# FERTILITY PRESERVATION FOR CHILDREN WITH CANCER: LEGAL AND ETHICAL CHALLENGES

Dr. Neil Maddox and Claire McGovern[1]

**Abstract**

*Fertility preservation for cancer patients (oncofertility) is a new and developing area of medical practice presenting unique legal and ethical challenges. This is particularly so when the patient is a child. This paper traces the development of this new discipline and the medical options for fertility preservation for children and young adults. It then examines the legal and ethical issues presented by oncofertility for children by considering the right to reproduce, consent of minors and proxy consent, as well as the question as to who controls the fate of the child's cryopreserved reproductive tissue. Some tentative conclusions are drawn.*

## 1. Introduction

**[1.01]** A cancer diagnosis can and does have profound effects on the lives and prospects of any person. This is particularly the case when the stricken patient is a child. Paediatric oncology has understandably been exclusively focused on providing the most effective treatment available to prolong the lives of their child patients. In recent years, however, improved survival rates for paediatric cancers (an aggregate survival rate exceeding 80 percent with this rising to 90 to 95 percent for certain forms of cancer), has led to an increased focus in ensuring the long term quality of life and mitigation of harmful treatment effects upon children who are now much more likely to survive into adulthood. (Lautz *et al*, 2016; Saletta *et al*, 2014).

**[1.02]** This focus is understandable given one study estimates that the vast majority of patients treated successfully for childhood cancer develop chronic health difficulties later in life and this includes the development of a serious medical condition in eight percent of survivors. (Hodson *et al*, 2013). One of the most significant and serious side effects of many forms of cancer treatment is infertility or significantly diminished fertility. For child cancer patients this is particularly harrowing, as they are forced to consider a means of preserving their fertility for later life at an age when such matters are far from the thoughts or normal considerations of other healthy children.

**[1.03]** Empirical research confirms the intuition that the future ability to have biological children is a central concern of patients in ensuring their quality of life into adulthood. (Lautz *et al*, 2016).



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Law Department, Maynooth University, in collaboration with the Irish Cancer Society.

The unfulfilled desire for a child and interrupted fertility may result in poor mental health outcomes for the survivor and loss of fertility may adversely impact upon a person's self-confidence. As such, and as noted by the Irish Cancer Society, the decision to undergo fertility preservation is not just a medical question, but a psychological one as well. (ICS, 2020). Advances in the detection and treatment of cancer have also resulted in increasing survivorship and life expectancy in the adult population. (O'Connor *et al*, 2019).

**[1.04]** Nonetheless, the needs of childhood, adolescent and young adult cancer survivors are distinct from that of adult cancer survivors and form a unique group which is a subset of all cancer survivors in Ireland. On average there are 160 cases per year of childhood cancer in Ireland in individuals aged 0 to 15 years and a further 58 cases in the 16 to 19 year old age bracket, making an average of 218 cases of cancer diagnosed annually among children and teenagers. (O'Connor *et al*, 2019). Incidents of childhood cancer are higher in boys than girls but not at such a level as to be statistically significant. Between 2008 and 2013 about two thirds of children with cancer received chemotherapy, and 20 percent received radiotherapy (with or without chemotherapy), both treatments known to impact future fertility.

**[1.05]** The five year survival rate for all childhood cancers in Ireland is close to the international mean at 81 percent between the years of 2004 and 2013. (O'Connor *et al*, 2019, p. 9). Currently, it is estimated that there are between 300,000 and 500,000 survivors of childhood cancer in Europe. One of the needs that childhood cancer survivors commonly report are information needs regarding their diagnosis, treatment, and the risk of late effects of their cancer treatment. Unmet informational needs are particularly pertinent in an area such as oncofertility which is a new and developing area of research and study. There may be little cross-communication between a child's oncologist and the fertility experts who are in a position to advise on new procedures that may be available for fertility preservation of their patient following treatment.

**[1.05]** Notwithstanding the recommendations of several medical and ethical societies, studies have shown that only 50 percent of childhood cancer survivors had discussed fertility with their physicians and half of the surveyed oncologists rarely or never raised the issue of fertility preservations with their patients. (Shah, 2011). This is despite the fact that interviews with young survivors of childhood cancer have suggested that the possibility of biological parenthood in adulthood is a powerful motivator for recovery and a significant majority identify their illness as a life experience that may enhance their ability to successfully parent a child in the future. (Shah, 2011).

## 2. Assisted Human Reproduction

**[2.01]** The variety of different techniques that are now described under the umbrella term 'Assisted Reproductive Technology' (ART) have been made possible by the development of *in vitro* fertilisation (IVF) in 1969 with the first live birth of an IVF baby in the world occurring in July 1978 (Mulligan and Mills, 2017, p. 417). *In vitro* is Latin for "within the glass" and *in vitro* fertilisation has come to mean any process of fertilisation of human gametes that takes place outside the body, usually in a laboratory context. Modern IVF utilises a procedure called ovarian hyper stimulation to induce a woman to produce multiple eggs which are collected using a needle guided by ultrasound technology. The man is then asked to provide a sperm sample through masturbation and this sample is collected and used to inseminate the eggs which are monitored under a microscope to see if fertilisation has taken place (American Society for Reproductive Medicine, 2014).

**[2.02]** It is also possible to cryopreserve human eggs and sperm by freezing. These techniques are of particular value for people who are suffering from conditions such as cancer that are likely interfere with their future fertility and where the survival of their reproductive function and reproductive tissue in a usable condition is at risk. Sperm freezing technology is already quite advanced and there is evidence to suggest that sperm can be stored indefinitely and still remain viable. However, egg freezing technology lags somewhat behind and cryopreservation of human ova is a significantly less reliable process (Mills and Mulligan, 2017, p. 418).

**[2.03]** With regard to the regulation of ART, there is a diversity of approaches across the globe. Some countries, including Ireland to date, have yet to regulate while others such as the United Kingdom, Israel and Belgium are regarded as having exceedingly liberal regimes, leading to what is loosely described as 'reproductive tourism' to these more permissible countries (Pennings, 2004). And, some countries, such as Germany, might be described as restrictive or conservative towards permitting artificial reproduction (Bernat, 2002).

