different origins ranging from an extremely prohibitive legislation (e.g. in Italy, Germany, Lithuania and Austria), versus a cautious regulatory approach in Denmark, Sweden and France and a liberal regulatory system in the United Kingdom, Spain, Greece and Netherlands [14].

Presently, heterologous fertilization is ruled and allowed in the following countries: Belgium, Bulgaria, Croatia, Denmark, Estonia, Finland, Greece, Hungary, Italy (after the judgment of the Constitutional Court), Latvia, Spain and United Kingdom, whereas in France, Germany, Romania and Sweden it is allowed with some restrictions. No specific legislation in this field is in force in the following countries: Cyprus, Ireland, Lithuania, Luxembourg, Malta, Netherlands, Poland, Slovakia and Slovenia, whereas it is forbidden in Austria, Czech Republic and Portugal [15-23]. A geographic representation of current legislation ruling heterologous fertilization among European Union Members is reported in (Fig. 2).

CONCLUSIONS

The decision of the Constitutional Court, taking into account the importance of scientific advances and the changes that may affect ethically sensitive issues, has further undermined the essence of the law n. 40. Is it ethically acceptable to give up the new opportunities offered by medical science, or rather it is preferable, through a fair balance of protected rights, to accommodate and legitimize these new possibilities? Has a child, born thanks to heterologous fertilization, performed in accordance with appropriate regulatory safeguards, less chance of being loved than one born without these techniques, but in difficult or potentially difficult conditions? Certainly, what strongly emerges from the recent legal judgments, which have shattered the Italian law n. 40/2014, is that the concepts of family and parenting are flexible and constantly evolving and it depends on the common feeling which should be the driving force of this law.

On ethically sensitive issues as the beginning and end of life, can Italy still find comfort in a legislator who pays little attention to these changes? In this *vacuum* the only answer

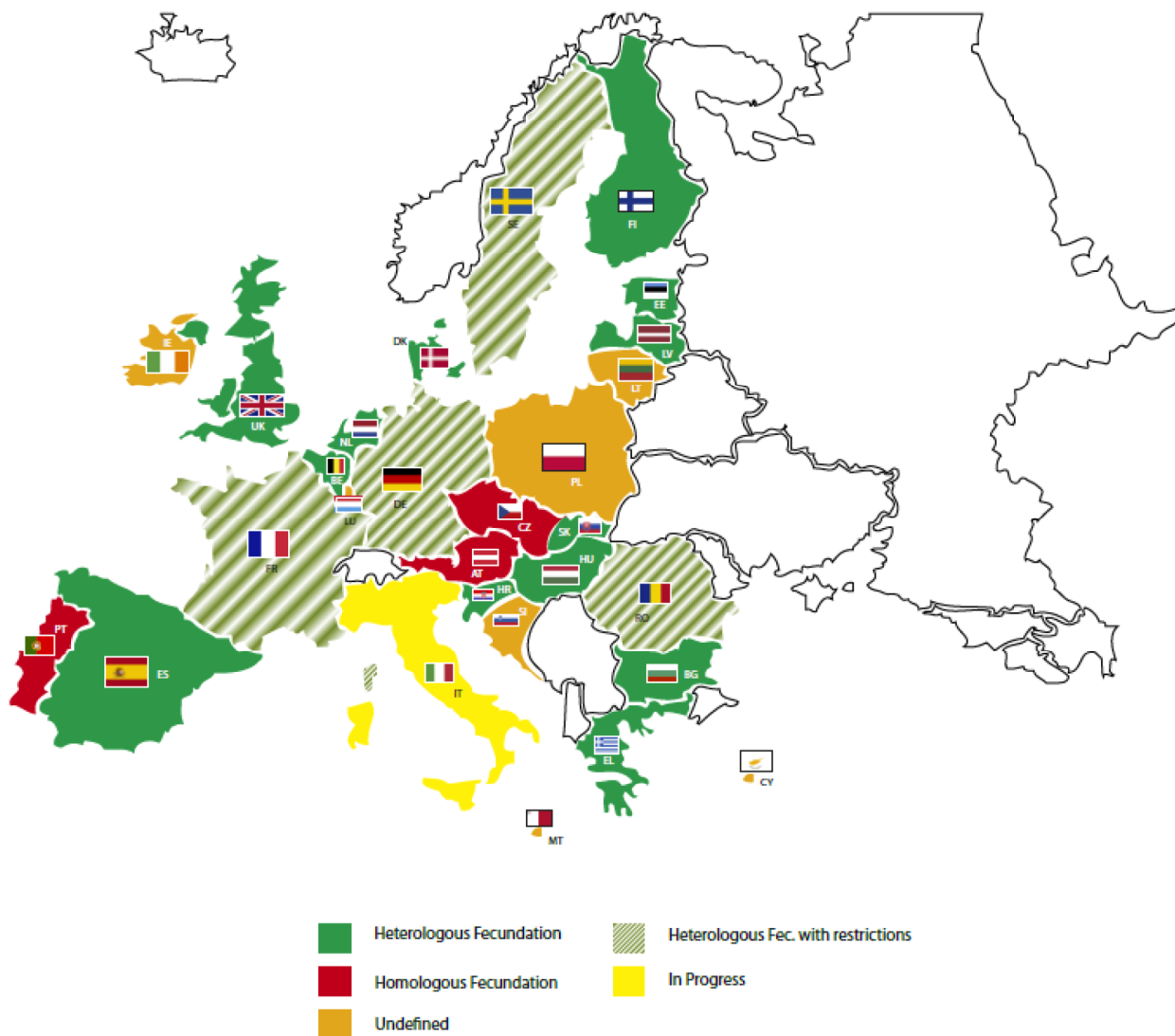


Fig. (2). Geographic representation of current legislation ruling heterologous fertilization among European Union Members.

seems to be offered by the judiciary, which is open to the evolution of Italian social sensitivity with a prospect of great interest in the socio-cultural evolution that characterizes the majority of Europe.

CONFLICT OF INTEREST

The author(s) confirm that this article content has no conflict of interest.

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