

Recommendation

Establishment of a public platform for the proper operation of Preimplantation Genetic Testing (PGT) with ethical issues - Focus on Preimplantation Genetic Testing for Genetic Disorders (PGT-M)



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Science Council of Japan

This Recommendation is largely the outcome of the deliberations of the Subcommittee on Preimplantation Genetic Testing, especially for PGT-M, Section II of Science Council of Japan(SCJ), and is issued under the auspices of the SCJ.

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Abstract

1. Background

Preimplantation Genetic Testing (PGT) is a genomic medical technology in which a fertilized egg obtained by in vitro fertilization is cultured to form a blastocyst, and a few cells are biopsied from the part that will become the placenta, from which DNA is extracted and amplified for genetic analysis. Among PGT, preimplantation genetic testing for genetic diseases (PGT for monogenic/single gene defect, PGT-M) is a technology that aims to avoid the birth of a child with a serious genetic disease and can benefit the patient and family suffering from the disease. On the other hand, this technology also makes it possible for parents not to create children with unwanted traits, which raises a serious bioethical issue of life selection and raises the proposition that certain regulations may be necessary. Currently, Japan Society of Obstetrics and Gynecology (JSOG), which has adopted PGT-M as a medical technology, regulates it, but this regulation is only for its members, and there is no consensus from general society. Furthermore, there is no legal binding force at all, and it is possible to perform PGT-M, which is not approved by JSOG, by going to a foreign country where regulations are less strict, which causes confusion in the medical field and general society.

2. Current Status and Problems

(1) Ethical issues and the need for regulation of PGT-M

The benefits of PGT-M include: the increasing possibility of having healthy children by not passing on one's genetic disease to one's offspring, thereby reducing the psychological burden on the parents; the health economic benefits of fewer patients in the future, which in turn can be expected to provide more support for people with genetic diseases. It is also expected to be less mentally and physically burdensome than abortion which is performed as a result of prenatal diagnosis, and to respect Sexual and Reproductive Health and Rights (SRHR) as defined by WHO. On the other hand, disadvantages include the possibility of unlimited expansion of coverage beyond the scope of "serious genetic diseases," the possibility of increased discrimination against patients and

their families, the possibility that diseases with varying severity among patients and diseases for which treatment methods may be developed in the future may also be covered, and the possibility that the right to fetal survival may be disregarded in the SRHR of women. There is a misunderstanding in the field of psychiatry that the onset of psychiatric disorders is determined by genetics, and there are concerns that implementation without a system to provide genetic counseling may lead to prejudice against psychiatric disorders and even the exclusion of patients with psychiatric disorders. There are also concerns such as lack of assurance of the safety of PGT embryos, the invasive nature of IVF for women who are capable of conceiving naturally, and the possibility of unregulated application of the technology due to commercialism. Thus, given that PGT-M has many disadvantages as well as advantages, unrestricted application of the technology is not desirable and some form of regulation is necessary.

(2) Legal possibility of implementing regulations on PGT-M

The right of individuals to overcome illness and form families, the freedom of professional activities of physicians engaged in clinical practice, and the freedom of life scientists to conduct research are all included in the basic human rights guaranteed by the Constitution of Japan. The Constitution also guarantees basic human rights to “future generations”, and while regulating PGT-M could be viewed as harming patients' right to the pursuit of happiness, unrestricted genetic selection through PGT-M would promote discrimination against people with genetic diseases and could lead to eugenics ideology. In the long run, it could undermine the diversity of the human genome, potentially affecting the sustainability of human as a species and harming the basic human rights of future generations. The principle of adjustment in the Constitution when such rights conflict with each other is "public welfare," and Japanese law establishes various systems based on the concept of balance of interests. If only the right to overcome illness and form a family, the freedom of professional activities of doctors engaged in clinical practice, and the freedom of life scientists to conduct research are taken into consideration, the welfare of people who may be subjected to genomic discrimination and that of future generations will not be protected. It would be possible to introduce a public regulation that balances the various interests and harmonizes them, while taking into account the interests of these people and referring to the cultural and religious backgrounds of other countries' legislation.

(3) Desirable regulatory framework for PGT-M

Currently, the only regulation on PGT-M is based on JSOG's opinion, but assisted reproductive technology that deals with genetics such as PGT-M is closely related not only to medical issues but also to people's views on life, family, and women. When considering how PGT-M should be regulated, 1) consideration should be given to the views of the patients concerned and the opinions of obstetricians and gynecologists, clinical geneticists, pediatricians, psychiatrists, and other specialists who actually treat the patients, 2) While paying attention to trends in the international community, efforts should be made to reach a consensus in Japanese society by considering the social, ethical, and legal aspects of reproductive medicine that are appropriate for Japan's contemporary environment. 3) Regulations can always be updated to meet the needs of the times. The Assisted Reproductive Technology Act and Genome Medicine Act clearly stipulates the responsibilities of the national government in these areas. It would be appropriate for the regulation of PGT-M not to be conducted by a single academic society, but to be conducted in a flexible manner with the involvement of the national government in a manner that is representative of general society.

3. Recommendations

Since PGT-M has many disadvantages as well as advantages, and the unrestricted application of the technology is considered undesirable, some regulation should be imposed.

The regulation of PGT-M should not be left to a single academic society, i.e., Japan Society of Obstetrics and Gynecology.

The Assisted Reproductive Technology Act and Genome Medicine Act clearly stipulate the responsibilities of the government in these areas. In the regulation of PGT-M, a platform should be established jointly by academia and general society with public support, after basic laws are established. For this purpose, it is necessary to establish a public organization with jurisdiction over reproductive medicine and bioethics, including PGT-M, where it is desirable to discuss and reach consensus on the ethical framework “concerning medical care for children yet to born” and to standardize these principles.