

Embryo Protection (Amendment) Bill

Bill No. 38 (2018)

MATTERS OF CONCERN

REFLECTIONS BY ACADEMICS

May 2018

Contents

Executive Summary	3
Embryo Protection (Amendment) Bill - Matters of Concern	4
1. Embryo Freezing	5
2. The Disposal of Surplus Embryos	6
3. Anonymous Donation of Gametes [Sperm and Ova]	7
4. Surrogacy	8
Conclusions	9
Signatories	11
Appendix - Results of Oocyte Vitrification in Malta	12

Executive Summary

This document reflects the opinion of 100 academics at the Faculties of Science, Medicine and Surgery, Laws, Built Environment, Theology, Education, Arts, Economics, Management and Accountancy, Health Sciences, Engineering, Information and Communication Technology, Media and Knowledge Sciences and Social Wellbeing at the University of Malta on *The Embryo Protection (Amendment) Bill*, Bill No. 38 (2018).

They note that the existing law focuses on the dignity of the human embryo and its protection. The proposed amendments gravely weaken the protection of the human embryo at its most vulnerable stage by allowing:

a) *Embryo freezing*: The proposed changes are based on the assumption that increasing the odds would increase the chances of success. This is potentially true. However, this does come at a psychological, legal and moral cost – namely the production of excess embryos and the need for ‘embryo orphanages’ and ‘embryo donations’. It also involves selecting some for implantation and others for freezing, giving the former a chance to develop and placing the latter in a ‘frozen limbo’. One should note also that, under the current legislation, IVF service in Malta, including oocyte vitrification, has been performing fairly well in comparison with other European countries.

b) *The disposal of surplus embryos that are not adopted/implanted*: The proposed selection of two out of three or five fertilised embryos entails unequal treatment between one embryo and another, discriminating against some simply because they cannot take action to protect their interests. The amended law prescribes that these embryos (already deemed to be inferior at the first selection process), if not taken up by their biological parents, will be offered for adoption by other couples. Prospective parents would most probably be reluctant to adopt these frozen embryos who would have already been deemed inferior at the first selection process.

c) *Anonymous donation of gametes [sperm and ova]*: Anonymous gamete donation may lead to a number of health risks. The proposed amendments to the *Embryo Protection Act* do attempt to reduce the transmission of genetic disease. Risk reduction, however, is not the only issue. Gamete donation may result in potential psychological consequences which may complicate the identity formation process of eventual offspring. Anonymous gamete donation makes a mockery of the child’s right to know his or her biological origin. Children born as a result of gamete donation will never be able to establish any relationship with their biological parents.

d) *Surrogacy*: Surrogacy, which is another form of commodification of women’s body, involves a fragmentation and trivialisation of parenthood. The proposed legislation permits only ‘altruistic surrogacy’. The very term ‘altruistic surrogacy’ is a subterfuge since, according to the law, the surrogate mother would relinquish any responsibility to bring up the child as her own, and the child would not have the possibility of being conceived, gestated, born and raised by the same mother. Although *prima facie* maternal surrogacy would appear to constitute a wonderful gesture of selfless altruism, it is, in practice, fraught with numerous biological, legal and ethical problems.

Embryo Protection (Amendment) Bill

Matters of Concern

The *Embryo Protection (Amendment) Bill*, Bill No. 38 (2018), takes no account of the opinions voiced in the course of the public consultation coordinated by an Inter-Ministerial IVF Review Committee in 2015. As no report has been published on the results of this consultation, it is not possible to establish the impact of public opinion on the way that the Government is proposing to legislate on a very serious and particularly sensitive area of social life. Similarly, the views in the position paper, *Legislation Regulating Assisted Human Procreation*, written at the request of the Church in Malta by experts in the field of medicine, law, psychology, social policy, family studies, philosophy and theology, were also completely ignored. Given the gravity of the matter, it is morally imperative to protest against the use of IVF at the expense of the human embryo.

