

WOMEN AND CHILDREN AT RISK: LEGAL CHALLENGES OF THE POTENTIAL THREAT THAT IN VITRO FERTILISATION TECHNOLOGY POSES TO THE SOCIETY IN MALAYSIA

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ABSTRACT

The reproductive technology of in vitro fertilisation (IVF) demands an urgent response from legislators who wish to regulate the use of this important technology and have not already done so, and existing legislation or guidelines may require revision and development in order to deal with the particular ethical issues that this technology raises. This research endeavours to develop a coherent conceptual framework based on legal, ethical and Islamic perspectives which can be used to analyse the basis of the IVF legislation in Malaysia. It also considers the social and legislative background to IVF and ARTs generally in Malaysia by drawing comparisons with the legal framework in the UK and assessing the rights of the women and children involved from both the UK and Islamic perspectives. In doing so, this research aims to explore the challenges that will be faced in obtaining the benefits and advantages offered by IVF technology, but will also analyse how the Malaysian government can control the use of the technology and guide it in the direction that best suits Malaysian society which is strongly influenced by traditional and often diverse religions and cultures. Failure to control the use of the technology may cause harm and risks to the parties involved in the technology particularly women and children. This research then will consider whether and how the proposed legislation could seek to ensure that the legal, ethical and religious complexities are dealt with in a clear framework.

Key words: women, children, legal challenges, in vitro fertilisation

INTRODUCTION

From the outset, the use of IVF technology throughout the world has been considered as an exceptional branch of medicine that has attracted special regulatory attention (Petersen and Johnson, 2007) but Malaysia has not yet introduced legislation. This means that there is no centralised legislation that applies to all infertility centres that utilise IVF technology in Malaysia; different clinics adopt different practices and requirements relating to quality control, safety, selection of patients and the kinds of services and treatments offered. The lack of legislation in Malaysia pertaining to the application of IVF technology importantly raises ethical and safety issues regarding the protection of the institution of the family and society, the parties involved in IVF, the embryo and children born as a result of the treatment. The purpose of this paper is to discuss why legislation is necessary in order to provide adequate protection for the parties involved in IVF.

LEGISLATION IS NECESSARY TO PROVIDE ADEQUATE PROTECTION FOR IVF PATIENTS

The only unenforceable guideline that Malaysia has in place, which broadly governs assisted reproduction, at present is the Guideline of the Malaysian Medical Association on Assisted Reproduction. However, this guideline is not adequate to govern IVF technology in Malaysia as its provisions lack power in both their content and enforceability to ensure safety and the efficacy of the treatment, especially since it cannot be enforced on private clinics. These shortcomings pose challenges for the medical professionals involved in providing IVF services and those who seek access to them.

There is a need for better regulation to protect all parties involved in IVF in order to ensure the safety of IVF procedures, the protection of health and to uphold social, cultural and religious norms. In this paper, I argue that IVF legislation is urgently needed to ensure that medical facilities and their staff are adequately qualified and reliable. In a similar vein, Bennett Moses (2006) argues that in this context “the usual purpose of regulation is to protect those affected by the use of a technology” (p. 527). Such regulation, she believes, could increase the efficacy of the technology as well as protecting the health and safety of those seeking to benefit from the technologies. This argument is further supported by Butler (2003) who comments that “the lack of appropriate guidelines and regulations in most developing countries is a serious drawback in efforts to improve the quality of the services provided” (p. 2).

At root, the utilisation of IVF technology in Malaysia carries with it particular challenges for the regulation process, as it must balance the needs of society, cultural influences and religious limitations regarding whom the technology is offered to and how it works. Vayena et al. (2009) argue similarly that the provision of ARTs in developing countries poses challenges that need to be addressed by the global community and the State (p. 413). It will not be easy for the Malaysian government to formulate legislation that satisfies and adheres to the religious constraints and provide all of the medical safeguards and facilities required for IVF technology to thrive. This might be the reason why there is no legislation as yet, because the Government has been taking time to carefully consider cultural and religious views and the use of IVF before incorporating these into the proposed legislation. However, the fact that the Government has clearly stated its intention to create a bill clearly indicates that this is deemed to be a necessary way forward. In the following sections, the reasons why the proposed legislation is necessary to protect the parties involved in IVF in Malaysia will be further explained, in relation to the safety and efficacy of the treatment, autonomy and consent requirements and the IVF process.

