



CONFERENTIA
EPISCOPALIS
MELITENSIS

LEGISLATION REGULATING ASSISTED HUMAN PROCREATION

A POSITION PAPER

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Executive Summary

1. Introduction

- 1.1. This position paper, which has been prepared at the request of the Church in Malta by a group that includes experts in the field of clinical medicine, law, psychology, social policy, family studies, disability studies, philosophy and theology, is meant to respond to the amendments that the Government is apparently planning to introduce to the *Embryo Protection Act, 2012*.
- 1.2. The Church participates willingly in a spirit of dialogue, basing her contribution on the values she upholds, which are the values of a great number of Maltese citizens, and on her long experience in listening to and supporting persons in difficulties, including those related to infertility.

2. The Embryo Protection Act

- 2.1. The objective of the *Embryo Protection Act* is clearly the protection of the human embryo and the legitimate interests of the future child. Its central ethical concern is human dignity as defined and prevalent in Maltese (and European) Law.
- 2.2. The list of unlawful procedures under the current law also confirms its central concern and objective to protect the human embryo.
- 2.3. The exception that the law allows in the case of embryo freezing is not meant to become the rule but to provide for emergency situations in which one may resort to a measure which is generally not allowed but permissible, under certain conditions, to preserve the life of the human embryo.

3. Legal Considerations

- 3.1. As Government sources have stated, one of the reasons for amending the *Embryo Protection Act* is to bring it in line with recent Maltese legislation and to certain judgments recently delivered by the European Court of Human Rights (ECHR).
- 3.2. Both the *Constitution of Malta* and the *European Convention on Human Rights* guarantee protection from discrimination. Nevertheless, the *Embryo*

Protection Act cannot be considered to be discriminatory when it excludes same-sex couples from having recourse to medically assisted procreation. Medically assisted procreation in favour of a heterosexual couple, whereby the gametes are provided by the couple itself, and medically assisted procreation in favour of a homosexual couple or heterosexual couple, where gamete donation or surrogacy are used, are neither similar nor comparable, and no discrimination can exist when one does not compare like with like.

- 3.3. The recent judgments of the ECHR are not at all relevant. A number of cases of the ECHR have been singled out to justify the need for amendment of the current legislation regulating assisted human procreation. The explicit basis of these judgments is however that every country has the right to establish its own rules in matters of assisted procreation. Every country is entitled to establish its own definition of “person.” Malta has, through its consistent legislation, exercised the wide margin of appreciation recognized to it by the ECHR to consider as “persons” not only human beings who are born viable, but even persons who have not yet been born, whether they are embryos or foetuses, provided that they have been conceived.
- 3.4. In Malta, throughout the whole Maltese legal system, the right to life extends to the human embryo. Both in the *Civil Code* and in the *Criminal Code* the human embryo is protected by law, is considered as a subject of law and is afforded rights not only at birth but from the moment of conception onward.

4. Medical Considerations

- 4.1. When compared to other European countries, the current IVF service in Malta has already achieved good results with oocyte vitrification. The argument that freezing embryos will avoid the need for the prospective mother to undergo ovarian stimulation is being achieved by oocyte vitrification. Hence, there is no “value added” to freezing embryos. A high (ethical, moral, financial, psychological) price to pay is involved, especially as embryo freezing is very likely to result in embryo wastage and destruction, thereby negating the robust protection offered to the unborn child currently enshrined in Maltese Law.
- 4.2. It is difficult in practice to restrict pre-implantation genetic testing to aneuploidy alone. In all probability, other genetic conditions will be discovered and, in practice, most if not all “abnormal/defective” embryos will not be implanted and subsequently discarded. Choosing which embryos to

implant would amount to selective eugenics and would involve wilful and deliberate destruction of innocent human embryos.

5. Matters of Concern

- 5.1. *The Human Embryo as a Commodity:* The freezing of human embryos, gamete donation, surrogacy and human embryo selection promote a culture of manipulation that reduces the prospective child to a mere object of desire or even a mass of cells to be used, selected and discarded. The child has the right to be *conceived* by one's own parents, *carried* in the womb by one's own gestational mother, as well as to be *brought up* within marriage or a stable relationship.
- 5.2. *Changing Fertility and Childbearing Patterns:* Fertility rates in Malta have fallen over the years, in line with the rest of Europe. More research on the causes of infertility in Malta, and investment in education and in the prevention of infertility are required.
- 5.3. *Having a Child at all Costs:* One should ask: Is there a right to have a child at all costs? The main concern is that this question is often answered on the basis of what the individual desires rather than on what is in the child's best interest. The creation of children, albeit facilitated through ever-advancing technology, should still be based on the rights and interests of the child. Third-party needs and desires, however genuine, cannot be considered at par with those of the child.
- 5.4. *Commercialisation of the Woman's Body:* The mindset behind a woman gestating a child at all costs, even someone else's biological child, objectifies the woman, reducing her to a mere level of incubator. Surrogacy in particular, fragments and trivializes the notion of parenthood. Maternity should not be divided into genetic, gestational, and social motherhood. This practice is exploitative of both the woman and the child, and damages the way conception and gestation are regarded in society as a whole.

6. Ethical Aspects

- 6.1. *Protection of the Most Vulnerable:* A sure mark of a civilised society is its concern for its vulnerable members. Any legislation that fails to protect the innocent fails in its primary purpose. The Maltese legislation regulating assisted procreation is called the *Embryo Protection Act* precisely because it

ensures safety and full protection to the vulnerable human embryo. The rights of children to protection from physical and social harm – before and after birth – should be of paramount ethical concern.

- 6.2. *Moral Status of the Human Embryo:* If human life begins at fertilization and the human embryo is the same individual as the older human being, then the human embryo has from its very inception, the dignity proper to a human being. The respect for the individual human being, which reason requires, is further enhanced and strengthened in the light of faith: thus, there is no contradiction between the affirmation of the dignity of the human embryo and the affirmation of its sacredness. The right to life and to physical integrity of every human being from conception to natural death must be respected. The wilful and deliberate discarding or destruction of the human embryo, the freezing of supernumerary embryos, their use for basic scientific research, and their exposure to serious risk of death or physical harm are ethically unacceptable.
- 6.3. *Gamete Donation:* Gamete donation may not be simply construed as an act of generosity of donating a sperm or an egg to someone for the purpose of having a child. It involves a complex interchange of rights and obligations. It is wrong to create a child and exclude from the very start to also undertake the responsibilities for one's child or even for a relationship with him/her. Gamete donation has a crucial bearing on the child's life course and identity development. Gamete donation cannot be justified by comparing it to organ donation or to half-adoption.
- 6.4. *The Welfare of the Prospective Child:* The practice of medically assisted human procreation involves the rights of children. Safeguarding the welfare of the child should include the recognition of the child's need for both a father and a mother. Similarly, children have an interest to be brought up within a stable family environment and to be reared by their own genetic parents.
- 6.5. *The Wish for a "Perfect" Baby:* When a human embryo is created *in vitro*, parents and the medical experts are more compelled to think that, because they invest so much in the process, they have a "duty" to subject the human embryo to "quality control" to ensure that the finished "product" meets everyone's expectations. The reasoning behind pre-implantation genetic diagnosis (PGD) reflects this technical and consumerist mindset that transforms the human embryo into a commodity that can be manipulated to achieve a predetermined "ideal." Yet children have the right to be welcomed *unconditionally* from the start of their life. All deliberate discarding or

destruction of human embryos on the basis of disability or undesirable traits is ethically unacceptable.

6.6. *Rights of Disabled Persons*: The value and dignity of human persons does not derive from their physical characteristics or intellectual capacity.

