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NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY (ART) POLICY

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

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The National Assisted Reproductive Technology (ART) Policy

was developed by

Obstetric & Gynaecological and Paediatric Services Unit
of the Medical Services Development Section, Medical Development Division,
Ministry of Health Malaysia,
in collaboration with
the multidisciplinary team from Ministry of Health Malaysia, universities,
private sector, Malaysian Medical Council (MMC)
and National Population and Family Development Board (LPPKN)

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FOREWORD

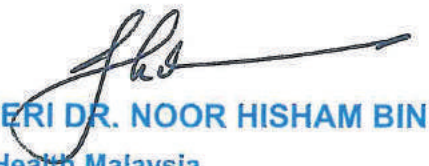
DIRECTOR-GENERAL OF HEALTH MALAYSIA

Assisted Reproductive Technology (ART) has successfully treated millions of infertile couples the world over. The increasing popularity of the technology in Malaysia and around the globe has prompted governmental bodies, and professional organisations to formulate mechanisms that evaluate, regulate, and even legislate the practice and utilisation of ART. Rapid medical advances spurred following the success of the first IVF baby in 1978, generating a myriad of new social, ethical, religious, and legal concerns further emphasising the need for regulation.

As of today, the Guideline on Assisted Reproduction 003/2006 published by the Malaysian Medical Council, and the Standards for Assisted Reproductive Technology for Facility (MOH/P/PAK/204.10 (GU)) published in 2012, provide the only guidance for the practice of ART in Malaysia. The proposed ART bill is currently in progress and may still take some time before the proposed legislation is read in parliament.

Therefore, it is both timely and relevant that the Ministry of Health establishes the National Assisted Reproductive Technology (ART) Policy in the interim period to serve as a policy for all personnel, both public and private involved in all aspects of the ART practices in Malaysia. This policy encompasses all aspects of ART practices including research activities involving gametes and embryos. The National Assisted Reproductive Technology Policy also addresses the religious sensitivities of both the patients and the healthcare providers. The Ministry of Health would like to remind the person in charge to ensure that ART practices in any facility in Malaysia are within those stipulated in this policy.

I would like to convey my sincere gratitude to the working group that formulated this policy, which included experts in the field of reproductive medicine from both public and private institutions, as well as from relevant agencies and stakeholders. The Ministry of Health is committed to maintaining the quality of care, safety, and ethical aspects of the practice and utilisation of ART in Malaysia of a high standard.



TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH

Director-General of Health Malaysia

1. Introduction

1.1. Assisted Reproductive Technologies (ART) is all interventions that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of reproduction. This includes, but is not limited to, in vitro fertilization (IVF) and embryo transfer (ET), intracytoplasmic sperm injection (ICSI), embryo biopsy, preimplantation genetic testing (PGT), assisted hatching, gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer, gamete and embryo cryopreservation, semen, oocyte and embryo donation, and gestational carrier cycles.

1.2. This national policy covers use and storage of human embryos, sperms and oocytes in all ART facilities in Malaysia. This policy describes the scope of ART services that can be practised in Malaysia, inclusive of clinical and laboratory practices.

1.3. The ART should only be offered and performed on heterosexual couples, who are legally married. Gamete and reproductive tissues are not included in this definition.

1.4. A woman must not be provided with treatment unless account has been taken to ensure the welfare of the child who may be born as a result of the treatment.

1.5. The ART services in Malaysia must also comply with the criteria as set out in the latest version of the Standards for ART Facility - Embryology and Operating Theatre (MOH/P/PAK/204.10 (GU)).

1.6. This policy also incorporated input from the guideline entitled Assisted Reproduction (MMC Guideline 003/2006) issued by the Malaysian Medical Council (MMC).

2. Objectives

2.1. The objective of this document is to:

2.1.1. Ensure delivery of optimal care for the treatment of infertility in Malaysia; and

2.1.2. Guide provision of ART services provided in Malaysia.

3. Pre-implantation Testing Policy

3.1. Pre-implantation Genetic Testing (PGT)

3.1.1 There are three types of preimplantation genetic testing (PGT, formerly known as PGD or preimplantation genetic diagnosis).

