

人の生殖補助医療と法制度

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わが国における非配偶者間人工授精児の初めての誕生は1949年のことで、既に半世紀が過ぎた。この間生殖補助医療はめざましい進歩を示したが、法制面においては、日本産科婦人科学会の自主規制ともいべき会告はあるものの、法律としての整備はなんなされてこなかった。学会、科学技術庁、文部省などによる幾度かの討論はきわだつた進展を示すものとはならなかった。厚生省は1997年に「厚生科学審議会先端医療技術評価部会」を、翌年10月にはそのワーキング・グループの一つに「生殖補助医療技術専門委員会」を発足させ、法的、社会的、倫理的の各角度から問題の所在とその対応の策定を行った。2000年12月には報告書が出され、現在法制化が検討されているところである。本報告はわが国における生殖補助医療の現況を伝えると共に近い将来における法制化への道すじを求めるものである。

In Japan, the first birth as a result of artificial insemination with donor sperm (abbreviated below as AID) was in August 1949.¹ There have been numerous developments in the half century since. In 1983 the media reported the birth of the first in-vitro fertilisation (IVF) baby.² In 1986 selective reduction of a multiple pregnancy was carried out.³ In 1989, a child was born following a frozen embryo transfer.⁴ In 1991, a Japanese couple registered a child born by surrogacy in the US as their legitimate child.⁵ 1992 witnessed the first child to be born as a result of microscopic fertilisation.⁶

Despite such rapid change in the field of human reproduction due to medical progress, legal change has been slow. There is still no legislation in Japan regarding this topic other than the official medical guidelines for Assisted Reproduction (AR) as laid down by the Japan Society of Obstetrics and Gynecology (JSOG). It took half a century (until 1997) for JSOG Guidelines to approve AID.⁷ More than 10,000 AID children were born

before any guidelines existed.⁸ Indeed, JSOG finally approved IVF and Embryo Transfer (ET) in 1983, because only married couples' gametes can be used.

The first symposium by the Society of Private Law took place in 1956 and included a debate on the question of parentage, but no agreement was reached.⁹ Conferences held by the Committee of the Science and Technology Agency involving research associations have failed to provide opportunities for drafting legislation although the necessity to do so has been pointed out.¹⁰ A working party on the Research Project of the Department of Education published its recommendations for legislation in 1994.¹¹

In the light of this situation, in 1997 the Department of Health (now Department of Health and Labour) set up the Assessment Subcommittee for Advanced Medical Care of the Health Science Council, and established two special committees on assisted reproductive technology and on preimplantation genetic diagnosis in 1998. These working groups are gathering opinions by analysing the feedback from questionnaires sent out by email or mail.¹² In December 2000, the Special Committee on Medical Technology for Reproductive Treatment (SCMTRT) published its report.

I shall report on the current legal situation in Japan concerning Assisted Reproductive Technology (ART), under two main headings :

1. The early legal environment surrounding the introduction of AID
2. The present state of AR as regards
 - 2.1. Technology
 - 2.2. The current legal environment
 - 2.2.1. Outlines
 - 2.2.2. IVF
 - 2.2.3. Surrogacy
 - 2.2.4. Preimplantation genetic diagnoses (PGD)
 - 2.2.5. Research
 - 2.2.6. Rights of the child to know his/her identity.
3. Future prospects for legislation on human fertilisation and embryology

4. Appendix 1 : Tables

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1. The early legal environment surrounding the introduction of AID

It is widely known that the first artificial insemination in the world was done by John Hunter (1728-1793) in the UK, although it was reported by Hame after his death.¹³ In Japan, the first reported AI experiment was conducted in 1907,¹⁴ and the next was in the 1920s, but it was not successful.¹⁵ Prof. Kakuichi Ando (then of Keio Univ.) knew of the technique from documentary records in the US. His team practised the treatment in 1948, and the first AID child was born in Japan in 1949. Before the treatment, Prof. Ando conducted consultations on the legal problems between the father and child with Prof. Ryuichi Koike (then of Keio Univ. Dept. of Civil Law). They studied jointly, and concluded that Sec.772 (1) of the Civil Law (Presumption of legitimacy), implies that if the wife gives birth to a child, her husband is presumed to be the child's father. This means if a wife is inseminated artificially with sperm donated by a man not her husband but with his consent, the husband is treated as if he were the natural father of the child. According to Japanese Civil Law, a father can deny the presumption of fatherhood (Sec.774 above) within one year after knowing of the child's birth (Sec.777 above).