**[2.03]** The UK has enacted legislation, in the form of the Human Fertilisation and Embryology Act 1990 (HFEA 1990) and its' amending acts, that prescribe detailed statutory regulation of ART procedures and establishes a licensing body for clinics operating in the jurisdiction. This approach has been broadly adopted in New Zealand and certain Australian states. In New Zealand, for example, all reproductive procedures are subject to the Human Assisted Reproductive Technology Act 2004 (HART Act 2004). The legislation only prohibits a small number of procedures, allowing an advisory committee broad powers to licence novel procedures and issue guidance and advice in respect of same (Peart, 2015). Ireland looks set to adopt the UK model and heads of bill for

proposed assisted human reproduction legislation were published in 2017 (AHR Bill 2017), although little progress appears to have been made in securing these proposals passage into law.

## 3. Oncofertility

**[3.01]** ART has created an emerging clinical field called fertility preservation that utilises medical and technological advances in reproductive medicine and applies them to patients with serious diseases, such as cancer, or with clinical conditions associated with the premature onset of gonadal insufficiency. (Rodriguez-Wallberg *et al*, 2020). With regard to cancer patients, a new inter-discipline— oncofertility— has emerged in recent years (Woodruff, 2007) with the term oncofertility being coined in 2006 (Woodruff, 2010). The worldwide decline in cancer rates has been linked to the passage of the National Cancer Act in the United States as part of President Richard Nixon's war on cancer in 1971. In addition, the subsequent and consequent funding for the National Cancer Institute in the US, which was focussing on the diagnosis and treatment of the disease, aided this trend. During this time, rapid advances were being made in artificial reproductive technology (Woodruff, 2010, p. 2).

**[3.02]** Fertility plays a fundamental role in the development and identity and future hopes of individuals. Cancer patients and their families have an interest in preserving fertility, but there are still lacunae in the understanding of the underlying medical techniques for fertility preservation as well as patient and clinical awareness. (Quinn *et al*, 2007). While some cancer patients are advised by their oncologist to consider oncofertility (the cyclist Lance Armstrong was told to do so when diagnosed with metastatic cancer at the age of 25) many are not (Woodruff, 2010).

**[3.03]** Oncofertility thus attempts to describe an integrated network of clinical resources that focus on developing techniques to preserve reproductive function in patients who are diagnosed with cancer and this requires an interdisciplinary approach integrating societal, ethical and legal issues which arise as a result of these new reproductive techniques and this has proved particularly challenging. There are a number of reasons for this; first, the fertility treatment may delay and thus threaten and interfere with the cancer treatment, presenting a myriad of ethical problems for clinicians to deal with; secondly, the medical procedures are novel, developing and immature; thirdly, as noted, the problem requires an interdisciplinary approach between different clinical areas in oncology and fertility preservation including social research sciences as well as the humanities, law and education in order to create an integrated and coherent approach to this problem.

## 4. The Right to Reproduce

**[4.01]** What might broadly be described as a person's "right to reproduce" is no longer just a moral claim or of mere academic interest, as rights claims have started to appear in legal cases involving reproductive issues in recent years. Discussions of this right have, in particular, been spurred by novel legal questions raised by the modern development of artificial reproduction, although the justification for any such right, and its scope and limits are far from clear (Quigley, 2010).

**[4.02]** The right to reproduce is traditionally perceived as a moral right (American Society for Reproductive Medicine, 1994). In essence, the right may or may not be protected by the law. The basis for a moral right is that the right *should* be protected. Moral rights are traditionally relied on by virtue of their moral principle rather than finding protection from an established law (Sen, 1996).

In addition, the right to reproduce is generally regarded as a negative claim of non-interference. As such, recognising a right to reproduce will impose a correlative duty on all others not to interfere with a person's choice to reproduce or their choice to avoid reproduction (McLean, 2002). Nonetheless, there are some who contend that the right to reproduce may impose some positive obligations regarding access to fertility treatment (Sparrow, 2008).

**[4.03]** One of the most prominent commentators in the field of reproductive rights and bioethics, the late John Robertson, argues that the right to reproduce is derived from the right to procreative liberty and consists of two components: a negative right and a positive right (Robertson, 'Children of Choice', 1994). As a negative claim, the right to reproduce protects people from interference with their decision to reproduce or their decision not to reproduce. A negative right to reproduce will not confer a correlative duty on others to provide one with the services or resources necessary to exercise reproductive choices. At the most basic level, Robertson claims that the right to reproduce provides the holder with the freedom to reproduce and the freedom to avoid reproduction without coercive interference. This freedom will extend to the right to choose with whom one reproduces, and under what circumstances. A direct violation of this negative right would include rape, denying a woman access to abortion and forced sterilisation or forced abortion.

**[4.04]** This negative right features prominently in Constitutional jurisprudence in the second half of the twentieth century; in particular in the contraception (*Griswold v. Connecticut*, 381 US 479, 1965; *McGee v. Attorney General* [1973] IR 284) and abortion jurisprudence (e.g. *Rowe v. Wade* 410 U.S. 113,1973; *X v. Ireland* [1992] 1 IR 1), where the doctrine of privacy was expanded so as to invalidate laws that would directly, or otherwise, prevent a women from controlling her fertility and choosing if and when to reproduce.

**[4.05]** Less clear cut is a positive right to reproduce; although such a right has some basis in constitutional and human rights documents. For example, the United Nations Declaration of Human

Rights includes the right to found a family, and furthermore, Article 23(1) of The International Convention on Civil and Political Rights (ICCP) provides that "The family is the natural and fundamental group unit of society and is entitled to protection by society and the State…The right of men and women of marriageable age to found a family shall be recognized." Article 41 of the Irish Constitution provides that the family is "the natural primary and fundamental unit group of Society … possessing inalienable and imprescriptible rights, antecedent and superior to all positive law", although makes no specific reference to the right to have children. Similarly, Article 12 of the European Convention on Human Rights ('the ECHR') expresses the right in marital terms indicating that men and women 'have the right to marry and found a family'.