The First Challenge: Ensuring Clinical Standards and Safety

After nearly 40 years, IVF in Malaysia is no longer considered unusual or exceptional. It is today a routine clinical procedure, to the extent that between 3000 and 5000 IVF cycles are conducted in one fertility centre per year (The Star Malaysia: 2009). The fact that a certain level of advanced protection via legislation is not available for IVF and other forms of assisted reproduction treatment in Malaysia is not in itself a sufficient reason to argue such legislation should replace the protection that already exists in the ART guidelines. Hence, it is necessary to demonstrate that there are positive benefits that the proposed new legislation could better provide than the guidelines Malaysia has relied on until now. The first benefit of the proposed legislation for parties involved in IVF is that it will ensure clinical standards and safety. For instance, Jackson (2001) contends that the regulation of ARTs generally has two main purposes, the first is to ensure the techniques used are safe; and the second is to ensure that the use of the techniques is ethical according to the particular society's values (p. 183).

Clinical safety and quality control are two important factors in ensuring efficacy and reliability in the provision of IVF services, and these depend on using properly regulated facilities and properly qualified staff, both of which could be assured through the introduction of legislation. Referring to the first National Reproductive Medicine Congress in Kuala Lumpur, it is arguable that the proposed assisted reproduction legislation in Malaysia will ensure that only appropriately qualified and competent personnel are allowed to treat the patients in all infertility centres (Samy: 2009).

The current guidelines do not sufficiently address safety issues because there are no provisions for monitoring the success and failure rates of IVF and consistencies between IVF providers. This in essence, could only be rectified by the introduction of carefully drafted legislation which is the best means to standardise rules among public and private hospitals. Until recently there has been a *lack of concise provision on enforcement and procedures in the current guideline to address safety issues such as proper scrutiny of IVF techniques and licensing process. This is a matter of concern for the Ministry of Health (MOH). For example, the Guideline of the Malaysian Medical Council (MMC) on Assisted Reproduction provides that for safety reasons, the medical 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. Guidance on the way in which laboratory and clinical practice and the accepted level of satisfaction for the assessment should be interpreted is not provided in any guidelines, thus leaving room for the question as to what standards of quality control should be reached. Schenker and Shushan (1996) argue that it is only through legal interventions that quality control and the highest standards of assisted reproduction can be assured, so that the best services can be achieved and offered to all parties concerned (p. 908).*

Bearing in mind that since then, there has been an increase in demand as well as in the advancement in IVF, it is necessary to determine success rates in IVF and factors that contribute to its success, in order to ensure the efficacy and safety of the treatment. Currently, success rates in IVF depend on many factors, including the quality of sperm and eggs, and quality management in handling, culturing and storing the embryo (Coetsier and Dhont, 1998, p. 2663). There should be an effective monitoring system to ensure high standards of security wherever gametes and embryos are handled and stored. For instance, in the early days of IVF in the UK, Edwards and Beard (1997) stated that concerns were raised about issues such as the storage of gametes and embryos because clinics were not required to have specific and minimum storage requirements (p. 3).

Whilst it may be the case that no doctor wishes to expose women and the 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. One of the important risks associated with it is the increased chance of having a multiple pregnancy, which could significantly increase the chances of complications for mother and baby (Kennedy, 2005, p. 4). IVF also carries increased risks of miscarriage and birth defects, both of which seem to increase with the age of the woman undergoing IVF.