Faced with the *Bill to Amend the Embryo Protection Act*, we note that, although the law will retain its name, the amendments make a mockery of the same since they uphold the needs of prospective parent/s to the almost complete disregard of the protection of the human embryo. In the existing law, the central focus is the dignity of the human embryo with the PROTECTION of the embryo being paramount throughout. The proposed amendments alter this focus radically, such that the focus is now entirely shifted towards the accommodation of those seeking IVF at the expense of the embryo. Indeed, the status of the human embryo has been downgraded from a crucial player with independent rights and deserving of dignified respect, to little more than a commodity. The amendments propose to dismantle rather than consolidate the protection of the human embryo since they broaden the options of assisted procreation precisely at the expense of the full protection of the human embryo, the most vulnerable person in human society.

The inconsistencies in the language used in the proposed Bill reflect an ambivalent attitude that demeans the human embryo. The term “embryo” is used interchangeably with “fertilised egg”, “fertilised cell” and “fertilised egg cell”. “Embryo” is favoured with reference to any part of the parental project (e.g. the product implanted after successful IVF or embryo adoption), with the less emotive term “fertilised egg” referring to those undergoing cryopreservation (freezing), when these are both absolutely equal to one another. Indeed, clause 6(b) of the Bill, whilst referring to article 8 in the Embryo Protection Act, directly proposes that the term “embryo” is changed to “fertilised egg”. This is a deliberate, if not cynical attempt, to downgrade the status of embryos to fertilised eggs, thereby lessening the impact that befalls most of those committed to cryopreservation. The dignity of the human embryo surely is not defined by the manipulation of language, yet this approach epitomises the gist of the proposed Bill where the embryo is now, almost exclusively, transformed into a commodity that is used to meet claims which, while not necessarily egoistic, cannot be automatically given priority over the the right to life, the inherent dignity of the human embryo and its future flourishing as a human person.

The protection of the human embryo would be gravely weakened through the following proposals:

1. Embryo freezing;
2. The disposal of surplus embryos that are not adopted/implanted;
3. Anonymous donation of gametes [sperm and ova]; and
4. Surrogacy.

1. Embryo Freezing

The proposed changes allow for a significant increase in the number of embryos being produced per cycle, namely three ova being fertilised in the initial treatment cycle and five ova in subsequent cycles. They are based on the assumption that increasing the odds would increase the chances of success. This is potentially true, the more ova submitted to the process of fertilization the better are the chances of success of the procedure. However, this does come at a psychological, legal and moral cost – namely the production of excess embryos and the need for ‘embryo orphanages’ and ‘embryo donations’. It also involves *selecting* some for implantation and others for freezing, giving the former a chance to develop and placing the latter in a ‘frozen limbo’.

It is certainly not in the embryo’s best interest to be frozen when, according to Britain’s Human Fertilisation and Embryology Authority (HFEA), 10 - 30% of all embryos will not survive the freezing-thawing process.

When compared to other European countries, the current IVF service in Malta, regulated by the existing Embryo Protection Act without the need for any amendments, has already achieved good results with oocyte vitrification (see Appendix).

The medical facets engendered by allowing the creation and freezing of extra embryos had been detailed in the previous 2015 Position Paper of the Church in Malta.¹ These arguments still hold today. The 2015 Position Paper had warned that:

‘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.”’

Under the current Embryo Protection Act, which is truly protective, embryo freezing is limited only to

¹ Conferentia Episcopalis Melitensis. *Legislation regulating Assisted Human Procreation – A Position Paper*. November 2015, Malta, 18-25.

absolutely exceptional circumstances and always to safeguard the embryo.² It is essential that the legislative mechanism for allowing the creation and freezing of excess embryos in the proposed Bill is reviewed and markedly restricted.