**[4.06]** A positive claim to reproduce is problematic as it may lead to the claim of a correlative duty on others to provide the right holder with the resources that they require to reproduce or the services that they need to avoid reproduction. A positive claim to reproduce could possibly grant people the right to start a family through assisted means, or alternatively, permit one to avoid reproduction, not merely through abstinence but also by refusing to seek treatment for infertility, taking contraceptives or terminating a pregnancy after conception has occurred (Brake and Milhum, 2018). However, such a broad claim as to the scope of any positive right is unlikely to have legal force given the longstanding difficulties of enforcing socioeconomic rights in the courts. One notable commentator indicates that such a right would work better, not as a call on equal resources, but rather equal concern and respect for the right in political decision-making (Quigley, 2002, p. 411).

**[4.07]** Intimately related to the question of the right to reproduce are the differing forms of parenthood that exercising the right may lead to. Although they most commonly overlap in one individual there is a distinction between genetic, gestational, legal and social parenting. For instance, a surrogate is a gestational parent, but is not the genetic parent and will cede legal parentage to others. An adopted child has different genetic and legal parents, and someone may act in *loco parentis* to a child, as a social parent, without any genetic link or recognition by the law. It is an unfortunate truth that fertility preservation procedures for children ill with cancer will sometimes result in viable reproductive material being preserved, even though the child's cancer treatment is unsuccessful and the child is deceased. The only viable parenthood for the child in these circumstances is posthumous *genetic* parenthood, with their clearly being no possibility to have legal or social or gestational parenthood because of the death. There may also circumstances where a female child survives, but is unable to carry a pregnancy so cannot be a gestational parent, but may have the option of genetic, legal and social parentage through the use of a surrogate.

**[4.08]** The question arises as to whether a more attenuated form of parentage, such as genetic parentage, affects the strength of the claim that a surviving child may have under the right to reproduce. Robertson does not seem to think that there is any effect and defines the right to reproduce in genetic terms which may or may not include rearing the child (i.e. social parenting (Robertson, 1994, 'Children of Choice', pp. 22-23). This broad definition of the right would seem to include a right to reproduce 'non-coitally' and broadly encompass a variety of ART procedures.

**[4.09]** Rather than advocating for an unfettered 'right to breed' it is more accurate to describe Robertson's position as valuing the right to choose to reproduce very highly as reproduction 'is central to personal identity, to dignity and to the meaning of one's life' (Robertson, 'Children of Choice' 1994, p. 24.), and thus any interferences with it must be justified. Nevertheless, there is still some scepticism as to the scope of Robertson's proposed right to reproduce, and Quigley notes of his claim on the value of genetic parentage as follows:

> "Even though this may contain a large element of truth, to attribute this to the passing of one's genetic material may be to overstate the case. Taking this to the extreme might lead to support for some morally problematic practices. For example, if a man were to say that passing on his genetic material was what established his identity, afforded him dignity, and imbued his life with meaning, we would find it highly questionable for him to claim a right to the unfettered distribution of his sperm." (Quigley, 2009, p. 406).

**[4.10]** In contrast, the philosopher Bonnie Steinbock contends that it is wrong to claim a right in relation to genetic reproduction when there is no intention to rear (Steinbock, 1995). Her view is that any right should only be derived from an interest so important as to justify protection by a right and its corresponding duties. An interest in mere genetic reproduction in her view is not worthy of the protection of a right as it would create a right to pass on one's genes and create children with no responsibility for bringing them up an taking care of them. (Steinbock, 1995, p. 549). If one accepts that an intention or capacity to rear is a fundamental component of the right to reproduce, then the argument that the right to reproduce mandates that a person's gametes can be utilised after their death to give effect to their wishes to be a genetic parent, is significantly weakened. This would have significant implications in circumstances where a child has preserved gametic or gonadal material, but has not survived into adulthood.

**[4.10]** In recent years, the right to reproduce has been litigated in the courts have related to progenitor disputes as to the fate of frozen embryos, and as to the harvesting and control of frozen gametes after their source has died (See Maddox, 2017). Two notable cases before the European Court of Human Rights—*Evans v. UK* no. 6339/05 (2006) and *Dickson v. UK* no 44362/04, ECHR

(2006)— demonstrate that states will enjoy a relatively wide margin of appreciation under the Convention when dealing with disputes concerning the right to reproduce and access to artificial reproduction.

**[4.11]** This entails that the Strasbourg court will be unlikely to interfere in the domestic regulatory requirements for ART unless there is a clear or egregious breach of the Convention, as there is little consensus among member States as to how to regulate what is a new and developing area. Article 8 of the Convention protects *inter alia* private and family life and is undoubtedly engaged by a couple seeking access to ART technology, but this does not necessarily lead to any positive obligations on member states. *Dickson* is instructive in this regard. The applicants were a married couple who had met in prison and sought access to ART as, by the time of the husband's release date, the chance of the wife conceiving would be exceedingly small. The Secretary of State refused the request for a number of reasons, including that it would undermine public confidence in the deterrent effect of prison sentences, and that any child born of the procedure would be without a father for a significant portion of their upbringing. The European Court rejected that there was any positive obligation on member States to give effect to the right of access to ART, as claimed in this case, noting that the policy reasons were not arbitrary or unreasonable and were within the margin of appreciation.

**[4.13]** In *Dickson* the court noted that there is nothing in the Convention that guarantees a right to procreate, rather the right to found a family, and one of the concurring judges doubted whether the claim of a prisoner to artificial insemination came within the ambit of Article 12 (*Dickson v. UK*, Judge Bonello at 33). In contrast, the dissenting judges in *Dickson* cited the US case of *Skinner v. Oklahoma* (1942) 316 US 535, a case involving compulsory sterilisation, as one establishing the fundamental nature of the right to procreate by the U.S. Supreme Court. *Skinner* is interesting as the court reasoned the sterilisation statute should be subject to strict scrutiny because of the social and biological implications of reproduction *and* the irreversibility of any sterilisation procedure. The *Evans* case is also cited by the minority as the Court in that case indicated that article 8 of the Convention "incorporates the right to respect for both the decisions to become and not to become a parent" (*Evans*, at 57).

