Regulating In-Vitro Fertilisation Treatment in Malaysia: Obligations to Protect and Assist the Parties

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Abstract: The reproductive technology of in-vitro fertilisation (IVF) demands substantive response from legislators who wish to regulate the use of this important technology, and the existing guidelines may require revision and development in order to deal with the particular ethical issues that this technology raises. This paper aims to explain the risks as well as the types of harms which relate to the shared morality of Malaysian society, the parties involved and the resulting children born as a result of IVF, and further delineates why the Guideline of the MMC on Assisted Reproduction does not adequately address these harms. In prioritising the health of the resulting child, I advocate that the risks are of equal concern and it is appropriate for the Government to call for legislation. It is my contention that if the protection of these identified groups is dealt with conscientiously, and new laws are introduced, this will help to achieve the intended goal of introducing robust IVF legislation in Malaysia. This paper will conclude that only through the enactment of legislation which accurately reflects the cultural and religious values and the shared morality within Malaysian society, will the Government instil public confidence in medical law in Malaysia, particularly in IVF.

1 INTRODUCTION

Today, assisted reproductive technologies (ARTs) are available throughout most of the world and the practice has gradually developed and is now largely different from that used during the early days because of refinements in laboratory technology and clinical practices. As a result, the technologies bring with them many new and challenging legal and ethical issues, some of which will be highlighted throughout this paper. This paper aims to highlight the question of why Malaysia has to balance the IVF needs, risks and harms in regulating the IVF practice in a way that suits the country's needs, cultures and religions. Nonetheless, this paper attempts to explain the physical and psychological risks as well as the types of harms that relate to the parties involved and the resulting children born as a result of IVF, and further delineates why the Guideline of the Malaysian Medical Council (MMC) on Assisted Reproduction does not adequately address these harms in order to protect and assist the parties.

2 MATERIALS AND METHODS

This paper employs a qualitative and doctrinal research method through content analysis approach where the Guideline of the MMC on Assisted Reproduction is examined. It comprises of primary and secondary sources through the library-based research. Whilst the first encompasses of Malaysian legislation, policies and judicial decisions, the latter constitutes a significant proportion of online databases content including LexisNexis, Westlaw and others.

3 RESULT AND DISCUSSION

It is clear that ARTs are designed to address the traumatic problem of infertility and offer powerful techniques to help people to have biologically related children. At root, there are three main types of fertility treatment: medical treatment (such as use of drugs for ovulation induction); surgical treatment (for example, laparoscopy for ablation of endometriosis); and assisted reproduction such as IVF and other

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techniques. Assisted reproduction frequently involves the handling of gametes or embryos and offers a wide range of methods to circumvent human infertility including IVF, embryo transfer, intrauterine insemination (IUI); donor insemination intracytoplasmic sperm injection (ICSI), gamete intra-fallopian transfer (GIFT), and zygote intra-fallopian transfer (ZIFT), and many of these procedures are combined with IVF. Since IVF technology is currently the most popular and common procedure used in public and private hospitals in Malaysia, to overcome infertility.

Undoubtedly, the technical aspects of IVF were first pioneered and developed by Robert Edwards and Patrick Steptoe in Oldham General Hospital in England, culminating in the first IVF baby in 1978 (Vaughn: 2010). The science of IVF has improved considerably in more than 30 years since the first IVF baby was born. Originally, this technology was designed for women with tubal factor infertility, but now has become the most common treatment for all causes of infertility. Thus, it is evident that since the arrival of the first IVF baby in the UK in 1978, IVF technology has opened the door to a solution that gives infertile couples hopes that infertility problems can be overcome (The Warnock Committee: 1984). However, whilst the point of this advancement, particularly in relation to in vitro fertilisation (IVF) technology is widely understood, its uses are controversial and concerns pertaining to the appropriate use of IVF are one of the vital matters for public policy in Malaysia. The reproductive technology of in-vitro fertilisation (IVF) demands substantive response from legislators who wish to regulate the use of this important technology, and the existing guidelines may require revision and development in order to deal with the particular ethical issues that this technology raises.