Although the MMC Guideline was put into operation in 2006 to deal with assisted reproduction, the novelty of the technologies and the degree of public concern that they raised mean that this Guideline will soon be tested to its limits. While there is a lack of important safety provisions in the Guideline, the public will certainly question what steps the Government will take in order to ensure the safety of the technology in the future, especially when it relates to the success rate of the treatment. Therefore, the risks are sufficiently great to justify legislation in this field.

Limiting the Numbers of Embryo Transfer

Having already examined the risks involved in IVF, Hamiton (2007), Horsey (2006) and Kennedy (2005) said 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 (Newton et al, 2007, p. 5). Nevertheless, infertility patients particularly IVF patients, often see multiple pregnancies and especially twin pregnancy as a desirable outcome. When comparison has been made between infertile patients and fertile patients with previous children, the former patient group rated multiple-embryo transfer and associated risks as more acceptable than the latter. Initially, infertile patients were less well informed of the risks and complications associated with multiple pregnancies, being primarily interested in having their own biological child. As a result, Glazebrook et al (2007) stated that many infertile couples choose to have more than one embryo transferred (p. 44).

To limit the occurrence of multiple pregnancies, I argue that the maximum number of embryos transferred in each cycle should be restricted to two, though this may be varied depending on the number of IVF attempts and the patient's age. Many countries have now restricted the numbers of eggs or embryos which can be implanted in any one cycle in order to reduce the incidence of multiple pregnancies and ensure the safety of the parties involved in IVF, according to Nordin (2011). If the procedures of stimulating and monitoring egg production are closely monitored by proficient staff and the numbers of embryos implanted are restricted via IVF legislation, then the likelihood of generating excessive multi-fetal gestation would be minimised. Nordin (2011) further said that the assisted reproduction guideline in Malaysia recommends that no more than three eggs or embryos can be implanted into a woman in any one cycle. However, there is an exception for patients who are 35 years old and above, and have undergone no less than two unsuccessful attempts. In contrast, in the UK, since 2004, Eijkholt (2011) stated that clinics have only been allowed to transfer a maximum of two embryos in each cycle to women under the age of 40, with no exceptions, and a maximum of three to women aged 40 and over.

Whatever the merits of the various arguments, it has to be recognised that couples who want children will go to great lengths and risks to have them, and there will always be issues concerning safety, as providers will endeavour to make services available to those who can pay for them. It is arguable that public hospitals' services are provided under the budget allocation of the Malaysian New Economic Policies (NEP), which aim to provide a subsidised medical service for the whole of Malaysia. In contrast, private clinics' services function on a profit basis, hence they tend to concentrate on low risk curative care in urban areas. Chee (1990) acknowledges that access to private clinics is largely dictated by market forces and the availability of money (p. 90), which contributes to the business of reproductive tourism as highlighted in the same section. The fact that IVF is intended to be a business of reproductive tourism further strengthens the argument that the Government has a responsibility to ensure that the services provided – whether in the public or the private sector – are safe and effective (Butler, 2003, p. 2). It is thus essential that the safety provisions within future legislation in Malaysia apply to *all* treatment service providers.

Considering a Maternal Age Limit

In Malaysia, the number of babies born to women in their late 30s has progressively increased over the past decade due to later marriages and delays in having children because of career potential and financial reasons (The Star, 2005). Advanced maternal age is recognised as a risk factor for miscarriage and stillbirth, independent of IVF. Jolly et al. (2000) confirm the hypothesis that the risk of stillbirth is significantly higher in older women (p. 2437), and conclude that pregnant women aged 35 and above are at increased risk of complications in pregnancy compared to younger women. Therefore, one of the safety issues relating to this argument concerns whether the State should impose an age limit on IVF. In other words, even though it may be discriminatory, it is arguable that women older than a certain age should not be allowed to undergo IVF in order to protect them from these risks.

