Pre-Implantation Genetic Diagnosis (PGD): A Critical Analysis of the Malaysian Guidelines

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Abstract—Pre-implantation Genetic Diagnosis (PGD) is an early form of prenatal diagnosis, in which embryos created in vitro are analyzed for well-defined genetic defects; only those free from the defects are replaced into the womb. The ability to screen for a variety of characteristics has led to disagreement over what conditions is acceptable for screening. From its emergence, Pre-implantation Genetic Diagnosis (PGD) has been opposed by a variety of parties and groups who advocate several grounds and reasons. The variance of opinions concentrates particularly on the new applications of PGD to screen embryos for susceptibility and late-onset conditions, for HLA-matching for tissue donation to an existing sick child, and for sex selection. Like in other countries, debates on the use of PGD had also taken place in Malaysia since few years back. Similarly, Malaysians are also divided when it comes to determining whether PGD should be allowed to continue in the country. This paper first describes the current and potential future uses of PGD. Further, it appraises the existing guidelines relating to PGD in Malaysia so as to establish whether it is able to adequately regulate the use of PGD and safeguard against the abuse of the technology. The paper concludes that the current Malaysian guidelines is inadequate to address the complex issues surrounding PGD and thus proposing that the technique should be regulated through statutory legal regulation and not via Professional Self-regulation.

Keywords—Pre-Implantation Genetic Diagnosis, PGD, ethical, Malaysia, Legal, Regulatory, Framework.

I. INTRODUCTION

Pre-implantation genetic diagnosis (PGD) is an early form of prenatal diagnosis, in which embryos created in vitro are analyzed for well-defined genetic defects; only those free from the defects are replaced into the womb. It is a procedure for testing the embryo for the presence of chromosomal disorders or defective genes. It aims at reducing a couple’s risk of transmitting a genetic disorder while at the same time provides a realistic chance for the birth of a healthy child. Since early 1990s, this technology has expanded in scope and applications. Today, PGD is an established reproductive option offered worldwide at specialist centers [1] [2] [3]. The ability to screen for a variety of characteristics has led to disagreement over what conditions is acceptable for screening. From its emergence, Pre-implantation Genetic Diagnosis (PGD) has been opposed by a variety of parties and groups who advocate several grounds and reasons. The disagreement focuses especially on the new uses of PGD to screen embryos for susceptibility and late-onset conditions, for HLA-matching for tissue donation to an existing sick child, and for gender selection. Whether PGD should be accepted for medical or non-medical uses should depend upon a careful assessment of the proposed use’s importance to the person or couple requesting it, and the harmful effects, if any, which it might cause. [4]

This paper discusses the current and potential future uses of PGD. This is then followed by an overview of the practice of PGD in Malaysia and the debates that took place surrounding the technique. It further analyses the relevant provisions and guidelines in Malaysia related to this technique.

II. PRE-IMPLANTATION GENETIC DIAGNOSIS & ITS USES

In PGD, one or two cells (blastomeres) are extracted from the pre-embryo and tested (cell biopsy). PGD allows doctors to transfer only unaffected embryos to the woman’s uterus [3]. Parents may not be aware that they carry a genetic disorder until they have an affected child. PGD can then be used to avoid the condition in any subsequent children. For couples who are at risk of passing on a genetic disorder, PGD enables them to avoid undergoing prenatal diagnosis and (possibly repeated) abortion and instead start a pregnancy in the knowledge that the resulting child will not have a particular abnormality [5].

At present, PGD analysis can be used to check for any abnormalities in the number of genes or chromosomes. It can also be used to detect specific genes, as may be required in disorders such as Duchenne’s muscular dystrophy, haemophilia, haemoglobin diseases, cystic fibrosis, Huntington’s disease and achondroplasia. Early detection of human disorders such cleft lip and palate and spinal bifida have also become possible too [2] [3] [6].

Through PGD, the sex of a zygote can also be identified [4]. In practice, the most common uses of PGD are sexing an embryo to avoid X-linked disorders. These include thalassemia, haemophilia, muscular dystrophy, and hereditary cancer of the breast and prostate [7]. This technique has made it possible for a couple to avoid having a child with a sex-linked recessive condition [7] [8]. There are a number of genetic
conditions that result in blood disorders. Techniques for treating these include transplants of haemopoietic stem cells (precursors of blood cells) from a tissue-matched donor. Sources of such stem cells are the bone marrow and the umbilical cord blood. PGD with Tissue-typing helps to identify embryos that were not carriers of the disease and who would also provide a tissue match for a patient suffering for example from Beta Thalassemia, and who requires a bone marrow transplant in order to improve his/her fatal prognosis [9].

