

Ethical Issues Currently Being Discussed in Relation to Reproductive Medicine and the Laws Governing Reproductive Medicine

Ethische Fragen der Reproduktionsmedizin und des Fortpflanzungsmedizinrechts in der aktuellen Diskussion

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Abstract

Reproductive medicine laws in Germany currently mean that the relationship status of prospective parents is taken into consideration in decisions on whether their application for assisted reproduction is approved or rejected. In the light of new forms of shared parenthood, we should ask ourselves whether the current regulations are still an appropriate way of guaranteeing the best for the child. Current medical practices and their legal basis will be illustrated using the examples of sperm, egg and embryo donation. From an ethical perspective, the question at stake is to what extent an “Ethics of Parenthood” can make it possible to act responsibly with regard to the changes occurring in forms of shared parenthood. Such an ethics is aimed at supporting parents in realising the reproductive autonomy guaranteed in the German Constitution through social and ethical aspects of the child–parent relationship.

Introduction: Liberal Reproductive Medicine Legislation Which Fails to Assess Social and Ethical Consequences?

Time and again, the dynamics of the scientific and technical advances in medicine (see also **Table 1**) and changing societal attitudes to wanting children and relationships between partners give grounds to demand a modern, “up-to-date reproductive medicine law” in Germany [1]. On the other hand, there is doubt that such a law is necessary at all, with reference being made to the most recent amendment made to the German Embryo Protection Act (EPA), which introduced pre-implantation genetic diagnosis (PGD) [2]. In contrast to this, however, a group of six legal experts from Augsburg and Munich have put a draft reproductive medicine law up for discussion which suggests moving away from the “strategy

Zusammenfassung

Im Fortpflanzungsmedizinrecht in Deutschland entscheiden auch Bestimmungen des familiären Personenstands über die Zulassung oder Ablehnung von Wunscheltern zu einer assistierten Reproduktion. Angesichts neuer Formen geteilter Elternschaft stellt sich die Frage, ob die bestehenden Regelungen zur Gewährleistung des Kindeswohls noch zeitgemäß sind. Am Beispiel der Gameten- und Embryonenspende werden die aktuelle medizinische Praxis und ihr rechtlicher Hintergrund dargelegt. In ethischer Perspektive geht es um die Frage, inwieweit ein „Ethos der Elternschaft“ einen verantwortlichen Umgang mit den familiären Veränderungen geteilter Elternschaft ermöglicht. Eine solche Ethik will Eltern dabei unterstützen, dass die vom Grundgesetz gewährleistete reproduktive Autonomie durch sozial-ethische Aspekte der Eltern-Kind-Beziehung konkretisiert werden kann.

of outdated law” employed up until now [3]. The draft contains new regulations for artificial insemination, pre-implantation genetic diagnosis (PGD), sperm and egg donation, embryo transfer, surrogacy, and how to deal with “excess” embryos and clones. The authors of the so-called “Augsburg-Munich Draft of a Reproductive Medicine Act” justify the need for reform in that “the actual developments in technology have created many legal loopholes in embryo protection: The more outdated the EPA [Embryo Protection Act] becomes in terms of biotechnology, the more it loses its normative regulatory effect. This means that regulatory sovereignty moves from parliamentary legislators to professional medical bodies” [3]. Based on the “initial presumption that every person is completely free”, the draft law proposes an overall liberal regulation of reproductive medicine in Germany. Its declared intention is, firstly,

Table 1 Methods of assisted reproduction.

1.	Insemination	Insertion of prepared sperm into the uterus of the patient who would like to become pregnant
2.1	In vitro fertilisation (IVF)	Fertilisation of an egg cell with a sperm cell outside the female body in a cell culture dish ("in vitro")
2.2	Intracytoplasmic sperm injection (ICSI)	IVF procedure during which a sperm cell is directly injected into an egg cell in order to fertilise it (especially for patients with extremely low sperm counts)
3.	Embryo transfer	Transfer of an in vitro fertilised embryo into the uterus of the patient who would like to become pregnant (for example following cryopreservation)
4.	Polar body diagnosis (PBD)	Investigation of the first (and, if possible, of the second) polar body following extracorporeal fertilisation, in order to determine any changes in the (haploid) female chromosome set before the embryo is formed.
5.	Pre-implantation genetic diagnosis (PIGD)	Investigation of the embryonal or trophoctodermal cells of an in vitro conceived embryo in order to detect chromosomal changes or hereditary diseases

to "take into account the relevant interests in the fundamental rights argument [...] – and not to exclude these prematurely, for example due to ethical, religious or other preferences" [3]. And indeed, neither the civil status of the parents nor societal attitudes towards the family and wanting children play any role in the draft law.

