



The need to address legal ambiguity on conceiving saviour siblings in Malaysia[☆]



Chee Ying Kuek^{a,*}, Sharon Kaur Gurmukh Singh^b, Pek San Tay^b

^a Faculty of Law, Multimedia University, Malaysia

^b Faculty of Law, University of Malaya, Malaysia

ARTICLE INFO

Article history:
Available online 9 July 2019

Keywords:
Haematopoietic stem cell transplant
HLA typing
Law
Policy
Preimplantation genetic diagnosis
Saviour sibling

ABSTRACT

Conceiving a saviour sibling can be a vital treatment option for a child suffering from a haematological condition. However, the legality of this option may be called into question in countries where there is no clear law or policy regarding the use of preimplantation genetic diagnosis with HLA typing (PGD-HLA typing) or HLA typing alone for this purpose. In Malaysia for instance, there is no legislative framework governing the use of assisted reproductive technology and the only guidance appears to be provided by guidelines issued by the Malaysian Medical Council. In the absence of clear direction, broad guidelines or policy positions taken by such statutory bodies may heavily influence the practice or roll out of certain technologically advanced therapeutic interventions.

Previous literature has construed this Guideline narrowly as prohibiting this practice. This paper argues that the narrow and traditional interpretation method used in previous literature is wanting and suggests a more meaningful approach to the interpretation of the Guideline and advocates that this interpretative method should be applied in similar instances involving technologically advanced treatment modalities in other similar situations. Such guidance documents should be interpreted in a manner which takes into account the nature of the technology, its implications and intended use.

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Introduction

Haemopoietic stem cell (HSC) transplant is a common curative therapy for many haematological disorders. Donors and recipients for HSC transplants are matched by way of Human Leukocyte Antigen (HLA) typing. There is a lower risk of graft rejection if the donor is HLA-matched with the recipient [1] and a transplant has a higher success rate and less complications when the donor is an HLA-matched sibling compared with an unrelated matched donor [2–3]. Therefore, an HLA identical sibling is always considered as a preferred HSC donor. However, the chance of two siblings having a complete match in HLA type is only approximately 25% [1,4–5]. If there is no compatible donor among family members, an alternative option is to find an unrelated matched stem cell donor in a national or even international donor registry. The search will consume some time and chances will very much depend on the pool of the registry and the patient's ethnicity. About 30% of patients

have an HLA match among siblings while the rest have to rely on unrelated donors who are HLA compatible [6].

When there are no matching siblings available, parents now have the option of conceiving a potential HSC donor for their sick child and this child is often referred to as a 'saviour sibling'. A saviour sibling is conceived using preimplantation genetic diagnosis (PGD) combined with HLA typing (PGD-HLA typing) or HLA typing alone. Embryos are created by *in vitro* fertilization and genetic testing is done on the cells extracted from the embryo. Embryos will then be selected based on their genetic health and HLA compatibility before being transferred to the mother's womb.

Currently, conceiving a saviour sibling may be a viable treatment option for parents who have children with beta thalassaemia, fanconi anemia, sickle cell disease, severe aplastic anemia and diamond blackfan anemia, which can be cured by an HSC transplant [7–8]. PGD-HLA typing or HLA typing alone has been used as an alternative or last resort in the USA [9], UK [10], Australia [11] and other countries [12–16] when there is no existing matched sibling in the family or a matched unrelated donor. By permitting the use of saviour siblings, it provides a medical alternative for affected children who are in desperate medical situation and need an HSC transplant. However, the legality of this therapeutic option may be called into question in certain countries like Malaysia where there

[☆] The authors thank the anonymous reviewers for their helpful comments. All errors remain ours.

* Corresponding author.

E-mail address: cykuek@mmu.edu.my (C.Y. Kuek).

are no clear laws or policies regarding the use of PGD-HLA typing or HLA typing alone.

PGD has been available in Malaysia since April 2004 [17]. At present, it is mainly offered by private fertility centres in Malaysia. HLA typing services, on the other hand, are available at certain institutions such as the Institute for Medical Research (IMR), the immunogenetic and transplantation laboratory of the University Malaya Medical Centre (UMMC) and a number of genetic testing centres in the private sector. Although there is no reported case of any saviour sibling having been successfully conceived using PGD with HLA typing or free-standing HLA typing in Malaysia, this technology is already available and attempts have been made in the private sector for this purpose [18]. Therefore, it is conceivable that this may happen in the near future.