The next step beyond screening out the embryos with undesired genes, as in PGD, is the possibility of ‘fixing’ those embryos by replacing undesired genes with desired ones; i.e. genetic modification or sometimes known as genetic engineering, that is, by undertaking gene therapy. Genetic modification or sometimes known as genetic engineering means changing the genes in a living cell to produce a desired change in the organism’s characteristics [10].

III. PRE-IMPLANTATION GENETIC DIAGNOSIS IN MALAYSIA

In Malaysia, the practice of PGD which enables the diagnosis of more than 200 genetic diseases and the determination of the sex of an embryo is relatively new. The technique is carried out mostly in private fertility clinics and that it is not available in government or university hospitals [11]. In April 2004, the Damansara Fertility Clinic [12] launched its PGD program and by August, it had 28 Malaysian patients seeking for the technique. Out of these, 19 had successful embryo transfers. It is claimed that the clinical pregnancy rate after the successful embryo transfers is 36.8 per cent [13].

It was also alleged that in 2004, ten Singaporean couples have consulted the doctors at the Damansara Fertility Clinic, which has branches in Kuala Lumpur, Johor Bahru and Kepong for PGD with the purpose of selecting the sex of their future babies [14]. Eventually, in December 2004, the 1st Malaysian designer baby, Yau Tack, was born in Damansara Women’s Specialist Center via PGD technique. This was then followed by another birth of the 1st Blastocyst PGD Baby in Malaysia & Singapore on the Valentine’s Day, 14th Feb 2005 [15]. It was also reported that in April 2006, the TMC Fertility Center had continued to perform Malaysia’s and Singapore’s 1st Sequential Transfer (PGD) Pregnancies on Day 3 & Day 6. [16] In response to this scenario, the Government has said ‘no’ to designer babies [17]. “To choose a baby based on its gender, the color of its eyes or hair will not be allowed,” said the former Health Minister Datuk Dr Chua Soi Lek. According to the Minister, the Government is against the sex-selection as it will cause serious socio-economic implications on society. PGD with sex selection, if not controlled, would cause a negative effect in the long run where the number of males would greatly outnumber the females. In response to the issue, it was also announced that a new law, now being drafted, will forbid parents to choose the gender of their yet-to-be born child. [17]

On the same issue, the Malaysian Medical Association (MMA) wants the same for Malaysia. In a press release, Association’s President at that point in time, Datuk Dr. Teoh Siang Chin said that he is urging the authorities to come up with sanctions and guidelines to prevent Malaysia from becoming a haven for such practices [18]. The President added that while the centre is to be congratulated for advancing medical techniques in this country, it should be cautioned against performing this technique without the consensus of the medical fraternity and society. For the MMA, pre-implantation genetic testing techniques should only be used to diagnose serious medical conditions. The MMA’s stance in the matter is supported by the Religious groups. For Hindu Sangam President Datuk A. Vaithilingam, sex selection is “against the order of nature” and sexist. Similarly, Harcharan Singh, the vice-president of the Malaysian Consultative Council of Buddhism, Christianity, Hinduism and Sikhism, is also against it. On the other hand, the former Institute of Islamic Understanding Senior Fellow Shaikh Mohd Saifuddin Shaikh Mohd Salleh, looks at it in a different manner. To him, if a technology alters the natural order of things as created by God and is detrimental to man, it is prohibited. However, under circumstances where the technology is performed to ensure that the progeny does not carry hereditary illnesses, the Senior Fellow recommends that the matter should seriously be looked into in further details by the Muslim scholars and jurists. In a different perspective, the Buddhist Missionary Society of Malaysia President, Ang Choo Hong, raises the concern of what will happen to the “wrong sex” embryos which will be destroyed simply because they are male or female. [18] However, it is surprising that despite these statements more designer babies were produced using PGD technique. Meantime, while waiting for the new law to come into existence, it is expected that more designer babies are to be produced in the future.

IV. ANALYSIS OF THE MALAYSIAN GUIDELINES ON PGD

At present, there are few Guidelines developed in Malaysia to provide guidance for the medical practitioners and scientists which are relevant, directly or indirectly, to PGD. As human embryo is an entity inseparable from Assisted Reproduction, as will be seen later, some of the guidelines on the handling of embryo and PGD happened to be other guidelines on assisted reproduction which were developed by the local medical bodies. These include the Code of Practice and Guidelines for Assisted Reproduction Techniques Centers designed by the Ministry of Health in 2002, and the Malaysian Medical Council’s (MMC) Guidelines on Assisted Reproduction, 2006 (MMC Guideline 003/2006), Guideline on Medical Genetics and Genetic Services (MMC Guideline 010/2006) and Guidelines on Clinical Trial and Biomedical Research (MMC Guidelines 009/2006) would also be relevant to the current discussion. These guidelines shall be discussed in the following sections.