The term *in vitro fertilisation* scientifically refers to the uniting of sperm and egg in a laboratory dish, instead of inside a woman's body, to create embryos that can be transferred to the woman's uterus after going through certain developmental stages outside the body. The IVF technique itself is now well-known among infertile couples and is fast becoming a routine part of infertility treatment in many countries. On the first day of IVF, an infertile woman will be given hormone treatment which may include either pills of *clomiphene-citrate,* or injections, to induce her ovaries to produce more than one egg in her next cycle. Having removed the eggs from the woman's ovaries, they then will be placed in culture in small glass dishes known as petri dishes. Interestingly, there are no test tubes involved in this procedure despite the popular label of *test tube babies*. Sperm is then prepared and obtained from the male partner by means of masturbation and insemination, allowing fertilisation to take place in at least 80 percent of the ripe eggs. Not more than a specified number of the selected embryos are transferred to the woman's body with the hope that all or at least one of them will implant in the lining of the uterus and develop successfully to be born nine months later. Regarding the transfer, when the embryo(s) is or are in the uterus, the remainder of the process is effectively out of the hands of medical science, and it is at this point that things are most likely to go wrong. Even with the most experienced IVF teams, there are cases where the majority of embryos transferred, fail to implant in the uterus. Given that the success rate of IVF relatively differs from one patient to another patient depending on their age, diagnosis and length of infertility, this means that sometimes the procedure may have to be repeated many times and this is one of the greatest risks attached to IVF for those undergoing treatment (Deech and Smajdor: 2010). This might explain why it can be physically, financially and emotionally burdensome, but still those burdens are often regarded as a price worth paying to those who seek treatment, in order to have own biological children.

3.1 The Risks to the Mother

Like any other form of reproductive technology, IVF brings with it a long list of risks – most of which have provoked a raft of thorny ethical questions related to issues such as multiple births and the use of gamete donation in Malaysia. These have led to the introduction of legislation and other legal controls. On the other hand, IVF is undoubtedly a great technology which could be used to help many infertile couples overcome their infertility and enable them to have their own biological children. But what few couples may not fully comprehend until they undertake the actual process of IVF is that there are very real risks involved. The risks are necessarily different and asymmetrical for a couple: generally, the woman will suffer more compared to the man as he does not have to undergo any invasive procedure or take drugs for superovulation as she does. She therefore is the person who must bear the burden of intervention and inconvenience in the IVF process because, in IVF, the woman's body is the focus of medical intervention and monitoring, regardless of the cause of infertility within the couple (De Lacey et al: 2009). However, the stresses and emotional pressures involved in IVF may affect men as well as

women especially after an unsuccessful IVF procedure. These pressures in themselves are of sufficient seriousness to justify legislation in this field to protect the parties.

Studies have shown that there is a direct causal link or significant relationship between stress and reproductive failure (Nakamura et al: 2008). In approximately 90 percent of unsuccessful IVF cases, the patients are likely to experience a sense of failure, loss and grief as well as, quite possibly, anger and depression (Sutton: 2004). To support this, De Lacey et al. (2009) assert that "the experience of infertility and the escalating series of interventions involved in diagnosis and treatment culminating in IVF procedures is widely recognised to represent an unforeseen source of stress for the majority of couples". Sometimes, the procedures involved can put a strain on relationships and men may experience feelings of stress, guilt or anxiety. For women too, the tensions and uncertainties involved may take a toll. During these difficult times, support should be provided by the staff of the infertility unit, and usually patients may find benefit and get advice from counselling. For instance, the European Commission in July 2008 issued a proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care, which states that a physician has a partial responsibility for the patient he/she refers, especially regarding the provision of information and counselling (Pennings: 2008). It is suggested that this requirement should also be extended to all countries that offer IVF across the world. Hence, patients should be able to receive counselling in any country they are receiving IVF in, as it is vital for them to fully understand the effects and consequences of the treatment. Thus, it is true to say that whilst embarking on IVF may ultimately fulfil the couple's quest for a child, in the meantime, it is likely to involve physical risks and negative emotions during the process.

The evidence on IVF techniques and procedures shows that IVF cycles can pose severe health risks for the mother. The whole procedure of IVF (the superovulation, the surgery, the monitoring, the transfer, the waiting) and then any subsequent pregnancy and delivery, demands physical and emotional strength and can be uncomfortable, inconvenient and stressful (Vaughn: 2010). There is a chance of complications from taking the fertility drugs to stimulate ovaries, including abdominal pain, memory loss, mood swings and headaches; and the surgery itself comes with a risk, however low, of side effects such as bleeding, infection and damaged tissue (Sutton: 2004). Perhaps the most worrisome among these is a rare, but potentially dangerous condition known as *ovarian hyperstimulation syndrome* (OHSS), characterised by swollen and painful ovaries caused by the drugs used for superovulation. In its severe form, OHSS can cause nausea, vomiting, sudden weight gain and fluid retention, difficulty in breathing, the formation of blood clots and, very rarely, death (Deech and Smajdor: 2015). In relation to these risky circumstances, there was a case in the UK where a woman named Temilola Akinbolagbe suffered a massive heart attack two days after she began IVF treatment. It was discovered that her body reacted fatally to the drugs given for ovarian stimulation and sadly her life-support machine was switched off five days after she was admitted to a hospital in London. She had been a healthy young woman who had simply yearned for a child via the treatment. Similarly in Malaysia, a newspaper report recently revealed that a young woman died after going through an intrusive IVF treatment in a fertility clinic. The cause of death was due to her "multi-organ failure secondary to ovarian hyperstimulation syndrome" (Khoo: 2011). It was believed to be the first death in the history of IVF in Malaysia.

