Regulating Reproductive Technology in Hong Kong

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Submitted January 21, 2003; accepted April 2, 2003

INTRODUCTION

In Hong Kong, donor insemination service was first established in 1981 and the first baby conceived after in vitro fertilization (IVF) treatment was born in 1986. In light of these developments in RT, the Secretary for Health and Welfare in 1987 set up a multidisciplinary Committee on the Scientifically Assisted Human Reproduction to advise Government on the social, moral, ethical, and legal issues arising from RT. The general consensus of the Committee was that RT should be regulated through a licensing system and the establishment of a statutory council. In 1995, the Secretary for Health and Welfare appointed a Provisional Council on RT to advise on the regulatory framework for RT and to draw up a code of practice. The Provisional Council was a multidisciplinary body comprising 21 nonofficial members (including medical practitioners, social workers, lawyers, theologians, sociologists, nurses, and others) and government representatives. The Human Reproductive Technology Bill was first introduced into the Legislative Council in January 1997. Important constitutional issues during the 1997 handover meant that it could not be enacted. The Bill was reintroduced into the Legislative Council in September 1998 and it was enacted on June 29, 2000 (1). The Code was recently published on December 30, 2002 (2).

This paper aims to give an overview of the legal regulation of RT in Hong Kong, which is predominantly Chinese society. In the next section, how RT is slowly accepted by Hong Kong people despite the traditional values on family and blood tie will be first described. This will be followed by an overview of the Ordinance and the Code. This paper concludes with some areas of concerns highlighted in the regulatory regime.

CHINESE VALUES ON FAMILY AND BLOOD TIE

In Hong Kong, traditional values of children, marriage, and family are still regarded as important to many people. Traditional Chinese culture emphasizes the importance of having many children and continuation of a male's family line.

A family with many children has been highly valued in Chinese culture. This can be seen in the concept of family, the Chinese word "jia." The Chinese calligraphy of family "家" means a pig under a roof. Thus an ideal family should bear many children like pigs do. This word does not only correspond to the English word "family," but to a kind of extended family with two to three generations, based on the nuclear family (3). The preferred mode is to have five generations living together and under one roof. In societies upholding a strong belief of intergenerational family. Therefore, married couples bear heavy social and moral responsibilities to produce new members to extend the family tree.

Blood relationship ties family members together. Relatedness is created through blood and marriage (4). Traditional Chinese culture emphasized the importance of men sowing the seed for his family to

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extend the family tree. A Chinese proverb says, "there are three unfilial sins against which a man may commit and to die without a male issue is the greatest sin of all" (5). Consequently, having a son to continue the blood line is the most important function of marriage. Indeed, the failure of a wife to give birth to a son was a ground for the husband to unilaterally divorce the wife under customary Chinese law (6).

Today, the importance of either having many children or a male issue is probably overshadowed by a couple's desire to have at least a child (male or female). As such, *childlessness* means an incomplete or less than perfect family. Whether imposed by in-law parents, friends, or themselves, infertile couples feel much pressure with respect to their family responsibility. With the decreasing emphasis on blood ties, infertile couples are open to the idea of adoption. RT procedure offers an advantage to adoption in that the resulting child may be genetically related to both husband and wife or at least one of them. As will be seen below, the Ordinance and the Code allow the use of donated gametes where necessary.

HUMAN REPRODUCTIVE TECHNOLOGIES ORDINANCE (ORDINANCE)

The Ordinance is divided into five main parts: establishment of Council on Human Reproductive Technology, prohibitions, licenses, access to information, and enforcement and offences. They will be outlined briefly.

Establishment of Council on Human Reproductive Technology (Council)

The Council is tasked to (a) keep under review information developments concerning various aspects on RT; (b) publish lists of premises at which RT are carried out; (c) publish statistics and summaries concerning RT; (d) provide information for actual and potential service providers and patients; (e) promote informed public debate on the medical, social, moral, ethical, and legal issues arising from RT; (f) liaise and cooperate with counterpart outside Hong Kong on current developments; and (g) prepare and maintain a code of practice giving guidance about the proper conduct of any RT to a license holder. The Council has since established three committees on ethics, inspection, and investigation, and two working groups on code of practice and new developments in RT.

