

GUIDELINE OF THE MALAYSIAN MEDICAL COUNCIL

MEDICALLY ASSISTED REPRODUCTION V2/2025

PREVIOUSLY PUBLISHED AS 'MMC GUIDELINE 003/2026 – ASSISTED REPRODUCTION'

PREAMBLE

Medically Assisted Reproduction (MAR) is brought about through various interventions, procedures, surgeries and technologies to treat different forms of fertility impairment and infertility. These include ovulation induction, ovarian stimulation, ovulation triggering, intrauterine, intravaginal insemination with semen of husband and all Assisted Reproductive Technology (ART) procedures which incudes in vitro fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI), Fertility Preservation (FP), embryo transfer (ET), and uterine transplantation. Details of these procedures are listed in the Appendix 1.

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 (oocytes, sperms), and 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.

This guideline complements and should be read in conjunction with the Code of Professional Conduct, and other related guidelines of the Malaysian Medical Council (MMC).

In this guideline, the word "doctors", "physician", "medical practitioner" trained in their respective fields, are used interchangeably, and refer to any person registered as a medical practitioner under the Medical Act 1971 (Act 50).

The word "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.

The last Malaysian Medical Council's (MMC) guideline on Assisted Reproduction was published back in 2006. Since then, with advancement of knowledge and technologies, a new guideline is warranted.

CONTENTS

1. DE	EFINITION	1
2. PR	INCIPLES	2
3. PR	RINCIPLES FOR QUALITY OF CARE	2
4. CC	ONSENT	3
5. EG	GG DONATION/EMBRYO DONATION/SPERM DONATION	3
6. SE	X SELECTION	4
7. EN	IBRYO TRANSFER	4
8. SE	LECTIVE FOETAL REDUCTION	4
9. SU	RROGACY	4
10. UT	TERINE TRANSPLANT	4
11. PR	OHIBITED/ UNACCEPTABLE PRACTICES	5
12. RE	CFERENCES	6
13. NC	OTE	7
APPE	NDIX 1	8
1.1.	Intrauterine Insemination (IUI)	8
1.2.	In Vitro Fertilisation (IVF)	8
1.3.	Intra Cytoplasmic Sperm Injection (ICSI)	8
1.4.	Embryo Transfer (ET)	8
1.5.	Preimplantation Genetic Testing (PGT)	8
1.6	Fertility preservation (FP)	9
1.7	Uterine transplant	9

1. **DEFINITION**

Assisted reproductive technology (ART): includes a range of methods used to circumvent human infertility, including in-vitro fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI), Fertility Preservation (FP), embryo transfer (ET), and all manipulative procedures involving gametes, 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"

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 example, a 60-year-old woman may request to have assisted reproduction 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.

Infertility 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.

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

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

Indeed, infertility is now accepted as a medical condition and there are tremendous social and mental effects on a couple that suffers from infertility.

The development of MAR to help couples with infertility has brought new social, legal and ethical issues related to the management of infertility. Medical practitioners should be fully cognizant of these issues whenever they are able to treat and 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 used inappropriately without consent.
- The need for patient's safety and 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 maintain constant checks on the same must be realized as a practical difficulty for medical practitioners. Be that as it may, in this country, MAR should only be offered to legally 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 MAR 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 should ensure that proper standards are maintained in storage and handling of gametes and embryos. The practitioner in this context is defined as registered medical doctors trained in their respective fields.

Setting up of Assisted Reproductive Technology lab and practitioners of the lab should comply to the Standards for Assisted Technology Facility- Embryology Laboratory and Operation Theatre Guideline (2012) and any future modifications thereof.

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 and gametes 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 in transit. Transferring of gametes or embryo in or outside of Malaysia should be in accordance with the National ART policy.

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 fertilisation.

4. CONSENT

The patients generally have the right to give or withhold consent to examination and treatment. No MAR 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. During the discussion, the following aspects must also be brought up, considered and, where appropriate, consent obtained.

Written consent shall be obtained from individuals*/couples for treatment, storage, disposal and/or the use of genetic materials for research and training. Disposal of gametes or embryos must be properly documented.

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) the stored embryos or the deceased gametes shall not be used for conception.