**[4.14]** *Evans* itself concerned a dispute between two private individuals who were the progenitors of frozen embryos that were created during a relationship they had had, which ultimately was unsuccessful. One of the individuals—E—had been rendered infertile by cancer treatment while the other did not wish to be made a genetic parent and the court action was to seek to allow use of the embryos by E overriding the requirements for the consent of both parties contained in the UK

HFEA Act 1990. The Grand Chamber ultimately found the case to concern a conflict of rights, and the rights of both parties to be essentially incommensurable or irreconcilable. The UK legislation promoted the primacy of consent and legal certainty, and fell within the wide margin of appreciation afforded to states in these matters. This case lends some implicit support for something at least akin to a right not to reproduce, and also that such a right trumps any purported right to reproduce by artificial means when conflicting with it.

*The Right to Reproduce of Minors*

**[4.15]** There is no reason in principle why minors would not be entitled to the same moral and legal claim to reproduction as adults, and this is reflected in the case-law. As with adults, the law reports are concerned with the negative aspect of right to reproduce (i.e. the right to control one's fertility and choose not to reproduce). One of the most influential cases in the common law world, *Gillick v, West Norfolk and Wisbech AHA* [1986] AC 112, was concerned with an English mother's attempts to seek a declaration that her children, who were under 16, would not be prescribed the contraceptive pill without her knowledge or consent. The House of Lords found against her and indicated that a child under the age of 16 did have capacity to consent to this form of medical treatment if she had sufficient understanding of what she was consenting to.

**[4.16]** In contrast, courts in the Unites States have generally been sympathetic to legislative requirements that parents be notified of a decision to have an abortion by a minor (*Planned Parenthood v. Casey*, 505 US 833, 899: 1992; *Ayotte v. Planned Parenthood*, 546 US 320, 326: 2006). However, attempts to mandate parental consent to such a procedure have been struck down as unconstitutional in the absence of a judicial bypass of any such requirement (*Casey*, 505 U.S., at 899). And, in accordance with the *Gillick* jurisprudence in the common law world, most States in the US permit minors access to contraception without the permission of an adult. The positive right to reproduce is arguably far broader and the age of consent is below the age of majority in most jurisdictions, sometimes far below. Furthermore, third parties cannot compel a child to get an abortion against their wishes (Dolin *et al*, 2010, p. 4). As noted in one study of oncofertility:

> "…although parents are generally permitted to make medical decisions for their minor children, these decisions must be in the best interests of the child. In the area of sexual health and reproduction, parents' decisional rights are further limited…There are weighty reasons why reproductive decisions are vetoed from otherwise nearly plenary parental authority to make medical decisions on behalf of their offspring. First, because decisions that affect the reproductive capacities of minors necessarily interfere with "one of the most basic civil rights of man" (*Skinner v. Oklahoma* 316 US, at 541) they must be heavily scrutinised and sometimes disregarded. Second, it may be more likely that parental involvement in a minor's decisions on such sensitive issues as sexual activity and pregnancy will not serve a minors best interest (Dolin *et al*, 2010, p. 8)"

## 5. Medical Options for Fertility Preservation for Children and Young Adults

**[5.01]** Cancer treatments such as chemotherapy and radiation therapy can lead to immediate infertility in some patients, and sub-fertility in others (subfertility being a lower sperm count in some men and accelerated loss of follicles in women) (Doolin *et al*, 2010). There are a number of options available to newly diagnosed cancer patients. There are more traditional options such as third party reproduction via a surrogate, or adoption (Rosen, 2005). While these traditional avenues for family formation are often utilised, they do not fulfil the wishes of many people for genetic and gestational parentage of a child.

**[5.02]** With the rapid progress of ART in recent decades novel assisted reproductive technologies now present option to persons who would otherwise be infertile to have the hope of reproduction and the experience of a genetic connection to their child.

*Cryopreservation of Frozen Sperm*

**[5.03]** The cryopreservation of sperm is the standard treatment for post-pubertal adolescent males facing treatment that is likely to be gonadotoxic and result in infertility or sub-fertility. It is usually viable from about twelve years of age and many studies on fertility preservation advocate that the option to bank frozen sperm should be advised prior to any therapy that is likely to affect fertility (Ohsawa, 2000; Dohle, 2010). In cases where there is ejaculatory difficulties, search for viable spermatozoa in a urine sample is possible, as well as testicular sperm extraction and extraction through such methods as penile vibratory stimulation and electro-ejaculation (Rodriguez-Wallberg *et al*, 2020).

**[5.04]** Thus, for post pubertal males, fertility preservation is relatively straightforward, effective and quick. In most cases sperm can be obtained without the need for invasive procedures and without the need to delay any cancer treatment in any significant way. Sperm can also be preserved, perhaps indefinitely, in a viable state and there is this no need to create embryos with it at the time it is extracted. So, sperm retrieval (and the attendant protocols that govern it) does not usually delay treatment and avoids the legal complications of creating and then seeking to subsequently utilise or destroy frozen embryos at some indeterminate point in the future (Crockin, 2019).

**[5.05]** Fertility preservation for paediatric male patients is less straightforward. Prior to the onset of puberty, the child does not possess mature spermatozoa that could be utilised for fertilisation with an ovum. Thus, sperm cryopreservation is not an option for these patients, and there is not, currently, any established clinically proven methods to preserve fertility for pre-pubertal males (Woodruff, 2011). In such circumstances where a sperm sample cannot be provided the focus of

oncofertility has shifted to the cryopreservation of testicular tissue. This is as pre-pubertal sperm tissue contains spermatogonial stem cells, which when given the opportunity to mature can restore full spermatogenesis to the testis on re-implantation (Edmunds *et al*, 2019).

**[5.06]** As with sperm freezing, testicular tissue cryopreservation is regarded as coming with minimal risk to the patient and can be performed quickly, allowing the patient to return to cancer therapy almost immediately. There are currently a number of experimental ART procedures being investigated as to how to utilise cryopreserved testicular tissue, including testicular tissue transplantation, *ex vivo* sperm maturation and *in vitro* induced spermatogenesis, as well as possible stem cell therapy (Johnson *et al*, 2017). There is optimism that these therapies currently in the pipeline "will see success at the bench and translation into the clinic in the near future" (Edmunds *et al*, 2019), thus raising the prospect that these procedures offer much more than a slim prospect of future effective fertility preservation for the pre-pubertal male cancer patient.