3.1.1.1 Preimplantation genetic testing for aneuploidy (PGT-A)

3.1.1.2 Preimplantation genetic testing for monogenic (single-gene) disorders (PGT-M)

3.1.1.3 Preimplantation genetic testing for structural rearrangements (PGT-SR)

3.1.2 This diagnostic laboratory procedure must be carried out by qualified embryologist, in a certified ART centre. 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.

3.1.3. The PGT procedure must be carried out in a safe and appropriate laboratory, with facilities and equipment according to MS ISO 15189. A quality management system which looks into all aspects of the safety of cryopreserved materials must be addressed including laboratory and human resources. Traceability, record keeping and identification of gametes and embryos are mandatory.

3.2 Sex selection

3.2.1 Selection of the sex of embryos for social or personal reasons is not allowed. However, sex selection may be allowed if a particular sex predisposes to a serious genetic condition e.g. haemophilia, Duchenne muscular dystrophy, fragile X syndrome, etc.

4. Gamete Use Policy

4.1. Gamete definition

4.1.1 Gametes are the cells used during sexual reproduction to produce a new individual organism or zygote. The male gamete, sperm, is a smaller, mobile cell that meets up with the much larger and less mobile female gamete, egg or ova.

4.2. Gamete donation

4.2.1 Gamete donation for fertilization is unethical and prohibited.

4.3. Use of foetal gamete

4.3.1 The use of foetal gametes for fertilisation is prohibited.

4.4. Transferring gamete and reproductive tissues between centres

4.4.1 The transfer of gametes and reproductive tissues from one facility to another facility within Malaysia at the request of the couple will require approval from all parties concerned.

4.4.2 Transferring such tissues and material across Malaysian border will require special permission from the Ministry of Health.

4.5. Gametes harvested from cadavers

4.5.1 Gametes harvested from cadavers for use in ART treatment programmes is prohibited.

5. Embryo Use Policy

5.1. Embryo definition

5.1.1 The biological organism resulting from the development of the zygote, until eight completed weeks after fertilization, equivalent to 10 weeks of gestational age.

5.2. Embryo donation

5.2.1 Embryo donation for fertilization is unethical and prohibited.

5.3. Length of culturing of embryos

5.3.1 Culturing of an embryo in vitro for more than 14 (fourteen) days is prohibited as primitive streak and spinal cord would have developed by that period.

5.4. Embryo splitting

5.4.1. Embryo splitting with the intention of increasing the number of embryos for transfer is prohibited.

5.5. Replacing nucleus of embryo

5.5.1 Nucleus of a cell is defined as a dense organelle present in most eukaryotic cells, typically a single rounded structure bounded by a double membrane, containing the genetic material.

5.5.2 Nucleus of a cell of an embryo is not allowed to be replaced with a nucleus of a cell of another person or another embryo for the subsequent development of an embryo.

5.6. Number of embryos transferred into a patient

5.6.1 For patients below 40 years of age, the number of embryos transferred shall not be more than two (2) to reduce the incidence of multiple pregnancy.

5.6.2 For patients aged 40 years and above, a maximum of three (3) cleavage stage embryos or two (2) blastocysts can be transferred with the agreement of all parties involved.

5.6.3 Informed consent on success rate and risk of multiple pregnancy should be clearly explained and documented.

5.6.4 Blastocysts is defined as the stage of preimplantation embryo development that occurs around day 5–6 after insemination or ICSI. The blastocyst contains a fluid filled central cavity (blastocoele), an outer layer of cells (trophectoderm) and an inner group of cells (inner cell mass).

5.7. Transfer of embryos in a body cavity other than the human female reproductive tract

5.7.1 Placing an embryo in a body cavity other than the human female reproductive tract is prohibited. Under no circumstances should a human embryo be placed in the uterus of another species for gestation.

5.8. Transferring embryos and reproductive tissues between centres

5.8.1 The transfer of embryos and reproductive tissues from one facility to another facility within Malaysia at the request of the couple will require approval from all parties concerned.

5.8.2 Transferring such tissues and material across Malaysian border will require special permission from the Ministry of Health.

5.9. Embryos harvested from cadavers

5.9.1 Embryos harvested from cadavers for use in ART treatment programmes is prohibited.

6. Research & Development

6.1. Research or experimentation on human gametes and/or embryos

6.1.1 No research or experimentation shall be performed using any human gametes and/or embryos without the explicit consent of the donors and approval obtained from Medical Review & Ethics Committee (MREC) and National Medical Research Register (NMRR).

