Year	98/99
Meeting	BC144-02
Date	14.10.98
File Name	P416C4
Pages	Scan 30

Consultation Paper

on the Draft Reproductive Technology Bill

Consultation Paper
on the Draft Reproductive Technology Bill

INTRODUCTION

This consultation paper invites views from the public on certain issues arising from the Reproductive Technology Bill now being drafted.

BACKGROUND

2. Reproductive Technology (RT), formerly known as scientifically assisted human reproduction (SAHR), refers to technology and medical treatment directed at assisting human conception by artificial means.

3. In 1987, Government appointed a Committee on SAHR to consider the social, moral, ethical and legal issues arising from local developments in SAHR, to assess the public's reaction towards them, and to advise Government on how these issues should be addressed. Subsequently, the Committee published two reports -- an Interim Report in 1989 and a Final Report in 1993, each followed by a public consultation exercise.

4. In brief, the two consultations indicated public support for statutory regulation of RT through a licensing system and the establishment of a statutory Council.

5. Taking into account the Committee's recommendations and public views, Government put together a package of proposals to regulate RT which was endorsed by the Executive Council in 1994. The broad principle is that Government should neither promote nor completely prohibit the practice of RT. Rather, it should put in place statutory measures to ensure safe and informed practice of RT.

6. In brief, the package of proposals recommended that :

(a) a statutory body should be set up to license medical institutions to carry out RT procedures;

(b) Artificial Insemination by Husband (AIH) should be allowed without specific statutory control[1], while Donor Insemination be available at institutions licensed for the purpose and subject to control under the RT Ordinance;

(c) the semen donor's identity should be kept confidential from the commissioning couple and the child, and vice-versa. The law should provide the right for all people over the age of 18 to ascertain whether they were born following a RT

[1] The only general requirement is that Artificial Insemination by Husband should be administered by a qualified medical practitioner and therefore subject to professional ethics and conduct.

procedure, and if so, to have access to certain non-identifying information about the donor;

(d) surrogacy should be actively discouraged. Specifically, commercial surrogacy, and its arrangement or advertising, should be a criminal offence. Only genetic in-vitro fertilisation (IVF) surrogacy should be allowed, i.e. both of the commissioning couple must contribute the genetic material, with no semen or ovum donor involved;

(e) embryo research should be subject to control. Creation of embryos for the purpose of research, cross-species fertilisation and cloning of embryos should be prohibited; and

(f) a provisional board, to be chaired by a person who is not a medical practitioner and with an equal number of male and female members, should be appointed to advise on the drafting of legislation and a Code of Practice.

7. To take the proposals forward, a draft Bill on RT (the Bill) and associated Regulations, as well as a Code of Practice are under preparation[2]. In December 1995, the Secretary for Health and Welfare appointed a Provisional Council on RT to assist in this important task.

---

[2] While the Bill, once enacted into legislation, will be legally binding, the Code will not be. Persons convicted of any breaches of the provisions in the future RT Ordinance will be guilty of an offence. On the other hand, failure to observe any provisions in the Code will not of itself render any person liable to any proceedings, but it will affect the statutory Council's decision to grant, vary, suspend, revoke or renew a licence.

8. The mission statement of the Provisional Council is as follows :

> "With a view to establishing a statutory council to provide a framework of regulatory legislation, code of practice and public education, the mission of the Provisional Council on Reproductive Technology is to take a multi-disciplinary approach in formulating proposals to ensure the safe and informed practice of reproductive technology in a way which respects human life, the role of the family, the rights of service users and the welfare of children born through reproductive technology".

The terms of reference and membership of the Provisional Council are at Appendices 1 and 2.

THE NEED FOR FURTHER PUBLIC CONSULTATION

9. RT is a fast-developing area. New techniques have been developed subsequent to the last two consultation exercises. Both the Provisional Council and Government consider it necessary to gauge the views of the public in drawing up regulatory proposals on the new and sensitive areas of sex selection and the use of fetal tissue in infertility treatment and in research.

