The Malaysian Medical Association's Position Paper on Assisted Reproduction

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ABSTRACT:

The importance of fertility treatment in a Malaysian context has taken on extra significance given the declining birth rate over the last 50 years. This trend has been particularly alarming over the last decade specifically. There needs to be a holistic approach to this issue with regards to the patients as well as the governance of the healthcare providers who engage and treat all these couples. The paper below will highlight key definitions as well as provide both administrative as well as facility guidelines while paying emphasis to ethical, religious and financial considerations.

DEFINITION:

Assisted Reproductive Technology (ART) includes all fertility treatment in which eggs (oocytes) and embryos are handled. A general example of this would be stimulation of the ovaries followed by surgical retrieval of the eggs and subsequently fertilization with sperm in a laboratory prior to reinserting the embryo into the woman's reproductive tract. Therefore, the procedures of stimulation of ovaries without retrieval or insemination of sperm alone do not qualify as ART. ART encompasses 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) and gamete and embryo cryopreservation.

The declining birth rate in this country from 4.9 children per couple in 1970 to 1.6 children per couple in 2022 is a cause for some concern. At this rate of decline the National Statistics Bureau estimates our population will plateau by 2050 and subsequently start falling thereafter. On a personal level, it is undeniable that for individual couples, the inability to have a child gives rise to feelings of sadness, inadequacy and depression. The purpose of ART is to be able to offer a solution to the majority of these couples and in the long run combat the declining population problem.

Now while the right to have children is considered universal it is still beholden upon the moral, religious and legal framework of any particular country. The main tenets of the National Assisted Reproductive

Technology Policy published by the Ministry of Health (MOH) Malaysia in 2021 is that ART be offered or performed on legally married heterosexual couples. A woman may not be provided with treatment unless the welfare of the child can be ascertained during initial evaluation of the couple. The Malaysian Society for ART (MSART), the Obstetrics & Gynaecological Society of Malaysia (OGSM) and the Malaysian Medical Council (MMC) have all provided input as to allowing clinicians to work within the existing ethical and religious framework in this country while also balancing the rights of all citizens to seek treatment for subfertility.

The handling and usage of the gametes or embryos in question aside from the explicit use for reproduction in individual couples will be legislated by MOH with respect to ethical issues. These include approval by the Medical Review & Ethics Committee (MREC) and National Medical Research Register (NMRR) prior to conducting any research or experimentation. To invoke a call made in the previous position paper by the MMA, after consultation with MSART and OGSM, there still is a need to establish a Standing Committee to oversee matters relating to ART in this country. This committee should be made up of senior MOH officials, clinicians both in the government and private sectors as well as representatives of all major religious groups to deal with the constantly evolving technological, religious and societal issues faced by ART practitioners and couples dealing with subfertility in Malaysia.

ADMINISTRATIVE AND FACILITY GUIDELINES:

An ART facility is defined as any premise that deals with the procedures of ART such as in vitro handling of human oocytes, spermatozoa and embryos, for the purpose of establishing a pregnancy, including but not limited to, in vitro fertilization (IVF) and embryo transfer (ET), intracytoplasmic sperm injection (ICSI), assisted hatching, embryo biopsy, gamete intra - fallopian tube transfer (GIFT), gamete and embryo donation.

The Person in charge (PIC) or clinical director is required to be a registered medical practitioner who is registered as such under the Medical Act 1971 [Act 50] and holds a valid annual practising certificate (APC)with postgraduate qualification in O & G and is registered as a subspecialist in Reproductive Medicine by the National Specialist Register. The laboratory director needs to have a minimum qualification of Bachelor of Science Degree in a related Biomedical field with at least two years of post-qualification supervised training and a minimum of 100 complete hands-on cycles of IVF/ICSI (either as part of the degree programme or as post-degree training). The embryologist needs to have a minimum qualification of Bachelor of Science Degree in a related Biomedical field with at least one year of post qualification supervised training and a minimum of 50 complete hands-on cycles of IVF/ICSI (either as part of the degree programme or as post-degree training).

Laboratory facilities must follow the guidelines set out in the Standards for Assisted Reproductive Technology (ART) by Medical Development Division, Ministry of Health Malaysia (SAMM), STR 2.7 – Specific Technical Requirements For Accreditation Of Assisted Reproductive Technology (ART) Laboratories, Issue 1, 30 August 2008 published by Department of Standards Malaysia.

All centers should have standard reporting procedures that emphasis accurate and comprehensive documenting of all activities and clinical procedures carried out in said center. This will allow for

accurate reporting with MOH where desired while still protecting the confidentiality of the patient to ensure the propagation of safe and technologically sound ART services in the foreseeable future.