In Malaysia, the Guideline, at present includes no provision pertaining to an age limit for couples receiving IVF. However, obstetricians and gynaecologists in Malaysia believe that 35 should be the age limit for IVF, as they consider that above this age, the success rates are low because the body's response to the treatment is weak (Tee, 2005). In the UK, the National Health Service (NHS) does not usually recommend IVF to women over the age of 42 because the chance of a successful conception is too low. The National Institute for Health and Clinical Excellence (NICE) in reviewing its guidelines recommends that only 23 to 39 year old patients are entitled to expect three free cycles of IVF on NHS. Generally, private clinics will not treat women older than 50. The most important reason behind this recommendation, according to Bowen-Simpkins and Lockwood (2009), is that when women are in their fifties and sixties, they are potentially likely to develop hypertension and diabetes which might endanger their and their baby's life. However, they do not offer an opinion concerning the condition of the woman's uterus when having a pregnancy at an older age. Medical research shows that the success of IVF procedures seems not to be influenced by age, as the success depends on the administration of *estrogens* (the female hormone produced by the ovaries) and *progesterone* (the female hormone which prepares the lining (endometrium) of the uterus (the womb) to receive and sustain the fertilized egg and so permits pregnancy) in the woman's uterus (Fasouliotis and Schenker, 2000, p. 174).

The key problem is that the success rate of IVF in older women depends on the age of the *eggs* and not on the age of the uterus, and most evidence suggests that the factor that is most influential in determining whether IVF is successful in older women is the quality of the woman's eggs (Coetsier and Dhont, 1998, p. 2665). A study (Templeton et al., 1996, p. 1402) revealed that the highest IVF success rates were in the age group 25 to 30 years; showing that younger women whose eggs are usually in better condition, had higher rates with a sharp decline in older women. At all ages over 30, the study showed that the use of donor eggs

had promoted a significantly higher success rate than the use of the woman's own eggs. In the face of this finding, when women who are older than 45 undergo IVF, they generally use eggs donated by younger women.

However, in Malaysia, the Guideline clearly prohibits any kind of egg or sperm donation, on the basis that IVF must only be available in circumstances where there will be cultural and religious acceptance. Therefore, older women seeking IVF in Malaysia must use their own eggs and their husbands' sperm. So, the concern here is that older women might be put at risk of complications for IVF that may pose a threat to their life with very limited chances of success. Legislation is therefore urgently needed to specify requirements and protect the safety of this group because the harm of the treatment in this situation is potentially greater than its benefit. However, it might be considered that any potential harm is outweighed by the benefits of the treatment, since every woman should be given every opportunity to conceive their own biological child. To assist in making such a decision, it should be stated in the proposed legislation that medical practitioners must take special care when making a harm assessment if they are providing the treatment to older women. In the UK, NICE aims to ensure that no one is discriminated against on the grounds of age, hence women over the age of 40 could now get free fertility treatment on the NHS for the first time (Martin, 2010). However, this is not the case for all women, because the availability of IVF on health services depends on the 'postcode lottery' of provision and where the potential patients live. An example of the postcode lottery came into light in January 2005 when ten Primary Care Trusts (PCTs) in Hampshire refused to fund IVF treatments because of the low priority and limited funding of IVF in the county.

As mentioned, previously, NICE stipulated that IVF should only be provided to women aged only up to 39 years in its guidelines, which invited much criticism and later resulted in its revision (Martin, 2010). One of those who has criticised this rule, Harris (2005), argues that this is discriminatory, stating that it is none of NICE's business to evaluate patients rather than treatment (p. 375). To add to this, the British Medical Association (BMA) (2004) opines that as it is wrong to discriminate solely on factors such as the patient's age, other criteria such as the likelihood of success are relevant to whether or not an option is offered (p. 27). Thus, this paper concurs with Martin (2010) and Harris (2005), that on the basis of safety concerns, it is more acceptable to test how many eggs women have and the condition of their ovarian reserve, rather than imposing a blanket ban over a certain age. Also to support my argument, Biggs (2006) contended that everyone should be given the opportunity to become a mother regardless of the age of those who chose to take on that role. She argues that "women who delay becoming mothers for their own reasons and then deliberately choose to embark on parenting at a time when they really want to and when they believe they can best provide for their child, have much to offer". There is evidence according to Bowen-Simpkins and Lockwood (2009), to suggest that children born to older women tend to receive better-quality parenting and have greater financial security. In fact, older women themselves should be allowed to weigh the risks of pregnancy which undoubtedly increase with their age but in certain situations must be guided so as not to threaten their own health.