Besides the risks attached to mother, there are also concerns that IVF may lead to birth defects, low birth weight and diseases such as cancer, for the potential future children. Multiple pregnancy, which is a common result of IVF transfer involving more than one embryo, potentially raises the risks to children's life and health by increasing the chances of high blood pressure, *anaemia* and gestational diabetes. Having already examined the risks involved in IVF, it is evident that multiple births resulting from IVF can carry risks for both mother and child. For instance, it can increase the health hazards to the mother and her unborn children who are more likely to be medically aborted or to be delivered prematurely with all the attendant complications of prematurity. Also, the children's health and development can be affected: they have an increased risk of cerebral palsy and they are more likely to die around the time of their birth.

3.2 The Harms to the Resulting Child

Whilst it may be the case that no doctor wishes to expose patients and potential children to physical harm or psychosocial stresses involving the feelings of failure, loss and grief, as well as anger and depression, especially after an unsuccessful IVF procedure, it is well-known that IVF has inherent risks which can be minimised by adequate legal protection. One of the serious risks associated with

IVF is the increased chance of having a multiple pregnancy, which can significantly increase the development of complications for mother and baby.

It must be highlighted that ensuring safe and effective use of IVF is the goal of ethical practice and sound public policy in Malaysia. Enabling a child to be born via IVF when there is a proportionate risk that the child will be born harmed or damaged, would raise significant public concerns. For instance, Kew argues that the public in Malaysia expect safe and ethical practices from all doctors, and that the public has been critical of the medical profession, particularly in terms of having adequate regulation and addressing problems which are important to the society. Yet it is not easy to determine what kind of ethical and legal policy would be acceptable given the wide variety of situations potentially involving harm to IVF children. In order to identify this, a firm understanding of the potential harm must be well established. In other words, an analysis of the potential harm and risk situations for the child in IVF procedures must be developed.

Following the earlier discussions in relation to the risks and harms in IVF and pertaining to multiple pregnancy, miscarriage and birth defects, the potential harm associated with its use can be regarded as physical damage that may affect the child born as a result of this type of treatment. It is evident that the higher rate of multiple births in IVF due to the implantation of several embryos in the uterus at any one time, contributes to an increased rate of miscarriages as well as pre-term and low birth weight babies.

In fact, according to the UK's Human Fertilisation and Embryology Authority (HFEA), as IVF has become more successful, the number of multiple births has increased. Statistics in 2007 showed that around 40 percent of IVF babies are twins, and therefore three times more likely than single babies to be stillborn. An increased rate of twin births represents IVF's biggest risk for mothers and babies because twin births significantly raise the chances of mortality, prematurity, low birth weight and cerebral palsy for babies. However, with the introduction of single embryo transfer (SET) in 2007, the HFEA reports that the figure dropped to 22 percent based on the data for the first half of 2009. This shows that clinics have been working hard to reduce the number and risks of the multiple births in the UK. With regard to that, Hamilton states that the biggest risk to the health and welfare of the child born as a result of IVF is the hazards of multiple pregnancies. These are associated with an increased incidence of blindness, learning defects, lung problems and other ailments. A recent study also reveals that children in multiple births have a greater risk of serious health problems that can develop into lifelong impairments.

It is not only the children who are at risk - multiple pregnancies also pose risks to mothers, including *pre-eclampsia*, diabetes and heart disease. Although Robertson (2004) believes that in order to prevent the feared 'injury' to the child, parents should give up the uses of IVF that pose those risks, I am of the opinion that a better solution is to ensure the efficacy and safety measures of clinical and laboratory practices in order to reduce the burden of multiple pregnancy. Notably, Robertson (2004) offers no explanation pertaining to the definitions and assessment of risks, harm and feared injury to the child that should prevent would-be parents from using IVF and assisted reproduction treatments. Consequently, this might lead to an argument that giving up the treatment merely to prevent injury is not necessarily sufficient. an assessment of the risk of harm to the child should be made, alongside ensuring safety measures are in place in clinical and laboratory practices in IVF legislation in Malaysia to ensure that the future IVF children are afforded the maximum chance of a healthy start in life.