10. Moreover, the draft Bill contains detailed provisions on licensing requirements and procedures. As these will have significant implications on existing and potential service providers, we wish especially to solicit their views on the proposed licensing arrangements.

A SEX SELECTION ACHIEVED BY MEANS OF RT PROCEDURES

11. This section provides a brief description of RT-assisted sex selection procedures, argues the case for and against such practices, and seeks views on whether and how they should be regulated.

RT Techniques Available to Assist Sex Selection

12. The sex of a person is determined by the sex chromosomes in the male sperm. If a female ovum is fertilised by sperm containing an "X" chromosome, the product of conception will be a girl. If fertilised by a sperm containing a "Y" chromosome, the result will be a boy.

13. Sex selection might be achieved through non-RT procedures, such as the use of personal methods like special diets, vaginal douches and timing of intercourse, or through termination of pregnancy (abortion). These methods are NOT within the ambit of the draft Bill and are therefore not a subject of this consultation paper.

14. Sex selection may also be achieved by RT techniques. Two such techniques are sperm sorting and pre-implantation diagnosis:

(a) ***Sperm sorting***

Male sperm is sorted into those bearing the X chromosome (which is female determining) and those bearing Y chromosome (which is male determining). The sperm of the required sex is then used to inseminate a woman.

(b) ***Pre-implantation diagnosis***

This involves in-vitro fertilisation, then identifying and selecting an embryo of the preferred sex for implantation into the woman.

Reasons for Sex Selection

15. The reasons for sex selection may be medical or non-medical.

(a) ***Medical reasons***

There are around 200 sex-linked inherited diseases, mostly affecting males. Some sex-linked diseases, such as colour blindness, are not serious. Others like haemophilia and certain types of muscular dystrophy are very serious and debilitating. Couples with a family history of such serious diseases may wish to avoid the birth of a child with serious genetic diseases through sex selection.

(b) *Non-medical reasons*

Non-medical reasons for sex selection include personal (e.g. to balance the sex composition of children in the family), social (e.g. a higher social status attached to a certain sex in certain societies) and financial (e.g. eligibility to inherit title, assets or family wealth).

Existing Controls -- Local and Overseas

16. In Hong Kong, there is no legislative control over sex selection achieved by means of RT procedures.[3]

17. A few countries have in place controls over sex selection. In the United Kingdom, the latest Code of Practice provided for under Section 25 of the Human Fertilisation and Embryology Act 1990 states that centres should not select sex of embryos for social reasons nor use sperm sorting techniques in sex selection. In Norway, the treatment of sperm before fertilisation for sex determination is only permitted if the woman carries a serious sex-linked hereditary disease. In France, biological diagnosis carried out on cells removed from the embryo in vitro may only be authorised on an exceptional basis and the physician performing pre-natal diagnosis must certify that the couple are likely to

---

[3] As regards sex selection through abortion, the Offences Against the Person Ordinance (Cap. 212), makes it illegal to terminate pregnancy on the grounds of fetal sex, unless there is substantial risk that if the child was born, it would suffer from such physical or mental abnormality as to be seriously handicapped.

give birth to a child suffering from a particularly serious genetic disease recognised as incurable.

Arguments for Sex Selection

18. The main arguments for allowing sex selection are :

(a) ***Individual freedom of choice***

Some would argue that individuals should be allowed to exercise free will over their lives. The selection of the sex of one's own child could be considered a personal decision which does not affect third parties.

(b) ***Avoidance of a serious sex-linked hereditary disease***

Serious sex-linked diseases can cause immense suffering to individuals and their families, and can be a significant burden on a society's health and welfare system. Parents should be allowed a choice if sex selection can avoid the birth of a child with a serious genetic disease.

(c) *Social pressure*

In certain cultures, a higher status is accorded to one sex. It is often related to the inheritance of titles or assets. A woman who fails to give birth to children of the preferred sex may be subject to societal pressure including her husband and in-laws. Sex selection may thus provide relief to these women.

(d) ***Minimum effect on sex ratio***

Some argue that there is natural fluctuation in sex ratio in a population. Hence sex selection alone which only takes place on a small scale could not possibly upset the natural balance.