In 1956, a symposium on AID took place. Thus far there had been 150 instances of AID, resulting in 52 pregnancies and 24 successful births in Keio Univ. Hospital under the following conditions:¹⁶

- with the consent of both parents
- with anonymous donors
- screening of potential donors for genetic impairment.

Prof. Ando's team used donor sperm mixed from several donors in order to maintain the secrecy of the child's identity. The debate at the symposium was unable to reach an agreement on a new legal definition of parenthood.

2. The present state of AR

2.1. Technology

The progress of modern medicine has led to the development of various techniques to detect, treat and cure serious illnesses. Some illnesses which were considered incurable are now curable. Infertility treatment which was impossible before, is now possible. However, the media have reported that the number of instances of AID has been on the decrease the last few years (see Table 1). One of the reasons is the progress of infertility treatment technology (see Table 2).

2.2. Legal environment

2.2.1. Outline

The number of children reportedly born by AID in Japan since 1949 is over 10,000.¹⁷ The father of an AID-born child is taken to be the husband of his or her mother under Sec.772 (1) of the Civil Code. About half a century has passed since the first AID child was born, but Japan has no statute concerning AID. Unlike Europe and the US, no statute has yet been enacted regarding either AID or AR (see Table 3). JSOG is gradually making guidelines public (kaikoku). AID Guidelines were announced in 1997. These lack weight, however, because the only penalty they provide for is the formal removal of a physician who disregards them, and no matter why the physician is removed by the JSOG, he can continue to act as a physician as long as he or she has a license. Only the Department of Health Minister can revoke licenses (Medical Law Sec.7).

To give an example, in Japan, the JSOG IVF Guidelines prohibit the use of donated gametes. So, as mentioned above, IVF is limited to married couples. In June 1998, the JSOG ordered the removal of a Dr Netsu because he had been practising IVF using the eggs of patients' sisters or the sperm of patients' brothers thus flouting the JSOG's guidelines.¹⁸ However, no legal proceedings resulted.

For half a century, no lawsuit has been instituted in the matter of AI. However, in December 1998, the Osaka district court issued a judgement denying legitimacy to an AID child because of the absence of the husband's

consent.¹⁹

The reasons why there are few disputes over legitimacy are as follows.

- Parents register the AID-born child as their legitimate child, and they withhold the truth from the child.

In Japan, in the case of adoption, the parents tend not to tell the truth to adopted children, and traditionally bring up them as their birth children.

After the children grow up, sometimes they find out the truth by looking at the family register. But it is very rare for matters to progress to a lawsuit

- In Japan, the concept of self-determination is gradually widening, but traditionally the individual was inseparable from the community, although the concept of responsibility has existed since the dawn of Japanese history.

- In Japan, the primary unit of social organization was the household (*ie*).

In 1947, after World War 2, the new Civil Code gave equality to family members. Despite the decline of the household system, the basic concept has survived as a basic structure of modern Japanese society.

In April 1996, a mail-order firm began to enlist sperm donors by e-mail. After 2 months, the media reported that nobody had bought the mail-order sperm but 42 applicants wishing to sell their sperm were registered. There are no statutes to regulate this activity.²⁰ In addition, public opinion is still against all forms of ART (see Table 4).

2.2.2. IVF

The first IVF child was born in Japan in October 1983, 5 years after the first IVF birth in the UK. Seventy-four per cent of registered clinics now practise IVF or ET (See Table 5). The JSOG decided to recommend to all its members a set of guidelines on IVF and ET in June 1983, and these were published that October.

They include:²¹ - only cases where there is no other way to conceive are legitimate for IVF

- written consent of well-informed client couple required
- genetic manipulation prohibited
- clients' privacy to be respected.

As the JSOG prohibits the practice of IVF with donor gametes, the parents are the genetic parents. Therefore Sec.772 applies to the relationship between parents and child, and it can be argued that the husband's consent for IVF includes recognition of the child's legitimacy. However it is foreseeable that the pre-sumption of legitimacy in Sec.772(1) of the Civil Code will not apply to IVF with donor gametes. In this event, anyone can deny the parentage by lawsuit at anytime.²² It should also be pointed out that since the present Civil Code did not anticipate donated gametes, the concept of motherhood may also become unclear. So, if we recognise IVF by donor gametes, we should reach a legal definition of both 'father' and 'mother' through debate.