2. The Disposal of Surplus Embryos

The amended Act will, invariably and inevitably, create a surplus of embryos. The proposed Bill includes a provision for embryo donation for adoption³ but appears to assume, naively, that this will be a reality for all surplus embryos. In practice, this will not be the case for many of these surplus embryos and, significantly, the Bill does not even address let alone provide any legal framework to cater for them. Surplus embryos will be in limbo, having been created but having their life suspended until third parties decide whether they may or may not continue to develop normally. Their right to life and development into a child is that suppressed by the capricious decision of that person who decides who will be born and who will be frozen. In addition, the proposed selection of two out of three or five fertilised embryos will create an underclass of non-selected embryos, thereby breaching human rights as embryos are not afforded equal treatment but are discriminated against arbitrarily, simply because they cannot take action to protect their interests. These amendments mean that eugenic (and therefore discriminatory and unequal) practices will have been made legal in Malta.

The amended law dictates that these embryos (already deemed to be inferior at the first selection process), if rejected by their biological parents, will be offered for adoption to other couples. The new proposal assumes, again naively, that these couples will accept these adoptee embryos without question. Yet these embryos will, by definition, be second choice embryos, will be older, and would have gone through one freeze-thaw cycle, all of which will mitigate against a viable pregnancy. Even if these issues are totally ignored in the amended law, prospective parents would soon realise that the option of hand-me-down embryo adoption is less than satisfactory and reject this offer. Even if this does not occur at the start of the new programme, it will become clear within a few adoption-cycles and will, inevitably, result in an ever increasing rejection of embryos for adoption by prospective families, whilst the supply from on-going IVF cycles will continue to grow at an alarming rate.

Within a short period of time, Malta will have accumulated a large and ever-increasing number of unwanted, decreasingly-viable and increasingly-unadoptable embryos 'on ice'. What is or will be the position for these embryos? Why does the Bill not allow any provision for this eventuality? Are these embryos to be frozen indefinitely? Will these embryos be denied the right to life and to develop? If so, this will entail a significant expense and, therefore, has an appropriate budget been

² K. Sansone. Two embryos remain frozen at Mater Dei hospital because of mother's illness. *Times of Malta*, 11th April 2017.

³ The present proposed amendment [Section 4:2 of Chapter 524 (as amended)] will allow for the donation of frozen embryos, in situations where:

- (1) the biological mother dies before implantation could take place; and
- (2) where, for whatever reason, implantation in the biological mother cannot take place including:
 - a) those instances where the biological mother refuses the implantation; or
 - b) where the biological mother goes beyond the permissible age for undergoing the implantation procedure; or
 - c) when the biological mother fails to renew the contract with the holding agency.

While the first reason resulting in 'unclaimed embryos' is unfortunate and can be considered a viable reason for finding adoptive parents for the frozen embryos, the other options are unacceptable and will be open to abuse.

identified? Why should these embryos be deprived of their right to life – the fundamental human right *par excellence* – or why should their right to life be suspended for years through artificial selection making it a matter of chance whether an embryo enjoys the right to life and the right to develop into a child? Incredibly, this scenario and all of these questions are simply ignored by the new proposals. For all the above reasons, the policy of implanting all fertilized ova by the current legislation should be retained.

3. Anonymous Donation of Gametes [Sperm and Ova]

Certain medical conditions result in absolute infertility where pregnancy can only be achieved through the use of gamete donation. In the female, these would include situations where the woman has no ovaries or is in premature menopause. In the male, these would include azoospermia due to failure of spermatogenesis. There may also be situations where an individual with a severe genetic medical disease is advised to refrain from transmitting his or her genetic material. However, all these situations are rare and legislative changes should be introduced to safeguard the rule and not the exception.

The health risks linked with gamete donation have already been outlined in the 2015 Position Paper prepared for the Maltese Episcopal Conference.⁴ We reiterate that anonymous donation may lead to a number of serious problems. Sperm donation is risky if biological children of the same man or woman meet and procreate with potentially grave genetic outcomes. This likelihood is more acute in Malta bearing in mind the population's small size. A normal health check of the donor does not exclude all common recessive disorders, and a family history of certain disorders is only available in a minority of cases.

