NEWS AROUND THE WORLD

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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 northern 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 sterility 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

result in a unique person; this could extend to gametes (sperm and egg).

The fetus deserves respect, but as a nonautonomous being does not have absolute claims that can override those of an autonomous person, usually the mother. Nevertheless, another party to be considered is the child born as a result of medical intervention; this is more than a potential human being and is the most vulnerable party. The doctors who intervene to generate a pregnancy have particular duties to ensure that the resulting child is not foreseeably disadvantaged. However, the best interests of the potential child are difficult to assess when the alternative is "nonexistence."

Another important problem in assisted reproductive technology is the possibility of multiple pregnancies and, by consequence, the selective reduction of fetuses. Today, the transfer of three embryos or eggs in IVF or GIFT has come to be accepted practice internationally, and this is the maximum limit allowed by the actual Italian law. Preimplantation selection of any kind is forbidden, and for gender selection it could be considered only in cases of risk of passing on gender-linked diseases such as muscular dystrophy, but not for social or cultural reasons.

Bioethics may be defined as applied ethics in the biological (animal-vegetal) kingdom. It is that kind of discipline that concentrates on discerning the parameters for good within the medical and health care professions. As a result, there are six principles, partly derived from Hippocratic ethos and partly unique, that may be considered as a foundation: autonomy, justice, nonmaleficence, beneficence, veracity, and confidentiality (7).

The bioethical process may be described as the application of the general principle to the specific singular case. The active agent of this process is the human conscience, the second component of the bioethical triad (principle-conscience-case). On the other hand, the essence of law is the direct application of the general juridical principle to the single case, which means definition of criminal offense, illegal behavior, professional responsibility, economical refund, and so on. In this case there is no place for the human conscience, but only for lawyers, legal consultants, judges, and so forth.

Ethics and law must be differentiated. The complete translation of own ethical principles and beliefs into law may result in abuse and injustice by one side: the negation of human liberty and autonomy by overwhelming religious beliefs. Since 1995, in the "Code of Italian Medical Ethics" (8), article 41, there has

been clear prohibition, in the interest of the future born, of four specific conditions of assisted reproduction:

- a. Maternal surrogate of any kind.
- b. Assisted reproduction apart from stable heterosexual couples (homosexuals, singles are excluded).
- c. Insemination after the death of male partner.
- d. Assisted reproductive technology in nonprecoocious menopausal women.

Violation of the ethical code by a doctor involves disciplinary measures by the local Medical Council, but the doctor's behavior is not considered criminal; passage of actual law, however, would establish the behavior as criminal. The Italian law on ART, approved by the Chamber of Deputies and in discussion in the Senate, will be even more restrictive than the Code of Medical Ethics, and violations will be punished with disproportionately severe penalties.

CONCLUSIONS

The ART issue certainly deserves serious attention, and a law defining principles and limits has been needed in Italy for many years; however, today we are waiting for legislation that would interrupt the application and scientific evolution of ART techniques, and would satisfy only the catholic intransigence that has influenced in a massive way the development of this law. The spirit of this law is strongly prohibitionist, legitimating a single model of family, with a strong intervention by the State in the inviolable rights of the human person, denying individual women's competence on procreation. In particular, the absolute prohibition of heterologous procreation, which is allowed all over the world, will bring several negative consequences; on one side the scientific evolution of many procedures will be paralyzed; on the other, it will stimulate the clandestine market of human gametes, without any control on sperm safety. Analogously, the prohibition of cryopreservation will prevent the use of many procedures that are usual clinical options for optimization of results with minimum discomfort for the patients.

Drawing inspiration from already-existing rules (for example, Code of Medical Ethics and self-regulation Code of CECOS), however, we hope that the Parliament would introduce at least few modifications, as follows:

- Reintroduction of heterologous procreation, even with restrictions and severe rules.

- Better definition of criteria and limits of embryo production for single cycle and modification of actual terminology, which appears equivocal.
- Cryopreservation must not be absolutely forbidden, but rather controlled by rigorous regulation, to avoid any kind of commercial exploitation, and to guarantee the respect due to human embryos and gametes.

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