2.2.3. Surrogacy

The JSOG does not recognise surrogacy. However, the media have reported:²³

- A Japanese obstetrician has sent the frozen fertilised egg of an infertile married couple to the US by air mail in order to transfer it to an American woman for surrogacy.
- Japanese obstetricians have introduced their clients to sources in the US and Korea to get IVF treatment using donor gametes.
- Agencies mediated in the case of a Japanese married couple seeking to have a child by a surrogate mother in the US.
- Japanese buy sperm from the US through the internet.
- Surrogacy in the US costs 10 million yen (about \$83,000 at \$1=120yen, { £52,000 at £1=190yen).

IVF using a donor egg in the US costs 5 million yen. These fees include the agent's mediation charge, the physician's treatment fee and payment to donors. (See Table 6 for procedure.) The JSOG guidelines cover only members of JSOG, and not treatment abroad.

In Japan, there is neither legislation nor social consensus on IVF/with donated gametes and surrogacy. But more than a hundred couples have had a child by surrogacy in the US, and registered it as their natural child.²⁴ Public opinion, and even couples who want children, are strongly against surrogacy with donated gametes, although surrogacy using the couple's own embryo is more acceptable (see Table 7).

2.2.4. Preimplantation Genetic Diagnosis (PGD)

The JSOG announced guidelines on the diagnosis of congenital disability in an unborn child, particularly chorionic villi sampling, in 1988. The guidelines discuss informed consent and counseling at the time of amniocentesis, chorionic villi sampling, fetoscopy, fetal blood-gathering and ultrasonic diagnosis. The fetus sex should not be disclosed except in the case of x-linked hereditary disease. Opinions for and against the matter are laid out, because the fetus may be aborted as a result of this diagnosis.²⁵

In 1998, the JSOG announced guidelines related to PGD, summarised as follows.²⁶

- The clinical facility must be a clinic that has a IVF/ET-related maternity facility, and has the technology and competence suitable for PGD.
- The purpose of PGD is only to diagnose serious hereditary disease. It is the JSOG which decides if the disease in question is amenable to PGD.
- It is necessary to receive permission from the JSOG to practice PGD. Before applying to the JSOG, permission from the Ethical Committee of the clinical facility in question must be received. The clinical facility must report its findings to the JSOG.
- PGD is approved only where there is consent and a strong request from a married couple. Their written, well-informed consent should be respected.
- Privacy of the couple and the resultant child should be maintained.

A list of diseases which PGD may be used to diagnose is given in Table 8.

The Chairman of the Special Committee on PGD announced to the media in March 1999,²⁷ that clinics should refrain from activity publicizing PGD to avoid a demand for mass-screening to find fetal disease and to avoid giving mental uneasiness to pregnant women.

2.2.5. Research

The JSOG pronounced guidelines regarding research involving gametes and embryos in 1985.²⁸ These include:

- Use of gametes and embryos needs donors' consent.
- Use of frozen embryo is permissible only within 2 weeks of insemination.
- Research should be supervised by a medical doctor.

In 1987, the JSOG announced guidelines on research involving the use of organs of dead fetuses and dead neonates. Researchers should also adhere to the Anatomical Act of 1949.²⁹

2.2.6. Rights of children to know their identity

In Japan, the right of AI children to know their identity has not been legalised and no case has been brought before the court. Most children born of AI are not aware of it. But even if they knew the truth, few would bring the matter before a court. The reasons, I feel, are as follows :

- As mentioned before, the concept of the *ie*,³⁰ household, persists in Japanese society.
- Modern Japanese society seems to be contract-based. But once we make a contract with others, the relation between the parties turns out to be subject to the social concept of *giri*,³¹ the obligation to act according to a particular social relationship.
- The concepts of *on* and *kou* also influence behavior. *On*³² is to return a favor and *kou*³³ is filial piety.

Although these concepts have become outmoded in modern Japanese society, they still affect conduct.

The survey by the Committee for Advanced Medical Technology

Assessment shows that 35.8% of Japanese do not support informing children of their identity (see Table 9). In my opinion, a person eighteen years old should be able to request the related body (e.g. family court or judicial committee) for information regarding their identity to prevent the danger of consanguineous marriage.

3. Conclusion : Future prospects for legalisation of human fertilisation and embryology

Basically, I am opposed to conduct which goes against the dispensation of nature. However, developments in modern medicine have made possible what was impossible before. At the same time, many infertile couples want to have children. It is natural that medicine should assist their efforts to reproduce. But it is very difficult to fix the boundary between assistance and creation. We therefore need to debate the problem in order to reach a consensus.