The functions of the Ethics committee are to seek the views of the public on any of the social, moral, ethical, and legal issues that arise from RT, to provide advice to the Council on any of those issues, and to liaise and cooperate with any other committee. The Inspection committee conducts inspections of premises for the purposes of deciding whether to grant a license and to make recommendation to the Council on the granting of a license. The roles of the Investigation committee are to investigate into any matter concerning revocation or temporary suspension of a license. The Council may carry out research into the social consequences of RT and promote research into the cause of human infertility. This means that the legislature recognizes the unique role the Council plays in both understanding the social implications of RT and pursuing medical advances and scientific development.

Prohibitions

Apart from using licensing as a regulatory framework, the Ordinance also prohibits certain RT activities including embryo, the keep and use of fetal ovarian and fetal testicular tissue for RT, sex selection, eligibility of treatment and commercial activity relating to fetal ovarian tissue, fetal testicular tissue, and surrogacy.

The following activities involving the creation of embryo as well as its manipulation outside the uterus are prohibited: (a) the creation of embryos for embryo research or the combining of human and nonhuman gametes or embryos or any part thereof such as to give rise to a two-cell zygote; (b) the keeping or using of an embryo beyond the 14 days; (c) the placing of nonhuman gametes or embryo in any human or vice versa; (d) the replacing of the nucleus of a cell of an embryo with a nucleus taken from any other cell; and (e) cloning any embryo.

Sex selection, whether directly or indirectly, is now prohibited unless it is done for the purpose of avoiding "a sex-linked genetic disease" which may prejudice the health of the embryo. At least two registered medical practitioners have to state in writing that such selection is for that purpose and such disease would be sufficiently severe to a person suffering it to justify such selection. Therefore, sex selection by preimplantation genetic diagnosis for social reasons is definitely prohibited. Sperm sorting as a gender selection technique is arguably caught by the prohibition. However, as the technique involves merely increasing the chance any embryo formed to be of a particular sex,

it remains to be considered how far the chance has to be tipped in favor of a particular outcome could it be said to amount to "causing the sex of an embryo to be selected, whether directly or indirectly."

On eligibility of treatment, the Ordinance stipulates that no person may provide RT to persons who are not parties to a marriage. This aims to prohibit the placing of gametes or embryo into the body of a woman who were no longer a party to a marriage but it does not prohibit the continuation of an RT when gametes or embryo was placed at the time when she was a party to a marriage. There are exceptions to this general prohibition: the provision of RT to an unmarried surrogate mother and the obtaining of gametes from an unmarried person, e.g., for storage.

The Ordinance prohibits commercial dealing in gamete, embryo, fetal ovarian or fetal testicular tissue for the purposes of supplying them for RT, embryo research, or surrogacy arrangement. However payment here excludes the cost of removing, transporting or storing an embryo or gamete to be supplied, and any expenses or loss of earning incurred by a donor. It also prohibits surrogacy arrangements on commercial basis. Thus, it prohibits a person from receiving payment for initiating negotiation with a view to the making of a surrogacy arrangement. This however does not prohibit a woman from agreeing to be a surrogate with a commissioning couple. Indeed, a surrogate may be reimbursed for any expenses incurred for any RT plus medical expenses arising from pregnancy and delivery of a child. But she may not be reimbursed for any loss of income arising from acting as a surrogate. The publication or distribution of an advertisement relating to surrogacy arrangement is not allowed. A surrogacy agreement remains unenforceable. To avoid complicated emotional and parentage issues, the use of gametes other than that of the commissioning couples for purposes of a surrogacy arrangement is not permitted.

Licenses

As mentioned earlier, no person shall carry out RT without a license. An applicant, an individual or a company, may apply to the Council for a license to carry on a relevant activity. "Relevant activity" is defined as "the provision of a RT procedure; the conducting of embryo research or the handling, storing or disposing of a gamete or embryo used or intended to be used in connection with a RT procedure or embryo research." But a license will not be granted unless the Council is satisfied that the relevant

activity will be conducted under the supervision of a person responsible (PR), who has the prescribed qualification, the character and the experience are required for the supervision of the relevant activity. In general, a license is valid for 3 years or such lesser period as specified in the license. Where the Council has reasonable grounds to suspect that there are grounds for revoking a license and is of the opinion that it should immediately be suspended, it may by notice suspend the license for a period not exceeding 6 months.

The Council may revoke a license if it is satisfied that information given in an application was in any material respect false or misleading; the premises to which the license relates are no longer suitable for the relevant activity; the PR has failed to discharge or is unable to discharge the duty and there has been material change of circumstances. Any person aggrieved by a decision to suspend, refuse to grant, or vary a license may appeal to the Administrative Appeals Board.

