

The Development of IVF in Malta. A Slippery Slope or Result of Dialogue?

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The Embryo Protection Act 2012 - Chapter 524 of the Laws of Malta is the 'Parent' Act governing the Fertility Sector. The Bill was passed through Parliament and provides for the protection of human embryos through the establishment of the regulatory Authority (The Embryo Protection Authority). Ever since the enactment of the first Embryo Protection Act of Malta [1] there have recurrently been significant decisions to improve access to different categories of people who experience various problems with conception ranging from infertility (be it biological or social) to genetic disorders. This article intends to update the progressive development of this law.

Before the enactment of the first law in 2012 the national Bioethics Consultative Committee had been working on a draft document for several years. Indeed, it passed through several legislature including both sides (labour and nationalist) of parliament. The first draft was rather conservative in nature and catered solely for infertile couples. This meant that the service was offering only to married couples or those in a steady relationship. This document was presented in the yearly Seminar organised by the committee in 2000 [2]. Following the presentation and the report on the local papers the archbishop expressed reservations and called the Minister of Health in this regard. Malta being a Catholic country, and IVF being defined as 'illicit' by the Catholic catechism due to its not being a natural way of conceiving and also due to fertilizing ova in the laboratory and potential freezing of embryos, legislating in this regard became controversial.

The issue was discussed several times by the Parliamentary Social Affairs Committee which regularly invited several experts, institutions, NGOs and groups to express their opinion. The main controversy was on the freezing of embryos. Of course, freezing is not killing but concern was expressed that in other countries, especially in the UK, many embryos remain permanently frozen and unutilized. Discussions on the status of the embryo were, in the case of Malta, futile as it was considered that life begins at conception - with the fertilization of the ovum. Private clinics had however already been providing IVF and infertility services for several years. It was this that gave momentum to the document by the Bioethics Consultative Committee. At the time it was stated that six ova were frozen and all of these were inserted. It was not uncommon in fact that women had quadruplets.

The nationalist government was in power for over twenty-four years with the exception of two year after their second legislature when labour was elected, only to fall within two years due to the dissent of their own former leader. The consequence was that the pro-Church Nationalist government delayed by as much as possible the law, with the President of the republic, Dr Eddie Fenech Adami, formerly the Prime Minister, refusing to sign any law which included the freezing of embryos. The leader of the opposition, later to become Prime Minister stated, almost on the eve of the impending election, that should the government not pass the law, the IVF law would be the first item on his party's agenda.

At the time cryopreservation of embryos was introduced and although this required the freezing of ova, many of which would be lost during the thawing phase for fertilization purposes, and also given that fertilization would be more difficult and the procedure more expensive, the law was finally accepted. The law was introduced by the nationalist government in June of 2012 and allowed the government hospital to offer IVF services to couples for a limited number of attempts. Freezing of embryos was avoided as one would fertilize only two eggs. However, it was immediately pointed out that this was difficult at time. The important stumbling block was avoided.

The procedure, as pointed out, was offered only to infertile heterosexual couples. This was a historical moment in Malta and it is no surprise that the law was not called in terms of Reproductive Technology Act, but the Embryo Protection Act. This set the scene for any future developments.

Upon the election of the Labour party, one of the first items tackled was the recognition of gay and lesbian couples. One could not introduce 'marriage' but legal partnerships, giving all the rights as married couples, were introduced. This of course opened the door to same sex couples having a right to IVF services but this was not to come immediately. The first issue tackled by the Minister of Health was to introduce embryo freezing and surrogacy. The advice given to him was that eight fertilized eggs be allowed to be frozen. Of course, this did cause controversy but the public seemed to be on the side of modernizing this law. The Bioethics Consultative Committee advised that only five embryos be frozen, and, not to introduce surrogacy at that point in time as this would be tackling one moral problem with another. It was assumed that surrogacy was to be introduced not only to help infertile couples but to help those who are not biologically, but socially infertile, that is homosexual couples, the male gay couples being most likely to have to resort to surrogacy.

The first amendment to the 2012 law was therefore in 2018, under a different President, coming from the former labour party, who was willing to sign the law. This law therefore allowed for the freezing of a limited number of embryos provided the couple did not already have cryopreserved eggs, in which case they had to be used, or, that the couple requested themselves, on moral grounds, that they wished only for the cryopreservation of their eggs, as per the existing procedure. At this stage the application of the law still applied only to heterosexual couples. The law provided that the frozen embryos had to be used by the couple and should something happen that precluded this, the embryos would be given up for adoption by the authority in charge. This was upon the recommendation to the minister by the Chairman of the Bioethics Consultative Committee at the time, in order not to allow for the possibility or the misinterpretation of the law, that embryos which remained frozen would be given up for research or indeed killed. Thus, the title of the law would be protected. In 2015 the Embryo Protection Authority Regulations were introduced to define the responsibilities and duties of the Authority in charge of overseeing IVF [3].

A radical change to the law came in 2018 [4], which amendment allowed for the use of IVF services not only by homosexual couples but also by single mothers. Moreover, the introduction of sperm donation (and by implication sperm banking) was allowed with the information of the donor being kept confidential other than for essential information which prospective parents would want to know - such as age, sex, race, and family history of disease which is relevant etc. The authority reserved the right to reveal information however to the parents or the child when it reaches the age of eighteen, should this be required for reasons which the same authority considered legitimate, such as disease which can be helped if the biological parent is known.