There is no specific statutory law in Malaysia relating to assisted reproductive technology (ART) and when PGD was first introduced in 2004, its application was completely unregulated. As such, its use was not limited to avoidance of hereditary genetic diseases as originally intended, but also for sex selection for social purposes. Such usage of PGD caused some disquiet among the medical fraternity, particularly the Malaysian Medical Association (MMA) [19] and the Ministry of Health. In 2006, partly as a response to concerns surrounding the unregulated application of PGD, the Malaysian Medical Council (MMC) which is a statutory body regulating the medical profession, published its Guideline on Assisted Reproduction (the MMC Guideline on Assisted Reproduction). The MMC Guideline on Assisted Reproduction contains two specific provisions relating to PGD and the creation of saviour siblings. Clause 14 provides for the application of PGD and briefly states that attempts have been made to select embryos which are not only unaffected by genetic disease, but also of the same HLA type with an existing sick child who needs an HSC transplant. Clause 15 sets out the list of prohibited practices. However, these two clauses do not expressly state the permissibility of the creation of saviour siblings.

In instances such as these, where there is no clear legislative framework governing the use of technologically advanced therapeutic interventions, broad guidelines and policy positions taken by statutory bodies such as the MMC tend to heavily influence the practice or roll out of these interventions. Given the impact of such guidance on practice, it is important to consider how they should be interpreted and to this end, rules of statutory interpretation are useful points of reference. The objective of this paper is to analyse the MMC Guideline on Assisted Reproduction to ascertain the legal position of the creation of saviour siblings in Malaysia. The discussion is divided into four parts. First, it sets out some of the traditional rules of statutory interpretation that are commonly used. It then focuses on the relevant provisions of the MMC Guideline on Assisted Reproduction and the current claim by some quarters that the creation of savior siblings is not permitted in Malaysia. Following from that, it argues that such an interpretation of the Guideline is wanting and that a more meaningful approach should be used. Finally, it demonstrates that such guidance documents should be interpreted in a broad manner, which should take into account the nature of the technology, its implications and intended use.

Rules of statutory interpretation

There are three traditional rules or approaches of statutory interpretation, namely the literal rule, the golden rule and the mischief rule. According to the literal rule, if the words in the statute are precise and unambiguous, they are to be given their ordinary, natural and usual meaning [20, p15]. However, if the literal rule leads to inconsistency with other provisions in the statute or produces an absurd result, the golden rule provides that the ordinary meaning of the words may be modified to avoid such absurdity but

no further [20, p16]. If the literal rule or golden rule does not assist the court, the court may apply the mischief rule. The mischief rule requires the interpreter to determine the defect which the statute sets out to remove, and to interpret the statute in a way that cures the defect [20, p11]. The mischief rule has subsequently developed over time, and from it, the purposive approach has been derived.

The purposive approach is broader interpretive method where one seeks to determine the purpose of the statute. When using this method, a judge may look beyond the four corners of the statute and construe the words in a way that promotes legislative purpose. Like the mischief rule, it is usually applied when the meaning of a provision is ambiguous [20, p19]. When interpreting a statute, the first step is to consider the words in their grammatical and ordinary sense. If this understanding appears to contradict the purpose of a statute, the secondary meaning of the words that would best advance the purpose of the statute may be chosen [20, p49]. In addition to this, the legislator is presumed to have intended a coherence or consistency in the law as a whole and policies in a specific area [20, p88].

In the absence of a specific statute on ART, the relevant guidelines affecting the creation of saviour siblings and HSC transplants need to be construed and analysed with the aim of ascertaining the possible legal position of conceiving saviour siblings in Malaysia. The following section considers the way in which the guidelines have been construed and argues that broader interpretive methods should be preferred.

Discussion

MMC guideline on assisted reproduction

The MMC Guideline on Assisted Reproduction deals with services or treatments that involve human gametes and embryos using ART. It is based on five guiding principles: respect for human life, rights of sub-fertile individuals, concern for the welfare of children, benefits resulting from the responsible pursuit of medical knowledge, and the sanctity of marriage particularly in relation to having children.

Clauses 14 and 15 of the MMC Guideline on Assisted Reproduction, address the issue of PGD. Clause 14 provides, among other things that:

“At present PGD is used mainly for the diagnosis of many diseases and to determine the sex of the embryo to avoid the transmission of severe sex-linked disease. Some have attempted to select embryos free of genetic disease but of the same tissue type as an existing ill child in order to harvest their umbilical cord blood for transplantation to the affected sibling...At present, it is best that PGD be used for only severe and life threatening genetic diseases. It would be unethical to analyse and select the inherited characteristics of embryos (e.g. intelligence, height, hair and eye colour); any social or psychological characteristics or any other condition which is not associated with disability or a serious medical condition [21].”