By making the assumption of freedom in the German Constitution and reproductive self-determination the starting point of their regulation proposal, the authors orient themselves towards an understanding of individual freedom which is drawn up "negatively" like the fundamental rights of the German Constitution as rights of defence of the individual against the state. Derived from these, they also assess elementary duties to protect in as far as they are relevant for the child's wellbeing. Nonetheless, issues of "positive" freedom, which apply themselves to the factors that enable individual freedom, are completely ignored. This makes sense if one wishes to avoid legislators being implicated in a dispute about the normativity of forms of family life. The "biopolitical compromise" which is aimed towards, is intended precisely to avoid excessive "standardisation of the biological" [3]. Of course, the question then arises as to how reproductive autonomy should be lived out nowadays in the light of pluralised forms of relationships, the complex issues of who should provide for families, and the fact that prospective parents can seek different reproductive medicine offers across borders.

Since it was made aware of a lack of regulation in many problem areas of the German Embryo Protection Act of 1990, the German Medical Association (GMA) has been regulating assisted reproduction for years. In the amendment to the Association's (Draft) Directive from the year 2006, it is stated that they take into account "the debate in the public domain about the opportunities, legitimacy and ethical boundaries of reproductive medicine, the evolution of social values on family, marriage and relationships, and the criteria of medical ethics". [4]. The GMA therefore wishes to adapt the "outdated" but nonetheless valid legal regulations of the EPA to today's reality, first and foremost with the help of an ethical (and legal) reflection on the role of the doctor in assisted reproduction. By taking on regulations from the German Civil Code on the civil status of mother, father and child and by interpreting them in the context of the availment of assisted reproduction, the GMA takes a clear stance on the issue of social and value-based forms of life as factors enabling basic freedoms in the practice of assisted reproductive medicine. Of course, soon after publishing the amendment to its (Draft) Directive, the GMA had to respond to the question of whether it, by limiting heterogeneous insemination to heterosexual couples, still takes into account the reality of relationships as they are lived out nowadays [5]. The following discussion of the social and ethical implications of reproductive medicine addresses the question of

whether the fact that offers of sperm, egg and embryo donation are dependent on issues of civil status is still in keeping with today's reality. Even if one, like the Augsburg-Munich Draft of a Reproductive Medicine Act, argues in favour of a broad relinquishment of criminal sanctions in a future reproductive medicine law, it still remains to be determined whether this must necessarily involve the unlimited ethical approval of all permitted measures.*

Shared Parenthood Via Sperm, Egg and Embryo Donation

▼ Sperm donation

Medical and legal aspects

In Germany, treating unwanted childlessness with sperm donation is permitted. To do this, prepared sperm cells from a man who is neither the husband nor the partner of the patient are used to induce pregnancy. The most common procedure is heterologous insemination (HI), during which the prepared donor sperm is injected directly into the womb of the patient who wishes to become pregnant. Donor sperm can also be used for more invasive methods of assisted reproduction (IVF and IVF/ICSI) and tends to be used for couples with extremely limited fertility or when the male partner is sterile. A less common reason for using the method is a genetic predisposition of the male partner which should not be passed on to the offspring.

Donor sperm for HI are usually procured from sperm banks which make their donors fulfil various requirements. In general, donors should be between 18 and 40 years old, in good health both physically and mentally and should have no hereditary diseases. The sperm bank documents the donor's personal details (name, date of birth, address, civil status, educational level, employment and other details) and keeps them for 30 years (§ 15 para. 2 German Transplant Act [TA]). Once they have reached the age of 18, all children have the right to find out about their genetic origins (§ 1598a of the German Civil Code; § 1600d of the German Civil Code; Article 7 of the UN Convention on Children's Rights [6]). This guarantees the right to know one's own genetic origins which the German Federal Constitutional Court derives

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from the right to protection of one's privacy [7]. Depending on the age of the patient, the chances of success are between 10 and 15% for each round of HI treatment. The cost of HI is not paid by German health insurance companies and must be paid by the couples themselves.