Not all couples are suitable to undergo ART. As mentioned earlier in the guideline, only those with legal and valid marriage certificates will be considered for treatment. Once this criterion is met, a thorough screening of the couple is done to determine suitability. For those who have medical conditions that may cause life threatening complications if subjected to ART, they will have to be excluded. There is also an age consideration as only patients below the age of 50 may still have the hormonal capabilities to have a child. As long as a couple is deemed fit, they are allowed to proceed with ART treatment. The types of ART commonly practiced in Malaysia are listed in the definition but can broadly be divided into In-Vitro Fertilization (IVF) and Intrauterine Insemination (IUI).

Consent:

Detailed consent needs to be taken from both members of the couple with regards to the procedures being carried out. This should include an explanation of the risks and sequelae of any medical procedures that are to be carried out. The couple must also be made aware of what options they have with regards to excess embryos prior to embarking on an IVF cycle. Once the couple has been briefed and their signatures affixed to the consent, only then should treatment be rendered. Under no circumstances shall treatment be carried out on any patient without their express consent.

Preimplantation Testing

As per the latest national ART policy, PGT (formerly known as PGD/PGS) can be carried out for three reasons :

i. Preimplantation genetic testing for aneuploidy (PGT-A)
ii. Preimplantation genetic testing for monogenic (single gene) disorders (PGT-M)
iii. Preimplantation genetic testing for structural rearrangements (PGT-SR)

Selection of gender is not allowed for social or personal reasons unless a particular sex may give rise to a medical disorder such as haemophilia, Duchenne's muscular dystrophy or Fragile X syndrome.

Gamete usage:

The clinician and couple must agree on usage of all embryos obtained after an ART procedure. This includes advice given with regards to the quality of the embryos and the possibility of causing harm to either the mother or child as a result of treatment. After careful consideration with regards to the problems associated with multiple pregnancies (especially higher orders of three and above) it is recommended :

i. For women below the age of 40, only 2 embryos should be transferred.
ii. For women above the age of 40, 3 embryos may be transferred after discussion with the patient.

Storage:

All embryos stored may only be done so after a new written consent differing from the pre procedure consent is obtained from the couple. If the couple declines storage of embryos not used in a primary procedure, then consent must be obtained from the couple for disposal of said embryos according to their preference. There are many religious and social factors governing a decision like this so the clinician must exercise extreme delicacy in obtaining this consent.

Embryo storage will be carried out as per laboratory guidelines and regular audits of storage equipment and process should be carried out to ensure proper cryopreservation of all embryos.

ART PROCESS AND OUTCOMES

The ART process thus begins with an in-depth screening of any couples that have struggled to conceive after regular unprotected sexual intercourse of a 1-year duration. The decision as to which form of treatment is suitable to each couple will be based on the factors below :

1. Age
2. Hormonal profile
3. Presence of medical or gynaecological disorders
4. Sperm or oocyte issues
5. Fallopian tubal function
6. Sexual dysfunction

Once an assessment has been made, the couple will then embark on an IUI or IVF cycle where medications will be administered after consent and adequate counseling is provided. They will then undergo surveillance for the first two weeks before the procedure is carried out. The result or the outcome will be known a further two to three weeks later. For those who are unsuccessful with an IUI procedure they can then choose to step up to IVF. For those who have not succeeded with IVF, there remains no other alternatives aside from trying another cycle. The greater the number of cycles, the greater the financial implications to the couple, which is why it is important they be made aware of the potential outcome.

Unethical Practices in ART :

1. Use of gametes/embryos for research without obtaining approval from MOH and consent from donors to the embryo
2. Using an embryo on a third party not involved in donating gametes to that embryo (surrogacy)
3. The use of hybrid DNA in an embryo such as animal or plant based
4. Placing the embryo anywhere other than the female reproductive tract
5. Using embryos for commercial gain
6. Performing ART on patients who are neither legally married nor heterosexual
7. The use of fetal gametes for fertilization

CONCLUSION

ART is achieving greater importance and plays a far more important role in society due to the declining birth rates which are attributed to many factors. It is crucial that ART implementation and governance have clear oversight to steer clear of professional, ethical and religious issues which a multicultural country like Malaysia will always be faced with. The challenges to the individual couples as well as healthcare providers can be handled by strict adherence to current policy.

REFERENCES :

1. CDC guidelines on Fertility Success rate and Certification Act 1992
2. The National ART Policy by Medical Development Divison, MOH 2021
3. The Standards For Assisted Reproductive Technology (ART) -Standards For ART Laboratories Working Committee, Medical Development Division, Ministry of Health JSM/AD-700/01/09 July 2010.
4. Guidelines of number of embryos transferred – ASRM 1998