The proposed amendments to the *Embryo Protection Act* do attempt to reduce the transmission of genetic disease.⁵ Risk reduction is however not the only problem. Gamete donation may result in potential psychological consequences to the eventual offspring when informed of their origins. While the literature in this regard is controversial, there is no doubt that the urge to seek the true biological parent/s is strong and this may complicate the identity formation process of the one born of gamete donation. Furthermore, the outlook to their adoptive parent may potentially be adversely influenced to unintentionally separate the child from the parents. The psychological issues associated with gamete donation are further compounded in the situation where embryo donation has occurred. Besides the potential identity crisis that disclosure of origins can elicit, these individuals will have to cope with the added psychological burden of having been abandoned by their biological parents.

⁴ Conferentia Episcopalis Melitensis, *Legislation regulating Assisted Human Procreation – A Position Paper*. November 2015, Malta, 18-25.

⁵ Risk reduction includes:

- a. Limiting the age of potential donors to 18-36 years [although the upper limit can be extended at the discretion of the Embryo Protection Authority];
- b. Donors must have a good mental and medical health profile [however some diseases may manifest themselves later in life or in donors with recessive genetic conditions that may not be easily identified as carriers];
- c. The medical history of the donor [although it is unclear whether this is at time of donation or updated later] will be made anonymously accessible to the offspring at 16 years of age, or earlier in cases where the health or life of the offspring is threatened.
- d. Each potential donor can participate in only one donation to be used in one prospective recipient.

The psychological consequences have been shown to vary from one culture to another, even in Europe⁶, and the effect of introducing gamete donation in the Maltese cultural environment has not been assessed.⁷

Anonymous gamete donation makes a mockery of the child's right to know his or her biological origin. This possibility at law will mean the deliberate creation of new kinds of orphans. Such children will never be able to establish any relationship with their biological parents. In addition, the children involved will be at greater risk for the rest of their lives since the generic medical information available could never be complete. Indeed, if these records are truly anonymised they are not of much use. If they are truly anonymous, the records cannot be updated; if they can be updated, they are not anonymous.

In addition, there would also be adverse effects on the child's identity, and his or her right to an identity, the basis on which anonymous donors were outlawed in the UK. Indeed, Article Seven of the *Convention on the Rights of the Child* states that "as far as possible [the child has] the right to know and be cared for by his or her parents."

4. Surrogacy

Surrogacy came to the fore in 1986 when the contracted surrogate mother refused to cede custody to the biological parents.⁸ This case illustrates the psychological pain a surrogate mother can experience when the time comes to give up the child she has carried and identified with during the pregnancy. Surrogacy is a highly debated method mainly used for treating women with infertility caused by rare uterine factors. Even in these clinical situations there are legal and ethical problems. Extending surrogacy to other situations, as envisaged by the amendments, will create serious problems.

The research background with regard to the obstetric, medical and psychological outcomes for the surrogate mothers, the intended parents and children born as a result of surrogacy is controversial with most studies having serious methodological limitations. A systematic review of the literature has concluded that most surrogacy arrangements are successfully implemented, and there is no evidence of harm to the resulting children. However, the advice is that these conclusions should be interpreted with caution and further studies are necessary.

The Bill defines commercial surrogacy as a criminal act [clause 4(d) referring to article 6(f) of the amended A]. This is in contrast with the current legislation where all forms of surrogacy are deemed illegal. In the proposed legislation, the regulation of situations where 'altruistic surrogacy' can be considered is left open and undefined and completely at the discretion of the Minister through the

⁶ S Zadeh, CM Jones, T Basi, S Golombok. "Children's thoughts and feelings about their donor and security of attachment to their solo mothers in middle childhood." *Human Reproduction* 32, no.4 (2017): 868-875; L Blake, V Jadva, S Golombok. "Parent psychological adjustment, donor conception and disclosure: a follow-up over 10 years." *Human Reproduction* 29, no.11 (2014): 2487-2496.

⁷ R Cook, I Vatev, Z Michova, S Golombok. "The European study of assisted reproduction families: a comparison of family functioning and child development between Eastern and Western Europe." *Journal of Psychosomatic Obstetrics & Gynecology* 18, no.3 (1997): 203-212.

⁸ B Steinbock. "Surrogate Motherhood as Prenatal Adoption." *Law Medicine and Health Care* 16, no.1 (1988): 44-50.

issue of a Legal Notice without proper parliamentary debate and popular discussion.

