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The European Court of Human Rights and the Emergence of Human Germline Genome Editing

'The Right to Life' and 'the Right to (Artificial) Procreation'

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Abstract

The field of human germline genome editing (HGGE) offers a promising reproductive potential to prevent inheritance of genetic diseases, yet also opens the door to undesirable eugenics. This stirred the debate about the acceptability of HGGE in light of human rights, particularly human dignity. The European Convention of Human Rights (ECHR) and the European Court of Human Rights (ECtHR) use human dignity as a guiding principle. Therefore, this article examined the clinical implementation of HGGE in light of relevant case-law regarding Article 2 and Article 8 ECHR. The analysis illustrates that the ECtHR broadens the scope of artificial reproductive rights under Article 8, however, Contracting States of the Council of Europe can limit these rights and the accessibility to reproductive techniques, such as HGGE. The ECtHR remains elusive about the legal status of unborn life, but protection under Article 2 with the introduction of HGGE should not be ruled out.

Keywords

germline genome editing – human rights – right to life – right to respect for private and family life

1 Introduction

The term 'genome editing' refers to a group of techniques that has the ability to modify the DNA.[1] Human germline genome editing (HGGE) involves modifying the human germline cells, or reproductive cells,[2] and has the potential to prevent inheritance of a genetic disease of which prospective parents are (both) carrier. The field of HGGE has rapidly evolved since the introduction of the CRISPR-Cas9 technique, which is considered easier and more efficient than existing techniques.[3] Once considered safe and effective, clinical implementation of HGGE has the promising potential to fulfil the wish of prospective parents to bring a healthy child in the world that would otherwise be born with a genetic disease. On the contrary, it opens the door to undesirable possibilities of 'human enhancement' and 'selection of persons' as well. This has stirred the debate about the acceptability of HGGE in light of human rights protection in Europe.

The main legal argument of opponents of clinical implementation of HGGE is its incompatibility with (respect to) human dignity.[4] This was first mentioned by the Parliamentary Assembly of the Council of Europe (CoE) that speaks of "the right to inherit a genetic pattern which has not been artificially changed."[5] From this perspective — that the human genome should be protected — interventions on the genome that enact modifications that are passed on to descendants are not acceptable. On the other hand, once considered safe and effective, the question is raised whether it is justifiable to potentially breach the procreative rights of parents by withholding them from the possibility to bring a healthy child into the world. This is often associated with the concept of human dignity as autonomy: the individual as independent, being capable of self-determination, free to make his/her own decisions and consciously

1 M.L. Maeder and C.A. Gersbach, 'Genome-editing technologies for gene and cell therapy', *Molecular Therapy* 24 (2016) 430–446.

2 Germline cells or reproductive cells consist of stem cells, gametes, egg and sperm cells and embryos.

3 M. Jinek, K. Chylinski, I. Fonfara, M. Hauer, J.A. Doudna and E. Charpentier, 'A programmable dual-RNA — guided DNA endonuclease in adaptive bacterial immunity' *Science* (2012) 816–821.

4 J. Harris, 'Germline Modification and the Burden of Human Existence', *Cambridge Quarterly of Healthcare Ethics* 25 (2016) 6–18; J. Halpern, S.E. O'Hara, K.W. Doxzen, L.B. Witkowsky and A.L. Owen, 'Societal and Ethical Impacts of Germline Genome Editing: How Can We Secure Human Rights?', *CRISPR Journal* 2 (2019) 293–298; S. Segers and H. Mertes, 'Does Human Genome Editing Reinforce or Violate Human Dignity?', *Bioethics* 34 (2020) 33–40.

5 Council of Europe, Parliamentary Assembly, *Recommendation 934* (1982) para. 4.

determine his/her own life.[6] Consequently, at the moment, the human rights debate does not provide a clear direction as to the acceptability of HHGE for reproductive purposes.

Although HGGE is still facing preclinical challenges, it is realistic that further development of HGGE will eventually lead to safe and effective reproductive use. Therefore, consistent legal frameworks should be established within Europe in order to adequately regulate the clinical implementation in accordance with human rights. Within Europe, human rights are mainly protected by the European Convention of Human Rights (ECHR). Although the ECHR does not explicitly safeguard human dignity, case-law of the European Court of Human Rights (ECtHR) indicates the use of human dignity as a guiding principle.[7] In the past decades, the ECtHR has played an important role in bridging the gap between medical-scientific developments within the field of assisted procreation and unresolved legal questions that are raised under Article 2 ('right to life') and most often, Article 8 ('right to respect for private and family life') of the ECHR. It is expected that the clinical potential of HGGE will raise important questions under these articles as well.[8] Consequently, the ECtHR will likely become a central player in the legal debate surrounding acceptability of HHGE-techniques for prospective parents. It is therefore important to examine existing case-law on both Article 2 and Article 8 in relation to (artificial) procreative rights and examine how the position of the ECtHR may be of relevance in light of regulating clinical implementation of HGGE.

This article aims to analyse the ECtHR's case-law in order to provide guidance for developing a clear human rights-based legal framework for HHGE in Europe. In order to achieve this objective, the second paragraph will discuss relevant background information regarding HGGE. Subsequently, Section 3 lays down the principle of *human dignity* in relation to the ECHR and its importance in the legal and ethical discussions surrounding HHGE. The fourth and the fifth paragraph will focus on Article 2 and Article 8 of the ECHR and relevant caselaw that has been examined by the ECtHR in the field of assisted procreation. Section 6 will analyse the decisions of the ECtHR in light of clinical

6 R. Bronsword and D. Beyleveld, *Human dignity in bioethics and biolaw* (Oxford: Oxford University Press, 2001).

7 Up to October 2016, the ECtHR has referred to 'human dignity' in 876 cases. A. Buyse, *The role of human dignity in ECHR case-law* (21 October 2016), available online at https://www.echrblog.com/2016/10/the-role-of-human-dignity-in-echr-case.html (accessed 16 January 2022); ECtHR 4 October 2016, 2653/13 (*Yaroslav Belousov v. Russia*) para. 92.

8 Council of Europe/European Court of Human Rights, Research report: bioethics and the case-law of the Court (20 October 2016), available online at https://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf (accessed 16 January 2022).

implementation of HGGE. Lastly, the conclusion will summarize the findings within the relevant caselaw of the ECtHR in relation to HGGE.

2 Background

An important distinction within the field of genome editing, the ability to *treat* or *prevent* genetic disorders. For treatment purposes, genome editing is performed on somatic cells (or other cells) in order to alleviate or treat the symptoms of a disease that existing patients are suffering from. On the contrary, germline therapy, or HGGE, involves modifying the germline cells, which are stem cells, gametes, egg and sperm cells and embryos. The difference is that with HGGE, the applied changes will be passed on to future generations. Thus, in a hypothetical situation, HGGE would be applied to an *in vitro* human embryo to cleave the DNA that is responsible for a genetic disease. The edited embryo would be implanted in the woman's womb and develops into a human being. Once the baby is born, it will not have inherited the genetic disease, nor will it be able pass on the disease to its (prospective) offspring. Somatic genome editing only modifies the somatic cells, which does not have consequences in case of reproduction, and is considered less controversial.[9] This article focuses on the ethical controversy around HGGE, which does have reproductive consequences for further generations as well.

