

Advances in Medically-assisted procreation technologies: can malpractice claims and “reproductive damage” be identified?

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Abstract

Medically assisted procreation and assisted reproductive techniques have made giant strides over the past decades, enabling countless couples to achieve parenthood. Still, the ethical and moral concerns that have come to the fore as a result of ART's rise pose a multi-faceted issue that lawmakers have struggled to keep up with; procedures such as heterologous fertilization are strictly regulated, and even banned, in several nations around the globe, among which Italy, where a controversial piece of legislation was passed in 2004; such a reform has been partly nullified by court decisions, among which the Italian Constitutional Court and even the European Court of Human Rights. Relevant scientific articles were identified from Medline, Cochrane Central, Scopus, Web of Science, Science Direct, EMBASE and Google Scholar, through February 2020, by using the following keywords: “assisted reproductive techniques”, “heterologous fertilization”, “European rulings on ART”, “reproductive damages”. The rise of ART has laid bare a shortage of adequate legal tools for the purpose of guaranteeing the exercise of reproductive rights for all. Hence, the harmonization of regulations, at least at the European level, is greatly needed in order to ensure equality of parental opportunities for all. *Clin Ter 2020; 171 (3):e225-228. doi: 10.7417/CT.2020.2217*

Key words: medically-assisted reproduction, donor anonymity, court rulings, reproductive damage

Introduction

Advances in fertility medicine and assisted reproductive technologies (ART) have enabled more and more people to fulfil their dream of parenthood as never before. Procedures such as heterologous fertilization and elective egg freezing appear to be on the rise worldwide. The latter, at times referred to as “social freezing”, has grown by almost 15-fold in the United States over the past seven years (1-4).

As for Europe, a EU directive has set some standards related to the use of human tissue and cells, but all ethical and legal questions on ART are still within the margin of appreciation to which EU member states are entitled (5, 6); hence, they are the prerogative of EU member national

legislatures. All over Europe, 157,500 children were born by ART in 2015. Still, major differences exist in legislation across the European Union (7).

A checkered European scenario

In Europe, national regulations range from permissive to relatively strict. Some countries do not even have targeted legislation, and medically-assisted procreation is regulated by general health norms (8).

In France, only heterosexual couples with medical infertility or other serious infertility-inducing condition may apply for ART treatments, while Across Europe there are diverse legal standards in place. Spain was the first European country to open ART to all women, in 1977, the year the first sperm bank was opened there. In the last 15 years legislation has evolved quickly. For example, Portugal made ART available in 2006 with conditions very similar to those in France, before amending the law in 2016 to allow lesbian couples and single women to benefit (9). In 2004, Italy set its legal standards by adopting Europe's strictest laws (10), thus making ART available to heterosexual couples, whether married or not; sperm donation is prohibited. Such a legislation has however presented substantial flaws in terms of constitutional viability; the Italian Constitutional Court has issued various rulings in that respect, as did the European Court of Human Rights in 2012 (11, 12). Besides, the Italian Code of Medical Ethics has enshrined a set of standards for medically assisted procreation, in article 44 (13), which reflects the legal evolution of Italian jurisprudence over the years; ART techniques are in fact increasingly sought by those who cannot reproduce through their own genetic and biological capacities (14). Heterosexual, same-sex couples (15) and single women and men who seek to have biologically linked offspring often turn to clinics and agencies in order to find gamete “donors” or gestational services, usually in exchange for monetary compensation. Residents of countries where such practices are banned often turn to “fertility tourism”, i.e. traveling to countries where ART are legally available; that is ethically controversial in and of itself, since only those who can af-

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ford to do so can have access to ART abroad (16). In other words, the right to family will be exercised only by those affluent enough to pay for it. Furthermore, donor-anonymity, legally required in most countries, conflicts with the right of donor-conceived children to discover their biological origins. According to a recent survey of European legislative statutes and approaches, strict anonymity is still the rule in 18 countries, although in 5 of these countries, donor identity disclosure is possible in cases of serious health conditions of the child born (17).