A. MMC Guideline on Assisted Reproduction

In 2006, a guideline on A.R.T[19] has been designed by the Malaysian Medical Council (MMC) and was formally adopted by the Council on the 14th November 2006. This Guideline on Assisted Reproduction 2006 was prepared with careful attention to details, cognizant of the current international stand
on the subject. It was submitted that before adoption, the guideline has been reviewed numerous times by the MMC and includes valuable response from individuals, organizations and professional bodies in the country. The guideline serves 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.

Basically, this Guideline concerns with Assisted Reproductive Technology which includes a range of methods used to treat human sub-fertility and all manipulative procedures involving gametes and embryos as well as treatment modalities to induce ovulation and spermatogenesis when used in conjunction with the above methods. In addition to that, it also provides explanations of the various treatment modalities used in A.R.T and addresses the ethical viewpoints regarding each modality.

In drawing the provisions contained in the Guideline, the MMC was guided by certain principles. These include among others, the 'Principle of Respect to Human Life' at all stages in its development. The 'Principles for Quality of Care' has also been outlined in the Guideline. In handling human embryos, application of Principles for Quality of Care should be exercised by the practitioners and A.R.T centers which include maintenance of high standards of security in embryo handling, storage, accuracy of record keeping and labeling, transportation from one site to another, and the use of stored embryo particularly upon separation or divorce between the parents or upon the death of either of them or upon disagreement by the next of kin. [19]

On the same vein, the MMC Guideline on Assisted Reproduction also makes provisions on the technique of Pre-Implantation Genetic Diagnosis (PGD). Explanations of the procedures involved in PGD technique and the potential benefits that could be gained from the technique are given under Article 14 of the Guideline. As far as the use of PGD is concerned, the MMC is at present taking the stance that it is best that PGD be used for only severe and life-threatening genetic diseases. However, MMC has not specified as to what genetic diseases considered as ‘severe and life-threatening’. Also, it has not been made clear of its stance on the use PGD for the treatment of the existing ill child of the same tissue type (PGD with tissue-typing). The MMC is also of the view that it would be unethical to analyze and select the inherited characteristics of embryos (e.g. intelligence, height, hair and eye color); any social or psychological characteristics or any other condition which is not associated with disability or a serious medical condition. Similarly, MMC holds the same stand on selection of the sex of embryos for social or personal reasons. However, Sex selection is allowed if a particular sex predisposes to a serious genetic condition e.g. haemophilia, Duchenne muscular dystrophy, fragile X syndrome, etc. [19]

These provisions are in line with the fatwa issued by the National Fatwa Council which provides:

“Rawatan kejututeraan genetik ke atas pra-embryo yang melibatkan pengubahsuaian sifat semulajadi seperti rambut, warna rambut, kebijaksanaan, ketinggian dan sebagainya, termasuk memilih jantina adalah haram. Bagaimanapun pemilihan jantina diharuskan sekiranya faktor jantina menatijahkan suatu penyakit genetik yang serius yang boleh membawa kematian.” [20]

Another essential element overlooked by the Guideline is the issue of ‘moral status of human embryo’ (in the case of A.R.T, embryo created in the laboratory outside human body). It is apparent from the Guideline that without a clear stand on the moral status of the human embryo in the Petri dish, the position of certain practices and procedures involving termination of the development of human embryo remain unanswered. Examples of such practices are: sex selection for reasons other than medical (in which embryo of unwanted sex are destroyed), the use of PGD with tissue-typing to treat existing ill sibling (in which embryos of different tissue type are destroyed) and the use of PGD to select only healthy embryo free from genetic disorders for implantation (in which embryos carrying genetic disorder are destroyed). The same question arises in deciding the fate of excess embryos created under certain Assisted Reproductive techniques, embryos exposed to a material risk of contamination that might cause harm, embryos no longer to be kept for treatment as well as stored embryo which no longer can be used by either one of its parents upon separation or divorce, or upon the death of either one or both of them or upon the disagreement of next of kin. The uncertainty over the termination and disposal human embryo is undoubtedly due to the uncertainty over the moral status of human embryo. This uncertainty is clearly illustrated in section 14 of the guideline.