The following are brief points which this radical change to the law introduced. The articles focus on changing definitions in the beginning and also on defining the parameters of the new additions as follows:

- Art 2. 'prospective parent' means any person regardless of gender or sexual orientation who has attained age of majority.
- Art 4. 'medically assisted procreation' changed to 'medically assisted procreation and gamete donation':

- 4.1.iii.g A register is to be kept of every medically assisted procreation procedure, germ line cell-donation, cryopreservation of germ line cells, cryopreservation of embryos and embryo donation and adoption.
- 4.2 authority may give for adoption to a third party who qualifies...
- Art. 6 para (b), provides provision for the fertilisation of more than two eggs, on permission of the authority, up to a maximum of 5 eggs.
- Art. 7 amended to:
- Allow cryopreservation of sperm cells during the life time of the person they originate from.
- Cryopreservation of embryos up to a maximum of five years renewable up to a maximum permissible age for the transfer thereof into the prospective parent. The authority shall authorise the donation.
- Art 9. was substituted to allow:
- Donation of germ line cells given a contract between donor and licensee.
- That there shall be no link of filiation.
- Donor must be over eighteen.
- Donor must not have attained age of 36.
- Identity of donor shall remain confidential; prospective parents allowed to obtain only generic information (specified in the protocol), eg, age, sex, race, etc.
- Medical records may be accessible to the child once age of 18 is reached subject to the consent of the authority and in exceptional cases before.
- If authority becomes aware of serious illness, it shall be obliged to disclose to the parents or the child if latter has attained age of 18.
- Donation of germ line cells are limited to one donation only which shall be used in one prospective parent only.
- No person shall pay consideration to a donor or to any other person involved in arranging for the services.
- There may be compensation for costs and expenses of the stimulation treatments.
- Art. 12 stipulates that: nothing in the Act shall be construed or interpreted as impeding....the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage for the generation of an embryo.
- Art. 19 Status of the Child: 'shall be considered to be the child of the prospective parent or prospective parents who have expressed their consent in writing...and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parent or prospective parents...any such child shall be registered in any act of civil status as the direct descendent of such prospective parent or prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

- In sub-regulation (1) of regulation 2 of the Leave for Medically Assisted Procreation National Standard Order the definition of ‘prospective parents’ shall be substituted by the following:
- ‘Prospective parent’ means any person regardless of gender of sexual orientation, who has attained the age of majority and is a receptor or user of the medically assisted procreation techniques regulated under the Embryo Protection Act...

The final act in the law to date came this year in 2022 when changes to allow people with genetic diseases in their family, such as Huntington’s disease, would be allowed to use IVF services to eliminate any fertilized eggs containing a gene which brings about a genetics disorder. The novelty to this law was in the debate ensuing. The opposition nationalist Party, which at the time was going through considerable internal turmoil, significant in the fact that it may not have had too much bargaining power, opposed the law based on the selective discard of embryos with a disability. Although the Bill to the law proposed that these embryos would be preserved and given up for adoption, many considered this to be rather naïve as no-one would actually choose to adopt such embryos in all probability. Conversely if Russian Roulette with fertilized eggs is not to be used on the parent, argued former chair of the Bioethics Consultative Committee, one could not do so with those adopting a frozen embryo. Unless this was done for altruistic reasons it these would probably remain ‘on the shelf’ [5]. Moreover, he argued, that the licit-ness conversely can be seen, if one considers that if no one would want to adopt such an embryo, who are we to judge and not allow people who carry a disease in their family to try to eliminate the disease in their germ-line. If we accept cure then we cannot call this discrimination against the embryo. The disability group, as far as the author has been did not express itself against this amendment but many pro-life groups did. The former chair continued to say that indeed even if someone would adopt these embryos, it would mean that these children would eventually have to be told about their condition and thus would come to know they were discarded by their biological parents. They would not have the consolation, if one can call it that, that it flows in their family. They would not be able to contact the genetic parents and they would have existential questions about their lives. Nevertheless, the article does balance of argument did balance in favour of the law [6].

There were two significant points in the controversy to be mentioned. The incumbent President of the Republic had frequently expressed, even before he was appointed President, that he would not sign any law to do with abortion or euthanasia and that if the government had to provide such a Bill he would resign. He was not comfortable with signing this law but on the other hand it did not provide for the freezing of embryos. This was resolved by his official visit to another country where he provided for the Agent-President (an acting President in his place during his absence) to sign the law.

Secondly the Nationalist party, as point out before, had opposed the law. It suggested the use of polar body biopsy on the ovum instead of testing a developing embryo. (Usually, the cells are taken following a few days from the outer cell mass which goes on to develop the placenta and not the embryo, which will not be harmed). However, such a procedure can only detect disease from the mother’s side. It is significant that following dialogue of the two parties, the Nationalist party accepted the law on the grounds that it promoted life. Having changed position took courage of course and indeed marked a probable historical event. It also proved to move itself away from a more conservative approach, which seems to be the will of the people. The most recent Bill is on termination of Pregnancy when there is threat to the mother’s life or severe health issues. What constitutes the latter will require dialogue; an essential issue to remove paternalism from medical practice and respect patients’ rights. It is still too early to comment on this development.

Rather than slippery slopes, laws evolve and have to take into consideration the will of the people. If conservative positions, or religious views are not upheld it is probable the fault of the balance of progressive media and lack of work on the part of religious institution to preach principles rather than virtues and by somehow losing the faith of the public even though they hold strong virtues moral positions. This is a pity but something which ought to be considered. Conversely true dialogue must involve the willingness of at least one party, but preferably both, to move towards common grounds on which agreement can be reached.

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