In summary, half a century has passed since the first AI child was born from donor sperm in Japan. However, since IVF with a donor's egg is not recognised by the JSOG, Japanese couples have sought IVF treatment in the US or Korea. The procedure to extract eggs used to entail a small risk, but as technology has developed, the risk has decreased. The IVF mother gives birth to a child herself. IVF with a donor egg should therefore be recognised because AI is recognised. In the case of IVF with both gametes, there is a need for debate. However as adoption is recognised, this should also be recognised. The status of children should be legalised out of respect for their welfare. The SCMTRT Report recognizes IVF donated gametes and embryos.³⁴

Surrogacy is also prohibited in Japan, although more than a hundred Japanese couples have had a surrogate child in the US or Korea. However, it has been reported that a baby was born by the wife's sister who volunteered to be the surrogate mother.³⁵ We should legalise matters in order to be able to deal with such cases, not only to protect the rights of

the child but to ensure that the surrogacy progresses appropriately, given that there is no relevant procedural legislation. We have a Children's Act, but it includes no provisions for unborn children. The only act to protect unborn children is the Mother's Body Protection Act 1997, which is an amendment of the Eugenic Protection Act 1948, which regulated conditions for abortion. Prima facie, a viable fetus is not expected to be born within 22 weeks of conception. The Mothers' Body Protection Act legalises abortion during this period. The specific term (now within 22 weeks) is to be confirmed in a notice appended by the Department of Health and Labour.³⁶

Japan ratified the Convention on the Rights of the Child in 1994.³⁷ We should debate this not only from the aspect of ART and women's rights, but also considering the welfare of the child. Sec. 33 of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) gives us a signatory power.³⁸ As mentioned above, the Japanese government has just begun preliminary investigations into setting up committees and working groups.

On the question of child legitimacy, the US prepared the Uniform Parentage Act in 1973, while Sweden added to this body of legislation with its Parentage Act (sec. 6) in 1985, and the UK with the Family Law Reform Act (Sec. 27) in 1987. As stated above, there is as yet no legislation in Japan to regulate legitimacy.

In conclusion, in my view, matters should be put on a legalised basis in Japan by establishing a body such as the U. K. Human Fertilisation and Embryology Authority to supervise human artificial insemination and research in this field.

