

**GUIDELINE OF  
THE MALAYSIAN MEDICAL COUNCIL**

**MMC GUIDELINE 003/2006**

**ASSISTED REPRODUCTION**



**Malaysian Medical Council**

## **PRELUDE**

**This Guideline complements, and should be read in conjunction with the Code of Professional Conduct of the Malaysian Medical Council (MMC).**

**In this Guideline, the words “doctor”, “Physician”, “medical practitioner” and “practitioner” are used interchangeably, and refer to any person registered as a medical practitioner under the Medical Act 1971. The words “hospital” and “healthcare Facility and service” are used interchangeably and refer to any premises in which members of the public receive healthcare services. Words denoting one gender shall include the other gender. Words denoting a singular number shall include the plural and vice versa.**

**Adopted by the Malaysian Medical Council on 14 November 2006**

## FOREWORD

The Malaysian Medical Council, with the objective of ensuring that registered medical practitioners are fully aware of the codes of professional medical practice, issues directives and guidelines from time to time. The purpose of these codes, guidelines and directives is to safeguard the patient and members of the public, to ensure propriety in professional practice and to prevent abuse of professional privileges.

The Guidelines are designed to complement, and should be read in conjunction with, the Medical Act and Regulations, Code of Professional Conduct of the Malaysian Medical Council and other Guidelines issued by the Council or any related organisation, as well as any statute or statutory provisions in force and all related statutory instruments or orders made pursuant thereto.

This Guideline on **Assisted Reproduction** has been prepared with careful attention to details, cognisant of the current international stand on the subject. The Draft has been reviewed numerous times by the Malaysian Medical Council and includes valuable response from individuals, organisations and professional bodies in the country, before formal adoption by the Council.

The Guideline is available in the printed form as well as in the MMC website. Registered medical practitioners are advised to familiarise themselves with the contents, as they will serve as documents to refer to or to seek clarifications from, when practitioners need guidance on matters of professional ethics, codes of professional conduct and medical practice in general.

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January 2007

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# **ASSISTED REPRODUCTION**

## **INTRODUCTION**

**Assisted reproductive technology (ART) includes a range of methods used to treat human sub-fertility, including in vitro fertilization (IVF), embryo transfer (ET), gamete intra-fallopian transfer (GIFT), and all manipulative procedures involving gametes and embryos as well as treatment modalities to induce ovulation or spermatogenesis when used in conjunction with the above methods.**

**The technology has been developed out of concern for individuals and couples who are unable to have children when they desire them. The very broad range of such desires inevitably raises numerous ethical dilemmas.**

**Reproductive cloning is not allowed and commercial trading in gametes, semen or embryos is prohibited under this Guideline.**

**Explanations of the various treatment modalities used in ART and the ethical viewpoints regarding each modality are also addressed in this Guideline.**

## 1. DEFINITION

Assisted reproductive technology (ART): includes a range of methods used to circumvent human sub-fertility, including in vitro fertilization (IVF), embryo transfer (ET), gamete intra-fallopian transfer (GIFT), all manipulative procedures involving gametes and embryos and treatment modalities to induce ovulation or spermatogenesis when used in conjunction with the above methods.

**“The reproductive rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health”<sup>1</sup>**

These concepts include concern for individuals and couples who are unable to have

children when they desire them. However, the above statement has also led to some controversial issue. For examples, a 60 year old woman may request to have assisted reproduction in order to achieve a pregnancy. A lesbian couple may want to have a child. Although these rights may be viewed differently in different societies and communities, it is important for the medical community to consider these issues in the context of individual rights, societal concerns, the norms of the community and the legal framework of the country.

Impaired fertility or sub-fertility may be due to a relative or absolute inability to conceive, or to repeated pregnancy wastage. It affects both men and women in approximately equal proportions, causing considerable personal suffering and disruption of family life.

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1. International Conference on Population and Development (ICPD) Cairo 1994)

The best strategy of dealing with sub-fertility is its prevention. Although some cases of impaired fertility can be corrected by simple measures, others require complicated diagnostic procedures and treatment.

An empathetic approach to individuals and couples who have sub-fertility problems is required. This includes an appreciation of cultural and social customs, the individual's perception of sexuality, an understanding of the reproductive function and awareness of the aetiology and prevalence of sub-fertility in the community.

Indeed sub-fertility is now accepted as a condition of poor health and there are tremendous social and mental effects on a couple that suffer from sub-fertility.

The development of medically assisted conception to help couples with sub-fertility has brought new social, legal and ethical issues related to the management of sub-fertility. Medical practitioners should be fully cognizant of these issues whenever they are in a position to refer patients for treatment or whenever they themselves establish a centre for such activities. These issues involve:

- Respect for the dignity and integrity of the human being.
- Protection of human genetic material so that it is not misused or used inappropriately without the donors consent.
- The need for quality of care.

