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Biobanking for Gamete and Embryo Donors: Insights into a Modifiable Guideline

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In recent years, infertility has been considered as a medical and social problem, so couples have sought medical help to overcome childlessness. However, the involvement of a third party in the creation of child is apparently very problematic in most countries (1). Getting pregnant is not necessarily the end of this problem, and treatment through assisted reproductive technologies (ARTs), itself, is a very difficult process from an emotional and physical point of view (2). Iran is the only Muslim country where there is no legal or religious obstacle to use embryo donation (Giving Life and Hope) for an infertile couple. Many couples have no other choice than using a third-party reproduction as a treatment option. Iran Embryo Donation to Infertile Spouses Act (IEDISA) was approved by the Iranian Parliament on July 20, 2003 (3), and the executive regulations of this law in Iran were approved and communicated by the Cabinet of Ministers on March 13, 2005 (4). Other formalities are carried out based on the “Fatwa of Taqlid” (a fatwa order from an Islamic religious leader, that addresses the permissibility, conditions, or implications of practicing Taqlid) authorities and Article 167 of the Constitution. Article 167 allows judges to issue fatwas in cases of lack of law (5). The supply of embryos is either from the extra frozen embryos of infertile couples, or from the donated sperms and eggs of fertile married couples (6). In a part of the executive letter of the Embryo Donation Law, the confidentiality of the process of obtaining, preserving and donating embryos has been emphasized. Such information is called "top secret government documents" and may be disclosed only by court order. This regulation allowed the establishment of embryo banks under the supervision of the Ministry of Health using various ART methods (1). Although in the past, other countries had also restricted the sharing of donor, recipient, and unborn child information (7-8), over the past several years, the legal landscape of gamete and embryo donation has changed significantly. In Sweden, Germany, Austria, England, Holland, Switzerland and Finland, identifiable sperm and egg donation is mandatory today, and many legal systems have changed from anonymous donation to a more transparent system (9). There has been much public and political debate about children's right to know their origins (10-11). Those in favor of registering information and removing confidentiality believe that knowing the genetic origin is a child's right, which is abandoned by legislators justifying the policies of non-anonymous gamete donation (12). Secondly, the anonymity of donation increases the possibility of marriage with siblings, incest, and genetic diseases in small communities (13-14). In Iran, genetic background of the baby is mostly kept secret

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and their relationship with the donors is cut off. None of the child's official identity documents indicate the child's genetic parentage.

IEDISA's implementing regulations require ART clinics to confirm the identity of donating couples and record their information confidentially. However, the events following the transfer of the embryo to the womb of the recipient woman are not covered by the law, and even tracing the genetic origins of the child in the absence of a reliable record may be very difficult, if not impossible (15). After the embryo transfer, the donating couple usually leaves the clinic forever and the recipient mother give birth in any hospital they wish, and the birth certificate of the baby is officially registered with the name of the recipient couple. Therefore, despite the fatwa of the authorities and the legal system, which still considers the genetic relationship as the most important issue, it is being neglected in this process (1, 13). From the point of view of Sharia, preservation and protection of genealogy and avoiding mixing has a high priority, and this importance has been used as the basis of many rulings regarding iddah (a Muslim woman’s waiting period after the death of her husband or after a divorce, before she can remarry), marriage with mahram (a close male relative with whom marriage is permanently forbidden), the Zina (unlawful sexual intercourse) and the prohibition of adoption. So, how should this important issue be ensured in the case of children resulting from embryo or gamete donation (13)? In Iran, the civil registry office does not record anything about donated embryos or gametes in the birth certificate. On the other hand, the current procedure of the courts and relevant authorities regarding the determination of lineage and traces of lineage on a person is based on his/her registry information and birth certificate, which lacks information on the genetic identity of the person. Due to the increasing trend of assisted reproductive technologies, the possibility of expanding the circle of incest and, as a result, mixing of lineage and incest marriages increase. It is very clear that in the near future, especially in small cities and communities, incest marriages will happen unintentionally. Although comprehensive ART clinics and healthcare providers maintain records of embryo donation parties, the system is designed in such a way that it seems unlikely that they will be operational. In order to avoid confusion, it is necessary to establish a central biobank to respond to inquiries from all regions. This biobanking plan responds to the vital needs of reproductive health and can achieve the following goals: 1) the possibility of donating extra embryos and gametes to other couples; 2) preventing wasting valuable reproductive tissues for future reproductive health research (16); 3) Providing a valuable national archive of the records of all embryos that were formed and born through embryo or gamete donation and in necessary cases such as marriage (fertility, contraception, tissue compatibility in cancers and other diseases) as soon as possible. The aforementioned centers could be accountable to all patients from anywhere in the country. They will even be one of the reliable sources for the country's civil registration office, and their information is always being exchanged with the civil registration office. In addition to gradually becoming a large-scale research resource, these biobanks will contain in-depth genetic and health information from a large number of participants in the assisted reproductive technology process in Iran, and the database will be regularly supplemented with additional data. It will also be a safe and reliable database regarding the information of the embryo donation parties.