Studies from the UK and Australia also suggest that some drugs which are used to stimulate women's ovaries to produce multiple oocytes in IVF procedures increase the risk of serious birth impairments in the resulting children. Other long-term studies have been undertaken to show the kinds and rates of physical diseases and abnormalities incurred by children born of IVF technology. A cohort study shows that the rate of birth defects in IVF children rises to around 50 compared to 35 in non-IVF children, out of every 1000 conceived babies (Derbyshire: 2010). The evidence also indicates that the children born as a result of this treatment are two or three times more likely to suffer serious diseases such as *spina bifida,* heart disease and diabetes compared to naturally conceived children. More recently, a study has indicated that the rate of multiple births and the risks they bring to women and the potential children is disproportionate for all types of fertility treatment, but especially IVF. In order to reduce the harm and risks of IVF procedures to the resulting children, a detailed and proper scrutiny of IVF procedures is urgently required along with the adoption of a regulatory framework. Peters (2004) voices his concerns regarding the issue of harm raised by the use of IVF technology, stating that:

> Because the welfare of future people matters, we all have a prima facie obligation to avoid the infliction of unjustified harm on

> our future children. And because their welfare matters, lawmakers must take their interests into account when deciding whether to regulate a risky reproductive procedure.

Based on Peters' arguments it is clear that states have responsibilities to safeguard potential children against the harmful consequences of assisted reproductive procedures (Peters: 2004). As of yet, there is no standardised legislation in Malaysia to protect IVF children from the risks of the procedures. Rosato (2004) believes that law is the only way to prevent this harm. She further explains that although there is self-regulation provided by medical professional organisations to govern fertility practices, the system is insufficient to prevent harmful and unethical activities. To justify this, the assessment of harm in this legal context must strike a delicate balance by protecting children while respecting the parents' autonomy and consent to IVF. Harm to individuals and society must be a real potential harm, although not necessarily demonstrable and imminent as argued by Dworkin (1978). Although the risk of harm to the child need not be imminent, it should be at least significant and serious. An undefined fear, or one that would not result in serious injury, is insufficient to be used as a justification to restrict access to IVF. There is a clear indication that the harm posed to IVF children by multiple births, miscarriage and birth defects is significant and serious. As previously mentioned, in the UK, for example, the use of multiple embryos has been restricted since January 2009 in recognition of the risks posed, through the introduction of SET by the HFEA.

Since there are risks and harms associated with IVF, particularly during and after the treatment, there should be legislation to protect both mothers and the potential children because the existing guideline in Malaysia currently is inadequate to provide such protection. Although these issues have been addressed in the current Malaysian Guideline, unfortunately they are not being observed and updated appropriately, so consequently, the harms in IVF continue to occur with no protection. It is arguable that on the basis of the same reasoning pertaining to the potential for harm that has been acted upon in the UK, a law is required to ensure compliance with the safety features contained in the Guidelines. In a similar vein, Malaysia should adopt similar safeguards such as the introduction of SET in all clinics. Such safeguards will also help to alleviate concerns regarding the roles of medical practitioners and the State authorities in allowing parents with high risk factors to undergo IVF, knowing that it would pose the potential of real harm for the future child.

3.3 Why the Guideline of the MMC is Insufficient

There are several reasons why the current MMC Guideline in Malaysia is insufficient to govern the provision of IVF technology in Malaysia. The Guideline does not have the force of law behind it and therefore is open to interpretation in the clinical context, which means that it can be disregarded. This has potentially deleterious consequences. Patients may be offered treatments that are ill suited to their clinical needs and the lack of legal enforceability of the Guideline may lead to a failure to safeguard the interests of the patients and the potential child, whether these interests are medical, cultural or religious. Hence, it is arguable that the lack of enforcement in the Guideline can seriously affect the quality of the IVF services provided in Malaysia.

Further, private IVF clinics are under no obligation at all to abide by the recommendations in the Guideline, allowing them to prioritise the obvious financial advantages that accompany the provision of treatment to couples from outside Malaysia, even if such patients do not conform to the religious and cultural concerns expressed in the Guideline. For example, the MMC Guideline clearly stipulates that ART should only be offered to married couples due to the prevailing religious and cultural norms of Malaysians, but the same condition is not incorporated into the private hospitals' guidelines, with the result that IVF treatment is offered to any couple regardless of their marital status, provided that they have financial means to get the treatment.