7. Concluding Reflections

On the basis of the arguments developed in this position paper, we conclude that:

- 7.1. The *Embryo Protection Act* should be maintained since it protects the dignity and integrity of the human embryo and the legitimate interests of the prospective child while maintaining high standards of ethics in fertility treatment.
- 7.2. The prevailing scientific data and the results obtained locally in IVF treatment actually show that the introduction of embryo freezing in connection with IVF procedures in Malta is both unnecessary and unreasonable. It will not improve the success rates of IVF, but will create “embryo orphanages” that will exacerbate ethical dilemmas and psychological distress.
- 7.3. There is no evidence that EU legislation and ECHR decisions require any change in the *Embryo Protection Act*.
- 7.4. Pre-implantation genetic testing is unlikely to be restricted to fatal (non-viable) conditions. Indeed, it is more likely to be extended to cover other conditions. This will give rise, almost invariably, to embryo selection, rejection and wastage.
- 7.5. Involvement of third parties complicates the process, creates dilemmas of parentage and raises serious ethical, legal and psycho-social issues.

8. Recommendations

- 8.1. The Social Affairs Committee of the House of Representatives should carry out a thorough consultation exercise so that any proposed amendments to the current *Embryo Protection Act* are studied in depth and all the concerns expressed by citizens in the local media be given due weight and consideration.
- 8.2. More research on the causes of infertility is needed and more investment directed at the prevention of sterility is to be encouraged.

- 8.3. Adoption and fostering need to be encouraged, promoted and facilitated by appropriate legislation so that children who have no parents can have a home that will contribute to their human development.
- 8.4. More weight needs to be given to the principles enshrined in other laws in Malta which grant rights to the human embryo, consider the embryo's best interest as being paramount, and balance the scales in favour of human dignity rather than in favour of the objectification and commodification of children.
- 8.5. Humane and pastoral support needs to be offered to those persons who for some reason may be unable to have children of their own. These persons deserve to find encouragement and vital assistance from society at large, bringing them to consider adoption or other forms of human flourishing.
- 8.6. A national register of all IVF cycles (public and private) is to be kept, and its results openly discussed and shared with the clinicians and embryologists involved, in order to be able to monitor and improve practices.

Position Paper

1. Introduction

1.1. Medical procedures to assist human procreation, including *in vitro* fertilisation (IVF), have been available in Malta for quite a long time, although they have been introduced only recently within the national health service. Up to three years ago, there was no specific legal framework to regulate their use; they were applied subject mainly to the law prohibiting abortion and the legal provisions regulating the medical profession, paternity and other relevant matters.

The current legislation is the outcome of a fairly long period of discussion, including hearings in the Social Affairs Committee of the House of Representatives. Though there were differences of opinion on certain matters, the unanimous vote in Parliament approving the *Embryo Protection Act, 2012*, showed that all members of Parliament agreed that the law should ensure that human procreative techniques must not be applied simply in accordance with a utilitarian kind of logic. A successful outcome of these techniques, however desirable it may be, should not come about at the expense of values that are basic to a truly human society. “Success” is humanly meaningful when it is measured by a set of criteria that go beyond the success or failure in achieving what one wants.

1.2. This position paper, which has been prepared at the request of the Church in Malta by a group that includes experts in the field of clinical medicine, law, psychology, social policy, family studies, disability studies, philosophy and theology, is not meant to discuss the ethical aspects of IVF or other human procreative techniques but to respond to the amendments that the Government is apparently planning to introduce to the *Embryo Protection Act*.¹ These amendments, it is claimed, are deemed necessary in view of recent developments, such as the Constitutional provision prohibiting discrimination on the basis of sexual orientation, the introduction of civil same-sex unions with the right to adoption, and certain judgments of the European Court of Human Rights (ECHR). An Inter-Ministerial IVF Review

¹ For the Church’s position on reproductive technologies see the two documents of the Congregation for the Doctrine of Faith: *Donum Vitae: Instruction on Respect for Human Life in its Beginning and on the Dignity of Procreation. Replies to Certain Questions of the Day* (1967), and *Dignitas Personae: Instruction on Certain Bioethics Questions* (2008).

Working Committee has been set up, made up of professionals from the Ministry of Energy and Health, the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties, and the Ministry for Justice, Culture and Local Government, to coordinate the consultation process launched by the Government.

The Church wants to participate in this consultation process. Reproductive technology is fraught with many moral, ethical, legal, socio-cultural, psychological and emotional issues that are evidently grave matters of concern for civil society. The Church participates willingly in this debate in a spirit of dialogue, basing her contribution on the values she embraces, which are the values of a great number of Maltese citizens, and on her long experience in listening to and supporting persons in difficulties, including those related to infertility.

- 1.3. This position paper seeks to answer the following questions: What are the concerns behind the current legislation? Would the amendments that seem to be envisaged improve or would they undermine the safeguards already established to protect particularly the dignity and integrity of the human embryo from conception? These questions are widely recognised as proper concerns not only of a specifically religious belief but also of every member of civil society who seeks to serve the community.

The paper will first discuss the objective of the *Embryo Protection Act* and its underlying central ethical values. Secondly, it will critically analyse the claim that a change in the current legislation on medically assisted human procreation is needed in view of the recent local legislation and judgements of the European Court of Human Rights. Thirdly, the success rate of the current local service in IVF treatment will be compared with the results achieved in other countries. Fourthly, some areas of concern resulting from the proposed radical shift of focus in the current legislation are highlighted. Fifthly, the ethical aspects of some techniques of IVF treatment which seem to be recommended for inclusion in the current legislation will be discussed. Finally, a number of recommendations will be proposed for public debate.

2. The Embryo Protection Act

2.1. The very title of the *Embryo Protection Act* encapsulates its basic concern and central ethical principle. Its objective is clearly the protection of the human embryo and the legitimate interests of the future child. The measures it establishes are intended to ensure that the use of human procreative techniques is in line with that objective. The Act provides for those measures that should normally apply, and those that may be taken in exceptional circumstances. The provisions set for exceptional cases are not meant to become the rule but to provide for emergency situations in which one may resort to a measure which is generally not allowed but permissible, under certain conditions, to preserve the life of the embryo.

One may see the way in which the law is generally seeking to protect the embryo by taking cognizance not only of the name given to the Authority responsible for the implementation of the law but also the tasks that it is assigned. In fact, the Authority is known as the *Embryo Protection Authority* (hereinafter referred to as “the Authority”), precisely to affirm that its mission is to ensure that the way legislation is being applied is actually that of providing the human embryo with adequate protection. More concretely, its task is, among others, to ensure that all personnel involved in procedures of medically assisted procreation maintain high standards of ethics; to intervene in justifiable cases of reasonable suspicion that the provisions of the law are not being followed by requesting all relevant information; and to carry out inspections to ensure that the standards of best practices are being respected.

2.2. The list of unlawful procedures under the current law again confirms its central concern to protect the human embryo. In order to avoid the discarding or freezing of embryos, not more than two egg cells are to be fertilized, even though three eggs may be fertilised in exceptional circumstances. This should be done in accordance with a protocol established in writing by the Authority, set up by the current legislation, following consultation with representatives of obstetricians and paediatricians. Instances of improper use of human embryos are identified precisely to make sure that the embryo is effectively protected and treated with respect. Of particular importance in this context are the provisions of the law regarding entitlement to medically assisted procreation procedures and emergency cases that justify embryo freezing.