The structure of the biobanks for embryo donors and gametes is suggested as follows (Figure 1).

A. It is the responsibility of the clinics to carry out all the evaluations for the donor couple and the embryo applicant couple. These evaluations include psychiatric assessment; B, gynecological l investigations; C, infectious (including blood type and Rh factor, and testing for sexually transmitted diseases including HIV, hepatitis, gonorrhea, chlamydia, and syphilis.) and genetic evaluations, and all necessary clinical and D, paraclinical evaluations. The purpose of these processes from one hand is to deliver a physically and mentally healthy child to the couple, and from the other hand the eligibility of the couple as such to have maximum physical and mental health to raise a child.

B. These processes must be completely confidential according to the IEDISA law in Iran

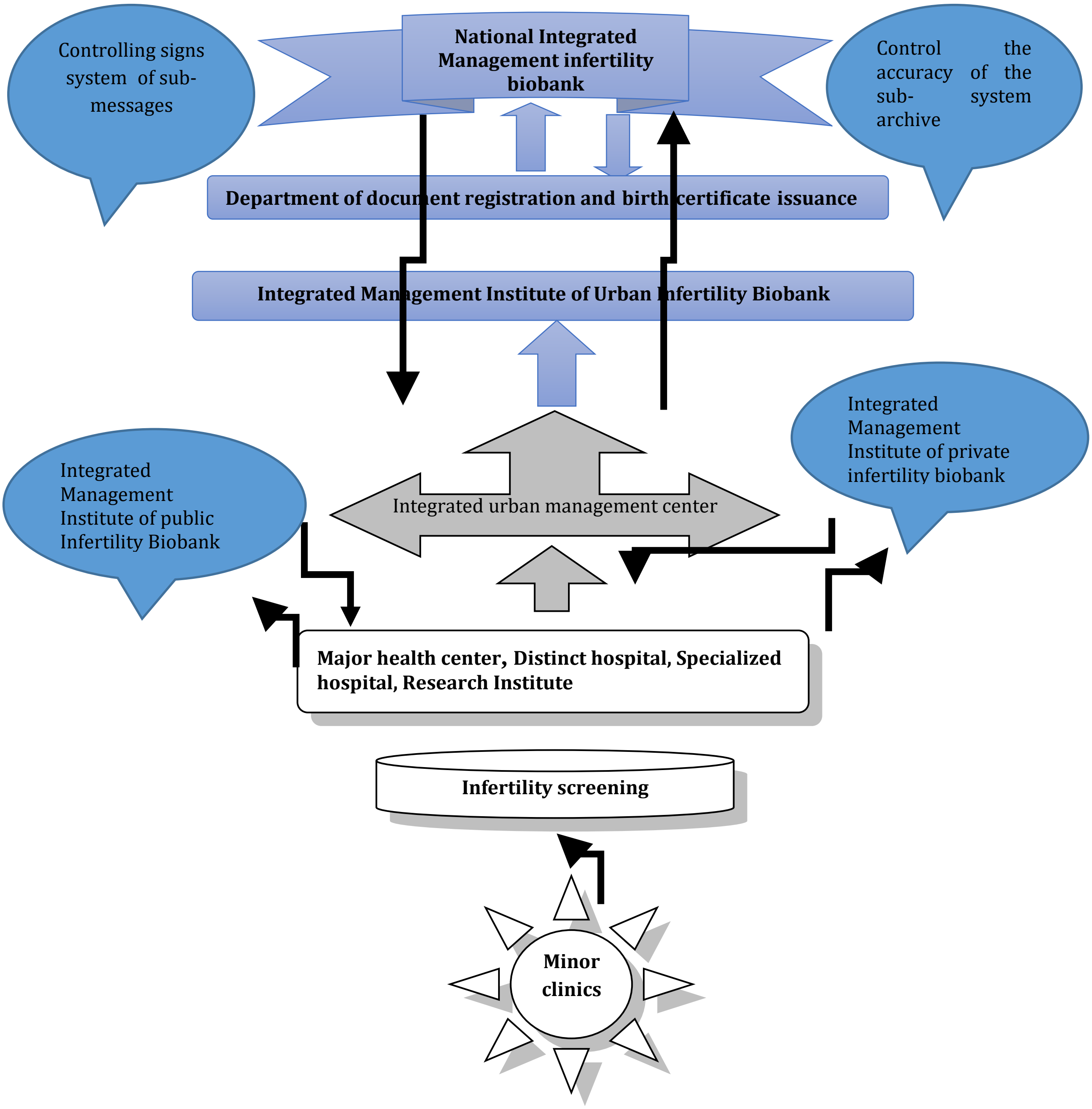

Figure 1. The communication process of public and private clinics with regional and national biobanks

C. Private and public clinics must report the pregnancy, birth time and characteristics of the baby, all characteristics of the donor and the recipient couple to the integrated Biobanking for Embryo Donors and Gametes (regional biobank).

D. In order to control and supervise the implementation, it is the responsibility of the government to oblige the Biobanking for

Embryo Donors and Gametesto record the information of all applicants daily. Also, the report of registered cases should be transferred to the national biological bank of daily infertility. These records will help control the number of times a donor can donate. Also, by establishing a legal and regulatory framework to track donors when medically necessary, and maintain comprehensive records, we can prevent marriages between individuals with close blood relations.

E. The civil registration office, which according to the law (in the interest of the child), does not record the genetic identity information of the children in the birth certificate, with the right link to the regional or national infertility biobank, can always find the exact information in case of inquiry. In fact, while the identity of donor-conceived children remains confidential, all necessary information is securely recorded within the system to ensure traceability when needed.

F. By establishing the biobank, the possibility of mixing genealogy, corruption of heirs, incest marriages, and giving up relatives, mostly based on Sharia rulings, is greatly reduced and prevented.

G. This method will help the Ministry of Health to be the operating entity for donating embryos, gametes and surrogates in the country.

Finally, the genetic information of each person is considered to be part of the definite privacy of the individuals in the society. So, the collection, archiving, protection measures, access protocols, permitted uses, authorized personnel to access, and the archival retention period for this information must all comply with confidential document regulations.

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Use of Artificial Intelligence

Artificial intelligence was not used in writing this manuscript.

Ethical considerations

In the present study, the ethical aspects of library research, including originality of texts, honesty, and trustworthiness in using and synthesizing data were observed.

Code of ethics

N/A.

Authors' contribution

Both authors (ZY and FG) jointly contributed to drafting, editing and reviewing the whole manuscript and agreed to be accountable for accuracy and integrity of any part of the work.

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