2.1 *HGGE for Research Purposes*

The use of HGGE for research purposes is non-reproductive, but rather focuses on the development and improvement of gene-editing technology (basic research), or addressing and solving issues that may arise with clinical implementation of HGGE for reproductive purposes (preclinical research). Basic research enables scientists to gain better understanding of the early developmental stages of the human embryo, for example, to improve infertility

9 K. Saha, E.J. Sontheimer, P.J. Brooks, M.R. Dwinell, C.A. Gersbach, D.R. Liu, S.A. Murray, S.Q. Tsai, R.C. Wilson, D.G. Anderson, A. Asokan, J.F. Banfield, K.S. Bankiewicz, G. Bao, J.W.M. Bulte, N. Bursac, J.M. Campbell, D.F. Carlson, E.L. Chaikof, Z.-Y. Chen, R.H. Cheng, K.J. Clark, D.T. Curiel, J.E. Dahlman, B.E. Deverman, M.E. Dickinson, J.A. Doudna, S.C. Ekker, M.E. Emborg, G. Feng, B.S. Freedman, D.M. Gamm, G. Gao, I.C. Ghiran, P.M. Glazer, S. Gong, J.D. Heaney, J.D. Hennebold, J.T. Hinson, A. Khvorova, S. Kiani, W.R. Lagor, K.S. Lam, K.W. Leong, J.E. Levine, J.A. Lewis, C.M. Lutz, D.H. Ly, S. Maragh, P.B. McCray Jr, T.C. McDevitt, O. Mirochnitchenko, R. Morizane, N. Murthy, R.S. Prather, J.A. Ronald, S. Roy, S. Roy, V. Sabbisetti, W.M. Saltzman, P.J. Santangelo, D.J. Segal, M. Shimoyama, M.C. Skala, A.F. Tarantal, J.C. Tilton, G.A. Truskey, M. Vandsburger, J.K. Watts, K.D. Wells, S.A. Wolfe, Q. Xu, W. Xue, G. Yi, J. Zhou and The SCGE Consortium, 'The NIH Somatic Cell Genome Editing program', *Nature* 592 (2021) 195–204.

treatment.[10] The general aim of preclinical research is to responsibly introduce new assisted reproduction techniques in the clinic.[11] Specifically with regard to HGGE, it aims to clarify the editing efficiency and the safety of clinical implementation. The first preclinical studies showed that that HGGE is not yet deemed safe nor (always) efficient.[12] Mosaicism, on-target and off-target mutations are important challenges. Although strategies have been developed to detect and reduce both mosaicism and off-target effects, and more advanced techniques have reached technical improvements and higher levels of efficiency, it is not guaranteed that all the effects are eliminated.[13] Due to serious health risks for the embryo and the human being it will develop into, it is essential to conduct preclinical research on HGGE before introduction to the fertility industry.

10 R.A. Lea and K.K. Niakan, 'Human germline genome editing', *Nature Cell Biology* 21 (2019) 1479–1489.

11 A. van Steirteghem, 'What next for assisted reproductive technology? A plea for an evidence- based approach' *Human Reproduction* 23 (2008) 2615–2616; J. Harper, M.C. Magli, K. Lundin, C.L.R. Barratt and D. Brison, 'When and how should new technology be introduced into the IVF laboratory?', *Human Reproduction* 27 (2012) 303–313; D.R. Brison, S.A. Roberts and S.J. Kimber, 'How should we assess the safety of IVF technologies?', *Reproduction Biomed Online* 27 (2013) 710–721; V. Provoost, K. Tilleman, A. D'Angelo, P. De Sutter, G. de Wert, W. Nelen, G. Pennings, F. Shenfield and W. Dondorp, 'Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment', *Human Reproduction* 29 (2014) 413–417.

12 X. Kang, W. He, Y. Huang, Q. Yu, Y. Chen, X. Gao, X. Sun and Y. Fan, 'Introducing precise genetic modifications into human 3PN embryos by CRISPR/Cas-mediated genome editing', *Journal of Assisted Reproduction and Genetics* 33(5) (2016) 581–588; H. Ma, N. Marti-Gutierrez, S.-W. Park, J. Wu, Y. Lee, K. Suzuki, A. Koski, D. Ji, T. Hayama, R. Ahmed, H. Darby, C. Van Dyken, Y. Li, E. Kang, A.-R. Park, D. Kim, S.-T. Kim, J. Gong, Y. Gu, X. Xu, D. Battaglia, S.A. Krieg, D.M. Lee, D.H. Wu, D.P. Wolf, S.B. Heitner, J.C. Izpisua Belmonte, P. Amato, J.-S. Kim, S. Kaul and S. Mitalipov, 'Correction of a pathogenic gene mutation in human embryos', *Nature* 548 (7668) (2017) 413–419. P. Liang, Y. Xu, X. Zhang, C. Ding, R. Huang, Z. Zhang, J. Lv, X. Xie, Y. Chen, Y. Li, Y. Sun, Y. Bai, S. Zhou, W. Ma, C. Zhou and J. Huang, 'CRISPR/Cas9-mediated gene editing in human triponuclear zygotes', *Protein & Cell* 6 (2015) 363–372.

13 T. Koo, J. Lee and J. Kim, 'Measuring and reducing off-target activities of programmable nucleases including CRISPR-Cas9', *Molecules and Cells* 38 (6) (2015) 475–481; S.Q. Tsai and J.K. Joung, 'Defining and improving the genome-wide specificities of CRISPR — Cas9 nucleases', *Nature Reviews Genetics* 17 (5) (2016) 300–312; H. Ledford, 'CRISPR gene editing in human embryos wreaks chromosomal mayhem, *Nature* 583 (2020) 17–18; G. Alanis-Lobato, J. Zohren, A. McCarthy, N.M.E. Fogarty, N. Kubikova, E. Hardman, M. Greco, D. Wells, J.M.A. Turner and K.K. Niakan, 'Frequent loss-of-heterozygosity in CRISPR-Cas9-edited early human embryos', *Proceedings of the National Academy of Sciences of the United States of America* 118 (22) (2020) e2004832117.

2.2 *HGGE for Reproductive Purposes*

Prospective parents that are carrier of a disease with a high genetic risk for their offspring have various reproductive options to eliminate or reduce the risk of passing on their genetic disease: the couple could opt for adoption, use a gamete donor, or undergo prenatal or preimplantation genetic diagnosis (PGD). Once HGGE is effective and safe, its addition to this range of options has important (medical) advantages. HGGE is a preventive intervention that could correct or erase disease-causing mutations around the stage of fertilization, thereby eliminating the risk of passing the genetic disease to offspring and further descendants.[14] This will have profound effects on the well-being of the future child, given that it is born without the disease it would otherwise have inherited, as well as on parents that are satisfied in their desire for a healthy child that is genetically related to both of them. Currently, due to the safety and efficiency challenges as described in Section 2.1., clinical use of HGGE for reproductive purposes has been prohibited or restricted in most European countries.[15]

2.3 *HGGE for Human Enhancement Purposes*

Although the concept of 'human enhancement' is hard to define, it often refers to alternating the genome to enhance *normal* human traits, such as muscularity or intelligence.[16] Associated terms such as 'designer babies', 'trait selection' and 'eugenics',[17] are the foundation of existing legal bans on HGGE in various legal frameworks.[18] Albeit this concern is not completely unjustified, it is extremely difficult to modify the genome in such an advanced manner. Genetics are complex — as is inheritability — which is often overlooked when it comes to the practical implementation of HGGE.[19] Biological conditions

14 M. Viotti, A.R. Victor, D.K. Griffin, J.S. Groob, A.J. Brake, C.G. Zouves and F.L Barnes, 'Estimating demand for germline genome editing: an in vitro fertilization clinic perspective', *The CRISPR Journal* 2 (2019) 304–315.

15 F. Baylis, M. Darnovsky, K. Hasson and T.M. Krahn, 'Human germline and heritable genome editing: the global policy landscape', *The CRISPR Journal* 3(5) (2020) 365–377.