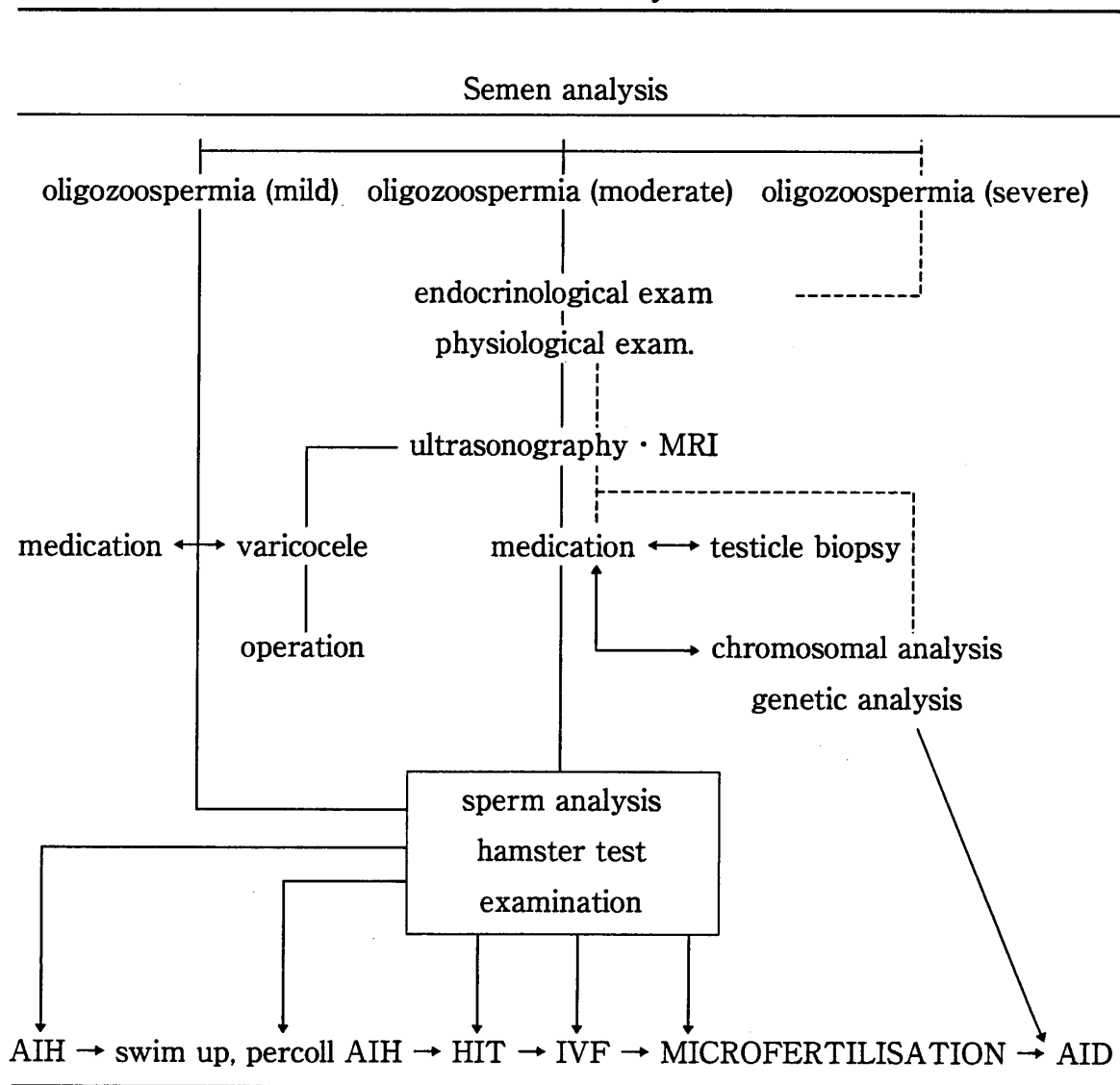
Appendix 1: Tables

Table 1 Cases of AID (Jan. 1995-July 1998)

| | |
|------|-------------------------|
| 1995 | 2324 |
| 1996 | 2065 |
| 1997 | 1673 (1079 to end July) |
| 1998 | (925 to end July) |

Source: Asahi Newspaper, Aug. 15, 1998, ed. 13, p. 3

Table 2 Male Infertility



Source: K. Sueoka, Y. Yoshimura, 'Seishokuhojoiryō no Tekiyo to Youshi' in Y. Taketani, et al. *Seishokuhojoiryō*, Nakayama Shoten Ltd. 1999, p. 53.

Table 3 Comparative legal environment for ART

| | AID | IVF(donated gamete) | SURROGACY | ACT |
|---------|-----|---------------------|-------------|--------------------------------|
| France | ○ | MorF | × | Loi n. 94 - 654 (1994) |
| Germany | ○ | × | × | ESchG (1990) |
| Sweden | ○ | × | × | Lag om I (1984), om BUK (1988) |
| UK | ○ | M&F | voluntary | HFE ACT (1990) |
| US | ○ | M&F | some States | Uniform Act (1973), (1988) |
| Japan | ○ | × | × | Guidelines of JSOG |

Table 4 % Japanese in favour / against ART

| | should not use even if spouse wants | may use if spouse agrees | no objection |
|----------------------|---|--------------------------------|--------------|
| AID | 71.6% | 25.0 | 3.4 |
| IVF/donor's sperm | 74.4 | 22.6 | 3.0 |
| IVF/donor's egg | 70.1 | 26.8 | 3.1 |
| ET/donor's embryo | 82.8 | 15.1 | 2.1 |
| SURROGACY | 82.4 | 15.4 | 2.3 |
| SURROGACY/own embryo | 68.8 | 26.1 | 5.1 |