Lawsuits and rulings lay bare the lack of consistency

A recent case in Europe has brought up that contradiction: in 2015, a 35-year-old French woman who was conceived through heterologous in vitro fertilization sought to gain access to information about her biological father, the sperm donor (18). However, it was later established by a court decision that her case did not qualify as an exception to the anonymity rule; in fact, an exception requires doctors to ask for the information, in cases of provable therapeutic need; anonymity is also meant to ensure that when both partners in a couple were born from donated sperm, they were not conceived from the same donor (19). Since neither condition had been met, the French court ruled that donor anonymity should be enforced. Germany, on the other hand, allows donor-conceived children to know the identity of their biological fathers. In fact, according to the German Civil Code (§ 1600 section 1 and 5), the child born through male gamete donation is entitled to look for his or her biological father; children can even apply for financial support from their donor father and claim inheritance rights (20). Back in 1988 and 1989, the German Supreme Constitutional Court acknowledged such rights in hallmark decisions. Still, often donor-conceived children in Germany have no way to discover their biological fathers' identities, since no national database of gamete donors exists, and doctors frequently do not keep records, although they are legally required to do so; hence, the right cannot be upheld due to the lack of identifying information. Moreover, German women and couples who seek anonymous sperm donations frequently travel to Denmark, when anonymity is still guaranteed. Their reasons to do so are quite diverse: frequently, many couples are determined to eliminate any connection to the donors/biological father because a social/intended father exists (21). In the United Kingdom, it used to be impossible for donor-conceived children to find out about their biological origins; in 2005, however, that approach was reversed: those born via heterologous fertilization procedures performed after April 2005 will be able to know their biological fathers' identities, upon reaching the age of 18, whereas for those born prior to that date, donor anonymity will still stand (22).

Fertility clinics and sperm banks: what about reliability?

In addition, the role of fertility clinics and sperm banks has been called into question as well, pointing to shady practices in donor selection and lack of transparency in information sharing. A telling 2015 case involved a Canadian

couple made up of two women, who had selected a sperm donor (identified by the donor number 9623) to be the father of their child from an American sperm bank (Xytex). Their choice was based on the donor profile as shared by the sperm bank: an eloquent, smart, healthy, mature individual. Nevertheless, almost seven years after the child was born, the couple received mail that, probably by mistake, identified the donor by name (23). After investigating, they found that the donor was schizophrenic, had dropped out of college and had just been charged with burglary. Moreover, his profile photo had been modified to hide a large mole on his face. This donor had fathered over thirty children. Apparently, as the women realized, poor oversight and surveillance is not uncommon in most sperm banks in the United States. In fact, the United States Food and Drugs Administration requirements for the assessment of sperm donors are only limited to testing for contagious infectious illnesses such as syphilis and HIV-AIDS. Also, there is no regulation establishing the maximum frequency and number of times that sperm can be donated by a single donor. In March 2015, the Canadian couple filed suit against the supplying sperm bank, but a judge in Fulton County, Georgia, dismissed their product liability lawsuit, which alleged that a sperm donor's background wasn't as described. The judge in fact ruled the lawsuit was actually a wrongful birth claim, which is barred under Georgia law. The donor's attorney also stated that he would sue and seek damages from the couple, arguing that their allegations about mental health problems were conclusions apparently drawn from social networks and other online posts (24). Overall, it can be argued that there is a growing trend towards repealing gamete donor anonymity; in fact, the volume of individual genetic information available is so vast nowadays that enforcing the anonymity of sperm or egg donors and the children conceived from their donation may no longer be guaranteed and mandated by law (25-27). In fact, new DNA testing tools are becoming available to virtually anyone: direct-to-consumer tests have already been used by more than 30 million people worldwide, and that trend seems to be growing (28, 29). Such new developments generate major consequences for donors and donor-conceived people alike, particularly for those who donated or were conceived when anonymity was (or still is) legally required (30).

