NEWS AROUND THE WORLD

BARI, ITALY

Assisted Reproductive Technology in Italy: Juridical and Ethical Considerations

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INTRODUCTION

In Italy, 256 centers work on infertility problems: 70% in private practice and 30% in public hospitals. Among public health institutes, 52.6% are in northern Italy, 19.2% in central Italy, and 28.2% in southern Italy. With regard to private centers, 50.8% are in the South, while 25.7% and 23.5%, respectively, are in the northeastern central and sections of the country.

Since 1968, De Vincentiis and Lauricella (1) pointed out that in many European countries artificial insemination, both homologous and heterologous, was currently performed, while in Italy the lack of legislation caused embarrassment among gynecologists and paralyzed the centers that diagnose and treat infertility.

Ten years later, 1978, Lauricella (2) reported: “A society which has produced modern laws on familiar relationship determining the end of patriarchal family, which has practically liberalised induced abortion, must not, for religious—ethical scruples of a party, delay mandatory solutions for the serenity of many infertile couples, or for scientific and social aims.”

THE SELF-REGULATION CODE OF CECOS ITALIA

In 1992, still waiting for official legislation from the parliament on assisted reproductive technology (ART), the Association CECOS Italia (Centre pour la Conservation du Sperm) elaborated the self-regulation code to guarantee ethically correct behavior (3). The aim of the code was to establish certain rules, while waiting for a future law and considering the new Italian Code of Medical Ethics, to guarantee the inalienable right of a couple to try to have a child, together with respect to the safety and the rights of the future born. In article 1 of the code, it is stated that interventions must be directed to couples of fertile age, heterosexual, married, or steadily cohabitant. Women are allowed to receive ovodonation until the age of 51 years. Articles 2, 3 and 4 establish the preliminary care of the couple.

In article 5, it is important to note that it is mandatory for every CECOS center to be equipped for collection and preservation of human gametes. Some cautions for donors of sperm and ovocytes are stated in articles 6 and 7. It is worth noting that article 9 states it is forbidden to use sperm that has been cryopreserved for personal use (autopreservation) after the death of the owner. Article 10 states that the cryopreservation of spare embryos is allowed. The maximum number of transferred embryos is limited to four, as articulated in article 11. Finally, article 13 sets limits on embryo manipulation, which is allowed only for diagnostic and therapeutic reasons. Gender selection is allowed only for gender-linked diseases; embryo dissection, cloning, and production of hybrids or human embryos for research only are forbidden. Enormous efforts have been made to provide against lack of legislation. Since 1994, the National Institute of Health, Epidemiology and Biostatistics Laboratory started the Italian National Register on Medically Assisted Reproduction in order to monitor all cycles, offering the detailed picture of what happens in the country and providing the necessary base for a correct national health policy in this field.

To be complete, the Catholic Church’s official position also must be reported. In the evangelic letter, “Evangelum vitae,” Pope John Paul II confirms that biomedical technology goes well beyond a reasonable human domain on the nature, in particular in nontherapeutic research and manipulation of human embryos, in their destruction or cryopreservation, in the selection
of characteristics or gender of future born, in cases of heterologous in vitro fertilization (IVF) and embryo transfer (ET), and in all cases of maternal surrogates. In cases of homologous techniques, the ethical negative aspects are reduced in comparison to extraconjugal procreation (4).

In order to avoid inevitable exploitation caused the confused legislative situation, since March 5th, 1997, the Health Ministry produced many ordinances, mainly to avoid commercialization of human gametes and embryos (5).

THE ITALIAN LAW APPROVED BY THE CHAMBER OF DEPUTIES AND ACTUALLY IN DISCUSSION IN THE SENATE

All different proposals of law in the Italian Parliament were resumed in one text (law No. 4048/1999), which was approved by the Chamber of Deputies on May 26, 1999. For the Italian legislative system, this text then must be approved without modifications by the Senate to be in force; currently, it is still in discussion in the Senate. It is worth mentioning some essential points of this law:

- In article 4 it is specified that all techniques of assisted reproduction are reserved for cases of inexplicable infertility after 2 years of procreative attempts and for cases of assessed and certified infertility or sterility. In the same article, the third paragraph reports: “It is forbidden the use of medical assisted reproductive techniques of heterologous type.”
- Article 5 reports that ART must be limited to heterosexual adult couples, married or cohabitants, at potentially fertile age. Differently from the past, a specific age limit is not specified.
- Another point worth mentioning is article 9, wherein a prohibition for the father to disown a child derived from ART and for the mother to claim anonymity after the delivery is established. These guarantees for the future born are very important and come from the experience of cases that have occurred in Italy.
- In the article 12, all the penalties for the forbidden techniques, such as heterologous reproduction, procedures in subjects different from those indicated in article 5 (adult heterosexual couples), all forms of maternal surrogate, use of gametes after the death of one partner of the couple, and every form of human cloning, import, export, and commercialization of human gametes or embryos are assembled.
- Article 13 states that every form of experimentation on human embryos is forbidden; clinical and scientific research is only allowed for diagnostic and therapeutic purposes to ensure the safety of the same embryo and only when there are no other possible alternatives. Every form of selection for eugenic reasons, early dissection of human embryo, hybridization, cryopreservation, and suppression of spare embryos are absolutely prohibited. Moreover, in the same article it is established that medically assisted reproductive technology must create the number of human embryos that are strictly required for one single implantation, and in any case no more than three; all produced embryos must be transferred into the uterus at the same time. Selective reduction of fetuses in utero is also forbidden.

BIOETHICS AND THE LAW

The field of assisted reproduction raises moral and social issues of extreme importance, and its complexity is caused by the presence of conflicting claims to rights (6). Fundamental distinctions must be made between a positive and a negative right, i.e., a “right” and a “liberty.” Claims to positive rights assume that there is a corresponding obligation of other people to supply what is claimed, for example, the right to demand appropriate health care. On the other hand, negative rights simply require others to leave right holders free, for example, the liberty to be free of interference in assisted reproduction.

One of the problems is to define whether infertility is a condition (many infertile people lead normal, healthy lives) or an illness in itself; infertility is often seen as a medical matter, while childlessness is seen as a social problem. As a disease, infertility would claim the positive right to appropriate health care and “right to life” for the potential future born, while childlessness, as a social condition, would require only the liberty to procreate, whenever desired, using all means that are not prejudicial to another’s interests or rights.

Conflicting rights may arise between those who have rights (human persons) and those who have only potential rights: “personhood” is lacking in nonautonomous beings (pre-embryos, embryos, and fetuses before the 24th week of gestation), but they have the potential to