The Code of Practice and Guidelines for Assisted Reproductive Techniques (ART) Centers, May 2002 [21] is a Code of Practice which has been approved by the Ministry of Health. This Code will form the basis of accreditation and licensing of ART Centers in this country. It was submitted that the object of the Code is wider than to secure the safety and efficacy of particular clinical and scientific practices which include among others, the handling of human embryo in IVF laboratories as well as treatments and research conducted on human embryos. As the Code deals with matters that are very much related to human and reproduction, concerns over certain fundamental ethical and social questions have also been addressed in the Code. In framing such fundamental questions, the Code has been guided by the following:

The respect which is due to human life and all stages in its development

The right of people who are or may be infertile to the proper consideration of their request to treatment

A concern for the welfare of children, which cannot always be adequately protected by concern for the interest of the adults involved and

Recognition of the benefits, both to individual and to society, which can flow from the responsible pursuit of medical and scientific knowledge

The Code also assumes that those involved in providing treatment or conducting research will observe the standards and requirements of good clinical and scientific practice. In doing so, the Code further recommends reference to other guidance
provided by other authorities or professional bodies on particular points. [22]

The practice of Embryo Splitting/Flushing and Sex-selection is outlined under Para. 8.7 of Part 8 of the Code which provides that centers “…should not select the sex of embryos for social reasons”. This in turn, would mean that sex-selection conducted for medical reasons, should be allowed. However, the said paragraph does not detail out what ‘reasons’ fall under the non-social reasons or more specifically, the medical conditions under which sex-selection should be allowed. The use of sperm sorting technique in sex selection is also not allowed under the Code. [21]

Termination and Disposal of embryo is indeed an important part of the procedures involved either in A.R.T or in research. As such, provisions concerning termination and disposal of embryo are also included in the guidelines. On the termination and disposal of embryo no longer to be kept for treatment, the guidelines provide that when an embryo is no longer to be kept for treatment, the centre 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, if they so wish. [21]

In the case where embryos have been used for research, the termination and disposal of the embryos is addressed by para 8.12. According to this para:

“In the case of embryos used for research, the centre should decide at the outset, the duration of the culture period, the method, which is to be used to terminate development, and the procedure, which will ensure the embryos, do not continue to develop after 14 days or earlier with the appearance of the primitive streak.” [21]

In considering how the development of an embryo is to be brought to an end, and what is to happen thereafter, due regards are given by the Code to the special status of the human embryo. Recognition of such a special status is reflected in para. 8.10 where it strongly advises centers to take into full account of the special status of the human embryo when adopting the approach to terminate the embryonic development and subsequently disposing it. [21] However, like the MMC guideline on Assisted Reproduction, the Code of Practice does not also make any declaration as to the moral status of human embryo.

Notably, the Code does not address the technique of Pre-Implantation Genetic Diagnosis (PGD) particularly for the selection of only healthy embryos free from genetic diseases for implantation, and for the selection of embryo with the same tissue type to treat an ill sibling. As far as sex-selection is concerned, the Code only prohibits attempt at selecting the sex of embryo for social reasons but does not specify the medical conditions under which sex-selection may be carried out. On top of that, provision on PGD to create “designer babies” are also absent from the Code.

C. Guidelines on the Medical Genetic and Genetic Services, MMC, 2006

Medical genetics is the field of medicine that is most centrally involved in providing services to persons with genetic conditions and their families. The goals of medical genetic services are to help people with a genetic disadvantage and their families to live and reproduce as normally as possible, to make informed choices in reproductive and health matters, to assist people obtain access to relevant medical services (diagnostic, therapeutic, rehabilitative or preventive) or social support systems, to help them adapt to their unique situation, and to become informed on relevant new developments.

The advances in human genetics during the last twenty years have revolutionized knowledge of the role of inheritance in health and disease. These advances will only be acceptable if their application is carried out with due consideration of accepted codes of medical ethics and social ethics, in relation to autonomy, justice and education and to the laws of the country. In Malaysia, even though the genetic service is still at infancy, it is timely that ethical consideration in genetic service should be given due regard so that the population can benefit from the advances of genetic knowledge from the beginning and without any harm. In this light, a guideline called Guideline on the Medical Genetic and Genetic Services [22] was adopted by MMC on 14 November 2006. The guideline was modified from the recommendations of World Health Organization (WHO) which have been adopted by many countries in the world. This Guideline on Medical Genetics and Genetic Services addresses various issues from counseling and consent for genetic screening, genetic registers, prenatal diagnosis, as well as other relevant related aspects.