Source: the Committee for Advanced Medical Technology Assessment, 7 May 1999

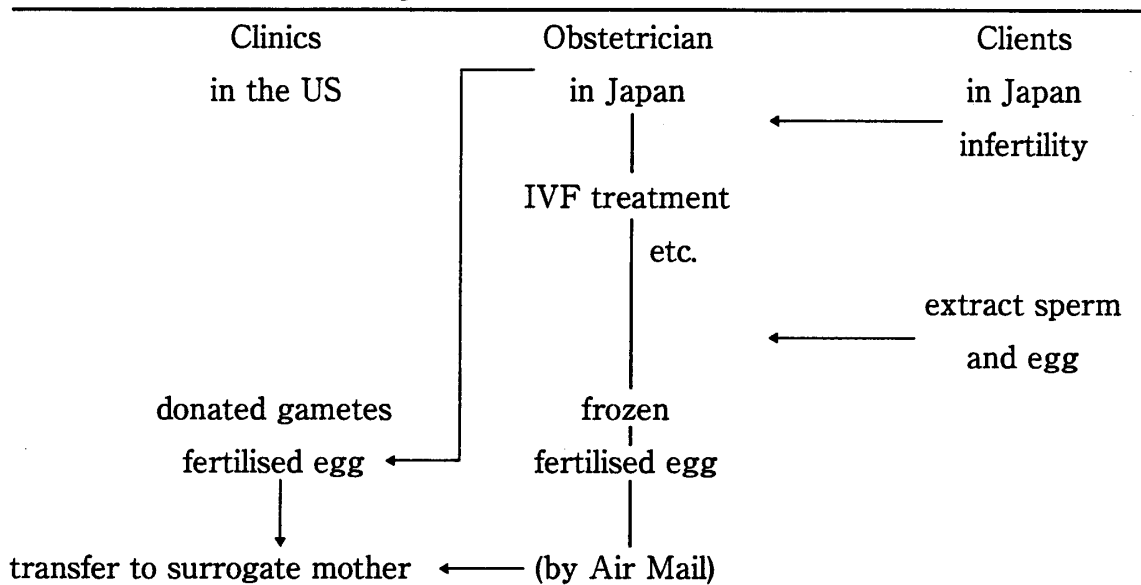
Table 5 Breakdown of registered clinics practising IVF/ ET in Japan

| | |
|----------------------------------|-----------|
| Registered clinics | 348 |
| Number of practicing clinics | 257 (74%) |
| Number of non-practicing clinics | 48 (14%) |
| No answer | 43 (12%) |

Source : Health Department Consultation Document 1998

<http://www.mhw.go.jp/topic/seisyoku/tp0114-1.html>

Table 6 Procedure for Japanese ART in the US or Korea



Source: Asahi Newspaper, 25 Oct. 1998, p.1

Table 7 Comparison of general v. client views on surrogacy in Japan

| | should not even if spouse wants (%) | | acceptable if spouse wants (%) | | acceptable (%) | |
|----------------|-------------------------------------|---------|--------------------------------|---------|----------------|---------|
| | public | clients | public | clients | public | clients |
| donated gamete | 82.4 | 84.7 | 15.4 | 13.8 | 2.3 | 1.5 |
| own embryo | 68.8 | 70.3 | 26.1 | 26.3 | 5.1 | 3.4 |

Source: Committee for Advanced Medical Technology Assessment, 7 May 1999

Table 8 Diseases which PGD may technically diagnose

| X-linked hereditary diseases | Single gene diseases |
|--|--|
| *Duchenne muscular dystrophy | *cystic fibrosis (only Δ F508 allele) |
| *hemophilia A | *Lesch-Nyhan syndrome |
| *Lesch-Nyhan syndrome | (a part of mutation of HPRT) |
| *fragile X syndrome | *Duchenne muscular dystrophy |
| *X-linked mental retardation | (only a case of deletion) |
| *Wiskott Aldrich syndrome | *Tay-Sachs syndrome |
| *adrenoleukodystrophy | *hemophilia A |
| *hypogammaglobulinemia | * α -1-antitrypsin deficiency |
| *X-linked spastic paraplegia | retinitis pigmentosa |
| *sensory motor neuron disease, type II | *fragile X syndrome |
| * α methyl thalassemia | *Marfan syndrome |
| | * β -globin defect |
| | *adenomatous polyposis coli |

Source : K. Sueoka, Y. Yoshioka, 'Seishokuhojoiryō no Tekiyō to Yoyaku' in
Y.Taketani et al, *Seishokuhojoiryō* Nakayama Shoten Ltd, 1999, p.60.

Table 9 Japanese views on the right to know identity

| | % |
|--|------|
| Children have the right to know their identity | |
| anytime | 19.8 |
| after growing up | 14.3 |
| at the marital age | 9.1 |
| Children should not know their identity | 35.8 |
| Donated gametes technology should not be used | 6.7 |
| Other | 13.7 |

Source: Committee for Advanced Medical Technology Assessment, 7 May 1999

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