There are three main features of the provision. First, it sets out the ways in which PGD is currently utilised. It states that it is typically used to avoid transmission of certain genetic diseases and sex-linked diseases. Significantly, it recognises that attempts have been made to choose embryos which are healthy and HLA-matched with an existing sick child to harvest the baby's umbilical cord blood so as to be transplanted to the sick child. Obviously, this refers to the creation of saviour sibling although the words “saviour sibling” are not used. Second, it makes a recommendation that PGD is best used for severe and life threatening genetic diseases. Finally, it declares as unethical the practice of selecting embryos for conditions not relating to any disability or serious

medical condition. Two preliminary observations can be made at this point. First, although the provision addresses the issue of saviour siblings in that it recognises that attempts have been made to create saviour siblings, it remains silent on whether this is ethical or permissible in Malaysia. Second, the provision declares unethical and therefore presumably does not permit, selecting embryos for conditions not related to any disability or serious medical condition.

Clause 15 sets out a list of prohibited practices. This includes developing embryos not for the purpose of an approved ART programme, creating designer babies for preferred characteristics or not for medical reasons, and social sex selection. There is no mention of the creation of saviour siblings.

Interpretation of MMC Guideline on Assisted Reproduction

There is hardly any literature on the legality of conceiving saviour siblings in Malaysia, which is probably due to the fact that as yet, there is no reported case of this having been successfully done in the country. It would appear that only Haniwarda Yaakob has considered the question of the ethics and legality of conceiving saviour siblings in Malaysia. While she agrees that the MMC Guideline on Assisted Reproduction is silent on the legal position of creating saviour siblings, she has construed clauses 14 and 15 as prohibiting the creation of saviour siblings in Malaysia. This is based on the ground that the technology involves “screening [of] embryos other than for medical reasons” and therefore is not within the ambit of an approved ART programme [22]. This is a literal and narrow interpretation of the Guideline which assumes that the reason for screening the embryo must be directly related to the interests of the embryo alone and discounts any broader familial, societal or policy interests.

It is contended that this literal interpretation of the clause is incorrect as it is inconsistent with the guiding principles set out in the Guideline. It fails to take into account three of the guiding principles stated above, namely, respect for human life, benefits resulting from the responsible pursuit of medical knowledge and concern for the welfare of children. The first two principles relate to broad notions of respect for human life in general and the benefits of pursuing medical knowledge. Any interpretation of clause 14 should take into consideration the value of respecting human life in general as well and the potential benefits of the technology as a whole. Significantly, the third principle does not speak solely of the welfare of the created embryo but uses the word ‘children’. It is therefore necessary to interpret the notion of medical reasons broadly and consider the value of the use of this technology beyond the individual embryo. Such broad interpretation will be consistent with the guiding principles of the MMC Guideline on Assisted Reproduction since it furthers the purpose of this technology while ensuring that it operates within the confines of the Guideline. It also does not conflict with the purpose of the Guideline, namely safeguarding the patient and the public, ensuring propriety in medical practice and preventing abuse of professional privileges. [21].

This approach is in keeping with current literature, which classifies the creation of saviour sibling as an “indirect medical model” [23], “therapeutic option” [24] or “therapeutic tool” [25] for an affected sibling. Pennings and Wert explain that under the indirect medical model, the resulting child of the PGD-HLA typing or HLA typing alone does not enjoy any medical benefit. However, the use of this technology has implications for the health of a third party or an existing sick child. This is because the saviour sibling will act as a compatible HSC donor for the sick child. Van de Velde et al. described PGD-HLA typing or HLA typing alone as a “therapeutic option” for the parents whose ill child needs an HSC transplant. Similarly, Kahraman et al. also acknowledged that in the case of

parents having an affected child, PGD-HLA typing has become a “therapeutic tool” for an HSC transplant. Therefore, it is possible to construe the medical purpose or reason as envisaged in clause 14 of the MMC Guideline on Assisted Reproduction as covering the “indirect medical model” and it is not limited to the strict medical model which only affects the resulting child.

The medical purposes of PGD and HLA typing to conceive saviour siblings should therefore be understood in a broader sense, in that it is legitimate to consider the impact on a third party or another sick child in this context. Such interpretation upholds the guiding principles of the MMC Guideline on Assisted Reproduction. The benefits that the technologies bring namely the curing of serious diseases and the saving of lives of the ailing children are in line with the principle of respect for human life.