Whilst it is accepted that doctors generally act in the best interests of their patients as is demanded by professional ethics and law, medical interventions such as IVF do carry inherent risks such as multiple pregnancies and birth complications (as demonstrated in the previous discussion), which must be assessed and balanced against the potential benefits. When it comes to determining whether legislation is required to protect individuals in this context, the principle of harm can be utilised to ascertain what level of risk is acceptable.

The Second Challenge: Applying the Consent Requirement

To ensure that all parties understand the risks and complications involved in IVF, Sawers and Avery (2006) said that ethical principles insist that a person should have control over their own body and should make their own decisions as to undergoing the treatment (p. 246). Many would accept that reproductive autonomy (or self-determination) is a morally relevant factor in an evaluation of whether the use of IVF technology is unethical. Accordingly, Malaysia needs to have its own legislation on IVF to allay public concerns pertaining to autonomy and the application of consent requirements in either public or private clinics, and to give a clearer picture about the risks of IVF.

The Consent Requirement

The Guideline on Assisted Reproduction explicitly states that no assisted reproduction treatment should be given to any couple without their written consent to that particular treatment. The treatment must be clearly explained to them, including success rates and complications (Petersen, 2004, p. 1). As already noted, this Guideline is not binding on private clinics offering IVF, and this has created problems and conflicts that result from the application of different rules (Nordin, 2011). Hence, the legislation would provide a better way to control all hospitals and clinics offering IVF under one, consistently applied law.

The difference in the application of consent to IVF procedures in Malaysia of course raises a number of issues regarding whether those who obtain and receive the treatment understand its implications, side effects, and likelihood of succeeding. This would certainly avoid conflicts of consent which might occur in the case of death or separation of the couple, such as what happened in the case of *Evans v United Kingdom* [2007] All ER 109, which I will discuss later, or an unexpected change of mind or failure of the treatment. Clear legislation, laying down rules regarding consent that apply to all treatment providers is an important way to encourage and maintain public confidence in IVF. In a similar way, Butler (2003) suggests that hospitals and centres should be encouraged to standardise procedures and rules (p. 2).

In conscientious medical practice, it is now a basic legal and ethical pre-condition that a patient must give not just a simple consent which means merely obtaining permission from the patient to carry out the treatment, but an *informed* consent to treatment (Rearne, 1999, p. 333). The principle requires that the patient must fully understand the treatment and its implications

(Maclean, 2009, p. 242). However, a problem of this principle for the law has been reaching a consensus on what amounts to informed consent. Heywood (2010, p. 172) infers that there is a significant conflict over whether disclosure of risks should be judged in relation to the accepted standards of the medical profession as stated in the case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. However, in the more recent case of *Smith v Tunbridge Wells HA* [1994] 5 Med LR 334, the Court suggested that in order to facilitate the understanding of the disclosure of risks in informed consent:

...the doctor, when warning of the risks, must take reasonable care to ensure that his explanation of the risks is intelligible to his particular patient. The doctor should use language, simple but not misleading, which the doctor perceives from what knowledge and acquaintanceship that he may have of the patient (which might be slight), will be understood by the patient so that the patient can make an informed decision as to whether or not to consent to the recommended surgery or treatment.

This is a first instance judgment so is not binding on subsequent cases but based on this argument, it is evident that the patient must understand both the risks and complications of the treatment before they give their consent. In order to achieve this, only good communication between doctor and patient will enhance the process that reflects ethical best practice as described in the recent guidance from the General Medical Council (GMC) in the UK.