16 N. Bostrom and J. Savulescu, *Human enhancement ethics: The state of the debate* (Oxford: Oxford University Press, 2009).

17 S.M. Suter, 'A Brave New World of Designer Babies', *Berkeley Techology Law Journal* 22 (2007) 897–915.

18 Explanatory report to the Convention on Human Rights and Biomedicine, *European Treaty Series, nr. 164*; International Bioethics Committee, *Report of the International Bioethics Committee (IBC) on Updating Its Reflection on the Human Genome and Human Rights* (New York, NY: International Bioethics Committee, 2015).

19 A.C.W. Janssens, 'Designing babies through gene editing: science or science fiction?', *Genetics and Medicine* 18 (2016) 1186–1187.

limit the possibilities of 'human enhancement', yet attempts to make simpler modifications to less complex traits should not be ruled out.

3 Human Dignity as a Guiding Principle in European Human Rights

After the second World War, the concept of human dignity begun to play an important role in different fields, including philosophy, politics and law.[20] In law, human dignity is often assumed to be the foundation of human rights.[21] It has been attributed a central role in various international legal human rights frameworks. UNESCO's Universal Declaration of Human Rights states in its first article that "all human beings are born free and equal in dignity and rights."[22] Other legal instruments, such as the EU Charter of Fundamental Rights (EU Charter) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) associate human dignity with similar notions of inviolability, alienability, equality and freedom. A coherent and single conceptualization of human dignity remains elusive — legal doctrine and practice continue to apply various variants of definitions. These definitions roughly amount to two main understandings about human dignity: either that human dignity is about respect for individual human being that is capable of making his/her own autonomous decisions ('empowerment'), or that human dignity is based on respect for and protection of the human being, and is a safeguard against inhuman or degrading treatment and practices ('constraint').[23] Albeit these approaches appear to be contradicting, one understanding does not necessarily exclude the other.[24]

In bioethics, there is a strong tendency to link human dignity to the human genome. The Universal Declaration on the Human Genome and Human Rights (1997) notably refers to this association in its first heading 'Human Dignity and the Human Genome'. Article 1 specifically indicates the human genome as "underlying the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic

20 C. McCrudden, 'Human Dignity and Judicial Interpretation of Human Rights', *European Journal of International Law* 664 (19) (2008) 655–724.

21 Preamble of the EU Charter: "the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity."

22 UN General Assembly, 'Universal Declaration of Human Rights', 10 December 1948, 217 A (I).

23 *Supra* note 7.

24 R. Andorno, 'Human dignity and human rights as a common ground for a global bioethics', *Journal of Medicine and Philosophy* 34 (2009) 223–240, p. 232.

sense, it is the heritage of humanity."[25] This has led to different views on the acceptability of technologies that aim to modify the genome. In light of human dignity, the question raises whether we should either refrain from altering the human genome ('constraint') or respect an individual's autonomous decision to do or do not so ('empowerment')? Current human rights frameworks regarding bioethics tend to pursue the 'constraint' dimension of human dignity by restricting the alteration of the human genome, particularly because of concerns related to dehumanisation and objectification. For instance, the Oviedo Convention posits that preventive, diagnostic or therapeutic interventions of the genome are allowed under the condition that "its aim is not to introduce any modification in the genome of any descendants."[26] The rationale behind this in light of human dignity is explained by "the ultimate fear of intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities," which seems to refer to 'human enhancement.'[27] Similar concerns about 'long term effects of HGGE' and 'selection of persons' have been expressed in the Universal Declaration of the Human Genome and Human Rights and the EU Charter as an explanation to restrict interventions on the human genome.[28]

In the ECHR, the concept of human dignity is remarkably absent. Nevertheless, the caselaw of the ECtHR often refers to human dignity as a guiding principle — more specifically has it stated that "the very essence of the Convention is respect for human dignity and freedom."[29] Furthermore, Article 3 of the ECHR is most often applied in reference to human dignity — as it prohibits inhuman or degrading treatment that may offend human dignity.[30] Yet, other articles are associated to human dignity as well. Particularly regarding bioethical

25 Article 1 UNESCO 'Universal Declaration on the Human Genome and Human Rights' (11 November 1997), available online at https://en.unesco.org/themes/ethics-science-and-technology/human-genome-and-human-rights (accessed 11 January 2022).

26 Article 13 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention), 4 April 1997, *ETS no. 164*.

27 Explanatory report to the Convention on Human Rights and Biomedicine, *ETS no. 164*, para. 89.

28 Article 25 in conjunction with International Bioethics Committee, 'Report of the International Bioethics Committee (IBC) on Updating Its Reflection on the Human Genome and Human Rights' 2 October 2015, para. 107; Article 3 (2) of the EU Charter: "[…] prohibition of eugenic practices, in particular those aiming at the selection of persons."

29 ECtHR 11 July 2002, 28957/95 (*Christine Goodwin v. United Kingdom*) para. 90 in conjunction with ECtHR 29 April 2002, 2346/02 (*Pretty v. United Kingdom*).

30 Article 3 ECHR: "No one shall be subjected to torture or to inhuman or degrading treatment or punishment."

developments and assisted procreation, the ECtHR often refers to Article 2 and Article 8 in its caselaw.[31] Human dignity is expressed in Article 2 — right to life — as protection of (unborn) human life against dehumanisation and objectification ('constraint'), whereas under Article 8 — right to private and family life — it is referred to as the right self-determination or personal autonomy regarding the body and person ('empowerment').[32] In the context of the expanding assisted procreation possibilities, various cases have been examined by the ECtHR about reproductive rights under Article 8 and the legal status of an embryo under Article 2. These decisions — that are guided by the concept of human dignity — potentially provide legal guidance on how Contracting States of the Council of Europe (thereafter: Contracting States) should shape their legislation in response to the clinical implementation of HGGE.

4 Article 8 ECHR: 'The Right to Respect for Private and Family Life'

This paragraph will further elaborate on Article 8 in the context of assisted procreation. As HGGE can be used for reproductive purposes, it is important to establish whether reproductive rights fall within the scope of Article 8 — and if so — whether and when it is possible to limit these rights under circumstances. Section 4.1 describes the normative framework of Article 8. Next, Section 4.2 discusses the relevant caselaw in the context of assisted procreation within this normative framework.

4.1 *Normative Framework of Article 8 ECHR*

"1. Everyone has the right to respect for his private and family life, his home and his correspondence"

The objective of Article 8 of the ECHR is protection against interferences by national authority with private and family life, home and correspondence. The scope of this article is not limited to the four interests as described in the article — as mentioned — the right to self-determination and personal autonomy are also considered to be protected by Article 8.[33] Although Article 8 holds a negative obligation for a public authority to abstain from intervening with

31 ECtHR 10 April 2007, 6339/05 (*Evans v. United Kingdom*); ECtHR 4 December 2007, 44362/04 (*Dickson* v. *United Kingdom*); ECtHR 3 November 2011, 57813/00 (*S.H. and others* v. *Austria*); ECtHR 28 August 2012, 54270/10 (*Costa & Pavan* v. *Italy*).

32 For instance, regarding sexual orientation, end of life choices and assisted procreation.

33 ECtHR 11 July 2002, 28957/95 (*Christine Goodwin v. the United Kingdom*).

private and family life, home and correspondence,[34] the second paragraph of this article describes an exception.