Heterosexual couples who have given consent for HI treatment to go ahead are subsequently not allowed to dispute paternity (§ 1600d of the German Civil Code). Only the children conceived by HI have the option of doing this. In the case of lesbian or single women, there is the problem that there is no second parent to whom legal paternity is transferred. In this case, both the prospective parents and the sperm donor run the risk of the donor being given paternity of the child. In the case of lesbian couples, the social mother can apply to adopt the baby as a stepchild following the birth in order to protect the donor from any legal implications. In Germany, this problematic has resulted in the GMA [4] and the Working Group for Heterogeneous Insemination [8] reserving treatment for heterosexual couples only, as the legal protection of the sperm donor is problematic in the constellations mentioned, and it cannot be clearly ruled out that even the doctor may be implicated in place of a legal father whose identity can no longer be determined.

Ethical issues

The child's right to know his/her own origins and the fact that sperm donations are reserved exclusively for "stable relationships" – for reasons of maintenance and inheritance law – make it clear that in the German legal system, parenthood is still understood as a biosocial form of living involving a mother and a father. This results in different binding effects of social parenthood on the one hand and biological/genetic parenthood on the other. While the former can in principle be ended, the latter lasts a lifetime. By excluding women who are in a same-sex relationship or no relationship at all from receiving heterogeneous insemination [4], the GMA is linking this medical practice to elementary parental duties which exist for the protection of the child's wellbeing for reasons of laws governing the protection of the private sphere and maintenance. However, the idea that only heterosexual couples should be given this right, for reasons of the successful psychosocial development of the child, seems questionable. For example, a representative study on the situation of children living with same-sex couples comes to the conclusion "that children and young people living in LGBT families develop just as well as children living in other types of family" [9]. In this context, the criticism that the current civil status regulations of the GMA no longer represent the life situations of same-sex partners/single parents, constitutes a significant objection. The question arises as to whether, in the light of this changing reality, the GMA should still encourage doctors to ensure that a stable relationship is forthcoming for reasons of the child's wellbeing. It is, of course, the right of the doctor to refuse assisted reproduction for conscientious reasons, for example due to fears for the child's wellbeing [4]. However, we should ask ourselves whether refusing reproductive assistance on the basis of the sexual orientation of the couple constitutes discrimination and disproportionately restricts reproductive autonomy [10]. Violations of the articles referring to equality (Art. 3 of the German Constitution), to the free development of personality (Art. 2 para. 1 and Art. 1 para. 1 of the German Constitution), and to the right to start a family (Art. 6 para. 1 of the German Constitution) are relevant in this regard. However, if one focuses exclusively on the wellbeing of the child, it is conceivable to insist in particular that the *couple* to be

parents are in a "stable" relationship – completely independently of the partners' sexual orientation. The consequence of this view would be that custody rights and maintenance duties in the case of assisted reproduction would be regulated in the same way as with adoption law. This would take into account the fact that, in the case of the biological father not being around, the parental bond to the child must be shaped in a lasting, reliable way.

If one focuses on the child's right to two parents, the issue of how to act in the case of heterologous insemination of single women remains unresolved. From the point of view of the child, who has the right to social support from both parents, it would be conceivable to allow other persons from the mother's support network (e.g. boyfriend or a relative) to take on the role of the absent social father, at least legally [10]. This would simultaneously decrease the potential risk of sperm donors being made responsible for providing for the child as social father in the event that the child filed a lawsuit. Especially if one had good reason to want to ensure the child's constitutional right to find out his/her biological origins, the biological father could be reasonably expected to go through with the potential encounter, as he would have to fear no legal responsibilities towards a child whose social father he never wished to become.

Egg donation Medical and legal aspects

In the case of egg donation, an embryo, which was created outside the body by fertilising a donated egg with a sperm from the partner, is transferred into the female patient in order to impregnate her. This is the only option available to women who would like to bear a child themselves, but whose ovarian reserves have been exhausted before this has been possible. Causes of the exhaustion of ovarian reserves can be age, a genetic predisposition, or previous gamete-damaging therapies – for example in the case of oncological diseases. Female patients who do not wish to use their own egg cells as they are afraid of passing on a genetic disease to their children, can also use donor eggs. However, egg donation is forbidden in Germany (§ 1 para. 1 No. 1 and 2 and para. 2 EPA) [16]. Nonetheless, independently of the issue of the legalisation of egg donation, the question of motherhood is clarified by § 1591 of the German Civil Code: The mother of a child is the woman who has borne said child.