(e) ***Parents' attitude***

It could be argued that a child of the preferred sex will receive more care and attention from the parents than that of the unwanted sex.

(f) ***Avoidance of female infanticide and abortion***

Some supporters for sex selection argue that sex selection helps reduce the incidence of female infanticide and abortion.

Arguments against Sex Selection

19. The main arguments against sex selection are :

(a) ***Interference with nature or the will of God***

Some argue that humans should not interfere with nature and "play God" by trying to determine the sex of their children.

(b) ***Seriousness of sex-linked diseases***

While certain sex-linked diseases could be life-threatening, it is doubtful whether others are serious enough to justify sex selection. Persons with genetic diseases may have disabilities but they can still lead a meaningful life and make significant contribution to the society.

(c) ***Perpetuates sexual discrimination***

It is argued that allowing sex selection for social reasons may reinforce sexual stereotypes and sexual discrimination in a society.

(d) *Upsets the natural balance between the two sexes*

Some argue that sex selection would upset the natural balance of males and females in a population.

(e) ***Parents' attitude***

Techniques of sex selection do not guarantee a 100% success. Some fear the negative attitude of parents towards a child of the "wrong" sex in a failed sex selection case may jeopardise the welfare of that child. On the other hand, the arrival of a child of a "right" sex may have adverse effects on other children in the family, especially those of the less preferred sex.

(f) ***Unsuccessful cases leading to termination of pregnancy***

Sex selection may increase the incidence of abortions in cases where a child of the "wrong" sex is conceived. Though in Hong Kong it is unlawful to terminate a pregnancy solely on the grounds of fetal sex, some parents may resort to illegal abortion.

Views Sought

20. On the issue of sex selection through RT techniques, we wish to seek the public's views on :

(a) whether sex selection for medical reasons should be allowed;

(b) whether sex selection for non-medical reasons should be allowed;

(c) if allowed, should it be regulated under legislation and the Code of Practice as for other RT procedures; and

(d) if not allowed, should it be prohibited under the legislation or the Code of Practice[4]?

B USE OF FETAL OVARIAN/TESTICULAR TISSUE IN INFERTILITY TREATMENT OR IN RESEARCH

21. This section provides a brief description of the use of fetal ovarian or testicular tissue in infertility treatment or in research, argues the case for and against such practices, and seeks views on whether and how they should be regulated.

---

[4] Please refer to footnote number 2 for an explanation of the difference between a statutory legislation and a Code of Practice.

Potential Uses of Fetal Ovarian/Testicular Tissues

22. "Fetus" refers to the product of conception from the end of the embryonic stage (eight weeks after fertilisation) until birth. Fetal tissue is obtained from the abortus of a pregnant woman. Fetal materials from spontaneous abortions are unsuitable for most research because the tissue is degenerated and often infected or associated with chromosomal abnormalities. For most research, fetal tissue is obtained from elective abortion. Fetal tissue has a wide variety of uses, including basic medical research, the development and testing of pharmaceutical products, pathology testing, viral diagnosis, medical education and transplantation treatment. These are however non-RT areas which are OUTSIDE the jurisdiction of the Bill.

23. The Bill is concerned specifically with the potential use of ovarian or testicular tissues from an aborted fetus in infertility treatment, and in research where no embryo is deliberately created[5]. Given advances in this field, it is possible that in future these tissues can be cultured into mature gametes and be used to provide an option for the treatment of infertile couples and for research.

24. We wish to highlight that such uses are still in their developmental stage. It is not known whether immature eggs and sperm from fetus could develop and be capable of giving rise to a baby after

---

[5] The Executive Council has endorsed that no embryo should be deliberately created for the purpose of research. The use of fetal tissue in research which involves the creation of embryos will therefore be prohibited. Hence, the present discussion is limited to the use of fetal tissue in research where no embryo is created.

fertilisation. Scientists believe that being able to grow and mature human eggs or sperm from fetal ovarian or testicular tissues or the grafting of human fetal ovarian/testicular tissue is still a long way off. Nevertheless, we acknowledge there has always been concern that scientific and medical research runs ahead of ethical and social considerations, and that the views of the general public are not taken into account at an early stage. It is therefore advisable to stimulate public debate on this area of RT which is still in the very early stage of development but which may lead to techniques for future medical treatment.