- 2.3. Access to medically assisted procreation procedures is limited to “two persons of the opposite sex who are united in marriage, or who have attained the age of majority and are in a stable relationship with each other.”² The limitation of medical procreation assistance to two persons of the opposite sex who are either married or living together in a stable relationship may seem problematic, if the principle of “equality of access” is not properly understood. The principle presupposes that the matter to which one may have access is of a particular nature. Restrictions are justifiable only if they are required by the *nature* of the case. For example, eligibility for citizenship depends on the *meaning and value* that we wish to attribute to citizenship.
- 2.4. The exception that the law allows in the case of embryo freezing is in the case “where the transfer of the fertilized embryos into the womb is not possible owing to grave and certified *force majeure* not predictable at the moment of fertilization.”³ In these circumstances, there would be no other option to preserve the embryo except by freezing it. The objective is to keep the embryo alive and be in a position to develop once it is implanted in its mother’s womb. In fact, the law requires that the embryo be transferred as soon as possible. Allowing embryo freezing in such cases is one thing; allowing embryo freezing to have at one’s disposal a number of spare embryos in case they may be needed to be implanted at a later stage is another. It is to be borne in mind that the *Embryo Protection Act* is dealing with embryos who are human beings endowed with human dignity from the moment of conception, and not with biological material which can be easily discarded.

The law also allows that when there has been a breach of any provision of the *Embryo Protection Act*, “the Authority may order the freezing of any embryo to preserve its life.” Once more, the reason for making an exception in this case is clearly that of preserving the life of the embryo.

According to government sources, one of the reasons for amending the current *Embryo Protection Act* is to bring it in line with recent Maltese legislation and to positions recently taken by the ECHR. It is therefore important to examine carefully both the recent Maltese legislation and the decisions that the ECHR has taken in the relevant cases.

² Art. 2.

³ Art. 7.

3. Legal Considerations

3.1. In April 2014, the *Civil Union Act*, Chapter 530 of the Laws of Malta, was introduced into Maltese legislation. Registration of a partnership as a civil union is permissible between two persons of the same or of different sex. This legislation grants civil unions the same rights, responsibilities, and obligations as marriage. However, the *Embryo Protection Act* does not allow same-sex couples to access medically assisted procreation. It is thus claimed that the *Embryo Protection Act* is discriminatory. Some therefore argue that the current legislation needs to be urgently amended to redress what they deem to be an unjust disparity.

3.2. Both the *Constitution of Malta* and the *European Convention on Human Rights* guarantee protection from discrimination. Nevertheless, the *Embryo Protection Act* cannot be considered to be discriminatory when it excludes same-sex couples from having recourse to medically assisted procreation. Medically assisted procreation in favour of a heterosexual couple, whereby the gametes are provided by the couple itself, and medically assisted procreation in favour of a homosexual couple or heterosexual couple, where gamete donation or surrogacy are used, are neither similar nor comparable, and no discrimination can exist when one does not compare like with like.

The limitation of assisted procreation to two persons of the opposite sex who are either married or living together in a stable relationship presupposes that “equality of access” is determined by the *meaning* and *value* that we see in human procreation. If we see human procreation as a process that may be manipulated and used to serve what we may *desire* to get out of it, restricting access to a particular group (such as a heterosexual couple) would be discriminatory. But if we see it as a process hopefully terminating in the birth of a child, the crucial issue would be how to ensure that the best interests of the child are truly respected. The extent of any possible repercussions of the involvement of third parties (through gamete donation and/or surrogacy) on the identity and well-being of the prospective child has yet to be seen.⁴

3.3. There are four ECHR cases which the Government has singled out as relevant to the proposed new legislation. These are *Evans v. the United Kingdom* (2007),⁵ *S.H. and Others v. Austria* (2011),⁶ *Parrillo v. Italy* (2015),⁷

⁴ It is not yet known how relationships with third-party play out over time because to date, children studied so far have been pre-adolescent both for children born through gamete donation and/or surrogacy. Susan Golombok, *Modern Families: Parents and Children in New Family Forms* (Cambridge, 2015).

⁵ Application no. 6339/05; Judgment in Strasbourg on 10 April 2007.

and *Costa and Pavan v. Italy* (2012).⁸ The articles of the *European Convention of Human Rights* which were invoked by applicants of the four cases related to assisted procreation are the following: Article 2 on the right to life; Article 8 on respect of privacy; Article 14 on discrimination; and Article 1 of Protocol no. 1 on the right to peaceful enjoyment of possessions. In the first three cases, the Court decided in favour of the respondent State and against the individual applicant. It found that the current domestic legislation did not violate the Convention. These cases do not support the Government's views. In the case of *Costa and Pavan v. Italy* (2012), although the Court found in favour of the applicants, this finding was based on the Italian Law on abortion which does not find a counterpart in Maltese Law. This case too does not support the Government's views.

Another case which, though not directly related to reproductive technologies, throws light on the moral and legal status of the human embryo is that of *Oliver Brüstle v Greenpeace e.V.* (2011).⁹ This constituted a landmark decision in the legal recognition of the dignity of the human embryo from its first moment of fertilisation. Any human ovum must, as soon as fertilised, be regarded as a "human embryo." This judgement makes it clear that fertilisation marks the beginning of the biological existence of a human being. Therefore, the human embryo, at every stage of development, must be considered as a "human being with potential," and not just a "potential human being."

- 3.4. In Malta, the situation is different from that of the countries where the above-mentioned four cases emerged. In its judgment of 7 March 2006 on the case of *Evans v. the United Kingdom* (2007), the Chamber observed that in *Vo v. France* (2004),¹⁰ in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere (every country has the right to establish its own definition when protected life begins and the Court does not interfere with or disturb this national finding). Exercising the margin of appreciation, acknowledged by the ECHR to all states, Malta has exercised the wide margin of appreciation recognized to it by the ECHR, and its laws consider as persons not only human beings who are born viable but even

⁶ Application no. 57813/00; Judgment in Strasbourg on 3 November 2011.

⁷ Application no. 46470/11; Judgment in Strasbourg on 27 August 2015.

⁸ Application no. 54270/10; Judgment in Strasbourg on 28 August 2012.

⁹ European Court of Justice, Judgment of the Court (Grand Chamber) on 18 October 2011.

¹⁰ Application no. 53924/00; Judgment in Strasbourg on 8 July 2004.

persons who have not yet been born, whether they are embryos or fetuses, provided that they have been conceived. Thus, in Malta, the right to life goes *beyond* the birth of a viable child, as it also includes an embryo and a foetus. Unless the opposite is mandated by some special law, Maltese law gives primacy to the best interest of the child not to the best interest of a couple, and the child includes also a person who, though conceived, is not yet born viable as is the case with an embryo or a foetus. This is gleaned from the following legal considerations:

a) The right to dignity is embedded both within the Constitution of Malta's Chapter IV on fundamental rights and freedoms of the individual, and in the *European Convention on Human Rights* and its Protocols. The notion of human dignity has been fundamental in justifying a number of important judgments of the ECHR. Consider for instance the following cases: *Pretty v. the United Kingdom* (2002),¹¹ *Christine Goodwin v. the United Kingdom* (2002),¹² *Valasinas v. Lithuania* (2001),¹³ *Yankov v. Bulgaria* (2003),¹⁴ *Kokkinakis v. Greece* (1993),¹⁵ *Saunders v. the United Kingdom* (1996),¹⁶ and *Keenan v. the United Kingdom* (2001),¹⁷ and the dissenting opinion of Judges Spielmann and Jebens in the case of *Vereinigung Bildender Künstler v. Austria* (2007).¹⁸ The common denominator of the latter judgment is that: "...the concept of dignity prevails throughout the *European Convention on Human Rights*, even if it is not expressly mentioned in the text of the Convention; ... [t]he very essence of the Convention is respect for human dignity and human freedom."