"2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society [...]*"*[35]

According to this exception, infringement of Article 8 is allowed with legitimate consideration of the competing interests of the individual and society, under the conditions that this is (a) in accordance with the law and (b) necessary in a democratic society. The first condition requires that the national legislation is clear, foreseeable and adequately accessible, and pursues one or more of the legitimate aims listed therein.[36] With regard to the second condition, the interference must correspond to a pressing social need and must remain proportionate to the legitimate aim pursued. In case of sensitive moral and ethical issues on which there is no consensus within Contracting States, a wide *margin of appreciation* is afforded. Within this *margin of appreciation*, Contracting States are allowed discretion to interpret the ECHR in light of their national interests regarding the subject.

4.2 *The Right to* (*Medically Assisted*) *Procreation*

Although it has been established by the ECtHR that the right to self-determination and personal autonomy fall within the scope of Article 8, this does not explicitly indicate that this is also the case for reproductive rights. This leads to the following question:

4.2.1 Is There a Right to (Medically Assisted) Procreation under Article 8?

In 2007, the ECtHR specifically examines reproductive rights in relation to Article 8 in the case of *Evans v. United Kingdom*.[37] Mrs. Evans wished to use the embryos that had been created with her eggs and the sperm of her ex-partner before she had her ovaries removed. After their break-up, the ex-partner withdrawals his consent to use the sperm. Mrs. Evans complains that this is in violation with her rights as protected by Article 8, as this prevents her from ever having genetically related offspring. The ECtHR recognizes that the decision

34 ECtHR 22 February 2018, 588/13 (*Libert v. France*), paras 40–42.

35 [...] in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

36 ECtHR 25 March 1983, 5947/72; 6205/73; 7052/75; 7061/75; 7107/75; 7113/75; 7136/75 (*Silver and others v. the United Kingdom*), para. 87.

37 ECtHR 10 April 2007, 6339/05 (*Evans v. United Kingdom*).

to have and to not have a child in the genetic sense falls within the scope of the right to respect for private life as protected by Article 8.[38] This was reaffirmed in the case of *Dickson v. United Kingdom*, which involved a prisoner and his wife who were refused access to artificial insemination facilities by the U.K. Secretary of State. The prisoner was still serving his prison sentence, which withheld them from inducing a natural pregnancy. Given the age of his wife, the chance at conception would be considerably low by the time the prisoner would be released. The couple complained that this refusal breached their rights under Article 8. The ECtHR decided that this concerned the right to respect for family and private life under Article 8, which includes the right to respect for the applicants' decision to become a parents in the genetic sense.[39] Given the fact that the case concerned artificial insemination, the access to assisted procreation techniques seems to fall within the scope of Article 8 as well. This approach was confirmed in the case of *S.H. and others v. Austria*, which concerned two infertile couples wished to use ova donation and sperm donation for medically assisted procreation (ivf). The Austrian law prohibits the use of (donated) sperm for ivf and includes a general ban for ova donation. The couples argued a violation of their rights under Article 8. The ECtHR considers that the choice to use medically assisted procreation is an expression of private and family life. Therefore, the right of a couple to make use of medically assisted procreation is protected under Article 8.[40]

The case of *Costa & Pavan v. Italy* specifically concerns the use of medically assisted procreation to become parents of a child unaffected by a genetic disease. Costa and Pavan are both healthy carriers of cystic fibrosis and resort to use assisted reproduction technology (ivf) and preimplantation genetic diagnosis (PGD) with the purpose to select an embryo that does not carry the disease.[41] However, the Italian law forbids the use of PGD and allows ivf treatment exclusively for specific reasons.[42] The Italian regulation does not consider the risk of transferring a genetic disease as one of these reasons. The law does provide the opportunity to terminate the pregnancy on medical grounds, such as a genetic disease.[43] This leaves Costa and Pavan with only one option: inducing natural pregnancy with the possibility for abortion on medical grounds in case the prenatal tests confirm that the child is affected by cystic fibrosis. They complained that this violated their rights under Article 8. The

38 *Ibid.*, para. 60.
39 ECtHR 4 December 2007, 44362/04 (*Dickson* v. *United Kingdom*) para. 62.
40 ECtHR 3 November 2011, 57813/00 (*S.H. and others* v. *Austria*) para. 82.
41 ECtHR 28 August 2012, 54270/10 (*Costa & Pavan* v. *Italy*).
42 Article 4(1) and 5 Law 40/2004 on medically assisted reproduction.
43 Article 6 para. 1 letter b Law 194/1978 on social protection of motherhood and abortion.

ECtHR finds the desire to use medically assisted procreation as to conceive a child that is unaffected by a genetic disease of which the (prospective) parents are healthy carriers, to be protected under Article 8.

However, what if the *initial* decision to become parents in the genetic sense changes due to certain circumstances, and so does the wish to use assisted reproduction techniques in order accomplish this? In the case if *Parrillo v. Italy*, Ms. Parrillo wished to donate the embryos that were initially intended for an ivf treatment, to scientific research. Given that her partner had passed away, Ms. Parrillo no longer had the intention to start a family. The ECtHR finds the choice to donate embryos to scientific research an aspect of the personal life, related to the right to self-determination. From a standpoint of the right to respect for private life, the case of Ms. Parrillo was applicable under Article 8.[44]

These cases indicate that the ECtHR considers (medically assisted) procreation to be protected under Article 8. In fact, the scope appears to broaden in accordance with the advancing scientific developments within the field of assisted procreation. This increasing focus on personal autonomy with regard to assisted procreation accentuates the 'empowering' dimension of human dignity.[45] Even more so, because it appears to expand outside the field of assisted procreation into a broader field of embryo donation (*Parrillo v. Italy*). However, the right to (assisted) procreation is not an absolute right. In these cases, the ECtHR refers to the moral and ethical sensitivity of the subject of assisted procreation and the little consensus between the Contracting States. It has assigned a wide *margin of appreciation* to the Contracting States to shape their reproductive laws and intervene with the right to medically assisted procreation if they consider this necessary.[46] In order to decide whether a Contacting State has not exceeded this wide *margin of appreciation*, the ECtHR balances the interests at stake.

4.2.2 A Positive Obligation or an Interference: 'In Accordance with the Law' and 'Necessary in a Democratic Society'?

In the case of *Evans v. United Kingdom*, the ECtHR examines the conflicting interests of Ms. Evans, who wishes to become a parent in the genetic sense, and her ex-partner, who does not want to become a parent in the genetic sense.[47] First, UK's Human Fertilisation and Embryology of 1990 (HFEA) is based on the

44 ECtHR 27 August 2015, 46470/11 (*Parrillo* v. *Italy*), para. 156.

45 *Supra* note 41, para. 71. In the case of *Evans v. the United Kingdom*, the ECtHR literally refers to 'personal autonomy' under Article 8.

46 *Supra* note 42, para. 83; *supra* note 39, paras 77–79.

47 These are two conflicting individual rights, rather than conflicting private and public rights.

principles of respect for human dignity and free will: the wishes of the donor are prioritized. The required consent of the donor before usage holds no exceptions, in order to ensure that donated gametes are not used without continuing consent, as well as to promote legal certainty. The ECtHR finds these general interests pursued by the law legitimate as well as consistent with Article 8.[48] With regard to the conflicting interests, the ECtHR decided that the interests of Ms. Evans did not outweigh the interests of her ex-partner. Otherwise stated, the competing interests were fairly balanced and did not violate the rights of Ms. Evans under Article 8 of the ECHR.