From a medical point of view, egg donation is not risk-free for the donor, as she must undergo controlled ovarian hyperstimulation treatment followed by follicular puncture. The ripe egg cells are usually cryopreserved so that it is not necessary to synchronise the patient's menstrual cycle with that of the donor. In most countries, egg donors receive financial compensation for their trouble (commercial donation); however altruistic donations are also possible from relatives or close friends. In some European countries, so-called "egg sharing" has become popular, as part of which women undergoing IVF/ICSI treatment donate some of their eggs in order to be partially or fully exempted from their own treatment costs in return. The health requirements demanded of the egg donor are similar to those involved in sperm donation, however the egg donor should not be older than 30 due to the increased risk of aneuploidy with age. As commercial donors in particular tend to be very young, chances of pregnancy are high – at up to 50% at each round of treatment. Due to the huge trouble that the egg donor has to go to, egg donation is associated with high financial costs for the prospective parents which cannot be reimbursed by German health insurance companies.

Ethical issues

The German Embryo Protection Act does not permit egg donation because, on the one hand, it leads to a splitting of genetic motherhood, and on the other hand because it leads to a splitting of biological and social motherhood. It has not been scientifically proven that egg donation puts the child's wellbeing at a higher risk than is the case with sperm donation. If one assumes that the quality of the relationship between parent and child is especially crucial for the positive identity development of the child, and that the child must of course be able to find out about his/her origins within this relationship, it is not very plausible that there should be a categorical difference to sperm donation in this regard. However, due to the more invasive nature of ovarian hyperstimulation and follicular puncture, the health risks for the egg donor must be weighed up appropriately. For this reason, the commercialisation of this treatment should not be permitted under any circumstances. This can be best achieved through "egg sharing" – the unpaid donation of excess egg cells – as it minimises commercial incentives.

Things are different, however, if a woman's own egg cells have been frozen for reasons relating to her life, in order to be thawed out at a "suitable" time for starting a family. This "social freezing" as a fertility reserve available for use at any time can lead to the optimisation of the plannability of a pregnancy made possible by reproductive medicine in such a way that it can be made to fit in with any life plans [11]. In addition to this, the success rate is lower once the age threshold of approx. 35 years is passed. After this age, there are higher health risks for the prospective mother and child. In general, the problem arises as to whether, by medicalising pregnancy, this process creates stronger incentives for wanting to solve problems of juggling career and family in a way which would be better addressed by social policy. A distinction must be made between this and the possibility of cryopreserving egg cells when younger women become seriously ill and fear that they may become infertile – for example due to cancer therapy. Even though the prospective parents are faced with significant psychological difficulties in this dramatic life situation, the vitrification of a patient's egg cells allows her to make decisions about her future later on [11].

Embryo donation Medical and legal aspects

Embryo donation involves a donated embryo being transferred into the uterus of the patient who wishes to become pregnant. This allows couples in which neither partner has any fertilisable gametes to be treated. Embryo donation can also be used to facilitate a pregnancy if one partner or both have a genetic condition which they do not want to pass on to their offspring, or following multiple miscarriages, or for lesbian couples and single women who wish to have a child but who either do not wish to or cannot use HI.

Conceiving embryos for the purposes of embryo donation is in principle not allowed by the German Embryo Protection Act (§ 1 para. 1 No. 2 EPA). The justification the law gives for this ban on embryo donation focuses on the wellbeing of the prospective child, whose ability to develop an identity is, in the eyes of the legislators, endangered by the split motherhood caused by embryo donation [12]. There is, however, no outright ban of embryo donation in the EPA: The pre-emptive punishment mentioned in § 1 para. 1 No. 2 of the EPA is intended to "make an outright ban of so-called embryo donation unnecessary. Such a ban in criminal law would not be without its associated concerns, at least in

those cases in which embryo donation offers the only way of preventing an embryo from dying" [12]. In this way, a loophole was consciously included in the EPA in order to avoid the throwing away of "excess" embryos. It would, however, also be conceivable to give them up for donation as long as they were not created due to a planned decision for this purpose before fertilisation took place. A heated debate is currently going on as to whether impregnated, pre-nucleotide oocytes are egg cells as defined by the EPA, which is especially linked to the question of to what extent the EPA contains a unified definition of fertilisation.

The embryos available for embryo donation originate from conventional IVF/ICSI treatments. For many couples, the number of impregnated egg cells in the pronuclear stage during IVF treatment is higher than the number required for the imminent embryo transfer. In this case, most couples decide to have cells in the pronuclear stage cryopreserved in order to keep them for another embryo transfer. If, once the family planning has been completed, additional cells in the pronuclear stage are still available, they can either be destroyed or given up for donation. The same applies to embryos which have been put into storage – in much smaller numbers – because it became impossible to transfer them into the woman for sudden medical or psychological reasons. The chance of success following the transfer of donated embryos is, to a great extent, dependent on the age of the donor and, according to data collected outside of Germany, is between 25 and 40% at each round of treatment.