As E. Decaux has stated, dignity and universality are indissociable because the foundation of human rights cannot be anything other than the "equal dignity" of all human beings.¹⁹ Moreover, the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (1997), provides in Article 1 that: "Parties to this Convention shall protect the dignity and identity of all human beings and

¹¹ Application no. 2346/02; Judgment in Strasbourg on 29 April 2002.

¹² Application no. 28957/95; Judgment in Strasbourg on 11 July 2002.

¹³ Application no. 44558/98; Judgment in Strasbourg on 24 July 2001.

¹⁴ Application no. 39084/97; Judgment in Strasbourg on 11 December 2003.

¹⁵ Application no. 14307/88; Judgment in Strasbourg on 25 May 1993.

¹⁶ Application no. 19187/91; Judgment in Strasbourg on 17 December 1996.

¹⁷ Application no. 27229/95; Judgment in Strasbourg on 3 April 2001.

¹⁸ Application no. 68354/01; Judgment in Strasbourg on 25 January 2007.

¹⁹ E. Decaux, "Dignité et universalité," in *Dignité humaine et hiérarchie des valeurs: Les limites irréductibles*, ed. S. Marcus Helmons (Brussels, Academia-Bruylant, Bruylant, 1999), 164.

guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.” Furthermore, the very first article in the *Charter of Fundamental Rights* of the European Union, now part of the *Treaty of Lisbon*, states that: “Human dignity is inviolable. It must be respected and protected”;

- b) the *European Convention on Human Rights* states in Article 2 that “Everyone’s right to life shall be protected by law” but falls short of defining the term “everyone” – it leaves that definition to be determined by each individual state;
- c) the *Constitution of Malta* in Article 33(1) states that: “No person shall intentionally be deprived of his life ...”. Once again no definition of “person” is afforded in the Constitution, though Maltese Law does extend the definition of the term to cover cases not only of a person who is born viable (see for example Articles 601 and 1747 of the *Civil Code*) but also of other persons who, though not yet born, are persons in so far as they are recipients of rights. Such is the case of a person who is conceived but not yet born to whom a curator *ad ventrem* is appointed to safeguard his or her proprietary interests up to the day of his/her birth as in the case of Article 170 of the *Civil Code*; or persons who are not yet conceived but at the time of the creation of a foundation can still be named as beneficiaries or form part of a class of beneficiaries even though their rights will arise only when they are born viable (Article 33(5) of the Second Schedule of the *Civil Code*);²⁰
- d) Articles 241 and 243 of the *Criminal Code* recognize and protect all unborn life, whether foetal or embryonic, by making all voluntary miscarriages a criminal offence, both by the mother and any person who assists in an abortion;
- e) the *Embryo Protection Act* defines an embryo as the human organism that results from the fertilisation of a human egg cell by a human sperm cell which is capable of developing and shall further include each totipotent cell removed from a human embryo or otherwise produced, that is assumed to be able to divide and to develop as a human being under the appropriate conditions;

²⁰ Other relevant provisions in the *Civil Code* referring to unborn children are articles 135, 136(1), 600(1).

- f) thus, a consistent interpretation of the expression “person” in the Constitution’s right to life has to reflect the other provisions of Maltese Law which grant proprietary rights to the unborn child as well as ensure that the pregnancy is brought successfully to term, that is, the embryo is not aborted;
- g) Maltese Law protects both the embryo and the foetus. In fact, the *Civil Code* specifically recognises as *persons* embryos and foetuses and classifies them under the category of a “child.” But doing so, the *Civil Code* applies to them in Article 149²¹ as a principle of law that of the best interests of the child which prevails over the interests of other persons, including their parents;
- h) The case law of the ECHR does, of course, take into consideration that every country is free to establish its own definition of human life and when this begins. In the case of Malta, an embryo and a foetus are recipients of rights and the law provides procedures and remedies to safeguard those rights and that, in Malta, it is not only persons who are born viable but even unborn children who have rights protected by the civil and criminal law.

3.5. A change in name of the present enactment is being proposed since, it is claimed, the current name does not do justice to the key subject, i.e. fertility treatment. However, it must be borne in mind that the current name encapsulates the notion of human dignity as prevalent in Maltese (and European) Law, not only in the *Embryo Protection Act* but also in the *Civil Code* and in the *Criminal Code* where the embryo is protected by law, is considered as a subject of law and is afforded rights not only at birth but even from the moment of conception onward. Hence, the current name of the law is in conformity with these various laws on the statute book which uphold human dignity. It is also consistent with Maltese Law which considers the well-being of the child, whether born or unborn (including an embryo) to be paramount. The objectification and instrumentalisation of a human embryo is not in conformity with Maltese Law.

²¹ And in other provisions such as articles 39, 55A(1) proviso (a), 66I(2)(b), 70(3), 77C second proviso, 92(6), 115(1)(a) and (4)(d), 116(2), 117(1)(a)(vii), 119(4), 120(2), 128(4), 160 and 188C(2).

4. Medical Considerations

The recent proposal to amend the *Embryo Protection Act* has put embryo freezing to the fore of public discussion. At present, current legislation and practice in Malta allows for ovum vitrification but not embryo freezing. The primary reason for this decision was based on valid ethical and administrative concerns, particularly in respect of what would be the eventual fate of any “unwanted” previously frozen embryos. The adoption of the alternative, i.e. ovum vitrification, completely abolishes all these ethical and administrative problems.

4.1. Oocyte Vitrification

Historically, IVF technology and practice has been based on embryo freezing. Artificial reproductive technologies (ART) centres have established a reputation of relative success based on this methodology and are therefore generally reluctant to change the laboratory techniques which they have perfected. To date, experience with the use of ovum vitrification has been limited, with only a few centres shifting from embryo freezing to ovum vitrification. The paucity of evidence, and reluctance to research and adopt new methodologies, has led to unscientific arguments denigrating ovum vitrification.²² In the main, experience of oocyte cryopreservation generally came from situations where couples undergoing ART but who did not wish to have embryos frozen for ethical and/or religious reasons, opted to preserve excess oocytes for use in subsequent cycles; or from young individuals with ovarian malignancy who had ova preserved to conserve future fertility.

Initially, lack of experience led to reported low success rates following the use of oocyte freezing-thawing cycles. However, recent and improved scientific research led to better methods of oocyte storage and a shift from traditional cryopreservation to vitrification. This has made the process significantly more efficient, and has resulted in rates of successful pregnancies that are comparable to those obtained by embryo freezing.²³ The results from oocyte vitrification have been promising, so much so, that various centres are also moving from embryo freezing to embryo vitrification.

²² Ana Cobo and Cesar Diaz, “Clinical Application of Oocyte Vitrification: A Systematic Review and Meta-Analysis of Randomized Controlled Trials,” *Fertility and Sterility* 96, no. 12 (2011): 277-285.

²³ Seung Wook Hong et al., “Improved Human Oocyte Development after Vitrification. A Comparison of Thawing Methods,” *Fertility and Sterility* 72, no. 1 (1999): 142-146.