Similarly, informed consent in IVF in Malaysia is no exception to this rule. This requirement is not intended to complicate the procedure of IVF or other assisted reproduction treatment, but rather it aims to assist the patient to come to a well-considered judgment about the nature and consequences of the risks and benefits and as Reame (1999) argues, the goal of obtaining adequate informed consent to medical treatment is not simply to obtain a signature on a form (p. 333). In Malaysia, the current guideline only provides general provisions regarding a consent requirement, but no mandatory requirement as to what kind of information should be disclosed is specified. It is highlighted in the case of *Chester v Afshar* [2004] 4 All ER 587 that for the first time in English law the Court has decided that failure of a doctor to give adequate information about a procedure to patients is negligent per se. This was considered to be a significant omission. Stipulating what information is required to be given to the patient to obtain their informed consent is surely one of the main ways of ensuring respect for patient autonomy and should therefore be included in IVF legislation which values and respects patient autonomy.

As noted above, in Malaysia, further consent requirements are provided under a separate guideline. The Guideline on Specific Technical Requirements for Accreditation of Assisted Reproductive Technologies Laboratories provides that a consent form shall be signed by patients. This is not expressly mentioned in the Guideline on Assisted Reproduction, except for a statement that IVF shall only be offered to patients with their written consent. This suggests that if there is no provision provided to *explain* the requirement of informed consent, given that all the public hospitals are bound, and assuming they have acted in accordance with these guidelines, women in Malaysia might be at risk when undergoing the IVF process without truly knowing the risks that IVF might hold for their health or the health of their potential children due to the lack of specified requirements in the guidelines.

Just as importantly, the requirements should include the right of patients to withdraw their consent as well. To fill in the gaps, the Malaysian Guideline on Medical Genetics and Genetic Services which complements and should be read with other guidelines issued by the MMC explicitly states that patients have the right to withdraw treatment at any time. In the UK, the English common law presumes that all adults have capacity to consent or refuse treatment and the provisions are enshrined in the Mental Health Act 1983 and the Mental Capacity Act 2005. These Acts describe the very limited circumstances when a patient can be forced to be hospitalised for assessment and/or treatment against their wishes and authorise the area assessing whether the patient is mentally capable of making the decision. It is not for the patient to prove he/she is capable, but rather, the medical authority must assert the patient lacks the capacity to prove its absence.

The Third Challenge: Facilitating the Treatment Process

IVF legislation is also needed in Malaysia to ensure that those who are involved in the provision of services or treatments are appropriately qualified and skilled to perform the procedures. Merican states that the proposed assisted reproduction legislation in Malaysia aims to ensure that only appropriately qualified and competent personnel are allowed to treat patients (Samy, 2009). Currently, no such requirements are detailed in the Malaysian Guideline on Assisted Reproduction.

Qualified Medical Practitioners

As far as IVF technology is concerned, there is no single guideline to define further the minimum benchmark of the accepted standard regarding a doctor's competence. This is obviously insufficient to ensure the safety of the parties unless the practitioners and clinics are constantly monitored through legislation. A lack of provisions that require the MMC to inspect and maintain a registry of competent and appropriately qualified persons in this field means that many individuals may go to the wrong person to get the treatment.

In order to ensure only qualified and skilled persons are involved in IVF in Malaysia, legislation is explicitly needed to authorise a licensing body to control the activities of the infertility centres. To reassure people that IVF technology is safe and under control, the pace of scientific progress must be constantly watched, and in order to do this, a licensing body is vital to the control and regulation of assisted reproduction techniques. Through this body, the Government can constantly observe the pace of scientific progress, reassuring people that the technologies are safe and under control.