## **2. PRINCIPLES**

In drawing these recommendations, the following principles have been used as a guide:

- The respect that is due to human life at all stages in its developments.
- The rights of people who are or may be sub-fertile and the proper consideration of their request for treatment.
- A concern for the welfare of children, which cannot always be adequately protected by concern for the interests of adults involved.
- Recognition of the benefits, both to individuals and to society which can flow from the responsible pursuit of medical and scientific knowledge.
- The sanctity of marriage and the importance of marriage prior to having children is a widely held belief by society in Malaysia. The difficulty of forcing potential patients to prove their marital status and maintaining constant checks on the same must be realized as a practical difficulty for medical practitioners. Be that as it may, in this country, assisted reproduction techniques must only be offered to married couples.

### **3. PRINCIPLES FOR QUALITY OF CARE**

The practitioner should have an effective system for monitoring and assessing laboratory and clinical practice to ensure that both the procedures and outcomes are analysed and can be shown to be satisfactory on independent assessment.

All persons undergoing ART should be adequately tested for transmittable diseases before procedures are performed on them. Detailed records must be maintained and be easily retrievable.

The practitioner must maintain accurate record keeping and labelling in respect of gametes and embryos, and he should ensure that proper standards are maintained in storage and handling of gametes and embryos.

There should be an effective monitoring system to ensure high standards of security wherever gametes and embryos are handled and stored.

Records should enable authorized staff to trace what happens to an individual embryo, oocyte or sperm sample from the date of collection.

Centres are responsible for ensuring that standards of quality and security of genetic material are maintained, wherever the material happens to be on the premises. This includes material being transferred from the laboratory for treatment or preparation for treatment. If gametes or embryos are transferred from one site to another, adequate arrangements should also be made to protect their quality and security.

Controversies on the use of stored embryos have raised legal disputes, particularly when the couple involved have since separated, divorced or one member has deceased or with disagreement by the next of kin. It is

therefore important that information on such matters should be included when taking informed documented consent at the time of initial in-vitro fertilization.

#### **4. CONSENT**

The patients generally have the right to give or withhold consent to examination and treatment. No ART treatment should be given to any couple without their written consent to that particular treatment which must be clearly explained to them, including success rates and complications.

In the course of the discussion, the following aspects must also be brought up, considered and, where appropriate, consent obtained.

Consent must be obtained from couples for the use of genetic material for treatment as well as possibly for research; the latter, however, is still not permitted in Malaysia.

The decision and consent whether couples who have had successful assisted reproduction would like either disposal or further storage of genetic material should also be obtained.

While couples have the right to determine the period of storage of the genetic material, they must be made aware of the period of maximum statutory period of five (5) years, which may be extended to ten (10) years if approved by the relevant authority, at the present this being the Ministry of Health.

The couple must also agree that in the event of them getting separated, divorced or one of them becoming deceased, one or the other (next of kin in the case of the deceased) cannot use the stored gametes. The gametes will then be destroyed.

## 5. OOCYTE/EMBRYO TRANSFER

Gametes or embryos which have been exposed to a material risk of contamination, which might cause harm to recipients or to any resulting children, should not be used for treatment.

The practitioner and the treated couple should agree upon the number of embryos transferred, informed consent documents completed and the information recorded in the clinical record.

Multiple gestation is an unintended result of assisted reproduction techniques. Multiple gestation leads to an increased risk of complications in both the fetuses and mother. It would be unethical for the individual practitioner not to generate his or her own data regarding patient characteristics, outcomes and number of embryos transferred in order to minimize these complications.

## 6. BLASTOCYST TRANSFER

In this procedure, the embryos are allowed to grow beyond the typical 2-3 days of culture and are allowed to develop to the blastocyst stage before they are transferred to the womb. A higher pregnancy rate is thought to result. There are no ethical objections to this practice as it uses the natural progression of embryo growth.

## 7. ASSISTED HATCHING

This is a procedure to help in *zona pellucida* thinning and thus in implantation. This procedure does not alter the progression of embryo growth and therefore there are no ethical objections to this procedure.

## **8. EGG DONATION/EMBRYO DONATION/SPERM DONATION**

Eggs, embryos and sperms are donated to treat human sub-fertility in others with the help of assisted reproductive procedures, provided the unethical and prohibited factors, as listed in Section 15, are adhered to. The religious and cultural sensitivities of the patient and the medical practitioner involved in ART procedures should be taken into consideration before embarking on these procedures.

## **9. SEX SELECTION**

There should be no selection of the sex of embryos for social or personal reasons. Sex selection is, however, allowed if a particular sex predisposes to a serious genetic condition e.g. haemophilia, Duchenne muscular dystrophy, fragile X syndrome, etc.

## **10. SELECTIVE FETAL REDUCTION**

Excessive multi-fetal gestation should be minimized by careful induction of ovulation and restriction of numbers of embryo transferred. If despite these measures, more than 3 fetuses are gestated, fetal reduction may be considered if the prospect of fetal viability is compromised or if the health or life of the mother is threatened. Patients should be counselled extensively and informed consent obtained if the procedure is to be performed.

## **11. STORAGE AND DISPOSAL OF GAMETES AND EMBRYOS**

A couple undergoing ART should be asked for instruction concerning the storage and disposal of embryos, as discussed under Consent.