With these new vitrification procedures, there has been enhanced oocyte survival rates post thaw.²⁴ Boldt has stated that:

For oocyte freezing to be considered as an alternative to embryo freezing, equivalent survival and pregnancy rates between the two methods would need to be achieved. ... Initial data compare favourably with both our own as well as national data on embryo cryopreservation. The programme started in 1998 with a 33.3% pregnancy rate for frozen embryo transfer (FET) and a 36.4% pregnancy rate for frozen oocytes. This study showed that oocyte freezing can be accomplished on a routine basis and that it offers an alternative for couples with religious and ethical concerns about embryo freezing.²⁵

This was substantiated by the American College of Obstetricians and Gynaecologists (2014) who, in their document reflecting emerging clinical and scientific advances, concluded that mature oocyte cryopreservation is a currently available method. Although IVF with cryopreservation of embryos is an established method of fertility preservation, women who want to consider banking mature oocytes have a reasonable fertility preserving alternative.²⁶

Similar conclusions were drawn by Kuwayama who initiated work on oocyte vitrification and was involved with setting up the first oocyte bank in USA and Japan in 2001.²⁷ Chamayou *et al.* have shown that oocyte vitrification does not affect embryo quality after oocyte thawing, thus making this method effective in preservation of female fertility.²⁸ Al-Azawi *et al.* have concluded that in the past oocyte cryopreservation achieved inferior results compared with embryo freezing simply because the method in use then gave low rates

²⁴ S.W. Hong et al., "Improved Human Oocytes Development after Vitrification. A Comparison of Thawing Methods," *Fertility and Sterility* 72 (1999): 142-146; Lilia Kuleshova, "Ten Years of Success in Vitrification of Human Oocytes," *Cryobiology* 59, no. 3 (2009): 374-375; Tae Ki Yoon et al., "Survival Rate of Human Oocytes and Pregnancy Outcome after Vitrification using Slush Nitrogen in Assisted Reproductive Technologies," *Fertility and Sterility* 88, no. 4 (2007): 952-956; M. Solé et al., "How does Vitrification Affect Oocyte Viability in Oocyte Donation Cycles? A Prospective Study to Compare Outcomes Achieved with Fresh Versus Vitrified Sibling Oocytes," *Human Reproduction* 28, no. 8 (2013): 2087-2092.

²⁵ Jeffrey Boldt et al., "Human Oocyte Cryopreservation as an Adjunct to IVF–Embryo Transfer Cycles," *Human Reproduction* 18, no. 6 (2003): 1250-1255.

²⁶ American College of Obstetricians and Gynecologists (Committee on Gynecologic Practice), Opinion 584: *Oocyte Cryopreservation*, January 2014.

²⁷ Masashige Kuwayama et al., "Highly Efficient Vitrification Method for Cryopreservation of Human Oocytes," *Reproductive Biomedicine Online* 11, no. 3 (2005): 300-308.

²⁸ S. Chamayou et al., "Oocyte Vitrification modifies Nucleolar Remodeling and Zygote Kinetics – a Sibling Study," *Journal of Assisted Reproduction and Genetics* 32, no. 4 (2015): 581–586.

of ovum survival, fertilization and development.²⁹ The situation is different now after the development of the process of vitrification which has been identified as the current method of choice of oocyte cryopreservation. The University of Southern California has shown that in their programme, the use of frozen ova gave a pregnancy rate of 65%, a figure higher than that of using fresh embryos, and twice that of using frozen embryos. Other leading centres have reported similar pregnancy rates.³⁰

The equivalent survival and pregnancy success of IVF cycles using fresh ova and vitrified ova have been very well demonstrated by the local experience, albeit based on a limited series. The reported success rates indicate that the pregnancy rates achieved were 27.91% (36/129) pregnancies/cycle started with fresh ova, and 30.77% (12/39) pregnancies/cycle started with vitrified ova. The success rate attained by the current Maltese service using fresh ova and ova after vitrification as reported by the Embryo Protection Authority in its 2014 Annual Report compares very positively with the success rates obtained from centres that rely on fresh ova or cryopreserved embryos.³¹

Furthermore, these rates compare favourably when viewed with pregnancy rates per Embryo Transfer (ET) following IVF techniques in the UK and Europe. As can be seen in Table 1, the pregnancy rate when using frozen embryos in the UK was 30.60%³² and 23.40% for the European Society for Human Reproductive Endocrinology (2011).³³ On the other hand, the IVF programme in Malta was superior with a 30.82% (49/159) pregnancy/ET rate from the use of fresh and vitrified oocytes, and no embryo freezing.

While the success rate for the first complete year (2014) of the local IVF statistics was high in terms of pregnancy rates, and comparable to foreign figures, the Live Birth Statistics for the same year have not yet been published.

²⁹ Tahani Al-Azawi et al., "Cryopreservation of Human Oocytes, Zygotes, Embryos and Blastocysts: A Comparison Study between Slow Freezing and Ultra Rapid (Vitrification) Methods," *Middle East Fertility Society Journal* 18, no. 4 (2013): 223–232.

³⁰ University of Southern California Fertility, "Frequently Asked Questions About Egg Freezing," <http://uscfertility.org/egg-freezing-faqs/>

³¹ *Paper Laid No: 5364 - Annual Report of the Embryo Protection Authority for 2014*. Paper tabled by Minister for Energy and Health at Sitting No. 291 (Wednesday, 15 July 2015), <http://www.parlament.mt/paperslaiddetails?id=24684&legcat=13>; accessed 6 October 2015.

³² Human Fertilisation and Embryology Authority (HFEA), *Fertility Treatment in 2013: Trends and Figures, 2013*, http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2013.pdf; accessed 6 October 2015.

³³ European Society for Human Reproductive Endocrinology, Annual Report 2011.

Table 1: Comparison of IVF pregnancies in UK, Europe and Malta

Pregnancy /ET			Preg/Cycle Started	Live Births/Cycle Started
2013 ³⁴				
UK	Preg/ET (Fresh oocytes)	35.50%		25.80% (Fresh oocytes)
UK	Preg/ET (Frozen Embryos)	30.60%		22% (Frozen Embryos)
2005-7 ³⁵				
ITALY	Preg/ET (Frozen Embryos)	16.40%	24.90% Fresh oocytes 12.50% Frozen oocytes	
2010 (Porcu) ³⁶			33.00% Fresh oocytes 26.00% Frozen oocytes	
2010 (Rienzi)	Preg/ET (Fresh oocytes) ³⁷	43.5%		
	Preg/ET (Frozen oocytes)	38.5%		
2000-8	Kaali – HUNGARY ³⁸		29.70% <u>Total</u>	
2013 ³⁹			-	
ESHRE	Preg/ET (ALL)	28.40%	23.00% <u>Total</u>	2006: 25.2%
2011 ⁴⁰			-	
ESHRE	Preg/ET (Fresh oocytes)	ICSI 31.60%	-	
		IVF 33.20%		
	Preg/ET (Frozen Embryos)	23.40%		
USA/EU Registers			27-29%	
2014 ⁴¹				
MALTA	Preg/ET (Fresh/Frozen oocytes)	30.82%	28.82% <u>Total</u> 27.91% Fresh 30.77% Frozen	Not yet published

³⁴ Human Fertilisation and Embryology Authority (HFEA), *Fertility Treatment in 2013: Trends and Figures*, 2013, http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2013.pdf; accessed 6 October 2015.

³⁵ G. Scaravelli et al., "Analysis of Oocyte Cryopreservation in Assisted Reproduction: The Italian National Register Data from 2005 to 2007," *Reproductive BioMedicine Online* 21, no. 4 (2010): 496-500.

³⁶ Quoted by Matthew Vella, "Freezing the Chances of Success," in *Malta Today* (20 August 2012), <http://www.maltatoday.com.mt/news/national/20433/freezing-the-chances-of-success>; accessed 6 October 2015.

³⁷ L. Rienzi et al., "Embryo Development of Fresh 'Versus' Vitrified Metaphase II Oocytes after ICSI: a Prospective Randomized Sibling-Oocyte Study," in *Human Reproduction* 25 (2010): 66-73.