Donor-conceived children's rights: a thorny issue

In Italy, for instance, there has been a lack of uniformity in terms of court decisions regarding the legal recognition of donor-conceived children born abroad. Even in countries where such practices are legal, fundamental questions still linger: should individual practitioners remain free to deny services to potential parents on conscience grounds, based on marital status, sexual orientation, age, or assessed child-rearing ability? Such doubts are similar to those stemming from abortion or emergency contraception (31), and expose conflicting rights (patients' vs. providers') that need to be somehow reconciled (32). In addition, how should law and policy protect donors/collaborators from exploitation? And on what grounds, if any, should individual states restrict who may benefit from third-party reproduction? These and many

other pivotal questions need answers, if ART practices are to become even more a valuable tool to uphold the human right to parenthood. It is worth stressing, however, that as assisted fertility treatments such as in vitro fertilization become more common, the same advancements that have made fertility procedures more accessible, have opened the door to uncharted ethical, moral and legal territories (33).

Undoubtedly, a cautious, evidence-based approach is necessary when dealing with and regulating such techniques, in light of the impact of ART on the population as well as the introduction of new diagnostic and therapeutic tools (34). As a matter of fact, MAP techniques have aided, and often times even replaced, natural reproductive practices. Nowadays, in fact, many people start their families later in life, and frequently put off having children; often, they count on the possibility to do so later on, by resorting to assisted reproductive technologies. However, there is no overcoming nature's limitations: as the ageing process unfolds, pregnancy could entail major unpredictable complications (35-37), despite the modern, sophisticated medical techniques currently available (38).

In fact, the risks inherent to ART have been highlighted by several scientific associations, particularly in multifetal gestations. Particularly, perinatal risks that may be associated with ART and ovulation induction include higher chance of multifetal gestations, prematurity, low birth weight, small for gestational age, perinatal mortality, cesarean delivery, placenta previa, abruptio placentae, preeclampsia, and birth defects (39, 40). Severe cases may even result in ovarian hyperstimulation syndrome (OHSS), predominantly in patients with polycystic ovary syndrome (41). In addition, a recent population-based study hints to a potential link between amniotic fluid embolism and assisted reproductive technology which warrants further investigation (42, 43).

Conclusions: ART-related lawsuits and the hazy concept of "reproductive damage"

From a medico-legal standpoint, a recent review has found that misdiagnosis and lack of informed consent were the highest award categories, whereas embryology lab errors had the lowest award per settlement, while being the most frequent causes of litigation. The average cost for out-of-court settlements is relatively high compared to settlements in other specialties (44). Still, under tort law in many jurisdictions among which the United States, the reproductive injury offence is still so ill-defined and hazy, therefore for those who suffer adverse consequences it is often hard to get redress in court. Tort law in most jurisdiction worldwide currently appears to be lagging behind the new, ever-developing ART/IVF techniques; hence, no theory of rights specifically devised and fitted out for ART/IVF currently exists; the regulatory framework is largely unprepared to effectively discharge its main functions: individual justice and effectual social regulation (45). A more functional and reliable system of legal accountability and regulation of the fertility industry is necessary; in fact, patients who are harmed in reproductive malpractice or negligence cases often have insufficient options for recourse. That is in part due to the ambiguous legal status of foetuses and embryos in many

jurisdictions (46, 47). The rule of law is inextricably tied to the precepts of ethical conduct; the determination of when exactly "personhood" begins has far-reaching ramifications that are bound to greatly impact health care, beginning-of-life and abortion legislation and individual autonomy and self-determination. Given the fast-moving advancements in assisted fertilization, as well as in cloning and stem-cell research, any attempt to define personhood faces multiple complex challenges (48). Within that framework, advancements in fertility medicine are undeniably transforming the world as we know it, by making the impossible possible for families all over the globe; yet, they present not only a host of legal complexities, but also ethical/moral issues, that need addressing.

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