This proposal creates a morass of difficulties, not least the commodification of women, trivialisation of parenthood and fragmentation of maternity in that the genetic mother, the gestational mother, and the legal mother could be as many as three persons. It would also create a 'stranger's' bond between the gestational mother – who would serve as a mere incubator – and the child. This would be harmful to both the surrogate mother and the child. The very term 'altruistic surrogacy' is a subterfuge since, according to the law, the surrogate mother would relinquish any responsibility to bring up the child as her own, and the child would not have the possibility of being conceived, gestated, born and raised by the same mother. The child-to-be would lose his or her right to an identity through recourse to three mothers and possibly two fathers.

Although *prima facie* maternal surrogacy would appear to constitute a wonderful gesture of selfless altruism, it is, in practice, fraught with numerous biological, legal and ethical problems. For these reasons, very few countries have any form of legislation that addresses let alone allows for this option. Those that do have legislation, have introduced surrogacy only after years of difficult discussion, and with major restrictions and conditions. It should be noted that countries such as Norway, Germany, France and lately Sweden have banned all forms of surrogacy. Yet the new amendment would introduce this in Malta '*carte blanche*' via a simple legal notice without any proper parliamentary debate and popular consultation. This proposal totally disregards the details, intricacies and problems associated with this practice.

Conclusions

1. The need for increasing the number of ova being fertilised in each cycle treatment is definitely not supported by the ART results reported by the Malta Embryo Protection Authority and would increase the number of orphans in Malta.
2. The proposed amendments to the Embryo Protection Act will increase the number of surplus embryos, many of whom will be abandoned in perpetual cryopreservation.
3. The adoption of human embryos is associated with psychological, medical, legal and moral problems. Many prospective parent/s would want to have a child who is biologically related to at least one of the partners. Others may simply not accept this option, both as donors and as recipients. The Bill makes no allowance and does not address any of these potential problems. The proposed amendments would appear to create a supply but not a demand for these embryos.
4. With the new proposals, the human embryo will be transformed into a commodity that can be transacted by the State without the need for any form of parental consent. In effect, parents will give up their embryos to the State, which will decide who can adopt them or what will eventually happen to them without any of the legal, political or judicial constraints that apply to every other stage of human life. The *Authority for the Protection of Embryos* would be responsible for matching the embryo with adoptive parent/s, yet there is no provision on how this will be carried out in practice.
5. Gamete donation is associated with problems particularly relating with the child's right to an identity, genetic counselling and complications in any matching process.
6. Surrogacy is a hugely contentious and complex issue that this Bill chooses to introduce through a simple Legal Notice and without any proper discussion whatsoever. This trivialises this problem altogether and underscores the lacunae that characterise the Bill.

7. Disregard for the protection of the human embryo is the hallmark of the Bill, in stark contrast with the existing Embryo Protection Act. In the Bill, the embryo is reduced to a commodity and stripped of any dignity deserving of a human being.
8. The gist of these amendments is that, from a rights perspective, in sum:
 - frozen embryos, whilst in that state, are denied the right to develop and the right to life whilst contributing to increasing the orphan population;
 - as a third of all embryos will not survive the freezing-thawing process, these embryos are denied the right to develop and the right to life – both being fundamental human rights;
 - embryos that are allowed to develop and live will end up denied of their human right to an identity;
 - the choice being made to select which embryos to implant and which to freeze is in breach of human rights – freedom from discrimination and the right to equality;
 - the law will now safeguard the interests of those persons who wish to have children to the absolute detriment of the most vulnerable persons in society – children in their embryonic stage;
 - the human dignity of women is imperilled in so far as they are legally being objectified when they are considered simply as incubators, whilst forcing them by law to renounce to the right of motherhood and ignoring the strong emotional bonds which may form in such women with the developing child;
 - the legal tenet that the best interests of the child are paramount is being turned upside down, quite contrary to other provisions in Maltese Law which uphold this tenet without reservation. Such abandonment of this basic principle in child law contributes to the dehumanisation of embryos, rendering them akin to tradeable objects;
 - the rights of the persons involved in the artificial procreation of the embryos are not considered at all when those embryos are forcefully taken by the State for donation purposes in breach of those persons' right to private and family life (and, once the Bill considers embryos as objects, those persons' right to property) and, worse still, without their approval as to whom such embryos are to be donated, thereby legalising traffic in embryos whilst objectifying embryos through their commodification;
 - signing away one's embryos as an obligatory condition of use of the proposed embryo freezing service breaches the principle of consent as it is carried out under duress at a time of vulnerability. Indeed, the price demanded in this duress is actually the giving away of one's embryonic child. Would this not go against one's basic human right to family life?
 - the right to know one's biological origin is imperilled with all the attendant biological, psychological, legal, ethical and social consequences this will entail.