The relevance of balancing competing private and public interests became clear in the case of *Dickson v. United Kingdom*. The policy of the Secretary of State stated that requests for artificial insemination by prisoners are only granted in exceptional circumstances, yet, according to the ECtHR, the threshold for 'exceptionality' was set so high that it excluded actual balancing of competing interests and a proportionality test of the restriction.[49] Given the importance of this assessment for the prisoner and his wife — artificial insemination was the only realistic hope on conceiving a child — the ECtHR finds that the national authority has exceeded the afforded *margin of appreciation*, and therefore violated Article 8 of the ECHR.

In the case of *S.H. and others v. Austria*, the ECtHR examines whether the bans on ova donation for assisted reproduction and sperm donation for the purpose of ivf were sufficiently justified to restrict the applicants' procreative rights under Article 8.[50] The Austrian legislation approaches the advances in medically assisted procreation with particular care, given the complexity of split motherhood and the risks for other undesired objectives such as 'selection' of children and exploitation of women in case of ova donation.[51] As to the specific prohibition to donate sperm for *in vitro* fertilisation, but not for *in vivo* fertilisation, it was stated that *in vivo* fertilisation had been clinically implemented for a while and gained societal acceptance over time — it would be hard to monitor a prohibition. To the question whether the latter argument by itself outweighs the procreative interests of the individual, the ECtHR answered that this argument is part of balancing interests in seeking to reconcile social realities with the general legislative framework that has been adopted by the Austrian authorities. The ECtHR understands the careful

48 *Supra* note 39, para. 89.

49 *Supra* note 41, para. 82.

50 There is a clear legal basis and the legitimate aim of the protection of health or morals and the protection of rights and freedom of others is pursued — hence that this was not in dispute.

51 *Supra* note 42, para. 101.

and cautious approach, yet it criticizes the Austrian authority for not taking sufficient steps to monitor the dynamic developments in science and society regarding gamete donation. Nevertheless, despite the prohibitions, the ECtHR notes that assisted procreation is not completely excluded, given that homologous methods are allowed, as is seeking the desired treatment abroad.[52] Both the ban on ova donation for assisted reproduction as well as the ban on sperm donation for the purpose of ivf are considered compatible with Article 8.

In the case of *Costa & Pavan v. Italy*, the important question is not whether the Italian law is compatible with Article 8 of the ECHR — the prohibition itself is not incompatible with Article 8 — but concerns the proportionality of the prohibition on PGD in conjunction with other reproductive laws. The ECtHR observes a clear inconsistency in Law 40/2004, as PGD in case of a genetic disease (cystic fibrosis) is prohibited, but termination of the pregnancy on medical grounds (cystic fibrosis) is allowed. The ECtHR recognizes the negative impact on the health of the individual who only has a choice to conceive an affected child and terminate the pregnancy after the prenatal tests. This restriction on the individuals' procreative rights as protected under Article 8 is considered disproportionate — and therefore a violation of Article 8 of the ECHR.[53]

4.3 *Concluding Remarks*

As mentioned, the scope of artificial reproductive rights is expanded with the medical-scientific possibilities. Yet the decisions of the ECtHR in the aforementioned cases imply these rights are not absolute. Given the wide *margin of appreciation*, interference by Contracting States is allowed under the conditions of a *coherence* within the reproductive laws (*Costa & Pavan v. Italy*), proportionality as well as legitimate consideration of the interests at stake (*Dickson v. United Kingdom*) and review of the highly dynamic science and society regarding assisted procreation (*S.H. and others v. Austria*). Although the increasing focus on the 'empowering' dimension of human dignity is notable in these decisions of the ECtHR, the *margin of appreciation* allows the Contracting States to decide to what extent their reproductive laws either respect the individual's autonomous decisions or limit reproductive rights in order to prevent that artificial reproduction becomes commodification or objectification of human life. On the other hand, the case of *Costa & Pavan v. Italy* illustrates that the ECtHR does no longer limit herself to the judgement whether the national legislation on assisted procreation itself is in accordance

52 *Ibid.*, para. 114.

53 *Supra* note 43, para. 70.

with Article 8, but rather examines the concrete content of the Italian legislation regarding its proportionality and coherence in the context of other reproductive laws. Further cases should confirm whether this indicates a shift from a reluctant approach of the ECtHR to more strict scrutiny of the *margin of appreciation* that is afforded to Contracting States regarding bioethical matters that fall within the scope of Article 8.

5 Article 2 ECHR: 'The Right to Life'

The following paragraph focusses on Article 2 of the ECHR, which aims to protect the right to life. The expanding possibilities to artificially procreate raises questions about the protectability of unborn life, or embryo — even more so in case of HGGE given that this introduces modifications to the unborn human being and its possible descendants. Section 5.1 describes the normative framework of Article 2. Subsequently, Section 5.2 explains this framework from the perspective of relevant caselaw of the ECtHR about the protectability of the human embryo.

5.1 *Normative Framework of Article 2 ECHR*

"1. Everyone's right to life shall be protected by law [...]*"*

The right to life is considered as one of the most basic fundamental human rights. Derogation of this right under Article 15 of the ECHR is inadmissible. The only exceptions are described in the second paragraph of Article 2, which requires an absolute necessity (a) in defence of any person from unlawful violence, (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained or (c) in action lawfully taken for the purpose of quelling a riot or insurrection. The article positively obligates the Contracting States to refrain from intentional deprivation of the lives of those who fall within its jurisdiction, as well as to take legal measures to protect those lives.[54] From caselaw of the ECtHR, in can be inferred that the scope of this obligation is rather broadly applied, such as in environmental context,[55] in the context of accidents[56] and in the context of both beginning and end of life.[57]

54 R.C.A. White and C. Ovey, *The European Convention of Human Rights* (Oxford: Oxford University Press, 2014), p. 145.

55 ECtHR 30 November 2004, 48939/99 (*Öneryıldız v. Turkey*).

56 ECtHR 15 December 2009, 4314/02 (*Kalender v. Turkey*); ECtHR 3 December 2009, 60255/00 (*Pereira Henriques v. Luxembourg*).

57 ECtHR 29 April 2002 (*Pretty v. the United Kingdom*), ECtHR 5 June 2015, 46043/14 (*Lambert and others v. France*); ECtHR 8 July 2004, 53924/00 (*Vo v. France*).

5.1.1 The Legal Status of a Human Embryo

Article 2 does not provide a definition of 'everyone' whose life is protected under the ECHR, neither does it specify when 'life' begins. Thus, it should first be established what is considered the beginning of 'life' to determine the protectability of a human embryo under Article 2. There are various moral and legal views on when and to what extent legal protection should be granted to the human embryo. Some consider the embryo a human being and argue that it should enjoy complete protection from the point of fertilization. Others state that this protectability is dependent on the developmental stage of the embryo, or that the embryo is not considered a human being at all and should not be afforded any legal protection.[58] As for the ECtHR, it has examined various cases that concerned the protectability of unborn human life under Article 2, particularly in connection with abortion.[59] In these cases, the ECtHR consistently addresses the European divergence regarding the definition of the 'beginning of life', yet it refrains from clarifying whether the embryo enjoys protection under Article 2. Instead, it decides that the definition of the 'beginning of life' as well and the extent to which it is legally protected fall within the *margin of appreciation* enjoyed by the Contracting States. Moreover, it observes that most reproductive laws of the Contracting States[60] do not regard the unborn child as a 'person' directly protected under Article 2 and that even if the existence of a certain 'right to life' of the unborn child would be assumed, that this right is implicitly limited by the mother's rights and interests.[61] However, this does not necessarily rule out the possibility that there are circumstances in which the ECtHR considers unborn life to fall within the scope of protection under Article 2 which will imply a positive obligation on national authorities to take preventive measures to protect this life.[62]

A remarkable case in relation to the right to life of unborn human life — that did not concern abortion — is the case of *Vo v. France*.[63] Mrs. Vo intended to carry her pregnancy to term, but when the foetus was 20 to 21 weeks old,

58 Steering Committee on Bioethics (CDBI), 'The protection of the human embryo in vitro', Strasbourg, 19 June 2003; Human Embryo Research Panel of the National Institutes of Health, 'Report of the Human Embryo Research Panel (Vol. 1)', 27 September 1994, p. 39.