*Female Fertility Preservation.*

**[5.07]** Fertility preservation for girls and women is inherently more invasive and costly (both in terms of price and time). It is also more complex legally, since the retrieval of eggs requires stimulation and retrieval procedures and, until recent advances in egg freezing, commonly involved the immediate creation of an embryo through *in vitro* fertilisation with sperm from a partner or donor. Unlike sperm cryopreservation, effective fertility preservation for female patients may involve delay and impact upon cancer treatment (Crockin, 2019).

**[5.08]** During a normal menstrual cycle, a female will ordinarily only produce one single mature egg. Thus, the first stage in the process of egg retrieval involves a controlled stimulated ovarian cycle (Chen *et al*, 2015). Ovarian hyperstimulation will manipulate the woman's hormonal environment and induce her to bring several egg follicles to maturation at once. This ensures that there are several mature eggs which are eligible for collection (Moffat *et al*, 2015). Before the eggs can be collected for cryopreservation, however, the oocytes must be at a certain level of maturity (Eun *et al*, 2011). Thus, the woman is provided with gonadotropin releasing hormones. Gonadotropin hormones cause the woman's ovaries to produce oestrogen and progesterone. The hormones are taken daily over a period of nine to ten days and will accelerate the growth of her egg follicles (Jungheim *et al*, 2015). Once the eggs are at a sufficient level of maturity, there are two primary methods for retrieving the gametes for later cryopreservation. These include ultrasound guided transvaginal oocyte retrieval and laparoscopic retrieval (Leung *et al*, 2016).

**[5.09]** Despite the availability of mature oocyte preservation, there may be some cases in which this procedure is not a viable option for the particular patient. The need to administer the required

hormone treatment for ovarian hyperstimulation may cause undue delay to the woman's prospective medical treatment. In addition, the technique of ovary hyperstimulation cannot be carried out on prepubertal girls (Gornet, 2019), and is not a permitted procedure for adolescents under the age of eighteen in many jurisdictions (Woodruff, 2010). In such situations, it is possible to harvest and cryopreserve the woman's ovarian tissue.

**[5.10]** Ovarian tissue retrieval involves a laparoscopic surgery which harvests a thin layer of the woman's cortex. The female cortex contains several early stage egg follicles which can be cryopreserved and stored for later use. Following the completion of medical treatment, the ovarian tissue can be successfully transplanted back into the woman (Donnez *et al*, 2018). The development of this technique is in its infancy, but has led to live births for patients who have completed their cancer treatment. However, the procedure comes with the risk of re-introducing cancer cells to the patient through the implantation (Redig *et al*, 2011).

**[5.11]** As an alternative to tissue transplantation, there is the possibility that egg follicles can be matured *in vitro*, which could theoretically remove the risk of reintroducing cancer to the patient if an oocyte developed by this procedure is subsequently fertilised *in vitro* before re-implantation in the patient. However, the technique of *in vitro* oocyte maturation is still an experimental procedure (Hatirnaz, 2018). Currently, it is possible to grow healthy human follicles *in vitro*, but the ability to mature them to healthy oocytes, fertilisation *in vitro* and transfer to a patient are still in development (Woodruff, 2010). Nonetheless, the removal and preservation of ovarian tissue preservation is a relatively straightforward procedure and may be the only option for attempting fertility preservation for pre-pubertal girls, notwithstanding the fact that it is still an experimental procedure (American Society of Reproductive Medicine, 2014). The field of ovarian tissue cryopreservation is progressing quickly and may become standard therapy in the near future (Crockin, 2019).

**[5.12]** However, the existence of these technologies for women is balanced by the fact that they have significant limitations. Many of the procedures involve hormonal treatment which can present complications in the treatment of a cancer patient. As noted, cancer treatment must be delayed while undergoing these procedures, which may greatly prejudice that treatment. Furthermore, there is also a concern that hormonal treatment may negatively impact the treatment for certain hormonally reactive cancers (such as some forms of breast and ovarian cancers). In addition, re-implantation carries a risk for certain forms of cancer, of implanting cancer cells that may lead to metastasis (Crockin, 2019).

**[5.13]** While a number of the procedures, such as cryopreservation of sperm and ovarian tissue extraction, are regarded as low-risk clinically and notwithstanding the optimism about the development of treatments for infertility by utilising cryopreserved ovarian tissue, there is still no guarantee that this will transpire in the lifetime of the patient. As well as clinical risk and uncertainty, there is also legal and ethical complexity and uncertainty with regard to the intertwined issues of consent and control of excised and cryopreserved gametes and gonadal tissue, both during the lifetime of the patient and after his or her possible death.

## 6. Consent

**[6.01]** In modern medical practice, consent is a necessary precursor to medical treatment being provided lawfully and failure to obtain adequate consent can lead to an action for battery or more commonly in negligence. Valid consent must be given voluntarily (i.e. provided of the patients own free will), must be based on sufficient information and the person must have capacity to consent (Mills and Mulligan, 2017, pp. 123-126). For obvious reasons, children under the age of 18 are often unable to give a valid consent to medical treatment. In such circumstances, a valid consent may be obtained from the parents or legal guardians acting in the best interests of the child. When a proxy consent of this nature is withheld by the parent, a third party may be justified in ignoring it if this withholding is unreasonable (Laurie *et al.* 2018, p. 69). The courts under the old *parens patriae* jurisdiction, which is now vested in the President of the High Court by the Courts (Supplemental Provisions) Act 1961, have decision-making authority for those who like capacity by reason *inter alia* of age.

**[6.02]** At common law, a person ceases to be incapacitated simply by virtue of age on their eighteenth birthday, but there is provision in s.23 of the Non-Fatal Offences against the Person Act 1997 that a minor who has attained the age of sixteen can give a valid medical consent to any treatment and it is not necessary to seek the consent of the parents. The definition of treatment is not all encompassing and it is not clear if it extends to a decision to refuse treatment or if consent to a medical course of action designed to prevent, rather than treat, a condition is encompassed by it (Mills and Mulligan, 2017, pp.179-181).