Existing Control -- Local and Overseas

25. In Hong Kong, there is no specific legislation concerning use of fetal tissue. The Medical (Therapy, Education and Research) Ordinance (Cap. 278) makes provision for the use of parts of bodies of deceased persons for therapeutic purposes and for purposes of medical education and research. However, it does not cover the use of aborted fetal tissue. The "Professional Code and Conduct for the Guidance of Registered Medical Practitioners" issued by the Medical Council of Hong Kong has guidelines on the use of new medical procedures but there is no specific reference to the use of fetal tissue.

26. In U.K., in response to public concern, the statutory Human Fertilisation and Embryology Authority conducted public consultation on the use of donated ovarian tissue for embryo research and infertility treatment in 1994. Taking into account public views, the U.K. Authority decided that the use of ovarian fetal tissue for embryo research should be

allowed subject to control, while its use for infertility treatment should be prohibited.

Arguments in Favour of Using Fetal Ovarian/Testicular Tissues

27. The main arguments for allowing the use of fetal ovarian or testicular tissues in infertility treatment or in research are :

(a) ***Assisting infertile couples***

It may provide assistance to infertile couples who are unable to produce eggs/sperm.

(b) ***Preventing the transmission of inheritable diseases***

Some women who can produce eggs are carriers of inherited disorders such as Duchenne's muscular dystrophy and haemophilia which are passed on through the mother's egg. The use of fetal ovarian tissue from another healthy woman can avoid the transmission of these diseases.

(c) ***Limited source of egg donation***

Egg-donors are usually women who are undergoing sterilisation surgery, who have surplus eggs after infertility treatment or who simply wish to donate anonymously to help other infertile women. The number of such donors is

however very small. Fetal ovarian tissue may provide an alternative source for research and infertility treatment.

(d) ***Avoidance of intrusive and uncomfortable medical procedures on live donors***

The current methods of obtaining mature eggs require adult women to undergo intrusive and uncomfortable medical procedures which are not without risks. The donor is required to take drugs to stimulate ovulation and the mature eggs are obtained with the use of laparoscopy.

Arguments Against the Use of Fetal Ovarian/Testicular Tissues

28. The main arguments against the use of fetal ovarian or testicular tissues in infertility treatment or in research are :

(a) ***Risk of abnormality and transmission of genetic defects***

Ovarian/testicular tissues from a fetus have not been subject to pressures which govern survival and normal development to adulthood. This raises the question of risk of abnormality in embryos produced using such fetal tissues.

(b) *Psychological impact on the resultant child*

The psychological effect on a child of knowing that it was born from the ovarian/testicular tissues of an aborted fetus is unknown. There has been concern about the likely adverse effect on a child of finding out that its mother was an aborted fetus that had never been born. This has been the reason most frequently put up when objecting to the use of fetal tissue in infertility treatment.

(c) ***Moral objection***

Some people oppose any form of assisted reproduction as breaking the law of nature.

(d) ***Problems with women achieving conception by tissues from her own abortus***

Some people are concerned that tissue from the aborted fetus of a woman may be used to assist her conception through RT. This means the woman will be carrying an embryo which has been formed from the eggs of her unborn daughter. People find this morally unacceptable and is concerned with possible complications of incest.

(e) ***Increase in abortion or lead to trading of fetal tissue***

Permitting the use of fetal tissue to assist conception or to further scientific research could encourage abortion or lead to an increase in the number of later abortions in order to harvest more mature fetal tissue. Such late abortion is associated with higher risk to the mother. Moreover, people are concerned that it may lead to commercialisation and trading of fetal tissue.

(f) ***Psychological impact on the donor and recipient***

Opponents express concern for the psychological well-being of the woman who donated her fetal tissue and that of the recipient.

(g) ***Inadvertent incest***

Some are concerned about possible inadvertent incest between offspring.