59 ECtHR 13 May 1980, 8416/79 (*X v. the United Kingdom*), ECtHR 19 May 1992, 17004/90 (*H. v. Norway*); ECtHR 8 July 2004, 53924/00 (*Vo v. France*); ECtHR 16 December 2010, 25579/05 (*A, B and C v. Ireland*); ECtHR 20 March 2007, 5410/03 (*Tysiac v. Poland*).

60 For instance, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal and Sweden.

61 ECtHR 13 May 1980, 8416/79 (*X v. the United Kingdom*), para. 19; ECtHR 19 May 1992, 17004/90 (*H. v. Norway*) para. 168; ECtHR 5 September 2002, 50490/99 (*Boso v. Italy*).

62 ECtHR 5 September 2002, 50490/99 (*Boso v. Italy*).

63 ECtHR 8 July 2004, 53924/00 (*Vo v. France*).

her pregnancy was involuntarily terminated due to medical negligence by the attending doctor. Mrs. Vo stated that this should be considered as unintentional homicide of her child, however, the unborn child (foetus) is not regarded as a 'person' under the French Criminal Code. Subsequently, Mrs. Vo appeals to the ECtHR with her complaint — raising the question whether harming the unborn child should be considered a criminal offence in light of Article 2.[64] Due to the lack of consensus on the nature and status of the embryo, the ECtHR decides that it is "neither desirable, nor even possible" to specify whether the unborn child should be considered a person as protected under Article 2.[65] The ECtHR did state that embryos are beginning to receive some protection in light of the scientific progress in the field of genetic engineering, medically assisted procreation and embryo experimentation.[66] However, this may only indicate that the human embryo is regarded as belonging to the human race and requires protection in light of human dignity, but not necessarily under Article 2 as a 'person'. As for the question whether harming the unborn child should be considered a criminal offence in light of Article 2, the ECtHR concludes that Mrs. Vo did not seize the alternative legal opportunity to bring an action for damages against authority on account of the doctor's alleged negligence. Had she done so, this would have enabled her to prove the medical negligence and obtain full redress for the damage.[67] The ECtHR sees no necessity in instituting criminal proceedings. Although the case is applicable under Article 2, the complaint of violation is dismissed.

Interestingly, in the case of *Evans v. United Kingdom*, which involved *in vitro* embryos generated for an ivf treatment rather than a foetus of 20 to 21 weeks, the ECtHR comes to a more straightforward conclusion. In reference to the British legislation, which reads that "an embryo does not have independent rights or interests and cannot claim — or have claimed on its behalf — a right to life under Article 2," the ECtHR concludes that the embryo did not fall within the scope of protection under Article 2.[68] This rather extreme position has later been described as the *Evans* anti-life principle in the case of *Parrillo v. Italy*.[69] Given the fact that the *Evans* case concerned *in vitro* embryos, it has been questioned whether the ECtHR considers the embryo *in vitro* to be different from an *in vivo* embryo (foetus) with regard to legal status.

64 *Ibid.*, para. 81.
65 *Ibid.*, para. 85.
66 *Ibid.*, para. 84.
67 *Ibid.*, para. 91.
68 *Supra* note 39, para. 54.
69 *Supra* note 46, para. 31.

5.2 *Concluding Remarks*

As to the legal status of the embryo, the ECtHR attempts to refrain from taking a position on questions regarding Article 2. Instead, it leaves the decision on the 'beginning of life' and the scope of protection under Article 2 to the Contracting States. Nevertheless, it is not ruled out that there are certain well-defined circumstances in which the embryo will be granted protection under Article 2. In light of advancing medical-scientific developments, the ECtHR has observed that embryos are beginning to receive more protection under in light of human dignity. In fact, research that has been commissioned by the Nuffield Bioethics Committee has found that under international law, recent decisions indicate a trend of acknowledging that while embryos and foetuses are not generally recognised as holders of human rights, they are becoming increasingly recognised as having human dignity.[70] This increasing recognition indicates the relevance of human dignity as a 'constraint', as it aims to protect the human embryo against medical-scientific developments that have the potential to objectify or commodify the embryo.

6 Articles 2 and 8 ECHR in Light of the Emergence of HGGE

Needless to say there have been no decisions of the ECtHR regarding HGGE, given that it has not been clinically implemented yet. Nevertheless, when further development results in safe and effective reproductive use of HGGE, this requires a consistent legal framework in consideration of human rights — in particular human dignity. The case-law on both Article 2 and Article 8 may provide relevant guidance to shape national legal frameworks regarding HGGE. This paragraph discusses how both articles and related caselaw could be interpreted in light of HGGE. Section 6.1 focuses on the question whether there would be a right to medically assisted procreation with use of HGGE, whereas Section 6.2 examines the right to life of a gene-edited embryo and the potential positive obligation to protect the life of the human being it develops into.

6.1 *The Right to Medically Assisted Procreation with Use of HGGE*

Albeit the scope of artificial reproductive rights appears to expand with the possibilities for assisted reproduction, this does not necessarily imply that HGGE will fall within the scope of Article 8 as well. Moreover, it should be

70 R. Yotova, *The regulation of genome editing and human reproduction under international law, EU law and comparative law* (Nuffield: Nuffield Council of Bioethics, 2017).

taken into account that the rights under Article 8 are not absolute. Within their *margin of appreciation*, the Contracting States can decide to intervene with the right to respect private and family life if this is considered necessary in a democratic society. The first question that should be answered:

6.1.1 Is There a Right to Medically Assisted Procreation with Use of HGGE?

Given the cases that have been discussed under the fourth paragraph that were applicable under Article 8, the applicability of a case that concerns the access to HGGE under this article would be based on the following:

Does the Case Involve a Choice or Decision to Become Parents in the Genetic Sense by Means of an Assisted Procreation Technique?[71]

The ECtHR has specifically examined various assisted reproduction techniques and decided that IVF, artificial insemination, ova donation, sperm donation and PGD are applicable under Article 8. In these decisions, the ECtHR emphasizes that the decision to become parents in the genetic sense and the choice to use one of these techniques, are expressions of the right to respect for family and private life. Thus, for the use of HGGE to be applicable under Article 8, it is important that it concerns a decision of (prospective) parents to become parents in the genetic sense and the wish to use HGGE to accomplish this.

However, as the case of *Parrillo v. Italy* has illustrated, if an *initial* decision to become parents in the genetic sense by using assisted reproduction, changes to a wish to donate the generated embryos to research, this would be applicable under Article 8 as an aspect of the right to respect for private life as well. This indirectly enables the opportunity that the wish to donate embryos to (preclinical) research on HGGE also falls within the scope of Article 8. Although the case of *Parrillo v. Italy* concerned the donation of embryos to research on pluripotent stem cells, the reasoning that this scientific development opens new possibilities for research and therapeutic applications to treat diseases that are incurable or difficult to cure, is applicable to research on HGGE as well.[72] After all, as has been set out in the first paragraph, HGGE opens new possibilities for research as well as for clinical application to treat genetic diseases.

71 *Supra* notes 39, 41, 42.

72 *Supra* note 46, para. 90.