The costs incurred by embryo donation are much lower than those incurred by egg donation, as the embryos already exist and just have to be approved for donation. The only costs incurred, therefore, are for storage following approval, preparation for the embryo transfer and the embryo transfer itself. Embryo donation *per se* is non-commercial; neither the donor nor the fertility centre responsible for storage receives *any* money for the approval or the placement of the embryos.

As is the case with egg donation, the women who carry the children to term enjoy legal certainty in terms of motherhood, while the legal safeguarding of the genetic father – similarly to with HI – remains problematic in the case of lesbian couples or single women.

Ethical issues

In principle, the creation of huge numbers of unneeded embryos should be avoided if at all possible. However, even if this principle is recognised, the issue of what to do with the excess embryos created in the context of reproductive medicine procedures still needs to be addressed. If embryo donation is conceived as an alternative to throwing the embryos away, this simultaneously broadens the therapy options available to women and men who are unable to have children. The most important point here is that embryo donation must always be completely voluntary and not for one's own profit. Neither the argument that the embryo must be "rescued", nor that of the desire of another couple to have children, nor the interests of reproductive medicine may be allowed to lead to a moral or legal duty to make a donation. For this reason, couples should only consider donating embryos or impregnated egg cells once it is absolutely certain that they will not be needed for further treatments for the donor couple themselves. In terms of the rights of the prospective child and the taking into account of its wellbeing, the requirements are similar to those involved in sperm/egg donation, while it should be emphasised that the prospective child is not genetically related to either of its parents, but possibly to siblings. In this case,

the guarantee that the child can find out about his/her origins must involve the right to contact one's own siblings – but: also other relatives?

On the Ethics of Responsible Parenthood

Reproductive medical practice in terms of sperm/egg and embryo donation results in diverse forms of shared parenthood, which involve new challenges for the current laws regulating assisted reproduction as included in the amended (Draft) Directive of the German Medical Association. Not only innovations in medical technology, but also changing social attitudes to wanting to have children and the make-up of families have resulted in the fact that the perception of what constitutes responsible ethics of parenthood is currently undergoing a transformation. If one focuses on the wellbeing of the prospective child when considering all these questions, as the German Medical Association rightly does, then we should nonetheless discuss whether this task of relationship ethics should rather be more the responsibility of the parents who are living together with their child [13]. The presumption that permanence and stability, which are central to our understanding of marriage and parenthood, will play a lesser role in same-sex relationships is disproved not least by the interest of more or less all same-sex couples in striving towards marriage-like forms of having their relationships recognised as binding by the law. But even if one – as demanded here – gives the ethics of responsible parenthood central importance in the perception of parental duties, this should not encourage people to underestimate the profound effects that traditional ideas of family can have on how people can construct an individual opinion of what kind of parents a couple would make. This is, of course, to a certain extent in conflict with the fundamental liberal character of the Augsburg-Munich Draft of a Reproductive Medicine Act, for which the perspective someone has of the parents does not represent an argument of constitutional law which justifies limiting the right to procreation. In this context, it is worth noting the judgment passed by the Grand Chamber of the European Court of Human Rights (ECHR) on the 03.11.2011 egg donation ban in Austria. The judgment did *not* confirm the condemnation of Austria by the judgment of a subordinate chamber, however it nonetheless criticised the lack of openness to change in terms of societal consensus in the field of reproductive medicine [14]. This is why, as pointed out by Hartmut Kreß, the “ordre public”, the opinions of state and society about good morals and public order [...] [are] not unchanging constants. Socio-cultural assessments change” [15]. This does not, however, mean that one should simply privatise the orientational function of traditional expectations of family and parenthood by no longer focussing on anything other than rights to “negative” freedom. In this way, the effort made by the GMA to interpret a consensus on ethical questions of the stability of relationships which orients itself towards the traditional idea of a family should not be underestimated, even if this consensus is changing – albeit slowly.

Conclusion

A liberal reproductive medicine law in particular requires issues of civil status to be thought about ethically in terms of their relevance for medical practice, as does the demand to keep oneself “up-to-date” in this regard.

Conflict of Interest

None.

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