**[6.03]** As noted in relation to the rights of minors under the age of sixteen, the leading case and most influential statement of the law in this area in the common law world is the House of Lords decision in *Gillick v. West Norfolk and Wisbech* [1986] AC 112. In *Gillick* a minor under the age of sixteen sought a prescription for the contraceptive pill, and the question arose if the doctor could give her the prescription with the knowledge or consent of her parents. The essence of the decision was that a minor under the age of sixteen could consent to such treatment if she had sufficient

understanding of what was involved. This is now referred to as 'Gillick Competence' and has adopted in various locations in the common law world. While there is no express endorsement of it in Irish law, it has been cited in the courts (*Re XY* [2013] 1 I.R. 574) and it seems likely as suggested by the leading textbook writers in the area that 'the Irish courts would recognise a qualified right to consent in the case of mature under-16s' (Mills and Mulligan, 2017, p. 192).

**[6.04]** Given the constitutional primacy of the family in Irish law, it is unsurprising that the granting or withholding of consent to medical treatment by parents is generally respected in the courts, with judges deferring to their decision unless it is one which poses an real and substantial risk to the health or welfare of the child . In *North Western Health Board v. W* [2001] 3 I.R. 622 (the *W* case) the Irish Supreme Court clarified that it is only in exceptional cases that the courts will intervene and overrule the parents' wishes where they have failed 'for physical or moral reasons' in their duty to the child. In this case the court refused to overrule the parents failing to consent to an invasive diagnostic test for their infant, which was held to be in the child's best interests. However, this zone of parental autonomy free from court interference only extends so far and in cases where the threat to the minor from the parents refusal of consent is more serious, the courts, despite rhetoric to the contrary, are quite interventionist. The most common example in the law reports is Jehovah witness parental refusal to consent to a blood transfusion for their child where the failure to get the transfusion would endanger the life of the child (e.g. *Re AB* [2011] 1 I.R. 665).

*Proxy Consent and Reproduction*

**[6.05]** Of course oncofertility treatment decisions can be distinguished from cases involving parental refusal of consent leading to the potential death of the child. The fertility preservation treatment itself is unlikely to endanger the child (the exception to this being cases where a significant delay may compromise cancer treatment). Such decisions, for the most part, concern the sexual and reproductive function of the child and parents tend to enjoy a narrower range of decisional autonomy in this area than in others.

**[6.06]** For example, the *Gillick* case established that a child of sufficient competence could be prescribed contraceptives without the parents' knowledge or authority, and the abortion decisions of minors have been upheld over the objections of the parent (*Planned Parenthood v. Casey*, 510 U.S. 1309 (1992)). This reduced deference to parents' wishes by the courts may be because of the uniquely personal nature of human sexuality, as well as the life-long consequences that follow reproductive decision-making. Furthermore, parental interests may often diverge from the best interests of the child in this area, given, for example, a desire for a grand-child or to uphold religious

values, colouring a decision to continue a pregnancy, or in contrast: the desire to avoid social opprobrium influencing a decision to terminate.

**[6.07]** There is no perfect analogy to the issues of consent and proxy consent presented by oncofertility for children, but there are a number of areas that might suggest the approach the courts will take in this area. Both male and female circumcision have been scrutinised in recent years, as being incompatible with a child's right to autonomy and bodily integrity. Nonetheless, male circumcision remains legal and the strength of custom, as well as the fact that it has been performed for religious and cultural reasons for many centuries and not held contrary to public policy, was deemed significant in this regard (*State v. Baxter* 141 P.3d 92 (Wash. Ct. App. 2006)). Female Genital Cutting (FGM), like male circumcision, is an ancient social and cultural custom, but nonetheless is regarded in western legal systems as a procedure to which parents cannot consent (Dolin *et al*, 2010, p. 9). The distinction is that male circumcision is a safe procedure (and which may provide some minor medical benefits), while FGM causes harm and no corresponding benefits.

**[6.08]** Sterilisation is perhaps the closest set of medical procedures to those of oncofertility in terms of the issues it raises for proxy consent. Sterilisation aims at ending a patients reproductive capabilities and doing so permanently. For the most part, these procedures are intended to be *irreversible*.

*Oncofertility, Children and Consent*

**[6.09]** Beauchamp and Childress in their leading work on medical ethics prose the following conditions for decision-makers for incompetent patients:

1. Competence (or ability to make reasoned judgments),
2. Adequate knowledge and information,
3. Emotional stability,
4. A commitment to the incompetent patient's interests that is free of conflicts of interest and free of controlling influence by those who might not act in the patient's best interests (Beauchamp and Childress, 2001, p. 154).

**[6.10]** The authors note that wide agreement exists that the patient's closest family member be first choice as surrogate because of their presumed impartiality and intimate knowledge of the patient's wishes. Nonetheless, the authority of the family is not absolute and physicians sometimes seek to have the decision of such a proxy reviewed by an ethics committee of the court exercising its' *parens patriae* jurisdiction, as *inter alia*: 'even the closest family member can have a conflict of interest' (Beauchamp and Childress, 2001, p. 155).

**[6.11]** This concern for partiality may present a particular issue for deferring to parents decision-making with regard to their child to opt for or against a fertility preservation procedure, given the narrower range of autonomy and deference that parental autonomy has traditionally been granted in this area. The refusal to consent to lifesaving treatment on behalf of a child is not analogous to the decisions to opt for fertility preservation on the child's behalf. Nevertheless, if the refusal is on religious grounds and involves the consequence of a permanent loss of reproductive function (which has a good chance of being preserved), one could see situations where a court would intervene to protect what it deemed to be the best interests of the child.

**[6.12]** The legal philosopher Joel Feinberg argues that certain rights of the child, which the child is not yet capable of exercising, are held in trust for the child by the parents who are under a duty not to engage in conduct that would foreclose the possibility of the child having certain options in the future when an autonomous adult (Feinberg, 1980). So central is reproductive capacity to many people's lives, a cogent case can be made that preservation of this function until adulthood where possible is one of such "rights-in-trust", and that at the very least the child should have some input into the decision-making process themselves (childhood assent) (Lotz, 2006; Dolin *et al*, 2010, p. 9).