Does the Case Involve the Desire to Use Medically Assisted Procreation as to Conceive a Child that is Unaffected by a Genetic Disease of Which the (*Prospective*) *Parents Are Carriers?*[73]

In the case of *Costa & Pavan v. Italy* the ECtHR has recognized the right of parents to procreate a child who is not affected by the disease of which they are carriers. This indicates that if HGGE would be used for reproductive purposes with the objective to procreate an unaffected child, this would fall under the scope of Article 8. The purpose would be to modify the genome of the *in vitro* embryo in order to eliminate the risk that the child is born with a genetic disease of which the (prospective) parents are carriers. This objective is similar to PGD — which selects rather than modifies — and HGGE can be considered as effective, if not more effective. After all, PGD cannot be used in all cases of (prospective) parents who are carriers of a genetic disease and wish to conceive healthy offspring. For instance, when both parents suffer from the same or two different genetic diseases it is simply not possible to select an embryo that has a high chance of developing into a healthy child. On the other hand, HGGE does not only impact the embryo that is edited and the person that results from it, but also his or her descendants, and so forth. Albeit this is an important difference, given the caselaw currently available, the use of reproductive HGGE would still meet the condition that there should be a desire to use medically assisted procreation as to conceive a child that is unaffected by a genetic disease of which the (prospective) parents are carriers. On the contrary, the use of HGGE for reproductive purposes with the objective of human enhancement would not be protected by Article 8 based on the case of *Costa & Pavan v. Italy*. Ultimately, this does not concern a genetic disease nor parents that desire to conceive a child that is unaffected by this disease.

Thus, based on existing caselaw of the ECtHR, both the use of HGGE for reproductive purposes as well as research purposes could fall within the scope of Article 8, either under 'private and family life' or solely under 'private life'. This indicates that there would be a right to medically assisted procreation by using HGGE under Article 8. However, the wide *margin of appreciation* with regard to sensitive moral and ethical issues on which there is no European consensus allows the Contracting States to intervene in the right to respect for private and family life, under the conditions that this is in accordance with the law and necessary in a democratic society.

73 *Supra* note 43.

6.1.2 A Positive Obligation or an Interference: 'In Accordance with the Law' and 'Necessary in a Democratic Society'?

The European landscape is (already) highly divergent with regard to HGGE, ranging from prohibitive or restrictive to intermediate to permissive.[74] Contracting States that have signed and ratified the Oviedo Convention are bound to implement Article 13, which explicitly prohibits the use of HGGE for reproductive purposes. As mentioned, this approach is based on the 'constraint' dimension of human dignity: "the ultimate fear of intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities."[75] Given the explicit reference to HGGE, it would not be disputed whether this measure is provided for by law and can be regarded as pursuing the legitimate aims of protecting morals and the rights and freedoms of others.

However, 'in accordance with the law' under Article 8 may not always be undisputed. For instance, the Contracting States that are also EU Member States are directly bound to the Clinical Trials Regulation and the EU Charter. Article 90 of the Clinical Trials Regulation on research with medicinal products prohibits gene therapy clinical trials that lead to alternations in the participant's germline genetic identity.[76] Similarly, the second paragraph of Article 3 of the EU Charter speaks about respecting "the prohibition of eugenic practices, in particular those aiming at the selection of persons." In order for a measure to be considered in accordance with the law, it should be clear, foreseeable and adequately accessible.[77] Yet, these provisions raise questions: when exactly is the germline genetic identity modified?[78] What exactly is meant by 'eugenic practices' and 'selection of persons'? Does that specifically refer to HGGE?[79] If a Contracting State would implement reproductive laws that prohibit HGGE for reproductive purposes, it is important to take into account these requirements.

74 Prohibitive or restrictive (Germany) to intermediate (Italy and Austria) to permissive (Belgium, Sweden and United Kingdom).

75 *Supra* note 29.

76 Article 9 Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. *Official Journal of the European Union*, 27 May 2014.

77 *Supra* note 38, para. 87.

78 COGEM and the Dutch Health Council, '*Editing Human DNA: Moral and social implications of germline genetic modification*' (Bilthoven: COGEM, 2017) pp. 37–38; B.C. van Beers, 'Rewriting the human genome, rewriting human rights law? Human rights, human dignity, and human germline modification in the CRISPR era', *Journal of Law and Biosciences* 7(1) (2020) lsaa006.

79 *Ibid*.

The next question would be whether a prohibition is necessary in a democratic society. In the case of *S.H. and others v. Austria,* the reasoning of the public authority to prohibit ovum donation for ivf was based on the inherent risk that medically assisted procreation techniques carried the risk of being employed for other purposes than therapeutic, such as 'selection' of children.[80] The ECtHR acknowledges that shaping legislation regarding rapidly evolving artificial procreation techniques is a complex process, as these techniques might have consequences that become apparent after a longer period. For this reason, the ECtHR finds it understandable that the Contracting States are cautious regarding the field of artificial procreation.[81] This indicates that the ECtHR does not exclude that the risk that HGGE may be used for eugenic practices, such as 'human enhancement', is considered a valid argument on the necessity to restrict the right to artificially procreate using HGGE. After all, similar concerns about long term effects have been expressed.[82] However, as emphasized in the case of *Costa and Pavan v. Italy*, the Contracting States should clarify how these restrictions avert the risk of eugenic selection and affecting the dignity and freedom of conscience of the medical professions.[83] Whether the prohibition is proportionate, depends on other reproductive laws of the Contracting States. In the case of *Costa & Pavan v. Italy*, the ECtHR considers the fact that the use of PGD in case of a genetic disease was prohibited, but the termination of pregnancy on similar medical grounds was an option, a disproportionate restriction on the individuals procreative rights under Article 8. It is not unthinkable that a similar scenario with the use of HGGE will transpire. In order to prevent this, it is important to shape coherent national reproductive laws and keep the dynamic developments in science and law under review.

It becomes clear that the ECtHR increasingly acknowledges personal autonomy and self-determination with regard to assisted procreation, yet the current legal frameworks with regard to HGGE tend to be prohibitive or restrictive. This illustrates tension between the 'empowering' dimension of human dignity with regard to reproductive rights and the 'constraint' dimension in light of the fear for eugenic practices and long term effects of HGGE.

80 *Supra* note 42, para. 101.
81 *Ibid.* para. 103.
82 *Supra* note 29, para. 107.
83 *Supra* note 43, para. 63.

6.2 *The Right to Life of a Gene-Edited Embryo*

The ECtHR tends to steer clear of the questions whether unborn life should be protected under Article 2. Yet, the determination of the legal status of an embryo and its protectability may become more important with the introduction of HGGE, given that this introduces modifications to the embryo that affect not only the unborn child, but future generations as well. Moreover, in light of the tendency in bioethics to link human dignity to the human genome, the 'constraint' dimension of human dignity that is based on respecting and safeguarding the human being against dehumanisation and objectification becomes more relevant with the clinical implementation of HGGE.

6.2.1 The Legal Status of the Gene-Edited Embryo

In the case of *Vo v. France*, the ECtHR has observed the changing perspective with regard to the protectability of the human embryo. With the advancing medical-scientific developments, embryos and foetuses are being increasingly acknowledged as having human dignity. As has been described in the third paragraph, the concept of human dignity can be interpreted both 'empowering' as well as 'constraining'. With regard to HGGE, current legal frameworks are prohibitive or restrictive, which is in line with the latter dimension of human dignity. It should be noted that these laws are founded by the concerns about HGGE (enhancement purposes), rather than by the medical advantages for the prospective human being in case of safe and effective application (reproductive purposes). Furthermore, the acknowledgement that an embryo should be protected in light of human dignity, does not necessarily afford it protection under Article 2 as well. This will still be dependent on the definition of the 'beginning of life' that is decided by the Contracting State within its *margin of appreciation*.