6.2. Developing embryos other than ART use

6.2.1 Developing embryos for a purpose other than for their use in an approved ART programme is prohibited.

6.3. Producing hybrid embryos

6.3.1 Mixing of human and animal gametes to produce hybrid embryos is prohibited. This includes mixing of gametes or embryos of different parental origin as to confuse the biological parentage of the conceptus.

6.4. Altering genetic structure

6.4.1 Alteration of genetic structure of any cell while it forms part of an embryo is prohibited.

6.5. Cloning

6.5.1 Human cloning for reproductive and research purposes is prohibited.

7. Surrogacy Policy

7.1. Surrogacy

7.1.1 Due to legal implications surrounding surrogacy and the welfare and rights of the child, surrogacy is prohibited. Surrogacy agreements are not enforceable by law, even if there is a signed legal contract between commissioning parents and surrogates.

8. Commercial Trading of Gametes and Embryos Policy

8.1. Commercial trading

8.1.1 Commercial trading is defined as trading activity that is done for the benefit of a business or institutionally managed portfolio.

8.1.2 Commercial trading of gametes or embryos is prohibited which includes advertisements.

9. Transmissible Diseases Screening Policy

9.1. Transmissible diseases

9.1.1 All persons undergoing ART should be screened for transmissible diseases e.g. HIV, Hepatitis B, Hepatitis C and Syphilis before procedures are performed.

9.1.2 Centres that provide treatment for such cases should have proper facilities and trained staff with appropriate safeguards to prevent cross contaminations, such as using separate storage tank for gamete/embryos and biohazard protection for staff.

9.1.3 Consent has to be taken and properly documented if the centre proceeds with the treatment. Affected couples should be appropriately counselled about the possible risk of transmission and the long term consequences.

10. Storage of Gamete and Embryo Policy

10.1. Storage of gametes reproductive tissues

10.1.1 Gametes and reproductive tissues can be stored for non-medical and medical reasons for fertility preservation such as patients with malignancy undergoing surgery and/or chemotherapy/radiotherapy.

10.1.2 Stored gametes and embryos is only allowed for own personal use, and not for donation or commercialization.

10.1.3 Consent should be obtained prior to storage following detailed discussion and must be documented.

10.1.4 All persons undergoing gamete and reproductive tissue storage should be screened for transmissible diseases e.g. HIV, Hepatitis B, Hepatitis C and Syphilis before procedures are performed.

10.2. Period of storage

10.2.1 The statutory period of storage of gametes, embryos and reproductive tissues is up to five (5) years which can only be extended to a maximum of ten (10) years with a mandatory written request by the couple.

10.2.2 Storage of gametes and reproductive tissues for fertility preservation may be extended beyond ten (10) years with a mandatory written request by the patient.

9.2.3 At the expiry of the statutory period of storage, the gametes, embryos and reproductive tissues may be discarded.

10.3. Status of stored gametes, embryos or reproductive tissues in the event of a divorce or death

10.3.1 The use of stored embryos must require the consent of both husband and wife who completed the initial ART treatment. Embryos will be disposed if there is a divorce or death of one or both spouses. [5,6]

10.3.2 Gametes and reproductive tissues will be disposed if the patient is deceased.

10.4. Fate of non-utilisable gametes, embryos or reproductive tissues

10.4.1 Information on the fate of non-utilisable gametes, embryos or reproductive tissues should be given to couple at the time of initiation of treatment.

11. Consent Policy

11.1. Consent

11.1.1 ART treatment should only be performed on couples with their written consent to that particular treatment, which must be clearly explained to them, including success rates and risks.

12. Conclusion

12.1 Disclaimer

12.1.1 Procedures and technologies on Reproductive Assisted Reproductive Technology (ART) is not exhaustive to this document.

12.1.2 Matters not described in this document is subject to change and decision of the Ministry Of Health Malaysia.

12.2. National Assisted Reproductive Technology (ART) Committee

12.2.1 A National Assisted Reproductive Technology (ART) Committee shall be established to oversee approvals and decide on matters regarding Assisted Reproductive Technology (ART) services in Malaysia.

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