The termination of the development of a human embryo and the disposal of the remaining materials are sensitive and delicate issues. The practitioner should take full account of this. Specific instruction concerning storage and disposal of embryos must be asked of the couple and informed consent duly obtained.

When an embryo is no longer to be kept for treatment, the practitioner should decide how it is to be allowed to perish, and what is to happen to the perished material. The procedure should be sensitively devised and described, and should be communicated to the people for whom the embryo was being stored.

Controversies on the use of stored gametes have raised legal disputes, particularly when the couple involved have since separated, divorced or one member has deceased (with disagreement by the next of kin). In such instances, the stored gametes cannot be used independently by either one of the parties involved. It is therefore important that information on such matters should be included when taking consent at the time of initial in-vitro fertilization, as indicated above.

## **12. SURROGACY**

In a surrogate arrangement a women agrees to becomes pregnant and bear a child for another person/persons and to surrender it at birth. The above practice is not acceptable to most of the major religions in this country. Such a surrogate pregnancy can also potentially lead to many legal dilemmas for the persons involved.

### **13. SPERM FREEZING/SPERM BANKING**

Cryo-preservation can be used to store sperm. The sperm can be thawed and used for artificial insemination or in-vitro fertilisation. The sperm can be stored for future use especially in patients about to undergo chemotherapy. Sperm can also be retrieved from the epididymis or testes in those with blockage of the vas deferens. Proper procedures must be in place for the identification of sperm specimens. The use of donor semen should be guided primarily by medical needs and the religious sensitivities of the couple and the medical practitioner involved.

### **14. PRE-IMPLANTATION GENETIC DIAGNOSIS (PGD):**

This procedure involves genetic testing and selection of embryos produced by in-vitro fertilization (IVF). Once an embryo is created using IVF techniques, a cell is removed from the embryo after about three days and tested for specific genetic abnormalities. Usually healthy embryos will be transferred to the mother's womb and embryos with the abnormality will be destroyed.

At present PGD is used mainly for the diagnosis of many diseases and to determine the sex of the embryo to avoid the transmission of severe sex-linked disease. Some have attempted to select embryos free of genetic disease but of the same tissue type as an existing ill child in order to harvest their umbilical cord blood for transplantation to the affected sibling.

As there is no worldwide agreement as to when human life begins or when it acquires moral significance, there is no agreement on the moral status of an embryo<sup>2</sup>. Nor is there any agreement as to whether discarding

2. In Islamic interpretation, a foetus is ensouled at 120 days, after which the conception is considered to possess the qualities of a human being.

an embryo with a genetic disorder, prior to implantation, is the equivalent of an abortion.

At present, it is best that PGD be used for only severe and life-threatening genetic diseases. It would be unethical to analyse and select the inherited characteristics of embryos (e.g. intelligence, height, hair and eye colour); any social or psychological characteristics or any other condition which is not associated with disability or a serious medical condition.

## **15. PROHIBITED / UNACCEPTABLE PRACTICES**

- No research or experimentation shall be performed using any human oocyte and/or sperms without the explicit consent of the donors and approval of the appropriate authority. At the present time, such research or experimentation is not permitted in Malaysia.

The following practices are ethically unacceptable and are prohibited under this Guideline:

- Developing embryos for purpose others than for their use in an approved ART programme.
- Culturing of an embryo in vitro for more than 14 (fourteen) days. Human oocyte fertilized with human sperms should not be cultured in-vitro for more than 14 days (excluding any period of storage at low temperature). Under no circumstances shall research be carried out on or using human embryos which are more than 14 days old from the date of conception or the appearance of the primitive streak, whichever is the earlier, except with the explicit

approval of the authorizing authority, which is at present the Ministry of Health..

- Experimentation with the intent to produce two or more genetically identical individuals, including development of human **embryonal stem cell lines** with the aim of producing **clones** of individuals.
- Under no circumstances should embryo splitting with the intention of increasing the number of embryos for transfer be allowed.
- Using fetal gametes for fertilisation.
- Mixing of human and animal gametes to produce hybrid embryos. There shall be no attempt at trans-species fertilisation
- Mixing of gametes or embryos of difference parental origin so as to confuse the biological parentage of the conceptus.
- Placing an embryo in a body cavity other than the human female reproductive tract. Under no circumstances should a human embryo be placed in the uterus of another species for gestation.
- Under no circumstances should the nucleus of a cell of an embryo be replaced with a nucleus of a cell of another person, another embryo or a subsequent development of an embryo.
- Under no circumstances should the genetic structure of any cell be altered while it forms part of an embryo.
- Embryo flushing.
- Commercial trading in gametes, semen or embryos.

- Pre-implantation diagnosis to create “designer babies” (those with specific physical, social or specific gender characteristics and not for the reason of avoiding serious medical illnesses).
- The use in ART treatment programmes of gametes or embryos harvested from cadavers.
- The use of ART in unmarried couples.

## **FURTHER READING**

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