In this environment, alongside concerns about parity of access to treatment, it is important to ensure that the treatments that are provided meet clinically and ethically accepted standards. At present this cannot be guaranteed because of the lack of effective regulation. The MMC Guideline only provides that the medical practitioners should have an effective system for monitoring and assessing laboratory and clinical practice, but the way in which the accepted standard of clinical practice and the level of satisfaction for the assessment should be interpreted are not explained, thus leaving room for the question as to what *exactly* the standards means. Schenker and Shushan advocate that due to the fact that there is no adequate supervision in IVF, some kind of quality control should be urgently instituted in all clinics offering IVF in Malaysia, since the technologies

involve such complicated and sensitive issues (Schenker and Shushan: 1996).

There is of course no certainty that the enactment of a statute modelled on other legislation such as the UK's Human Fertilisation and Embryology Act 1990 would provide standardisation, safe and effective treatments, or ensure equality of access. However, given the above, it seems likely that if such a law were enacted and properly enforced it would be an improvement on the current position.

4 CONCLUSIONS

In prioritising the health of the woman and the resulting child, I advocate that the risks and harms to Malaysian society are of equal concern and it is appropriate for the Government to call for legislation. It is my contention that if the protection of these identified groups is dealt with conscientiously, and new laws are introduced, this will lead not only to more effective control of IVF technology but will also help to achieve the intended goal of introducing robust and *appropriate* IVF legislation in Malaysia. To sum up, it is concluded that only through the enactment of legislation which accurately reflects the cultural and religious values and the shared morality within Malaysian society, will the Government instil public confidence in medical law in Malaysia, particularly in the areas of assisted reproduction and IVF.

REFERENCES

Christopher R. Newton et al. 2007. "Factors Affecting Patients' Attitudes Towards Single- and Multiple-Embryo Transfer," *Fertility and Sterility* 87, no. 2

De Lacey S. Smith C. A. and Paterson D. 2009, "Building Resilience: A Preliminary Exploration of Women's Perceptions of the Use of Acupuncture as an Adjunct to in Vitro Fertilisation," *BMC Complementary and Alternative Medicine* 9, no. 50

Deech R. and Smajdor A. 2015. *From IVF to Immortality: Controversy in the Era of Reproductive Technology,* Oxford University Press

Derbyshire D. February 23, 2010. "Infertility Time Bomb: IVF Children Have Higher Risk of Infertility, Obesity and Diabetes," *The Daily Mail*

Dworkin R 1978, *Taking Right Seriously* Harvard University Press

Hamilton M. December 4, 2007. "British Fertility Society Response to HFEA Calls for National Strategy to Reduce Multiple Births ", British Fertility Society

"IVF Multiple Embryo Use Reviewed," *BBC News* July 28, 2005

Khoo S. January 20, 2011. "Minister Orders Inquiry into Woman's Death after Treatment," *The Star*

Nakamura K. Sheps S., and Arck P., 2008. "Stress and Reproductive Failure: Past Notions, Present Insights and Future Directions," *Journal of Assisted Reproduction & Genetics* 25

Pennings G. 2008. "Cross-Border Reproductive Care in Europe," *BioNews*, no. 472

Peters P.G. 2004, *How Safe Is Safe Enough? Obligations to the Children of Reproductive Technology*. Oxford University Press

Robertson J. A. 2004. "Procreative Liberty and Harm to Offspring in Assisted Reproduction," *American Journal of Law and Medicine* 30

Rosato J. L. 2004. "The Children of ART (Assisted Reproductive Technologies) Should the Law Protect Them from Harm." *Utah Law Review*

Schenker J.G. and Shushan A. 1996. "Ethical and Legal Aspects of Assisted Reproduction Practice in Asia," *Human Reproduction* 11, no. 4

Sutton A. 2004, *Infertility and Assisted Conception: What You Should Know* Catholic Truth Society

The Warnock Committee, 1984. *British Medical Journal*.

"Understand Fertility Clinic Success Rates," http://www.hfea.gov.uk/fertility-clinics-success-rates.html. (Last visited: 09/02/2011

Vaughn L, 2010. *Bioethics: Principles, Issues and Cases*, Oxford: Oxford University Press.

Wang J and Sauer M.V. 2006. "In Vitro Fertilisation (IVF): A Review of 3 Decades of Clinical Innovation and Technological Advancement," *Therapeutics and Clinical Risk Management* 2, no. 4