(*refers to unmarried individuals who require fertility preservation treatment)

5. EGG DONATION/EMBRYO DONATION/SPERM DONATION

Gametes and embryo donation for fertilisation is not permissible and prohibited in accordance with the National ART Policy.

6. 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.

7. EMBRYO TRANSFER

The number of embryos transferred should be in accordance with National ART Policy.

8. SELECTIVE FOETAL REDUCTION

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

9. SURROGACY

Surrogacy is where a woman (surrogate) offers to carry a baby through pregnancy on behalf of another couple. This practice is prohibited by the National ART Policy.

10.UTERINE TRANSPLANT

Uterine transplant refers to transplantation of uterus, including the cervix, a cuff of vagina, the surrounding ligamentous and connective tissues, as well as the major blood vessels supplying and draining the uterus.

The religious and cultural sensitivities of the patient and the related medical practitioners should be taken into consideration before embarking on these procedures.

11. PROHIBITED/ UNACCEPTABLE PRACTICES

- 11.1 Developing embryos for purposes other than their usage.
- 11.2 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.
- 11.3 Experimenting 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.
- 11.4 Embryo splitting with the intention of increasing the number of embryos for transfer.
- 11.5 Using foetal gamete for fertilisation.
- 11.6 Mixing of human and animal gametes to produce hybrid embryos with attempt at trans-species fertilisation.
- 11.7 Mixing of gametes or embryos of difference parental origin so as to confuse the biological parentage of the conceptus.
- 11.8 Placing an embryo in a body cavity other than the human female reproductive tract. A human embryo placed in the uterus of another species for gestation.
- 11.9 Altering the genetic structure of any cell while it forms part of an embryo.
- 11.10 Commercial trading in reproductive tissues, gametes, and embryos.
- 11.11 Pre-implantation diagnosing to create "designer babies" (those with specific physical, social or specific gender characteristics except for the reason of avoiding serious medical illness).
- 11.12 Using in ART treatment programs of gametes or embryos harvested from cadavers.

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13. NOTE

1. The following are the members of the drafting committee for this guideline:

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- 2. This guideline was first published on 14 November 2006.
- 3. This is the 2nd edition of the guideline which was approved by the Ethics Committee on 21st April 2025 and adopted by the Malaysian Medical Council on 19th August 2025.
- 4. This document will be due for review in 5 years, or earlier as necessary.

MAR PROCEDURES

1.1. Intrauterine Insemination (IUI)

A procedure in which laboratory processed husband's sperm are placed in the wife's uterus to attempt a pregnancy.

1.2. In Vitro Fertilisation (IVF)

A sequence of procedures that involves extracorporeal fertilisation of gametes. It includes conventional in vitro insemination and ICSI.

1.3. Intra Cytoplasmic Sperm Injection (ICSI)

A procedure in which a single spermatozoon is injected into the oocyte cytoplasm.

1.4. Embryo Transfer (ET)

Placement into the uterus of an embryo at any embryonic stage from day 1 to day 7 after IVF or ICSI.

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.

1.5. Preimplantation Genetic Testing (PGT)

A test performed to analyse the DNA from oocytes (polar bodies) or embryos (cleavage stage or blastocyst) for HLA-typing or for determining genetic abnormalities.

5.1: PGT-A : PGT for an euploidies

5.2: PGT-M : PGT for monogenic / single gene

defects.

5.3: PGT-SR : PGT for chromosomal structural

rearrangements

All PGT should only be done if it is clinically indicated. The use of PGT to create embryo with specific physical social or gender characteristics is prohibited. This diagnostic laboratory procedure must be carried out by qualified embryologist in a certified ART centre as defined by the Standards for Assisted Technology Facility- Embryology Laboratory and Operation Theatre Guideline 2012 and any future modifications thereof.

1.6 Fertility preservation (FP)

Various interventions, procedures and technologies, including cryopreservation of gametes, embryos or ovarian and testicular tissue to preserve reproductive capacity.

1.7 Uterine transplant

Transplantation of uterus, including the cervix, a cuff of vagina, the surrounding ligamentous and connective tissue, as well as the major blood vessels supplying and draining the uterus.