³⁸ www.ivfpregnancycenter.com; accessed 6 October 2015.

³⁹ European Society for Human Reproductive Endocrinology, Annual Report 2013.

⁴⁰ European Society for Human Reproductive Endocrinology, Annual Report 2011.

⁴¹ *Paper Laid No: 5364 - Annual Report of the Embryo Protection Authority for 2014*. Paper tabled by Minister for Energy and Health at Sitting No. 291 (Wednesday, 15 July 2015), <http://www.parliament.mt/paperslaiddetails?id=24684&legcat=13>; accessed 6 October 2015.

Hence, what is the “value added” in freezing embryos, and at what price (ethical, moral, financial, psychological, embryo wastage, etc)? Malta, with a limited local experience, has already achieved superior results with oocyte vitrification without the need to resort to embryo freezing. The argument that freezing embryos will avoid the need for the prospective mother to undergo ovarian stimulation (with its inherent risks) in a future cycle, does not hold true, as oocyte vitrification will similarly avoid the same risks. Furthermore, oocyte vitrification offers more advantages compared to embryo freezing such as fertility preservation in women at risk of losing fertility due to oncological treatment or chronic disease, and eliminates religious and/or other ethical, legal and moral concerns related to embryo freezing.

Regardless of the good intentions of ART practitioners and prospective parents, freezing will result in surplus embryos. In contrast to what has been claimed in the media, it is unlikely that all these embryos will be implanted and given the chance to develop *in utero*. Those deemed to be “surplus” (or in some way “inferior”) will not be selected and, alternatively, will (i) be transferred into embryo trading (as part of surrogacy) programmes, or (ii) subjected to embryo wastage/discarding, or (iii) offered for research. The latter two options are likely to be the end point for most of these embryos and both these scenarios result in embryo destruction.

In the light of the prevailing scientific data and the results reported by the local service, the introduction of embryo freezing within the Maltese service is both unnecessary and unreasonable and is likely to create “embryo orphanages.”

4.2. Pre-Implantation Genetic Diagnosis (PGD)

Some justify medically pre-implantation genetic testing to exclude aneuploidy in so far as it would prevent the implantation of a non-viable embryo and therefore not “waste” an attempt at pregnancy (with all the concomitant psychosocial and medical consequences) “in vain.” Although other supposedly non-viable conditions such as trisomy 13 and 18 could be conceivably included in this list, children with these conditions (albeit the minority) have survived into late childhood.

Would pre-implantation testing be solely restricted to aneuploidy? In all probability, other genetic conditions will be discovered and, in practice, most if not all “abnormal/defective” embryos will not be implanted and subsequently discarded. Almost certainly none will be chosen by prospective

parents, and none frozen by ART teams for future cycles unless “required” for specific and selective research projects. Hence, allowing genetic testing – however limited – is very likely to create a scenario whereby many disorders and conditions would be confirmed after fertilisation and pre-implantation. These would include common conditions like Down Syndrome arising in 1:660 births and approximately 5-9 children per annum in Malta, as well as other chromosomal alterations, and inherited genetically-detectable mutations like cystic fibrosis, neurofibromatosis, gangliosidosis, etc.). Infants with gangliosidosis arise in approximately 1:4,000 births in Malta and generally die within a few months of life (and, therefore, could be considered akin to aneuploidy).⁴² Many others, unlike aneuploidy, are not fatal conditions in utero or may only be associated with a decreased life expectancy after several decades, yet all are likely to be “discarded” at an early embryonic stage as both the medical team and parents involved will opt not to implant “defective” embryos. This may make economic sense since the burden of the national healthcare would be reduced, but would amount to selective eugenics and would involve wilful and deliberate destruction of an innocent human embryo.

The same process will also open the possibility for the converse, whereby parents intentionally select and opt to implant embryos that carry their own disability (e.g. familial hearing loss), and will create offspring with a significantly increased risk of suffering and hardship during their lifetime. This would be tantamount to creating intentional disability on the part of the parents and participants, and is arguably perverse and difficult to justify.

Pre-implantation genetic testing is unlikely to be restricted to fatal conditions like aneuploidy alone. Indeed, it is more likely to discover several other conditions associated with variable disabilities and will give rise to embryo rejection and wastage.

4.3. Take-Home Baby Rate

The early figures published from the practice ART/IVF in Malta where both fresh and frozen oocytes are being used shows that the conception rates are comparable to those reported from reputable centres overseas using fresh oocytes or frozen embryos. To-date, the local data suggests comparable conception rates between fertilization attempts using fresh or frozen oocytes

⁴² H.M. Lenicker et al., “Infantile Generalised GM1 Gangliosidosis: High Incidence in the Maltese Islands,” in *Journal of Inherited Metabolic Disease* 20 (1997): 723-724.

(although the data available is based on very small numbers over a short time span where, arguably, the service has yet to complete its initial learning curve). Unfortunately, as happens with natural conceptions, whatever method is used, it is associated with a high loss. It is generally reported that following natural conceptions, the overall rate of loss is around 30 - 50% while the miscarriage rate in women who know they are pregnant is around 10 - 20%.

The early figures available from the local service appear to mirror the losses following natural conceptions. The introduction of frozen embryos in preference to frozen oocytes would not be expected to improve pregnancy retention rates more than that reported in the natural scenario with couples who have had absolutely no problem to conceive. Indeed, the pregnancy rate would be expected to be lower than the natural rate for all forms of IVF particularly as local population undergoing IVF/ET are a reproductively high risk sub-population and commonly include older couples/women – factors that in nature are known to be associated with a high pregnancy loss.

The current legislation regulating medically assisted procreation does not stipulate at which day human embryos should be transferred after fertilization. The local IVF practice followed so far is that human embryos are transferred three days after fertilization. Current legislation permits the fertilization of only two oocytes, and the fertilization of three oocytes is allowed only in exceptional circumstances. In order to increase the success rate of IVF practice, Government is planning to amend the current legislation to permit the fertilization of up to five human embryos. To ensure that at least two human embryos grow to the blastocyst stage, it is planned that the embryos will be left in culture for up to five days rather than three days after fertilization, assuming that only the “best quality embryos” would make it to the blastocyst stage. Indeed, day three embryo transfers and day five (blastocyst) embryo transfers have slight differences in ongoing pregnancy rate of around 35 vs 39%, respectively.

However, even with natural attrition, the fertilisation of five ova and subsequent implantation of the two morphologically “top grade/best” embryos will result in a serious risk of surplus human embryos that would then be frozen. Once thawed, around 10% of frozen embryos will not survive. What will become of those, previously “inferior graded” embryos that do survive thawing? It is highly unlikely that legislation can ensure their subsequent (forced?) implantation into their biological mother, regardless of whether one or both parents are in agreement or not. Many of these

“orphaned” or rejected embryos will simply be discarded, frozen indefinitely until “natural attrition” takes its toll, or may be offered to third parties through embryo adoption schemes, with or without compensation. All of the above options would seriously compromise the dignity and integrity of the human embryo. One must keep in mind that “success” in achieving pregnancy is humanly meaningful when it is measured by a set of ethical criteria that go beyond the success or failure in achieving what one wants.

4.4. Health Risks Linked with Gamete Donation

Regarding medical risks of donor oocytes and most especially donor sperm, anonymous donation may lead to a number of serious problems. Repeated use of the sperm from the same donor is risky if biological children of the same man meet and procreate (a possibility in a small country like Malta), with grave genetic outcomes.