Access to Information

The Council is to keep and maintain a Register A containing information on the provisions of RT involving the use of donated gametes or donated embryos. An offspring of RT may on reaching age of 16 (an applicant) request the Council to give a notice stating whether or not the information contained in Register A shows that the applicant has an unknown parent. This information confirms that the applicant was conceived as a result of RT using donor gametes and shows whether the person whom the applicant proposes to marry might be related.

This provision, unlike its counterpart in the United Kingdom's Human Fertilization and Embryology Act 1991, covers situation where information shows that the applicant was or may have been conceived as a result of donor gametes. Further, the Council may not give any identifying information on the donor, but what kind of information will be given is still a matter to be decided. The current practice appears that couples may not report successful pregnancies or birth resulting from RT or those who actually do report may choose not to tell their offspring. Thus although the purpose of the provision was intended to balance the interest of resultant children with that of secrecy desired by the couple and donor, its usefulness depends on the degree of openness the parties to RT bring with them.

Enforcement and Offences

A member of the Council or of a committee or a designated public officer has powers to enter licensed premises and take possession of anything which he has reasonable grounds to believe may be required for the purposes of the Council's licensing function or being used in evidence for an offence. It is an offence for a person to be involved in prohibited activities. However, two defences are available. It is a defence for a person charged with an offence for doing a thing which is prohibited except pursuant to a license to show that the defendant was acting under the direction of another and he reasonably believed that the other person was at the material time the PR and that he was authorized by virtue of license or directions to do that thing. It is also a defence for a defendant to show that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.

CODE OF PRACTICE ON RT AND EMBRYO RESEARCH (CODE)

The Code sets minimal standards, which aim to support best clinical and scientific practice, to safeguard the health and interests of service users, and to protect the welfare of children born through RT. Although the Code is not legally binding, the Council as the licensing authority for RT services and embryo research shall take into account any observance of or failure to observe the provisions of the Code when considering granting, renewal, variation, revocation or suspension of licenses. The Code will be reviewed and updated as necessary to keep up with the development in RT.

The Code covers the following areas: staff, facilities, and equipment in RT centers; assessment of clients, donors, and welfare of the children born through RT; information and counseling to clients and donors; consent, treatment method; use, storage, and disposal of gametes and embryos; research; surrogacy; gender selection to avoid sex-linked diseases; record keeping and information management, and handling of complaints. Several areas will be highlighted here.

Counseling

It is stated that counseling must be provided to all clients and donors by doctors, nurses, social workers, or clinical psychologists of the RT center as appropriate. The counseling should be independent of

the clinical decision-making process and provided by someone other than the clinician responsible for the treatment or donation. Nondirectional counseling on the implications of the RT procedure and consideration of other options must be offered to clients and donors before they consent to RT procedures.

Use, Storage, and Disposal of Gametes and Embryos

Normally, no more than three oocytes or embryos should be placed in a woman in any one cycle. Under special circumstances with medical justifications, the limit of three oocytes or embryos may be relaxed for patients above the age of 34 so that a maximum of four or five oocytes or embryos could be replaced in the cycle. However, such justification must be recorded in the medical record.

Gametes or embryos from any single donor should not be used to produce more than three "successful pregnancies." RT centers are required to inform the Council within 1 week of the date when a donor's gametes are used. If it is reported that a donor's gametes have been used for treatment for three times, centers will be informed to cease using the gametes of this particular donor for any further treatment. A successful outcome will be assumed after use of a donor's gametes for treatment has been reported unless the Council is informed otherwise. The donor can specify a limit lower than three pregnancies; this must be observed if practicable.

The maximum storage period for gametes or embryos stored for patients' own treatment should not exceed 10 years. RT centers may formulate their own policy for a maximum storage period less than 10 years. The maximum storage period for gametes for cancer patients for medical reasons is until that patient is 55 years old or for 10 years while the maximum storage period for embryos for cancer patients for medical reasons is also 10 years. However, the patient can specify an age limit lower than 55 or a maximum period shorter than 10 years.

A couple should have joint authority to determine what is to be done to the embryos created from their gametes. Their conjoint decision should be obtained in the consent form before collection of gametes and fertilization. They are informed that the service provider would be allowed to dispose of the stored embryos if the patient divorces or becomes legally separated. Stored gametes or embryos are not used to bring about a posthumous child, given the complexities and potential consequences of posthumous use of gametes or embryos.

Research

Prohibitions in connection with embryo research have been described above. Therefore, no person shall bring about the creation of a human embryo for the purpose of research. Researches involving alteration of the genetic structure of gametes or embryos may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants. Germ-line gene therapy should not be performed.

