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Editorial

The Culprit of Increased Complaints in IVF Clinics: New Technologies or the Growing IVF Popularity?

In the field of medical services, there are few treatment procedures with failure rate of more than 60-70%. Although infertile couples, as recipients of the service, are educated about the low odds of IVF success, many accept to undergo this practice. The success of infertility treatment and live birth depends on numerous factors including cause of infertility, couple's age, duration of infertility, number of previous treatment cycles, *etc*. Despite many advances in the diagnosis and treatment of infertility and use of various medical and surgical methods plus add-ons, there is no definitive procedure to guarantee the success of IVF due to unexplained causes of infertility in some couples. Considering the psychological burden and high costs of repeated treatment cycles, sometimes couples attribute recurrent failures to recklessness, negligence, and malpractice of the physician and the medical team, so that the development of negative mindset makes the couples determined to file medical malpractice lawsuits against the health professionals. However, in other cases, the couples might make complaints following the successful treatment and birth of their babies. These cases often occur due to some unwanted mistakes such as gamete and embryo mix-ups or the presence of some preventable defects and neonatal disorders and diseases, especially after using preimplantation genetic testing (PGT) technique which has recently become more popular in most IVF clinics (1).

During the last two decades, significant improvement has been made in the field of reproductive medicine, especially the clinical embryology and IVF lab, which has completely revolutionized the diagnosis and treatment of infertility. In addition, similar advances have been made in the field of medical genetics, performed in IVF centers, that enabled the physicians to prevent the birth of offspring with genetic defects through preimplantation embryo evaluation. These techniques provide an opportunity for couples who cannot deliver a healthy child despite their fertility. Although the advancement of these techniques has opened new horizons in the field of reproductive medicine and increased the quality of services in IVF clinics, many ethical and legal challenges have also been emerged in applying the new techniques (2).

Now, a significant question arises as to whether the number of complaints in IVF clinics is different from other specialized fields of medicine. Is the increase in the number of patients' complaints ahead of the development in diagnosis and treatment methods in different societies? Is the number of complaints the same or different in all specialized areas in ART, and whether the differences are the result of controversies in using ARTs in specific cases. Finally, is it ever possible to reduce the number of complaints against doctors and treatment teams by changing and modifying the existing approaches in the diagnosis and treatment of infertility?

Sometimes the treatment team is sued for refusing to provide medical care that is professionally inappropriate. The medical team involved in the treatment of infertility may not suggest certain techniques for some couples as they are aware of the subsequent medical problems and complications in the future. Physicians are legally and ethically entitled to exercise a conscientious objection to providing services that they have assessed as not being clinically appropriate or not of overall benefit to the health of the mother or the resulting fetus. As an enacted legislation in many countries, physicians may choose to opt out of providing ineffective treatments. In the context of assisted reproductive technologies (ARTs), there is no obligation to exercise a certain practice when the risk of treatment is too high and it potentially puts the patient's health and life at serious risk. For example, it is prohibited to transfer embryo to aged women (over 50) or transfer embryo to women with serious cardiovascular and pulmonary diseases, women with a family history of cancer or treated cancer with the risk of recurrence, and many other cases for whom the probability of adverse health effects is estimated to be high. Therefore, the physician is legally responsible in case of providing above services. While the infertile couple may sometimes be very insistent on undergoing the treatment and waive any future claims for these services, they may deny full responsibilities for the consequences in the future which might jeopardize the physician's condition. In addition, some treatments would not lead to physical or life-threatening harm to the patient, such as the transfer of aneuploid embryos or the transfer of *in vitro* arrested embryos to uterus. Yet, the practice is contrary to scientific standards and common moral values and principles (3).

Another example of these lawsuits is the damage to the embryos in the process of freezing, failure of embryo storage, and loss of all embryos for many couples. Although the development and improvement of cryopreservation and storage of gametes and embryos, especially the vitrification, has fundamentally increased the

success of ART, management of legal concerns for service providers is still a vexing challenge. In spite of the fact that few cases of above examples have been reported so far, the profound impact of such disastrous events has attracted the media coverage and led to serious financial crimes and even closure of the IVF clinic. Therefore, such concern requires a review of strategies in providing these services, the use of more reliable and precise tools and equipment, comprehensive consultation with the couples about the entire process, obtaining the essential informed consent, and using sufficient insurance coverage, which will, to some extent, eliminate the problems and concerns of the medical team and couples who own the embryos (4).

Review of complaints in IVF clinics around the world provides insight into areas of practice that may require modifications in procedures or patients' consultation. The medical team and managers of IVF clinics should actively involve in quality improvement activities to facilitate the identification of high-risk areas. Total quality management, risk assessment, and root cause analysis (RCA) are ideal tools for reducing errors, shortcomings or unfortunate events that endanger the patients' health and safety. Unlike specialties and fields such as anesthesia, surgery, obstetrics and gynecology, the number and rates of risk profiles, claims, and court outcomes are not precisely reported in reproductive endocrinology and infertility (REI) and clinical embryology field which are helpful tools in risk reduction and improvement of patient care. A better understanding of past and emerging trends in claims in IVF practices can identify areas of vulnerability to malpractice. This strategy would culminate in a smart change in diagnostic approaches, counseling and selection of treatment plan, thereby addressing the interests of both the patients and service providers. For example, if PGT or embryology lab errors are the reasons for many claims or serious financial burdens, these services must be scrutinized more meticulously to identify high-risk areas and subsequently opt for the best preventive actions or change of protocols (5).

IVF clinics, like other medical centers, have the responsibility to provide standard and professional care and efficient services to their patients. They must assure their patients that the operations will not damage their gametes, embryos, or child. Infertility specialists are also responsible for providing accurate and complete information to patients in choosing the best treatment plan and also giving advice when discontinuation of treatment is to their benefit. Clinicians should provide counseling to couples about the option of preimplantation genetic testing because if the IVF center and physician do not provide PGT services to a carrier couple and subsequently deliver a baby with a detectable genetic defect, both the physician and the IVF center will be responsible for the malpractice. Conversely, if patients request for genetic testing of their embryos but the medical team and clinic fail to perform successful PGT and transfer genetically abnormal embryo resulting in a child with birth defects, the clinicians will definitely be liable for malpractice. This is just an example of the extraordinary sensitivity of the critical practice of IVF. Since numerous services at IVF clinics are offered as available alternatives for the couples, legal and moral responsibilities of IVF clinics reach significance and negligence in addressing the challenges increases the number of patients' complaints. Therefore, IVF clinics and the medical teams can be held accountable for all mistakes, negligence or failure in treatment, and possible injuries to the patients or their future child.

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