(h) ***Other treatment options are available***

It could be argued that other treatment options are available for infertile couples. There is thus limited need for the use of fetal ovarian/testicular issue in the treatment of infertility.

Views Sought

29. On this issue of fetal ovarian or testicular tissue, we wish to seek the public's views on :

(a) whether their use for infertility treatment should be allowed;

(b) whether their use for research (where no embryo is resulted)[6] should be allowed;

(c) if allowed, should it be regulated under legislation and the Code of Practice as for other RT procedures; and

(d) if not allowed, should it be prohibited under the legislation or the Code of Practice[7]?

C LICENSING SYSTEM

30. Following community support, the draft Bill contains detailed provisions on the requirements and procedures for licensing medical institutions providing RT services. Government and the Provisional Council recognise that these provisions will have significant

---

[6] Please refer to footnote number 5 for an explanation on why the use of fetal tissue in research where embryos will be created is not the subject of this consultation.

[7] Please refer to footnote number 2 for an explanation of the difference between a statutory legislation and a Code of Practice.

implications on existing and potential service providers. Hence, we particularly welcome service providers' views in this area.

31. The following provides an outline of the proposed licensing mechanism :

Powers of the Statutory Council on Reproductive Technology

32. The Bill stipulates that all relevant activities must be carried out pursuant to a licence. The future statutory Council on RT has the power to grant, vary, suspend, revoke and renew a licence for a medical institution to carry on a relevant activity, i.e. an activity which consists of or involves :

(a) the provision of a RT procedure;

(b) the conducting of embryo research; or

(c) 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.

Granting of a Licence

33. In granting a licence, the Council needs to be satisfied, among other things, that :

(a) the application designates an individual as the person under whose supervision the relevant activity is to be carried out (i.e. the person responsible);

(b) the character, qualifications and experience of the person responsible are suitable for the supervision of the activities and that he/she will discharge the statutory duties as required; and

(c) the premises in respect of which the licence is to be granted are suitable for the activities.

Duties of the Person Responsible

34. The person responsible under a licence needs to ensure, among other things, that :

(a) the other persons to whom the licence applies[8] are of such character, and are so qualified by training and experience, as to be suitable persons to practice the activities authorised by the licence;

(b) proper equipment is used;

---

[8] "Persons to whom a licence applies" are the person responsible; any person so designated in the licence or in a notice given to the Council by the person responsible; and any person acting under the direction of the person responsible or of any person so designated.

(c) proper arrangements are made for the keeping and disposal of gametes and embryos;

(d) suitable practices are used in the course of the activities; and

(e) the conditions of the licence are complied with.

Revocation and Variation of a Licence

35. The Council may revoke a licence if :

(a) any information given in the application for a licence is false or misleading in any material respect;

(b) the premises are no longer suitable;

(c) the person responsible has failed to discharge, or is unable to discharge his duties;

(d) there has been material change of circumstances since the licence was last granted;

(e) the person responsible dies or is convicted of an offence under the Ordinance; or

(f) on application of the person responsible.

36. The Council also has power to vary any terms of the licence.

Temporary Suspension of the Licence

37. The Council has power to temporarily suspend a licence for a period not exceeding three months if it has reasonable grounds to suspect there are grounds for revoking a licence, and is of the opinion that the licence should immediately be suspended.

Validity of a Licence

38. A licence shall cease to be valid :

(a) upon the expiry of 3 years after the date of its last grant, or such lesser period, if any, specified in the licence; or

(b) if the licence is revoked by the Council.

Enforcement

39. An authorised person[9] may at any reasonable time enter and inspect any licensed premises and take possession of anything which may be required for :

[9] An "authorised person" means a member of the Council or its committee, or a designated public officer.

(a) the exercise of any function of the Council in relation to the granting, variation, suspension or revocation of licences; or

(b) any proceedings for an offence under the Ordinance,

and retain it for so long as it may be necessary for that purpose.