On the availability and the right to access to genetic services, The Guideline provides that:

“Genetic services for the prevention, diagnosis and treatment of disease should be available to all, without regard to ability to pay, and should be provided first to those whose needs are greatest.”

Section 6 of the said guideline provides certain guidance on genetic screening and testing conducted on competent adults, incompetent adults, child, young persons, newborn babies and fetus already exists in the mother’s womb. [22] However, no mention has been made on the genetic screening and testing involving the pre-implantation human embryo. Apparently, Pre-natal genetic diagnosis is outlined in section 10, but however, no provisions are given with regard to PGD. In contrast to Pre-Implantation Genetic Diagnosis which diagnoses pre-implanted embryo outside uterus, Pre-natal diagnosis is a diagnosis conducted on a fetus already exists in the mother’s uterus, with the purpose to rule out the presence of a particular medical condition in the fetus at risk. Such information is provided to the couple to assist in their decision-making process regarding the available options, such as carrying the pregnancy to term, preparing for a difficult delivery and for special newborn care, or terminating the pregnancy. Obviously, the fact that Pre-natal Genetic Diagnosis is not Pre-Implantation Genetic Diagnosis indicates that the guideline applicable to pre-natal genetic diagnosis under the guideline would not apply to Pre-implantation Genetic Diagnosis. Similarly, the provisions applicable to the genetic screening of newborn babies would also not applicable to the screening of pre-implanted embryo.

Even though section 12 of the guidelines did mention briefly on the relationship between medical genetics and assisted reproduction, and the alternatives options available to couples
who are at risk of having a child with a genetic disorder, however, the options only include egg or sperm or embryo donation and surrogacy, and do not include the option of resorting to Pre-implantation Genetic Diagnosis (PGD). In offering the reproductive alternatives, section 12 further emphasizes on the importance of consideration of not only the cultural traditions and beliefs of the country, but also with overall respect for the autonomy of individuals and families. [22]

V. CONCLUSION
From the above analysis, it is apparent that in Malaysia, at present, there is no specific legal statute directly governing assisted reproduction or medical practices involving human embryos. Apparently, it seems this far that Malaysia prefers adopting “professional self-regulation” approach in governing the practice of human reproduction rather than resorting to a “statutory regulation”. This is reflected by the existence of a number of guidelines relating to A.R.T issued by the respective medical authority, bodies and associations, particularly the Ministry of Health and the Malaysian Medical Council, and by the absence of a legislation which specifically addresses the practice of A.R.T.

“Professional self-regulation approach” has been criticized by many as lacking democratic legitimacy and control. “Professional self-regulation” runs the risk of an overemphasis on medical or biological aspects while sociological aspects may be neglected. Those involved in this regulatory process are generally fellow medical professionals and they may be too close to professional practice to take an entirely objective view. It depends completely on the common sense and decency of the medical community. Because of these, legislative control on IVF, embryo research and related matters has consistently been proposed as the most appropriate model for legal regulation. Most of the international Committee Reports in many countries either made detailed recommendations about the scope and content of the legislation proposed, or, had the scrutiny of draft legislation as their ‘raison d’etre’. Most countries have, on examination, eventually concluded that some form of regulatory control is preferable to no regulation, although the nature of that regulation and review differs from one country to another. However, in most cases, such control is seen to be more implementable through specially framed and implemented legislation. Statutory regulation has a number of advantages over professional self-regulation. These include: certainty, stability, consensus forming, political advantages; democratic accountability and legitimacy, and ability to remove or reduce “forum shopping”. Despite these however, it is also important to recognize that peer review and self-regulation, and statutory regulation are not mutually exclusive concepts. The role of self-regulation is to establish clinical and scientific standards, to protect the interests of the patients and to protect the interest of the profession. This is complimentary to the process of governments passing laws which address the social, ethical and legal consequences of the use of technology.

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[16] [12] Known as TMC Fertility Centre, was established in January 1994 and provides services in the area of women’s health but with special dedication to the management of infertility and laparoscopic surgery. TMC Fertility Centre has consistently achieved high IVF success rates. See “About us”, TMC Fertility Center, at <http://www.tmcfertility.com>.
[21] 2 separate embryos were implanted in a same patient 3 days apart (1 on day 3 and another one on day 6). Normally, when 2 embryos are transferred into a womb, it would be performed in one procedure. In this particular case, a couple wanted to have a male baby for family
balancing for they have already had 2 girls and opted for PGD for sex-selection.


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