One difference between Malaysia and the UK is the existence of a licensing body in the latter and it is recommended that a provision to this effect be incorporated into the proposed IVF legislation in Malaysia. In the UK, it is clear under the Human

Fertilisation and Embryology Act 1990 (the HFE Act) that the HFEA acts as a licensing body that inspects the applicant's infertility centre, and only if the facilities and staff are deemed suitable, will a treatment licence be granted (Jackson, 2001, p. 185). In fact, to control and regulate private healthcare facilities and services in Malaysia for example, a licensing unit has been formed via the implementation of the Private Healthcare Facilities and Services Act 1998 (Wan Abdullah, 2004, p. 5). This unit is responsible for the licensing of private hospitals, private nursing homes and private maternity homes to ensure that services provided by these premises comply with high standards of safety. I contend that a similar unit should exist regarding IVF. Whilst the Guideline's terms of reference purport to ensure that registered medical practitioners are fully aware of the codes of professional medical practice and to prevent abuse to patients and members of the public, the Guideline still lacks a provision pertaining to licensing. Merican notes that the law now being formulated in Malaysia is directed to providing for proper scrutiny, licensing and audit of ARTs centres (Samy, 2009).

The Counselling Process

Since IVF involves lengthy, intrusive and painful procedures for the woman, as well as many difficult decisions before, during and after the process of the medical intervention both for her and her partner, it is important for them to fully understand the implications. For this reason, patients must be adequately informed of any risk to which they are considering providing consent, as I have previously argued. Any risks must not be underplayed and patients should be made fully aware of them before treatment. Therefore, counselling is a key element in the provision of infertility services in order to facilitate and provide couples with a clear understanding about the process and implications of the treatment. More importantly, a physician or doctor has a partial responsibility for the patient he/she refers, especially regarding the provision of information and counselling. As I have noted, the European Commission has 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 to provide information and counselling for the patient he/she refers (Pennings, 2008). Also, in the UK, the HFE Act 1990 (as amended by the 2008 Act) recognised the need for counselling by incorporating Section 14(3)(6) into the 1990 Act, which clearly states that a woman shall not be provided with treatment services in accordance with Part 1 of Schedule 3ZA unless she and her partner have been given an appropriate opportunity to receive proper counselling and relevant information.

In determining that IVF is performed in a proper manner, the needs of each patient particularly women must be taken into consideration. These include the patient's condition, the complexity of the treatment and how effective the medical practitioners and patient are at communicating with each other. Since medical matters are private and confidential, the discussion should be conducted in a private room to avoid others overhearing. Maclean (2009) argues that the law should have regard for all of these factors in creating an environment that will facilitate the treatment (p. 242). Significantly, in Malaysia, there are no provisions to the effect that an opportunity for counselling must be provided prior to IVF in the MMC Guideline. Therefore, in order to ensure the efficacy and safety of IVF in Malaysia, provisions to this effect must form a part of future IVF legislation. This will assist the parties to sufficiently understand both the risks and complications of the treatment before they give their consent. To assist them through this process, counselling plays an important role and this can only be enforced if the provision is provided in the legislation. Thus, it is necessary for the Government to provide a provision regarding counselling in the proposed IVF legislation, particularly in a Code of Practice. The guidance in a Code of Practice serves as a regularly updated reference for staff and patients compared to primary legislation and therefore, it is the best way forward for the counselling provision to be provided in a Code of Practice.

CONCLUSION

Although the safety of IVF is generally accepted by the country and the medical authorities, greater protection could be offered to the Malaysian public than that which is currently provided. Accordingly, the Malaysian government should seek to ensure as far as possible that the principles relating to the efficacy and safety of assisted reproduction procedures that are outlined in this paper can be fully met, not only for the couples but also for the embryo and the potential children born as a result of IVF. To achieve this, regulation by way of legislation is necessary. Having said that, this paper has some limitations. The lack of literature discussing issues relating to IVF in Malaysia demonstrates that it is still an emerging technology and makes research problematic. In order to overcome the problem of the unavailability of data, much reliance is placed on government publications such as annual year books and reports.

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