As PGD-HLA typing and HLA typing alone do not seem to contravene clause 14 of the MMC Guideline on Assisted Reproduction, they are not likely to fall foul of clause 15 as well since the embryos are developed for therapeutic purposes, albeit as an indirect medical model. As noted earlier, the creation of saviour siblings is not in the list of prohibited practices set out in clause 15 of the MMC Guideline on Assisted Reproduction. A plain reading of clause 15 suggests that the creation of saviour siblings is not a prohibited practice. If the MMC Guideline on Assisted Reproduction intended to prohibit the creation of saviour siblings, it is highly likely that it would have been explicitly provided in clause 15 as with other unacceptable practices.

A broader reading of the principles of respect for human life and benefits of medical technology would also require a consideration of the implications of the use of the technology to patients, families and society.

Implications to patients, families and society

There are a few implications if clauses 14 and 15 of the MMC Guideline are to be interpreted as permitting the creation of saviour siblings in Malaysia. Firstly, affected children who can be cured by an HSC transplant but fail to find any existing suitable donor will have an additional treatment option if the creation of saviour siblings is allowed. This would be helpful as the volunteers who registered as stem cell donors are limited while the demand for HSC transplant has been on the rise due to the increase of the number of patients suffering from hematological diseases in this country [6]. However, it should be noted that the chance of finding an unaffected and HLA-matched embryo for a sick sibling is 18.75%, having considered the 75% chance of identifying unaffected embryo and 25% chance of HLA compatibility [26]. Notwithstanding this, it remains an additional treatment option when an HSC transplant is desperately needed to cure the genetic disease but no compatible HSC donor is available. In countries such as Turkey, the US and UK, saviour siblings were conceived to cure less common genetic disorder suffered by the existing siblings such as fanconi anemia, diamond blackfan anemia, sickle cell disease and severe aplastic anemia [3,9,10].

Furthermore, HSC transplants which are made possible by the creation of saviour siblings may benefit more pediatric patients and reduce healthcare expenditure in this country. For instance, the beta thalassaemia patients are conventionally treated with regular and lifelong blood transfusion and iron chelation [27]. However, to treat a thalassaemia patient who is a transfusion dependent for 30 years will cost around RM3.5 million (USD238,095) in Malaysia [28]. If an HSC transplant can be performed early when the Thalassaemia patient is still young and iron overload is yet to develop, this would cure the patient and would save the lifelong costs of care and treatment borne by patients, their families and the government.

In addition, Malaysia has emerged as one of the key players in the medical tourism in Asia. If conceiving saviour siblings is permissible in Malaysia, some medical tourists from other countries are expected to travel here for such service due to the relatively low medical cost and the availability of the technology in Malaysia. This may include medical tourists from countries which do not have clear law or policies regarding the use of PGD-HLA typing or HLA typing alone.

Conclusion

Conceiving a saviour sibling can be a vital therapeutic option for a child suffering from a haematological condition. However, whether such option is permissible depends very much on the law and policy of a country governing the use of PGD and HLA typing for this purpose. In Malaysia, the MMC Guideline on Assisted Reproduction does not explicitly approve or prohibit the creation of saviour siblings. The legal ambiguity of the related provisions, namely clauses 14 and 15, has caused some quarters in the industry to assume that the creation of saviour siblings is outlawed in this country on the ground that the screening and selection of embryo are not for medical purpose. However, such literal interpretation may be overly rigid and omits to make reference to other previous literature which categorised the conception of saviour siblings as an indirect medical model or therapeutic option for parents who have an affected child in need of an HSC transplant.

A broader approach to the interpretation of the MMC Guideline on Assisted Reproduction will be more meaningful and should be applied to ascertain the legal position of conceiving saviour siblings in Malaysia. Adopting this interpretation approach and by taking into account the guiding principles of the MMC Guideline on Assisted Reproduction, the nature of the technologies, their intended use and implications, the practice of conceiving saviour siblings using PGD-HLA typing or HLA typing alone is not intended to be prohibited in Malaysia. As PGD and HLA typing are already available in this country and attempts have been made to create saviour siblings with these technologies, it is desirable that the legal position of conceiving saviour siblings in Malaysia be ascertained or clarified so that all interested stakeholders can confidently act within the permitted ambit of the law.

Author statements

Funding

None.

Competing interests

None declared.

Ethical approval

Ethical approval by University of Malaya Research Ethics Committee (UMREC) dated April 19, 2017 (valid from September 2016 till August 2019). Reference number: UM.TNC2/RC/H&E/UMREC - 160.

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