Signatories

Professor Angela Abela
Rev. Professor Emmanuel Agius
Professor Kevin Aquilina
Ms Grace Attard
Rev. Dr Stefan Attard
Professor Simon Attard Montalto
Dr Charles Bonello
Judge Giovanni Bonello
Dr Joseph P. Bonello
Dr Marjorie Bonello
Professor Albert Borg
Dr Joseph Borg
Rev. Dr Joseph Borg
Dr Konrad Borg
Dr Tonio Borg
Dr Vince Briffa
Professor Joseph M. Brincat
Dr Roderick Bugeja
Professor Mario Buhagiar
Mr George G. Buttigieg
Dr Jean Buttigieg
Professor Sandra Buttigieg
Dr Colin Calleja
Dr Anne-Marie Callus
Ms Astrid Camilleri
Rev. Dr Charlò Camilleri
Professor Juanito Camilleri
Professor Frances Camilleri-Cassar
Professor Antoinette Camilleri Grima
Professor Sandro Caruana
Professor Carmel Cassar
Dr David Cassar
Professor George Cassar
Dr Maria Cassar
Professor Vincent Cassar
Professor Maria A. Cordina
Professor Alan Deidun
Dr Nadia Delicata
Dr Pauline Dimech
Professor Alexiei A. Dingli
Dr John Ebejer
Dr Bridget Ellul
Dr Josette Farrugia
Rev Dr Richard-Nazzareno Farrugia
Dr Rosienne Farrugia
Dr Ing. Emmanuel Francalanza
Professor J. Anthony Frendo
Dr Maria Frendo
Mr Ivan Galea
Professor Raymond Galea

Rev. Professor Paul Galea
Dr Maria Victoria Gauci
Professor Adrian Gellel
Professor Helen Grech
Dr Paulann Grech
Ms Ingrid M. Grech Lanfranco
Rev. Professor George Grima
Professor Joseph N. Grima
Dr Simon Grima
Professor Godfey Laferla
Professor Josef Lauri
Dr Natalie Kenely
Professor Mary Anne Lauri
Professor Victor Mallia-Milanes
Mr John Mamo
Dr Bernard Micallef
Dr Dione Mifsud
Dr Martin M. Musumeci
Ms Maria Navarro
Dr Nikolai Paul Pace
Professor Paul J. Pace
Professor Roderick Pace
Professor Joseph M. Pirotta
Dr Sarah Pule
Ms Lourdes Pullicino
Dr Ivan Sammut
Dr Roberta Sammut
Professor Tony Sant
Mr Albert Paul Scerri
Dr Clarissa Sammut Scerri
Professor Charles Savona-Ventura
Professor Pierre Schembri Wismayer
Ms Svetlana M. Schembri Wismayer
Professor Valerie Sollers
Rev Dr Mark Sultana
Dr Josef Trapani
Ms Lara Tonna
Professor Alex Torpiano
Dr Mark Anthony Vassallo
Professor Peter Vassallo
Dr Anna Vella
Dr Antoine Vella
Dr Sue Vella
Dr Patricia Vella Bonanno
Professor Patricia Vella de Fremeaux
Professor Edward Warrington
Dr Rita Xuereb
Professor David E. Zammit
Professor Martin R. Zammit
Rev. Dr Ray Zammit

Appendix

Results of Oocyte Vitrification in Malta

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.”

