

Comment

Prenatal Testing from a Legal Perspective

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My area of expertise is law, particularly family law. So I am not sure if I will be able to contribute to the discussion on these ethical and social issues. But I would like to ask some questions as well as make some comments focusing on the legal issues related to prenatal testing.

Choice and Consent

Today's seminar is entitled "Choice and Consent in Prenatal Testing", so the first question that comes to mind is "what is the difference between choice and consent", between "informed choice" and "informed consent"? Are the concepts or doctrines of informed choice based on those of informed consent? Is informed choice a pre-condition of informed consent? I think that the concept of informed choice is less familiar to most people in Japan.

On the other hand, informed consent has become a familiar word in everyday life, here in Japan and in other parts of the world, and means that a physician must inform a patient about the risks, benefits, and alternatives involved in any medical procedure and must obtain the patient's written consent to proceed. However, not all medical treatments require written informed consent. For example, in many countries ultrasound screening is used routinely and written consent is not considered necessary.

Ultrasound screening may detect fetus malformation, causing the woman emotional distress and leading her to face difficult decisions about the pregnancy. The same can be said for NIPT (non-invasive prenatal testing). If the NIPT result shows that the fetus has a chromosome condition, it can have significant emotional implications and affect women's reproductive autonomy. For this reason, a consensus emerged about the necessity of written informed consent that should be obtained from the patient before performing NIPT.

So, as Prof. Mills pointed out, there is not a coherent system of consent for non-invasive screening. Should same level of consent (e.g. written consent) be adopted for all non-invasive prenatal screening?

Routinization

In the case of ultrasound, written consent is generally not required probably because it is performed as a routine procedure to screen for potential pregnancy problems, even where the woman is not at any particular risk.

And it is exactly this routinization one of the major concerns facing NIPT. It may become a standard test that most women undergo simply because other women undergo. Many people argue that NIPT should not be a part of routine pregnancy care because of the negative impacts on informed decision making. Routinization could, according to them, potentially undermine the decision-making process.

Wrongful birth claim

Even though NIPT does not become part of routine pregnancy care, once the test is introduced to clinical practice, it might be expected that doctors offer this to the patients. Doctors must inform their patients about any known risks involved in a pregnancy, and failing to do so may lead to a medical malpractice lawsuit.

In a wrongful birth lawsuit, parents sue a doctor or hospital and seek damages for a child born with birth defects. The claim for damages is based on the cost to parents of raising an unexpectedly disabled child.

Parents in a wrongful birth lawsuit often claim that because they didn't have enough information to make an informed decision on whether or not to carry a pregnancy to term, their child was born with significant birth defects.

Restrictions on access

However, on the other hand, there is also debate over whether NIPT should be limited to serious medical conditions. Some countries currently restrict NIPT to women at increased-risk, only offering NIPT to women of advanced maternal age or to pregnancies where there is evidence from ultrasonography of fetal anomalies.

Japan

This is the case of Japan. As Prof. Tsuge mentioned, the Japan Society of Obstetrics and Gynecology has drawn up guidelines that limit the use of NIPT to a number of cases. So NIPT testing is available primarily to pregnant women of advanced maternal age and those found at risk of carrying babies with chromosomal abnormalities in earlier exams.

In addition, claims for wrongful birth are not generally accepted in Japan. The basic theory of a wrongful birth claim is that the doctor failed to advise the parents of the defect so that they could decide whether or not to terminate the pregnancy. But in Japan a doctor has no obligation to inform a patient about available testing that might reveal possible defects in a fetus.

Kyoto case (1997) ¹⁾

In 1997, the Kyoto District Court decided a case involving a 39-year-old woman and her husband's complaint that their daughter was born with Down's syndrome because the doctor refused to conduct amniocentesis and, as a result, she was deprived of her right to decide whether or not to give birth to the child.

The woman became pregnant and was 39 when she gave birth in June 1994 to a girl with Down syndrome. The woman claimed she consulted her doctor, in February 1994, when she was 20 weeks pregnant, and told him she wanted to perform an amniocentesis as she was over age 35. However, the doctor refused to perform it, saying that the amniocentesis results would be available only after the time limit for a legal abortion in Japan, which is 22 weeks of gestation. The woman claimed damages for psychological, emotional and financial consequences of giving birth, including the costs of raising a child with Down syndrome.

The Japanese court ruled in favor of the doctor and accepted his argument that there was no violation of the woman's right to decide whether or not to give birth because even if the amniocentesis had confirmed Down syndrome, the pregnancy could not be legally terminated.

The court also concluded that it was a physician's discretionary authority whether he or she recommends a test and that there is no right to know in advance about genetic disorders in order to prepare for the arrival of a child with special needs. The court noted that receiving the diagnosis in this case could be an emotional and traumatic event and could be an incentive to seek out illegal abortion.

Case of R.R. v. Poland (2011) ²⁾

This approach, adopted in Japan, was recently challenged before the European Court of Human Rights.

In a case decided in 2011, the European Court of Human Rights held that Poland had violated the prohibition against inhumane and degrading treatment for denying a woman timely access to genetic testing. The woman had been denied access to an amniocentesis and an abortion, and she eventually gave birth to a child with Turner syndrome.

The case concerned a pregnant mother carrying a child thought to be suffering from a genetic abnormality. She was deliberately refused genetic tests during her pregnancy by doctors who were opposed to abortion, so she missed the time limit in Poland for a legal abortion and gave birth in July 2003 to a baby suffering from Turner syndrome. She brought suit against Poland arguing she was subject to inhuman and degrading treatment and that her rights to private and family life were violated.

The Court stated that the human rights resulting from article 3 (prohibition of inhuman or degrading treatment) and article 8 (right to respect for private and family life) of the European Convention on Human Rights were violated in denying her timely access to prenatal tests to determine whether the fetus was suffered from congenital abnormalities ³⁾.

So, there are legal considerations surrounding the use of prenatal testing technologies, including national laws on abortion and assisted reproductive technology (ART). States will have to decide about regulating prenatal testing or not to ensure these technologies fit into existing legal frameworks of each country, and courts may face very difficult questions concerning reproductive autonomy and selective abortion.

Endnotes

- 1) Kyoto District Court, Judgment, 24 January 1997. Hanrei Jiho, n. 1628, p.71.
- 2) European Court of Human Rights, R.R. v. Poland, no. 27617/04, Judgment of 26 May 2011.
- 3) The Polish government was ordered to pay the woman €60,000.

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His recent publications and articles are as follows:

Marcelo de Alcantara, 2013. *National Reports: Japan*, in *International Surrogacy Arrangements: Legal Regulation at the International Level*, Katarina Trimmings and Paul Beaumont (eds), Hart Publishing, (in English)

Marcelo de Alcantara, 2013. *Brazil's Parental Responsibility Law*, *KOSEKI JIHŌ*, n. 695, 2013, pp. 11–17 (in Japanese)

Marcelo de Alcantara, 2011. *International Surrogacy: Legal Parentage Without Borders?*, *LEX MEDICINAE – REVISTA PORTUGUESA DE DIREITO DA SAÚDE*, 16, Coimbra, pp. 99–105 (in Portuguese)