40. A magistrate may issue a warrant if satisfied by information upon oath by an authorised person that there are reasonable grounds for believing that an offence against the Ordinance is being, or has been, committed on any premises, whether or not the premises are licensed. The warrant would permit an authorised person to enter and search the premises specified in the warrant, and take possession of anything required as evidence for an offence under the Ordinance.

Offences

41. Any person who

(a) carries out a relevant activity in any premises not licensed for that purpose; or

(b) for the purposes of the grant or renewal of a licence, knowingly or recklessly provides any information which is false or misleading in a material particular,

commits an offence and is liable

(c) on a first conviction, to a fine at level 4[10] and to imprisonment for 6 months; and

(d) on a subsequent conviction, to a fine at level 6[11] and to imprisonment for 2 years.

Views Sought

42. Public views, especially those from existing and potential RT service providers, are invited on whether the licensing system as outlined above is appropriate.

SUMMARY OF VIEWS SOUGHT

43. In brief, we invite views from the public on three major issues:

(a) sex selection achieved by means of RT procedures (paragraph 20) ;

(b) the use of fetal ovarian or testicular tissue in infertility treatment or in research (paragraph 29); and

---

[10] As stated in Schedule 8 of the Criminal Procedure Ordinance (Cap. 221), a fine at level 4 is presently set at $25,000.

[11] A fine at level 6 is presently set at $100,000.

(c) the licensing system for the provision of RT services (paragraph 42).

44. Please send your views before 15 September 1996 to :

Secretary, Provisional Council on Reproductive Technology
(Attention : Mr S M Wong)
2/F, Shun Feng International Centre
182, Queen's Road East
Wanchai
Hong Kong

45. Thank you.

Provisional Council on Reproductive Technology

Terms of Reference

The functions and powers of the statutory Council on Reproductive Technology will be prescribed in the Ordinance. The terms of reference of the Provisional Council are as follows :

(a) to keep under review local and international developments about, and information on, reproductive technology;

(b) to advise the Secretary for Health and Welfare on permitted and new reproductive technology procedures and areas of embryo research, having regard to the social, moral, ethical, legal and other implications of reproductive technology and to community views;

(c) to advise the Secretary for Health and Welfare on the drafting of the Reproductive Technology Bill and Regulation;

(d) to consider the arrangements for inspecting, licensing and monitoring service providers;

(e) to devise a Code of Practice on reproductive technology (including reproductive technology procedures, embryo research and gamete/embryo storage);

(f) to consider and make recommendations on what information service providers should be required to supply and what records the Council should maintain, including :

(i) a central registry of gamete donors;

(ii) a register of reproductive technology procedures performed;

(iii) a record of embryo research conducted; and

(iv) registers of reproductive technology centres, embryo research centres and storage facilities.

Appendix 2

Membership of the Provisional Council on Reproductive Technology

The members of the Provisional Council on Reproductive Technology are :

The Hon Denis CHANG Khen-lee, QC, JP	(Co-chairperson)
Ms Anna WU Hung-yuk	(Co-chairperson)
Professor Gerhold K. BECKER	(from June 1996)
Mr Colin CHAU Yu-nien	
Miss Audrey EU Yuet-mee, QC, JP	
Mrs FUNG LEUNG Kwai-ping	
Professor HO Pak-chung	
Mrs Minnie LAI WEI Kit-lin, JP	
Ms Ambar LAM Wai-fong	
Mrs LAU YU Po-kwan	
Dr Archie LEE Chi-chung	
Professor Rance LEE Pui-leung, JP	
Ms Cathy LEE Wai-yee	
Dr the Hon LEONG Che-hung, OBE, JP	
Dr Athena LIU Nga-chee	
Dr Edward LOONG Ping-leung	
Mrs Winnie POON YAM Wai-chun	
Mrs Katherine SHIN YEUNG Kwan-man	
Dr William SO Wai-ki	
Mr David WONG Wah-shun	
Mr Stephen YAU How-boa	
Mrs Shelley LAU LEE Lai-kuen, JP (Representative from Home Affairs Department)	
Mr Derek B. GOULD (Representative from Health & Welfare Branch)	
Dr MAK Sin-ping (Representative from Department of Health)	