The option of Oocyte Vitrification has been shown to be a viable option to safeguarding the woman from excessive ovarian stimulation. Repeated studies have shown similar successful pregnancy rates with frozen embryo transfer and with fertilization and transfer of frozen oocytes.¹ There is no medical reason to move away from restricting the number of ova fertilized per cycle and offering oocyte vitrification for the excess ova to be used in subsequent cycles. Oocyte vitrification does not carry the significant adverse consequences association with embryo freezing. The current control mechanisms for establishing the number of ova fertilized per cycle must be retained and not left to the whims of interested individuals, i.e. the clients and the practitioners working with these clients. The present control mechanism ensures that third parties can independently adjudicate each and every request made to go beyond the restraints placed by the current legislation. Section 6:b/c should definitely **not** be amended. There is no evidence to support the proposed changes considering the success rates reported by the Embryo Protection Authority.

The 2016 annual report of the Embryo Protection Authority showed that the success rate resulting in a successful implantation rate (clinical pregnancy rate) was 23.4% [In 2015, it was reported to be about 28%]. At the time of the report, the 64 successful implantations resulted in 7 miscarriages, and 14 live births. The remainder were still pregnant. Out of the 273 ART procedures carried out in 2016, 71% [194 cycles] were carried out using fresh ova, with a success rate of 24.2%. 79 ART procedures used thawed ova with a success rate of 21.5%, a difference that was not statistically significant.

¹ Jeffrey Boldt et al., “Human Oocyte Cryopreservation as an Adjunct to IVF–Embryo Transfer Cycles,” *Human Reproduction* 18, no. 6 (2003): 1250-1255; American College of Obstetricians and Gynecologists (Committee on Gynecologic Practice), Opinion 584: *Oocyte Cryopreservation*, January 2014; Masashige Kuwayama et al., “Highly Efficient Vitrification Method for Cryopreservation of Human Oocytes,” *Reproductive Biomedicine Online* 11, no. 3 (2005): 300-308; 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; 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.

Total number of Ova collected after stimulation	1630
Total number of Ova discarded as unsuitable	871 [53.4%]
• Total number of discarded fresh ova	705 [80.9%]
• Total number of discarded thawed ova	166 [19.1%]
Total number of ART procedures	273
• Total number of procedures using fresh ova	193 [70.7%]
• Total number of procedures using thawed ova	79 [28.9%]
• Total number of procedures using fresh & thawed ova	1 [0.4%]
• Total number of x1 embryo transfer	46 [17%]
• Total number of x2 embryo transfer	150 [55%]
• Total number of x3 embryo transfer	53 [20%]
• Total number of x2 embryo freezing	1
Total number of successful clinical pregnancies	64 [23.4%]
• Total number of clinical pregnancies following fresh ova	47 [24.2%] success rate from procedure
• Total number of clinical pregnancies following thawed ova	17 [21.5%] success rate from procedure
Total number of requests to attempt fertilize three ova	172
• Authorization granted	112 [65.1%]
Presumed number of ova frozen	100 [6.1%] of total ova collected

Reported ART Procedures in Malta – 2016²

These very good results produced by the current service available [a success rate of a quarter of attempts] negate the potential slight rise in successful pregnancies by increasing the allowable number of ova being fertilized in one cycle; especially considering the age distribution profile of the Maltese patients where the older woman is given a higher priority to undergo treatment cycles. Clinical pregnancy rates reported from Australia and New Zealand ranged from 25.2% in 2011 to 31.6% in 2015, where success rates depended on the age of the woman undergoing treatment [see figure below].³

² Embryo Protection Authority. Annual Work Report – Trends and Figures of Fertility Treatment in Malta 2016. Embryo Protection Authority, Malta, 2017.

³ Fitzgerald O, Harris K, Paul RC, Chambers GM. *Assisted reproductive technology in Australia and New Zealand 2015*. Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales Sydney 2017.

Clinical pregnancy rate for each embryo transfer for patients with their own eggs