**[6.13]** As noted, sterilisation is the closest analogy to a refusal of consent by a parent to procedures aimed to preserve the fertility of their child in the sense that the outcome in both cases is often an *irreversible* loss of reproductive function. Sterilisation can also be distinguished, of course, as it involves a positive act resulting in infertility and the circumstances in which it is sought tend to be very different; invariably involving an individual lacking the mental or physical capacity, or both, to raise a child so that there is a question as to whether the procedure would be in their best interests (Laurie *et al*, 2018). Nonetheless, it is instructive that judges have traditionally imposed a high standard of review upon decisions by parents or proxies to sterilise a vulnerable person given the centrality of reproduction to human identity and the often irreversible consequences of such a decision.

**[6.14]** Clearly, medical factors will need to be considered including the potential benefit to the child of the procedure, as well as any possible harm (such as loss of sexual function or prejudice to any necessary cancer treatment). While there is optimism that novel techniques such as ovarian tissue cryopreservation will lead to live births in the future, these procedures are still experimental and there are no guarantees that they will ever be viable (American Society for Reproductive Medicine, 2014).

**[6.15]** Complex decisions lie ahead in this area involving the weighing of various factors to determine a child's best interests; including the age of the child and their capacity to give consent or assent, any harms caused by the procedure, the chances of the procedure leading to successful fertility preservation within by the time of the child's normal reproductive age range, as well as the purpose of the parent's decision. For example, the decision of parents of a hypothetical child with very little hope of recovery to authorise gonadal tissue preservation, so as to have a genetic grand-child after the death of their ailing child, would be difficult to justify in the child' best interests (Dolin, 2010; Morgan *et al.*, 2020).

**[6.16]** This also leads to the final issue to consider; who is entitled to have control of any cryopreserved tissue during the patient's life, and what happens to this tissue in the unfortunate circumstances where the child dies?

## 7. Control of Cryopreserved Gametes and Tissue

*During the Life of the Child*

**[7.01]** Once gametes are extracted from a progenitor and cryopreserved, the stored materials are under the control of the person who is their source. The legal basis for this may be statutory, usually in jurisdictions that have adopted detailed statutory regulation of ART procedures such as pursuant to the Human Fertilisation and Embryology Act 1990, as amended (*Yearworth v. North Bristol NHS Trust* [2010] 1 QB 1). In a country such as Ireland (or certain States of the United States) which have not yet any detailed statutory regulation this will most likely be governed by contract as between the source of the materials and the clinic in which the samples are stored.

**[7.02]** There is law to suggest that the right to reproduce vests decisional autonomy in the source of these materials and that the clinic cannot do anything with the materials without the agreement of their source (*Davis v. Davis* 842 S.W.2d 588, 597, Tenn. 1992). Whether this agreement can be withdrawn at any time up to implantation, or whether the progenitor should be bound by a prior contract has been the subject of some legal dispute but such matters are beyond the scope of this piece (Maddox, 2017). In reality, there are three options for the fate of cryopreserved gametes: use in an ART procedure, donation for research or destruction (*Holdich v. Lothian Health Board* [2013] CSOH 197) and this is reflected in the standard consent forms that must be signed in the clinic prior to the production and freezing of a sample.

**[7.03]** There is also some EU law with regard to storage standards that are applicable to cryopreserved gametes. The EU Human Tissue and Cells Directives consist of three Directives.

Directive 2004/23/EC is the primary directive and Directives 2006/17/EC and 2006/86/EC outline the directives technical requirements. The purpose of these directives is to ensure that the quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells is consistent across Europe. Thus, the quality and safety standards outlined in these directives are applicable to the handling and use of reproductive cells in assisted reproductive treatment including posthumous conception. Other than ensuring that certain technical standards are met, however, these directives do not provide guidance for consent requirements to storage and use of the cryopreserved gametes.

**[7.04]** The proposed Irish legislation in this area has been published as the General Scheme of the Assisted Human Reproduction Bill 2017 (AHR Bill 2017) (whose passage is not imminent at the time of writing) and has mostly adopted a similar statutory scheme to the UK. Under Head 22 there must be a written, voluntary, signed consent to the storage of embryos from their source and that person must have capacity, although there is an allowance in Head 22.7(a) for a person under 18 to have consent given on their behalf by their parent or legal guardian. Nonetheless, the maximum statutory storage period under Head 22(8) is set at 10 years, something that clearly would render any fertility preservation procedure on behalf of a young child futile and a limit which should be adjusted before passage of this bill into law.

**[7.05]** The definition of gamete is also far too narrow merely comprising: "(a) a human sperm, which is formed in the body of and provided by a man, or "(b) a human egg, which is formed in the body of and provided by a woman." Given that many of the procedures previously outlined involve tissue extraction the current definition, if passed into law, would effectively exclude and effectively prohibit such procedures from lawfully taking place.

**[7.06]** Head 12(1)(b) of the Bill forbids the donation of gametes for use in an ART procedure or for research until the progenitor is 18 years of age. In reality, this is probably reflective of the current legal position, given it is difficult to see how a parent or other legal guardian acting as a proxy could validly give consent to anything but storage in the best interests of the child, during that child's lifetime. There are a number of reasons for this. First, to consent to such a donation would foreclose the child's future choices and their right to an open future. Secondly, there are only very limited circumstances in which children are regarded as suitable candidates for organ or liver donation. Lastly, it is difficult to argue that such a donation furthers the best interests of the child (Dolin *et al*, 2010, pp. 13-14). Of course, when dealing with children there is always the attendant risk of exploitation and an effective prohibition on consenting to anything other than storage until the child reaches his or her majority is an approach to be welcomed.

*Control of Excised Tissue after the Death of the Child*

**[7.07]** A more nuanced issue, and one which has only come to the fore in recent years, is in the unfortunate circumstance where the child who has preserved gametes or tissue with a view to future use, does not survive into adulthood. With advances in ART, it is possible to utilise these gametes for both conception and gestation of a child after the death of one of its genetic parents (Maddox, 2020).