Although it is not ruled out that the ECtHR will consider the introduction of HGGE as a 'certain circumstance in which the unborn life does fall within the scope of protection under Article 2', the existing caselaw provides no concrete guidance on the conditions for such a circumstance, nor on the context in which such a circumstance might occur. In the case of *Costa & Pavan v. Italy*, it appears that the ECtHR indirectly considers the *in vivo* embryo as 'other' — or bearer of legal status — when it refers to the Italian law that limits accessibility to PGD as pursuing the legitimate aims of protecting morals and the rights and freedoms of 'others'.[84] However, it also stresses that the concept of 'child'

84 *Ibid.* para. 59.

cannot be put in the same category as that of 'embryo'.[85] This position regarding the legal status of an *in vivo* embryo appears conflicting and, additionally, leaves the question whether the ECtHR distinguishes between *in vivo* and *in vitro* embryos, unanswered.

In light of association between the human genome and human dignity, the 'constraint' dimension of human dignity aims to respect and protect the human being against dehumanization and objectification. Hypothetically, if human enhancement were to be categorized as dehumanizing and objectifying, it could be argued that the unborn life should be protected under Article 2 in this 'certain circumstance' — the use of HGGE for enhancement purposes — on this basis of human dignity.

6.2.2 The Positive Obligation of Article 2 in Light of HGGE

Thus, if the clinical implementation of HGGE is categorized as a 'certain circumstance' in which unborn life is protected by Article 2, this would positively obligate a Contracting State to (i) protect the right to life by law and (ii) refrain from intentional deprivation of life.[86] The first obligates the Contracting States to take appropriate measures in order to protect the lives of those within its jurisdiction, which raises the question whether — in light of the right to life of the unborn child — a Contracting State should or should not refrain from providing the legal opportunity to apply HGGE in order to prevent an inheritable disease. On the one hand, there are potential risks to health and life that result from HGGE. On the other hand, health problems in the form of the genetic disease will manifest nonetheless. Is the Contracting State obligated to take preventive measures for health risks to the prospective child's life as a result of HGGE or will it fail to aspire its obligations by deprivation of access to a treatment that would save or substantially improve life?

Importantly, the ECtHR considers the obligation to take preventive measures under Article 2 as an obligation of means, not of result. If the appropriate measures have been taken by a Contracting State in response to a 'risk of life', and the risk materialises either way, this does not necessarily imply a violation of the right to life under Article 2. The circumstances will be assessed in light of what was known to the authorities at the relevant time.[87] For instance, in

85 *Ibid*. para. 62.

86 Council of Europe/European Court of Human Rights, *Guide on Article 2 — right to life* (31 December 2021), available online at https://www.echr.coe.int/documents/guide_art_2_eng.pdf (accessed 20 January 2022).

87 ECtHR 15 June 2021, 62903/15 (*Kurt v. Austria*) para. 160; ECtHR 28 October 1998, 23452/94 (*Osman v. the United Kingdom*) para. 116.

the case of *L.C.B. v. United Kingdom*, a patient suffering from leukaemia claims that she became sick because her father had been exposed to nuclear radiation before she was born. She complains to the ECtHR that her right to life has been violated because the authorities did not warn her parents about the health risks for their prospective children. The ECtHR found no link between the information available to the authorities at the relevant time concerning the likelihood of the patient's father having been exposed to dangerous levels of radiation and of this having created a risk to the health of the applicant. Therefore, there was no reason to assume that the authorities could, or should have taken measures. The ECtHR decided that Article 2 was not violated.[88] If a similar approach is adopted for complaints under Article 2 regarding the potential risks for life and health for a gene-edited embryo, it is important to consider what information was known to the Contracting State. Indeed, if it can be established that the authorities knew or ought to have known of the existence of certain risks of life of HGGE that should have triggered their obligation to take measures, a complaint under Article 2 would be legitimate. Nevertheless, as shown in the case of *L.C.B. v. the United Kingdom*, successful liability of the Contracting State requires causality between the application of HGGE and the materialised health risk, which will be difficult to establish, given that it is not possible to verify that the risk would not have materialised if the genome had not been modified.

With regard to deprivation of a treatment that would be life-saving, the ECtHR has emphasized in various cases that an issue under Article 2 may arise when an authority denies health care, thereby putting the life of an individual at risk.[89] Whether HGGE is considered 'life-saving' and therefore puts the life of the unborn child at risk in case of deprivation depends on various aspects. First, the life of the prospective child is not necessarily at risk without the treatment — this depends on the genetic disease — although the quality of life may be substantially lower. Second, if the treatment would be considered as life-saving, the ECtHR has formulated cumulative conditions for a 'denial of access to life-saving treatment' under Article 2.[90] The first condition focusses on mere error or medical negligence of the medical health-care providers in the awareness that the person's life is at risk if the treatment is not given. This is not directly applicable for HGGE application. Lastly, the access to

88 ECtHR 9 June 1998, 23413/94 (*L.C.B. v. the United Kingdom*).

89 ECtHR 4 May 2000, 45305/99 (*Powell v. the United Kingdom*); ECtHR 10 May 2001, 25781/94 (*Cyprus v. Turkey*); ECtHR 13 November 2012, 47039/11 and 358/12 (*Hristozov and others v. Bulgaria*).

90 ECtHR 19 December 2017, 56080/13 (*Lopes de Sousa Fernandes v. Portugal*).

HGGE is closely related to reproductive rights under Article 8 and the ability of Contracting States to restrict the accessibility to assisted procreation techniques. Thus, whether a Contracting State fails to aspire its obligations by deprivation of access to HGGE is difficult to establish based on existing case-law.

In short, whether a gene-edited embryo should be provided protection under Article 2 is difficult to deduct from existing caselaw, particularly because the ECtHR explicitly refrains from specifying 'the beginning of life' and the protectability of unborn life under Article 2. The ECtHR did not rule out 'certain circumstances' under which unborn life could be afforded legal protection, yet future caselaw should specify these circumstances. If, with the implementation of HGGE, the unborn life is afforded protection under Article 2, this will give rise to positive obligations for the Contracting States. How these positive obligations should be interpreted in light of the potential risk to health and life due to application or denial of HGGE, depends on various aspects, including the circumstances at the relevant time and the definition of 'risk of life'.

7 Conclusion

Due to the promising reproductive opportunities, the clinical implementation of HGGE is highly anticipated by both science and society. However, it is important to shape a coherent legal framework, based on human rights, particularly human dignity. Although human dignity remains an elusive concept, it runs like a thread through the ECHR and existing case-law of the ECtHR that addresses the advancing medical-scientific advances within assisted procreation. This article has provided insights on how the existing case-law on Article 2 and Article 8 could provide guidance in regulating the clinical implementation of HGGE. The analysis indicates that the ECtHR consistently broadens the scope of artificial reproductive rights that fall under Article 8, yet it leaves room for the Contracting States to limit these rights and therefore the accessibility to artificial reproduction techniques such as HGGE. The ECtHR tends to steer clear of the question whether unborn life falls under Article 2, but it has not ruled out 'certain circumstances' in which unborn life will be granted protection. Moreover, if unborn life would fall within the scope of Article 2 with the clinical implementation of HGGE, it remains debatable how Contracting States should interpret their positive obligations under Article 2. There is no clear answer to the question how the clinical implementation of HGGE should be interpreted in light of the ECHR and its existing case-law on Article 2 and Article 8. If anything, it shows that the process to develop regulation is a complex interaction between various human rights aspects that need to be balanced.