Record Keeping and Information Management

RT centers are required to send clinical information of every treatment cycle (whether involving or not involving donated gametes or embryos) to the Council. Pregnancy outcomes including congenital abnormalities are supplied later when available. Annual statistics of the RT centers should be submitted to the Council as well.

CONCLUDING OBSERVATIONS

The Ordinance Lags Behind Medical Advances

At the time of writing this paper, the Ordinance is not in force, except the part on the establishment of the Council. The reason is that the mechanism for licensing is yet to be established and it is envisaged that such a system will be in place by 2004. In the meantime, the Code is available for voluntary compliance. As regards the legal status of children born as a result of RT, this is now protected by the Parent and Child Ordinance (6). The reasons why the legislative process takes such a long time to complete are as follows.

- (a) RT procedures involve complex legal, social, and ethical implications, time is required to appreciate such implications and identify a solution most appropriate to the local culture.
- (b) Relevant professional bodies and the public need to be consulted.
- (c) Policy issues need to be decided before law drafting may begin. The then Provisional Council was, and now the Council are, charged with the responsibility of deciding these policy issues. Few members of both the Provincial Council and Council were full-time staff working on these policy issues.

It is already evident that science is progressing too rapidly for the Ordinance. For instance, both the

Ordinance and the Code are silent on the Dolly technique, which has implications both the reproductive and therapeutic cloning.

Given of the long time required to legislate, and presumably an equally long time to amend the Ordinance, it may be better for the Ordinance to lay down broad principles and regulatory framework. The actual practice and research can be regulated by the Code to be issued by the Council. The advantage of this approach is that the Code may be amended from time to time to cater for any new developments.

The Need to Allow Greater Flexibility on Research and Development

As mentioned previously, the Ordinance prohibits the creation of a human embryo for the purpose of research. There is concern amongst researchers that such prohibition will hinder research. Two points may be noted, first, as the supply of spare embryos donated for research is very limited, limited embryo research may be conducted in Hong Kong. Second, under the Code, the Council may grant licenses for embryo research if the research promotes advances in treatment of infertility. Although freezing ovarian tissue is a promising way to salvage the ovarian function in cancer patients prior to chemotherapy or radiotherapy, but the current cryopreservation protocols are still experimental. The effects of these cryopreservation protocols on subsequent embryo development must be studied and understood before it is used on patients as treatment. However, the prohibition on embryo creation for research purpose means that both the fertilizability of oocytes obtained from experimental cryopreservation protocols and the developmental potential of the embryos derived from these oocytes cannot be assessed in vitro. Consequently, cancer patients requiring this infertility treatment have to either wait for an established protocol developed elsewhere or accept clinical trial by way of the transfer of embryos obtained from experimental cryopreservation protocols. The former only means that Hong Kong research will lag behind other countries which has more liberal law governing research on embryo and the latter is far from acceptable from a clinical point of view, and arguably, ethically unacceptable.

It is also important to distinguish academic research from clinical trials for therapeutic purpose. An example in the Ordinance where academic research may be hindered is the prohibition of putting human gametes into an animal. The intention is probably to stop the replacement of gametes/embryos generated

from animals for replacement into humans as a form of RT procedure. Study of human gametogenesis is of great academic interest but is difficult to carry out in human for obvious ethical reasons. In vitro culture system disrupts the interaction of different cell types within the gonad making in vitro gametogenesis from primordial germ cells impossible at the moment. One way to study this important physiological event is to culture human gonadal tissue in immunodeficient animals. The information obtained could be used to design a diagnostic procedure and even a therapeutic procedure for the patient without involving the other partner of the couple.

Scientific research in Hong Kong may be hindered because of the conservative attitude of the public and restrictive nature of the Ordinance. It is important for the scientific community to educate the public on the nature and advantages of the research and scientific development. Such education, if successful, can allay unnecessarily fear on the part of the public, and hopefully, pave way for the progress of research and scientific development.

Public Education

Public knowledge and awareness of RT, its policies, regulations, and ethical considerations as well as the

legal issues are currently low. This may also lead to unnecessary delays in seeking appropriate support and services. Under the Ordinance, the Council is charged with the responsibility of providing information about RT and promoting by the dissemination of information to inform public debate on the medical, social, moral, ethical, and legal issues arising from RT. It is hoped that the Council together with other interested parties will bring about great public as well as patients awareness of RT-related issues.

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