**[7.08]** Over the years, the European Society of Human Reproduction and Embryology (ESHRE) Taskforce on Ethics and Law have published a series of ethical statements on moral issues relating to ART. In 2006, the Taskforce published an ethical statement that dealt specifically with the issue of posthumous assisted reproduction (ESHRE Taskforce, 2006). They concluded that posthumous conception was a 'highly controversial issue' and recommended that the procedure should only be accepted in the context of an initial parental project and only when written consent has been obtained from the deceased person, presumably, when they are in the process of storing their gametes or embryos prior to starting a cycle of *in vitro* fertilisation (ESHRE Taskforce, 2006, p. 3053). Posthumous conception is entirely prohibited in many States; for example: France, Germany, Italy, Pakistan and Sweden (Tremellen and Savulescu, 2015). Others, such as the UK and certain Australian States have permitted the practice subject to detailed statutory regulation and the imposition of strict pre-mortem written consent procedures.

**[7.09]** As it stands, there is no provision in the UK legislation which prevents a licenced facility from facilitating posthumous conception. However, the HFEA Act does severely limit the practice of posthumous conception by virtue of the strict consent requirements which govern the lawful storage and use of gametes and embryos (See for example, the HFEA 1990 (UK), Schedule 3). Ireland has not yet passed any detailed regulation in this area but the General Scheme of the AHR Bill 2017 proposes to adopt very similar requirements to the UK.

**[7.10]** Under Head 9 of the Bill the deceased must also have provided their voluntary consent in writing to the posthumous storage and use of their gametes in posthumous assisted reproduction. The consent must be from a person who has capacity, which would serve to exclude many (particularly young) children from being able to give a valid consent. However, under Head 24 the use of the material is limited to the surviving partner of the deceased, effectively excluding all others from the procedure, and minors are already subject to the prohibition in Head 12 on donation of gametes to others for the use in an ART procedure.

**[7.11]** In Irish law's currently unregulated state, it is still very difficult to see how minors can make a meaningful choice as to their preferences for future use of their gametes. As the authors of one study note, the existing cases in this area, which deal with disputes concerning the extraction and use of gametes from a deceased adult:

> "…provide little guidance here because minor children are often incapable of expressing or even forming intent as to the future use of their gametes. Very young children simply do not (and cannot) know whether or not they would want children, let alone whether they wish to have post-mortem children. This inability to express intent is especially acute in young female patients…[and]…male patients may not be able to fully appreciate the full meaning of fatherhood…(Dolin *et al*, 2010, p. 15)."

**[7.12]** After the death of the child, it would seem relatively uncontentious that the parents may seek to have the cryopreserved tissue destroyed, given that the legal responsibility rests with them to bury the child (Conway, 2003). The other two options available— that the tissue be donated for research or for use in an ART procedure with donor sperm or eggs— are fraught with legal and ethical difficulties. In the absence of any consent by the tissue's progenitor as to its fate after death, a situation that is likely when dealing with minors, the most obvious proxy will be the parents of the deceased. They may lack impartiality, however, given that they may have an interest in having a grandchild after the death of their child that is independent of any wishes that the deceased may have had.

**[7.13]** This is not a fanciful idea. For instance, in *R (M) v Human Fertilisation and Embryology Authority* [2016] EWCA Civ 611 a mother sought—successfully— to export her daughter's cryopreserved eggs in order to have them fertilised *in vitro* with donor sperm, so that she might have the resulting embryo implanted and gestate and give birth to her own grandchild (e.g. *R (M) v Human Fertilisation and Embryology Authority* [2016] EWCA Civ 611). Donation for research is even more problematic when dealing with minors, as absent clear evidence that such donation was desired, it is difficult to see how this would further the interests of the child.

**[7.14]** Even if the evidentiary difficulties of establishing that this was indeed the deceased's wishes are ignored, the fact that the deceased's parentage would be severely attenuated for posthumous conception—being genetic, but not gestational, legal or social— is an argument that directions for posthumous reproduction should be given much less respect than decisions about reproduction during a person's life (Robertson, 1994).

**[7.15]** Furthermore, where the source of the reproductive material is under 18 years of age, the adequacy of any such consent might be questioned, given the difficulties of a minor comprehending

the adult issue of reproduction. To avoid these difficulties and the risk that the deceased child's tissue is exploited to serve the interests of others, a case can be made that any future directives or regulation dealing with fertility preservation state that the preserved tissue must be destroyed on the death of the child (Maddox, 2020).

## 8. Conclusion

**[8.01]** Given the fact that oncofertility is a new area of medical practice and that many of its techniques are at an experimental stage, it is inevitable that much of the preceding discussion is speculative. Nonetheless, it is imperative that proper clinical guidelines, directives and statutory provisions are developed at this early stage to properly regulate a unique area of medical practice. In addition, fertility preservation for children presents legal and ethical complications. However, some common themes and tentative conclusions can be derived as follows:

*The Right to Reproduce*

- A child's claim to a right to reproduce is as strong as an adults, albeit it cannot be exercised until adulthood,
- At a minimum, it can be contended that the right entails that a child should not be prevented from the option of fertility preservation when fertility is threatened by cancer treatment,
- The Right to Reproduce after death is a much weaker claim as mere genetic parenthood is a greatly attenuated form of parenthood,

*Consent to Fertility Preservation*

- Minors aged 16 and above as well as mature minors who understand the nature of a medical procedure may consent to it without the necessity for parental consent,
- Where parental consent is required, the courts are more willing to intervene to protect the best interest of the child in matters relating to sexuality as parents often have a conflict of interest in such matters,
- A refusal of parental consent to fertility preservation would be vulnerable to being set aside by a court if they deemed it to be in the best interests of the child, particularly in circumstances where the child is facing an irreversible loss of fertility.
- Determining the child's best interests involves the balancing of a range of factors, such as the chances of the child benefitting from the procedure, the extent of the benefit and any possible harms.

*Control and Storage of Cryopreserved Tissue*

- Parental consent to storage of their child's reproductive tissue until adulthood is likely valid as being in the best interests of the child and for their benefit.
- Parental consent to the donation of this material for use in ART or research, or for the parent's own use is ethically suspect, and most likely legally prohibited,
- The proposed legislation on the regulation of ART in Ireland needs to incorporate considerations relating to fertility preservation for children; in particular, the maximum storage limit of 10 years needs to be extended, and the definition of 'gametes' need to be broadened to include gonadal tissue.

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