A normal health check does not identify all common recessive disorders. There will only be a family history of certain disorders in a minority of cases. This is the case for many disorders, including the various lipid, glycogen and other storage disorders, cystic fibrosis, bone disorders and blood disorders (thalassaemia, etc). Furthermore, the disease profile varies from one population to another, thereby increasing the possibility of introducing new genetic disorders.

5. Matters of Concern

If the focus of the current legislation on assisted procreation shifts from the protection of the rights and dignity of the human embryo to the extending of unrestrained options in fertility treatment, a number of serious concerns emerge. A paradigm shift is likely to be introduced in the Maltese ethos with long-term implications for the welfare of children, parenthood and family life in society which have been barely debated at all.

5.1. The Human Embryo as a Commodity

The freezing of human embryos, gamete donation, surrogacy and human embryo selection promote a culture of manipulation that reduces the prospective child to a mere object of desire or even a mass of cells to be used, selected and discarded. The child has the right to be *conceived* by

one's own parents, *carried* in the womb by one's own gestational mother, as well as to be brought up within marriage or a stable relationship. It is through the secure and recognised relationship of his/her parents that a child can discover his/her own identity and achieve his/her own proper human development. The very strong bond that is created between the mother and the child through gestation and childbirth can become a traumatic experience for both when this bond is severed.

5.2. Changing Fertility and Childbearing Patterns

Fertility rates in Malta have fallen over the years, in line with the rest of Europe. In 1990, Malta's fertility rate (live births per woman during her lifetime) was 2.04; by 2013, it had decreased to 1.38⁴³ – below the EU28 average of 1.48 and higher only than Greece, Spain, Cyprus, Poland, Portugal and Slovakia. This is considerably below the traditional “replacement rate” of 2.1, considered necessary to keep population size constant (without considering the effects of migration). The mean age of women at childbirth has risen, and now stands at age 30, close to the EU28 average of 30.3.⁴⁴ While we are not aware of any studies that have analysed the causes of the drop in fertility in Malta, hypotheses abound as to the reasons for this drop across Europe. These include longer spells in education (resulting in delayed childbearing for women); a later age for marriage; changing material expectations and the perceived material and emotional cost of providing for a child's educational and social needs as culturally understood today; the difficulty in balancing work and family life and the physical and emotional stress to which this gives rise. It is often suggested that good work-family policies have – by making this balance more possible – resulted in higher fertility rates.⁴⁵

But perhaps we also need to carry out more local research on the causes of infertility and to invest more funds in education and in the prevention of infertility. Moreover, other options, such as adoption and fostering, need to be more fully facilitated and made more easily accessible. Above all, humane and pastoral support needs to be offered to those persons who for

⁴³ Eurostat, “Fertility Statistics,” (2015), http://ec.europa.eu/eurostat/statistics-explained/index.php/Fertility_statistics; accessed 30 September 2015.

⁴⁴ Eurostat, “Mean Age of Women at Childbirth” (2015), <http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tps00017&plugin=1>; accessed 30 September 2015.

⁴⁵ A. Rovny, “Welfare State Policy Determinants of Fertility Level: A Comparative Analysis,” *Journal of European Social Policy* 21, no. 4 (2011): 335-347.

some reason may be unable to have children of their own. These persons ought to find encouragement and vital assistance from society at large, bringing them to consider adoption or other forms of human flourishing.

5.3. Having a Child at all Costs

Today's reproductive technologies offer several possibilities both to heterosexual couples who are unable to procreate in a natural way and to same-sex couples who may want to have a child through gamete donation and surrogacy. However, one should ask: is there a right to have a child at all costs? The main concern is that this question is often answered on the basis of what the individual *desires*. Indeed, there are few other stronger human aspirations than the wish to love and care for one's own child and therefore the pain of being unable to fulfil this deep wish may be seriously devastating for couples. However, the overriding principle should be the *child's best interest*. The procreation of children, albeit facilitated through ever-advancing technology, should still be based on the rights and interests of the child. Third party needs and desires, however genuine, cannot be considered at par with those of the child.

5.4. Commercialisation of the Woman's Body

The mindset behind a woman gestating someone else's biological child is derogatory to a woman, since whether she willingly chooses to carry another woman's child or not, she is being objectified and reduced to an incubator. Surrogacy, which is another form of commodification of women's bodies, involves a fragmentation and trivialisation of parenthood. A woman deliberately becomes a gestational mother with no intention of committing herself to caring for the child she gestates. Maternity should not be divided into genetic, gestational, and social motherhood. For this reason surrogacy or "womb renting" should not be socially condoned. This practice is exploitative of both the woman and the child, and damages the way conception and gestation are regarded in society as a whole. Moreover, this practice is fraught with legal, social, emotional and psychological complexity.

6. Ethical Aspects

6.1. Protection of the Most Vulnerable

A sure mark of a civilised society is its concern for its weaker members. One of the purposes of law is to protect the innocent from unjust harm. Any legislation which fails to protect the innocent fails in its primary purpose. The current Maltese legislation regulating assisted procreation is called the *Embryo Protection Act* precisely because it ensures safety and full protection to the vulnerable human embryo. The embryonic phase is the earliest stage in human life; accordingly the human embryo is the possessor of rights and its interests need to be respected. Being vulnerable, dependent and unseen, however, the human embryo is particularly at risk. For this reason it requires full protection of the law. The rights of children to protection from physical and social harm – before and after birth⁴⁶ – should be of paramount ethical concern.

6.2. Moral Status of the Human Embryo

There is a general agreement among human embryologists that a human being begins at fertilization. Recent evidence has confirmed the dynamic organization of the early embryo, the rapid activation of genetic information from the parents, and the fact that “polarity” is present from the earliest stages of the embryo’s existence. If the human embryo is the same individual as the older human being, this has immediate moral implications. There is no such thing as a “subhuman human”: a human being/organism with subhuman moral status. Human status is not something one “earns” by reaching some arbitrary level of functional ability. If fertilisation is, in the normal case, the origin of a new human individual – a life distinct from the parents – that individual will have rights and interests from fertilisation onward with regard to his or her well-being. Human embryos have rights and interests of which they are unaware, just as newborn babies do. These rights and interests should not be entirely subordinated to the interests, or perceived interests, or desires of adult human beings.

The human embryo deserves, from the outset, the respect proper to a human being. The dignity of the individual human being, which reason requires, is further enhanced and strengthened in the light of faith: thus, there is no contradiction between the affirmation of the dignity of the human

⁴⁶ United Nations, *Convention on the Rights of the Child* (1989), Preamble.

embryo and the affirmation of its sacredness. The right to life and to physical integrity of every human being from conception to natural death must be respected. Thus, in the treatment of infertility, the wilful and deliberate discarding or destruction of the human embryo, the freezing of supernumerary embryos, their use for basic scientific research, and their exposure to serious risk of death or physical harm are ethically unacceptable because human embryos are more than just “biological material.” Cryopreservation of human embryos exposes them to serious risk of death or physical harm, since a high percentage does not survive the process of freezing and thawing; it deprives them at least temporarily of maternal reception and gestation; it places them in a situation in which they are susceptible to further offense and manipulation.

6.3. Gamete Donation

Assisted reproductive technologies may require the use of sperms or eggs from third parties. These are not expected to play any role in the rearing of their children. Gamete donation may not be simply construed as an act of generosity of donating a sperm or an egg to someone for the purpose of having a child. It involves a complex interchange of rights and obligations. Gamete donation, whether sold or given as a “gift,” implies the transferring of parental responsibilities to other individuals. It is wrong to create a child and from the very start exclude to undertake responsibilities and maintain a relationship with him/her.

The issue of sperm or egg donation should not be trivialised since this question has a crucial bearing on the child’s life course and identity development. The child would have to grapple indefinitely with a confused identity as to who his or her parents are. The right of children to form a full picture of their identity, including one’s genetic heritage, is increasingly recognized as important for their physical and psychological wellbeing. Article Seven of the UN’s Convention on the Rights of the Child (1989) states that “as far as possible [the child has] the right to know and be cared for by his or her parents.”

Moreover, donation of sperm or egg may create conflict in the relationship among the couple since only one of them is the genetic parent of the child, while the other is not. The one who has not supplied genetic material to the child may eventually feel “left out,” and problems can arise in allocating responsibilities for – and commitment to – the child. Such a conflict does not

arise in adoption since both parents have a symmetrical relationship to the adopted child. The asymmetrical relationship of the couple with the child in the case of gamete donation may be a source of conflict and confusion.

Donation of sperm or egg is not like donating a kidney, because sperms and eggs contain the unique information and the inherited generative potential that is basic to one's own identity and the identity of the future child. It is ethically unacceptable, even when there is no exchange of money and donors consider their voluntary participation as an act of altruism for a relative or close friend. In fact, this altruism is clearly being directed to the satisfaction of the desire of an adult to have a child rather than to the safeguarding of the interests of the prospective child. The selling or giving of a sperm or an egg run counter to the basic ethical norm, namely, that of assuming personal responsibility for one's actions. One may not involve oneself so vitally and directly in the procreation of a child and then withdraw from the responsibilities one would have incurred towards the child that is born.

Moreover, gamete donation cannot be justified as half-adoption. Adoption is usually a post facto solution to the problem of a child whose parents are not in a position or are not willing to look after it.

6.4. The Welfare of the Prospective Child

The practice of medically assisted human conception concerns the rights of children, and therefore, the law in this area should be particularly robust. It is vital to protect children from being treated as a "consumer choice" of adults, rather than as human beings to be accepted unconditionally.

Children have an interest to be brought up within a stable family environment and to be reared by their own genetic parents. Of course, there are many children whose family circumstances are such that they do not know their father or mother, and who may nonetheless have a relatively healthy upbringing. But the fact remains that to have a mother and a father is a profound human need.

6.5. The Wish for a “Perfect” Baby

When a human embryo is created *in vitro*, both its parents and the medical experts are more compelled to think that, because they invest so much in the process – emotionally, financially and in terms of technical expertise – they have a “duty” to ensure that the finished “product” meets everyone’s expectations by subjecting the human embryo to quality control. The reasoning behind pre-implantation genetic diagnosis (PGD) reflects this technical and consumerist mindset that, while seeking the best outcome for all concerned, nonetheless transforms the human embryo into a commodity that can be manipulated to achieve a predetermined “ideal.” Such specifications can include the notion of a “perfect” baby – a baby that is chosen for implantation according to specific preferences.

Diagnosis before implantation is immediately followed by the elimination of an embryo suspected of having genetic or chromosomal defects or having other qualities that are not wanted. Cases are becoming more prevalent in which couples who have no fertility problems are using artificial means of procreation in order to engage in genetic selection of their offspring. Children have the right to be welcomed unconditionally from the start of their life. Human dignity belongs equally to every single human being, irrespective of one’s parents’ desire, quality of life and level of physical or mental development. All deliberate discarding or destruction of human embryos on the basis of disability or undesirable traits is ethically unacceptable. Society has a moral duty to protect and safeguard the vulnerable human embryo from any form of injustice and discrimination.

6.6. Rights of Disabled Persons

The value and dignity of human persons does not derive from their physical characteristics or intellectual capacity. However, where pre-implantation genetic diagnosis identifies human embryos with some form of disability, or indeed some undesired characteristic, this is likely to pose an agonising dilemma for prospective parents who certainly require skilled moral and emotional support at this time.

A major concern for many disabled people is the potential, which has actually been put to work in some countries, of encouraging non-disabled people using IVF to “breed out” disability. While it is now possible to diagnose disabling conditions before birth, it is notoriously difficult to predict

quality of life outcomes for the affected individual. Many conditions which, in the past, were considered disastrous for both the individual and the family, for which there were no remedies and for which no support services existed, no longer lead to despair. Not all impairments can be equated with suffering, that is, chronic unbearable physical and/or psychological pain. Indeed, many people with certain conditions consider themselves as “different,” not “disabled” and live productive and fulfilling lives.

7. Concluding Reflections

On the basis of the arguments developed in this position paper, we conclude that:

- 7.1. The *Embryo Protection Act* should be maintained since it protects the dignity and integrity of the human embryo and the legitimate interests of the prospective child while maintaining adequate standards of ethics in fertility treatment. The unanimous vote taken in favour of the current legislation reflects a consensus that one should reaffirm rather than break up, especially in the case of a value that here in Malta is held in such high regard.
- 7.2. The prevailing scientific data and the results obtained locally in IVF treatment actually show that the introduction of embryo freezing in connection with IVF procedures in Malta is both unnecessary and unreasonable; is likely to create “embryo orphanages,” and will not improve the success rates as opposed to what is being claimed. It will, on the other hand, introduce various dilemmas from the ethical, moral, psychological, and embryo wastage points of view.
- 7.3. There is no evidence that EU legislation and ECHR decisions require any change in the *Embryo Protection Act*.
- 7.4. Pre-implantation genetic testing is unlikely to be restricted to fatal (non-viable) conditions. Indeed, it is more likely to be extended to cover other conditions. This will give rise to embryo selection, rejection and wastage.
- 7.5. Involvement of third parties complicates the process, creates dilemmas of parentage and raises serious ethical, legal and psycho-social issues.

8. Recommendations

- 8.1. The Social Affairs Committee of the House of Representatives should carry out a consultation exercise – as it did when the *Embryo Protection Act* was being discussed – so that any proposed amendments to the current legislation are studied in depth and all the concerns expressed recently in the local media against Government’s proposals for change are given due weight and consideration.
- 8.2. More research on the causes of infertility is needed and more investment directed at the prevention of sterility deserves encouragement.
- 8.3. Adoption and fostering need to be encouraged, promoted and facilitated by appropriate legislation so that children who have no parents can have a home that will contribute to their human development.
- 8.4. More weight needs to be given to the principles enshrined in other laws in Malta which grant rights to the embryo, which consider the embryo’s best interest as being paramount, and which balance the scales in favour of human dignity rather than in favour of the objectification and commodification of children.
- 8.5. Humane and pastoral support needs to be offered to those persons who for some reason may be unable to have children of their own. These persons deserve to find encouragement and vital assistance from society at large, bringing them to consider adoption or other forms of human flourishing.
- 8.6. A national register of all IVF cycles (public and private) is to be kept, and its results openly discussed and shared with the clinicians and embryologists involved, in order to be able to monitor and improve practices.

Rev. Professor Emmanuel Agius (Chairperson)

Professor Kevin Aquilina

Ms Grace Attard

Professor Simon Attard Montalto

Judge Giovanni Bonello

Mr George G. Buttigieg

Ms Astrid Camilleri

Mr Joe Camilleri

Dr Nadia Delicata

Rev. Professor George Grima

Mr Raymond Galea

Rev. Professor Paul Galea

Mr John Mamo

Rev. Dr Paul Pace

Ms Joseanne Peregine

Dr Clarissa Sammut Scerri

Mr Albert Paul Scerri

Professor Charles Savona-Ventura

Dr Pierre Schembri Wismayer

Dr Sue Vella

Dr Anna Vella

Rev. Dr Ray Zammit

